

# TRANSPARENCY IN TRANSFER OF VALUE TO NON – PHYSICIAN HEALTHCARE PROFESSIONALS <sup>\*</sup>

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## ABSTRACT

As we know that healthcare service is one of the important factors that affect Thai people quality of lives. Healthcare professional is one of the occupations that gain public creditability. Public trusts that healthcare professionals expert in treatment and provide service by taking patients' benefits as their priorities. However, healthcare service is similar to other businesses in term of competition. Pharmaceutical companies have to compete in the market in order to gain profits. The said competition leads to marketing tactics aiming at healthcare professionals. Those marketing tactics cause conflicts of interests which are the roots of numerous problems such as irrational drug use, high price of drugs, negative effects on patients' health and et cetera.

Healthcare service sector consists of various kinds of healthcare professionals, thus, physician is not the only professional providing service in such sector. There are other non – physician healthcare professionals providing service in healthcare sector as well. For example, there are pharmacists and other healthcare service providers in the process of drugs and medical supplies selection and procurement of drugs and medical supplies. Hence, physicians are not the only healthcare professionals that conflicts of interests can arise in their relationship with pharmaceutical companies. Conflicts of interest can also arise in the relationship between pharmaceutical companies and non – physician healthcare professionals.

Accordingly, legal measure which aims to reduce conflicts of interests and enhance transparency should also focuses on relationship between non – physician healthcare professionals and pharmaceutical

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<sup>\*</sup> This article is summarized and arranged from the thesis “Transparency in Transfer of Value to Non – Physician Healthcare Professionals” Master of Laws in Business Laws (English Program), Faculty of Law, Thammasat University, 2016.

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companies. Focusing merely on the relationship between physicians and pharmaceutical companies leaves loophole in the law which can cause ineffectiveness in conflicts of interest reduction and transparency enhancement. Therefore, any benefit given by pharmaceutical companies to non – physician healthcare professionals should be disclosed to the public as well.

Since there is no legal measure concerning the disclosure between pharmaceutical companies and non – physician healthcare professionals, in this article, the author aims at studying foreign laws as a guideline in order to find the most suitable recommendation for conflict of interest reduction and transparency enhancement in the relationship between non – physician healthcare professionals and pharmaceutical companies in Thailand.

**Keywords:** Healthcare, Non – Physician Healthcare Professionals, Transparency, Disclosure

## บทคัดย่อ

เป็นที่ทราบกันดีว่า การให้บริการด้านสุขภาพนั้นเป็นหนึ่งในปัจจัยสำคัญที่ส่งผลต่อคุณภาพชีวิตของประชาชนชาวไทย ผู้ให้บริการด้านสุขภาพนั้นเป็นหนึ่งในวิชาชีพที่ได้รับความเชื่อถือจากสาธารณะซึ่งเชื่อมั่นว่าผู้ให้บริการด้านสุขภาพนั้นมีความรู้ความเชี่ยวชาญเป็นอย่างดีในการที่จะให้การดูแลรักษา และให้บริการโดยคำนึงถึงประโยชน์ของผู้รับบริการเป็นสิ่งสำคัญ อย่างไรก็ได้ การให้บริการด้านสุขภาพนั้นมีด้านที่เนื่องกับธุรกิจอื่น ๆ กล่าวคือ มีการแข่งขันในตลาดและผู้ประกอบการ คือ บริษัทยาและเวชภัณฑ์นั้นต่างมุ่งทำกำไรให้แก่บริษัทของตนซึ่งนำไปสู่การทำการตลาดต่าง ๆ โดยบริษัทยาและเวชภัณฑ์เหล่านั้นต่อผู้ให้บริการด้านสุขภาพ การทำการตลาดต่าง ๆ ซึ่งมีผู้ให้บริการด้านสุขภาพเป็นเป้าหมายนั้นส่งผลให้เกิดผลประโยชน์ทับซ้อนซึ่งเป็นต้นเหตุของปัญหาหลายประการ เช่น การใช้ยาโดยไม่จำเป็น ราคายาที่เพิ่มสูงขึ้น ผลกระทบด้านลบต่อสุขภาพของประชาชน เป็นต้น

