

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

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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

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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 article 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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บทคัดย่อ

เราไม่สามารถปฏิเสธได้ว่ายาปรึกษาโรคถือเป็นหนึ่งในปัจจัยหลักในการดำรงชีพของมนุษย์ อย่างไรก็ตามยาปรึกษานั้นจัดเป็นสินค้าอย่างหนึ่งที่เรียกได้ว่ามีลักษณะและคุณสมบัติเฉพาะตัวที่โดดเด่นกว่าสินค้าอุปโภคบริโภคทั่วไปเนื่องจากยาเป็นสินค้าที่สามารถส่งผลกระทบต่อชีวิตและสุขภาพของผู้บริโภคได้โดยตรง นอกจากนี้ยาไม่ใช่สินค้าที่ตัดสินใจซื้อหาได้ง่ายและอิสระอย่างสินค้า

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อุปโลกน์บริโกลทั่วไประหว่างนั้นในการบริโกลแต่ละครั้งนั้นผู้ปวยในฐานะผู้บริโกลจะมอบความไว้วางใจให้ให้กับผู้มีความรู้เฉพาะทาง โดยเข้าขอคำแนะนำหรือรับการตรวจวินิจฉัยจากแพทย์หรือผู้ประกอบวิชาชีพด้านสาธารณสุขเพื่อให้ได้รับคำแนะนำหรือการวินิจฉัยที่ถูกต้องและสั่งจ่ายยาที่เหมาะสมตรงกับอาการและโรคของตน ดังนั้นผู้ปฏิบัติหน้าที่ไม่ว่าในฐานะแพทย์หรือผู้ประกอบวิชาชีพด้านสาธารณสุข เช่น เกษักร ซึ่งเป็นผู้ที่ได้รับความไว้วางใจและความเคารพจากผู้ปวย จึงต้องปฏิบัติหน้าที่ของตนโดยคำนึงถึงความสำคัญของผู้ปวยเป็นอันดับแรก

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แม้ผู้บริโกลส่วนใหญ่จะเชื่อมั่นในตัวแพทย์และผู้ประกอบวิชาชีพด้านสาธารณสุขที่ตนเข้ารับคำแนะนำหรือการรักษาว่าบุคคลดังกล่าวจะปฏิบัติหน้าที่โดยคำนึงถึงผลประโยชน์ของผู้ปวยเป็นหลัก แต่ผู้บริโกลส่วนใหญ่ก็มิได้ตระหนักกว่าว่าเป็นสินค้าชนิดหนึ่งซึ่งถูกผลิตเหมือนสินค้าทั่วไปในท้องตลาดซึ่งบริษัทยังต้องใช้กลยุทธ์ทางการตลาดต่างๆ เพื่อกระตุ้นยอดขายและการตลาดส่วนใหญ่ที่บริษัทประยุกต์ใช้นั้นจะมุ่งไปทางแพทย์เป็นกลุ่มเป้าหมายหลัก เนื่องด้วยสถานะทางสังคมของแพทย์ที่ได้รับการพนับถือจากบุคคลทั่วไปในสังคม ดังนั้นอำนาจในการสั่งจ่ายของแพทย์ย่อมมีผลต่อยอดขายของยาแต่ละชนิด ดังนั้นจึงต้องยอมรับว่ากลยุทธ์ทางการตลาดนั้นย่อมมีอิทธิพลไม่โดยตรงก็โดยอ้อมต่อดุลพินิจในการสั่งจ่ายของแพทย์และผู้ประกอบวิชาชีพด้านสาธารณสุข ซึ่งความสัมพันธ์ในลักษณะเช่นนี้ค่อนข้างมีความซับซ้อน โดยประกอบทั้งการสนับสนุนทางการเงินอย่างแท้จริงจากบริษัทฯ และการตลาดที่มุ่งสนับสนุนทางการเงินในรูปแบบแอบแฝงอันนำมาสู่ปัญหาใช้ยาอย่างไม่เหมาะสมจนถึงปัญหาการทุจริต

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1. INTRODUCTION

From past to present it has been obvious that when people have their health problem, they always put their trust to the physicians and healthcare professionals to act in their best interests. However, 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 system¹ especially transparency in financial interactions among people in healthcare industry since the related stakeholders are various, different, and have many objectives. They comprise physicians, healthcare professionals, researchers, manufacturers, distributors, wholesalers, retailers, medical representatives² 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

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

² In this study, 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.

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in recent years the pharmaceutical sector has faced criticism over how it interacts with physicians and healthcare professionals.³ Another report from PWC also argued that too much money is spent on advertising by pharmaceutical company.⁴

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. This makes the issue of non-transparent financial interactions among those people more serious and reflects in a number of ways such as irrational use of drug, economic system, corruption and moral ethics. There is, however, an attempt to drive forward this concern including through research⁵ in this area. These are reasons why it is interesting to complete a 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)

³ 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).

⁴ PriceWaterhouseCoopers, **Pharma 2020: The vision which path will you take?**, 7 (2007).

⁵ ดาราวพร ธีระวัฒน์ และคณะ, รายงานฉบับสมบูรณ์โครงการการศึกษากฎหมายควบคุมการส่งเสริมการขายยาในต่างประเทศ, แผนงานกลไกเฝ้าระวังและพัฒนาระบบยา (2553) (Dr. Daraporn Thirawat ET AL, **Report on Study on Legal Measures to Control Drug Sale Promotion in Foreign Countries**, Thai Drug Watch Organization (2010)).

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the principle of disclosure obligation and 2) the principle of prevention of conflict of interest.

2. NATURE OF INTERACTION IN HEALTHCARE SYSTEM

This chapter will focus on the nature of physician-patient relationship (hereinafter referred to as PPR) and physician-pharmaceutical company relationship (hereinafter referred to as PPCR). The scope of study comprises of the ways that they are supposed to be and the way they really are including effects from inappropriate PPCR.

2.1 Nature of Interactions between Physicians or Healthcare Professionals and Patients in History and in Modern World

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.⁶

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

⁶ รติกร กุลวรกุลพิทักษ์, “ความรับผิดชอบทางแพ่งของแพทย์จากการฝ่าฝืนเจตนาปฏิบัติเวชการรักษาล่วงหน้าของผู้ป่วยาระสุดท้ายของชีวิต”, วิทยานิพนธ์นิติศาสตรมหาบัณฑิตสาขากฎหมายเอกชน, มหาวิทยาลัยธรรมศาสตร์, 11-12 (2557) (Ratikorn Kulvarakulpitak, “Civil liability of physicians in interference with advance directives”, Master of Laws’ thesis, Thammasat University, 11-12 (2014)).

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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.

2.2 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.⁷

2.3 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 contractual model could slowly

⁷ Kulvarakulpitak, *supra* note 6, at 12-13.

undermine and reduce the traditional paternalism model.⁸ 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.

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.

2.4 Nature of Interactions between Physicians and Pharmaceutical Companies

Pursuant to the high market value of the pharmaceutical industry, it is not surprising that pharmaceutical companies spend a lot on marketing to stimulate their sale volumes. According to many surveys⁹ and pieces of research,¹⁰ the great majority of these

⁸ อนุชา กาศลังกา, “การศึกษาปัญหาแพทย์และบุคลากรทางการแพทย์สังกัดกระทรวงสาธารณสุขและสำนักงานปลัดกระทรวงสาธารณสุขที่ฟ้องร้องจากการรักษาพยาบาล”, 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)).

⁹ Consumer International, *Drugs, Doctors and Dinners: How drug companies influence health in the developing world*, 23 (2007).

¹⁰ 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).

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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 leaving reminders (notepads, pens and other small gifts engraved with the company logo), leaving drugs samples and sponsoring academic and non-academic 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.

3. FINANCIAL INTERACTIONS BETWEEN PHYSICIANS OR HEALTHCARE PROFESSIONALS AND PHARMACEUTICAL COMPANIES IN FOREIGN COUNTRIES

This chapter will pay attention on existing transparency measures applied in 2 foreign countries and background before launching the measure of each country will be taken into consideration also.

3.1 USA

According to the survey,¹¹ 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

¹¹ Pew Prescription Project, “*Consumer Survey: Disclosure of Industry Payments to Physicians*” (2008), <http://www.pewtrusts.org> (last visited 11 July 2016).

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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.

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 Patient Protection and Affordable Care Act (hereinafter referred to as PPACA), which was first introduced and supported by Senators Charles Grassley and Herb Kohl¹² 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.

3.2 Australia

¹² 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)

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.¹³ The use of promotional activities in the drugs business in Australia is similar to that found in the USA in that most pharmaceutical companies spend a great deal of money on strategic marketing activities. The objective of these marketing activities is to stimulate sales. Research¹⁴ 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 survey¹⁵ which reveals that 76% of patients in Australia are not aware of any financial interactions with interest related to their physicians and

¹³ 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).

¹⁴ 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).

¹⁵ 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).

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 Australian Competition & Consumer Commission (hereinafter referred to as ACCC) on 26 July 2006¹⁶ 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."

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: principle of disclosure obligation and principle of prevention of conflicts of interest.

Accordingly, Medicines Australia adopted principle of disclosure obligation into the 18th edition of its Code of Conduct (hereinafter referred to as Australia 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. Moreover, the US

¹⁶ Martin H N Tattersall & Ian H Kerridge, "*Doctors behaving badly?*", 185(6), the **Medical Journal of Australia**, 299, 299-300 (2006).

PPACA has likewise been adopted as a model for its study as well.¹⁷ The Transparency Working Group suggested that even though financial disclosure under the US PPACA was all-inclusive and broad, it should be adapted to be less complicated and to be more practical to Australia's context¹⁸.

The core of the Australia Code of Conduct 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, 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 Therapeutic Goods Administration, Department of Health (hereinafter referred to as 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.

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

¹⁷ Medicine Australia, "*Transparency Working Group, Terms of Reference*", <https://medicinesaustralia.com.au/code-of-conduct/transparency-working-group/> (last visited 12 July 2016)

¹⁸ 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)

This chapter will focus on current situations in Thailand including transparency measures that are suitable for our country.

4.1 Situations in Thailand

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 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 particularities¹⁹:

¹⁹ นันทวัชร นวตระกูลพิสุทธิ์, “French Sunshine Act: กฎหมายเพื่อความโปร่งใสในความสัมพันธ์ระหว่างแพทย์หรือผู้ประกอบการด้านสาธารณสุขกับบริษัทยา”, 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)).

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(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 conditions²⁰:

(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,

²⁰ *Id.* at 92.

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 higher²¹.

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

4.2 Transparency Measure for Thailand

²¹ 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 1 (2009)).

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After reviewing 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 could reduce the risk to improper transactions between the pharmaceutical companies and the medical practitioners that could effect to 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.

After considering the four key purposes for reaching the transparency measure “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.

4.3 Loophole in the Principle of Disclosure Obligation in Thailand

After examining the Drug Act B.E. 2510 (hereinafter referred to as Drug Act) 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 11²² states about drug advertising only in terms of general principles which do not cover

²² The Drug Act B.E. 2510

issues 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 lacks of areas to cover 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 from Office of the Council of State version and public version are drafted. However, neither of these incorporates disclosure concepts into their drafts.

Furthermore, after reviewing 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, they include principles to prevent conflicts of interest by prohibiting gifting. However, it is found that the practice of unethical drug sale promotion through various complicated strategies is still going on in Thai culture²³.

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 acceptable, then there is no reason not to disclose such information.

²³ Resolution of National Health Assembly No. 2, *supra* note 21, at 2.

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5. CONCLUSION AND RECOMMENDATIONS

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5.1 Conclusion

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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 could be found 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.

As mentioned that the unhealthy relationship among said people might influence over research, discretion or decision of the physicians or healthcare professionals in ways that compromise between what they have got in return. Whilst only disclosure is not sufficient to separate between useful financial support and those that may raise conflict of interest, disclosure and transparency have goal to open the nature and extent of the relationships that exist and discourage development of inappropriate relationships. For Thailand, it is quite obvious that the Drug Act B.E. 2510 as an existing and most important law to control over drug system does not have principle of disclosure obligation even the Draft Drug Act (Office of the Council of State Version) and the Draft Drug Act (Public Version) do not include this principle either.

5.2 Recommendations

For that reason, this should have been developed to provide a more appropriate transparency measure in Thailand, and promote such measure to be the Act. The process to make transparency measure should have the strategies both in policy aspect and legal aspect. Even the National Drug Policy B.E. 2554 and National Drug System Development Strategy B.E. 2555-2559²⁴ as current national drug policy includes strategic plan for encouragement of ethical practice and stop unethical drug sale promotion, it would be more progressive to incorporate concept of transparency to control

²⁴ 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).

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financial interactions between the physicians or healthcare professionals and the pharmaceutical companies, assign the relating authorities to study all existing measures that we have and compare with the foreign laws to point out loopholes of the current laws and regulations to accomplish the purpose in a practical way.

For legal aspect, the author agree with the model law applied in USA since it is promote its transparency measure in to the legislative law so it has stronger enforcement than 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, PReMA Code, it is found that problem of unethical drug sale promotion still going on in Thailand. Therefore, encouragement of transparency measure into legislative would be more effective. Furthermore, amendment to the existing law by adding new chapter to control transparency in financial interactions between the physicians or healthcare professionals and the pharmaceutical companies in the Drug Act B.E. 2510 is better to include all provisions related to drug system into one statute to make it more practical for all relevant people to study and comply with.

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พระราชบัญญัติขายตรงและตลาดแบบตรง พ.ศ. 2545 (Direct Selling and
Direct Marketing Act B.E. 2545)

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พระราชบัญญัติคุ้มครองผู้บริโภค พ.ศ. 2522 (Consumer Protection Act
B.E. 2522)

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พระราชบัญญัติยา พ.ศ. 2510 (Drug Act B.E. 2510)

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ร่างพระราชบัญญัติยา พ.ศ.... (ฉบับสำนักงานคณะกรรมการการกฤษฎีกา) (Draft Drug
Act B.E.... (Office of the Council of State Version))

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ร่างพระราชบัญญัติฯ พ.ศ.... (ฉบับประชาชน) (Draft Drug Act
B.E....(Public Version))

ประกาศกระทรวงสาธารณสุขว่าด้วยเกณฑ์จริยธรรมการจัดซื้อจัดหาและการส่งเสริมการขายยา
และเวชภัณฑ์ที่มีโทษของกระทรวงสาธารณสุข พ.ศ. 2557 (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)

เกณฑ์จริยธรรมฉบับที่ 9 พ.ศ. 2555 ของสมาคมผู้วิจัยและผลิตเภสัชภัณฑ์ (Code of
Practices 9TH Edition, 2012 of Pharmaceutical Research &
Manufacturers Association)

เกณฑ์จริยธรรมว่าด้วยการส่งเสริมการขายยาของประเทศไทย (Code of Conduct for
Drug Sales Promotion in Thailand)

ข้อบังคับแพทยสภา ว่าด้วยการรักษายจริยธรรมแห่งวิชาชีพเวชกรรม พ.ศ. 2549 (The
Medical Council Regulations on Medical Ethics
Preservation of Thailand B.E. 2549)

8. Other Materials

มติสมัชชาสุขภาพครั้งที่ 2, ยุติการส่งเสริมการขายยาที่ขาดจริยธรรม: เพื่อลดความสูญเสียทาง
เศรษฐกิจและสุขภาพของผู้ป่วย, กรุงเทพฯ, 2552 (Resolution of National
Health Assembly No. 2, Stop Unethical Drug Sale Promotion
to Decrease Economic Lost and for the Sake of Patient's
Health, Bangkok 2009)

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