ในการให้บริการด้านสุขภาพนั้น ประกอบด้วยผู้ให้บริการด้านสุขภาพในหลาย ๆ ด้าน ไม่ได้จำกัดเพียงเฉพาะแพทย์เท่านั้น แต่ยังมีผู้ให้บริการด้านสุขภาพที่ไม่ใช่แพทย์ประเภทอื่น ๆ ด้วย เช่น ในกระบวนการการตัดเลือกเวชภัณฑ์และยา กระบวนการการจัดซื้อจัดหายาและเวชภัณฑ์นั้น ประกอบด้วย เภสัชกรและผู้ให้บริการด้านสุขภาพประเภทอื่น ๆ ผลประโยชน์ทับซ้อนระหว่างบริษัทยาและเวชภัณฑ์นั้นจึงไม่จำกัดอยู่เพียงแพทย์เท่านั้น แต่ยังเกิดกับผู้ให้บริการด้านสุขภาพที่ไม่ใช่แพทย์อีกด้วย ด้วยเหตุนี้ หากจะมีบทบัญญัติกฎหมายเพื่อลดผลประโยชน์ทับซ้อนและสร้างความโปร่งใสในความสัมพันธ์ระหว่างบริษัทยาและเวชภัณฑ์กับผู้ให้บริการด้านสุขภาพเหล่านั้น บทบัญญัติแห่งกฎหมายนั้นเพิ่งมุ่งไปที่ความสัมพันธ์ระหว่างบริษัทยาและเวชภัณฑ์ที่ต้องเปิดเผยประโยชน์ที่ตนให้แก่ผู้ให้บริการด้านสุขภาพโดยจำกัดเฉพาะแพทย์เท่านั้นจึงส่งผลให้เกิดช่องโหว่ในตัวบทกฎหมายซึ่งทำให้การลดผลประโยชน์ทับซ้อนและเพิ่มความโปร่งใสไม่สามารถก่อให้เกิดผลลัพธ์ที่คาดหวังได้ ที่สำคัญคือ บริษัทยาและเวชภัณฑ์ที่ให้แก่ผู้ให้บริการด้านสุขภาพที่ไม่ใช่แพทย์นั้นจึงควรถูกกำหนดให้ต้องเปิดเผยแก่สาธารณะ เช่นกัน

เนื่องจากประเทศไทยยังไม่มีบทบัญญัติเกี่ยวกับการเปิดเผยความสัมพันธ์ระหว่างบริษัทยาและเวชภัณฑ์กับผู้ให้บริการด้านสุขภาพที่ไม่ใช่แพทย์ ในบทความลับนั้น ผู้เขียนจึงมีจุดมุ่งหมายใน

การศึกษาภูมายจากต่างประเทศเป็นแนวทางเพื่อให้ได้ข้อเสนอแนะที่เหมาะสมที่สุดในการลดผลกระทบเชิงลบซึ่งส่อไปในความสัมพันธ์ระหว่างบริษัทฯ และเวชภัณฑ์กับผู้ให้บริการด้านสุขภาพที่ไม่ใช่แพทย์ในประเทศไทย

**คำสำคัญ:** การให้บริการด้านสุขภาพ, ผู้ให้บริการด้านสุขภาพที่ไม่ใช่แพทย์, ความโปร่งใส, การเปิดเผย

## **1. INTRODUCTION**

Nowadays Thailand is one of those countries with advanced medical practice with numbers of foreigners coming to Thailand for medication and treatment. Besides, healthcare has grown as a vital part of Thai citizens' quality of life. Physicians and other healthcare professionals are respectable professions with trust from public's eyes. Drugs and medical supplies are viewed as moral products to improve and sustain people's health. However, the market of drugs and medical supplies are like other products' market with companies trying to earn more profits and companies being competitive to each other which bring about various kinds of promotion that can lead to conflicts of interest between healthcare professionals, pharmaceutical companies and their sale representatives. Those promotion methods can sustain or build relationship between pharmaceutical companies and healthcare professionals and they can be viewed as an incentive to use the companies' products. The said promotion methods can impair the decision of healthcare professionals, affect greatly to the consumers' health as they give their trust to healthcare professionals and do damages to our country since it can lead to irrational drug use and high priced drugs which will result in the loss of national budget. Hence, conflicts of interest reduction and transparency enhancement is much needed in such marketing field in order to bring light to the public about the relationship from the professionals they trust and pharmaceutical companies and it can make those parties reconsider about the relationship and incentives since such things are to be disclosed to the public's eyes. However, Thailand remains no such disclosure provision to supervise the said issue.

The practice of pharmaceutical and medical supply companies providing benefits such as gifts, product samples, and other benefits to healthcare professionals through companies' pharmaceutical sales representatives which can be viewed as an incentive to make the healthcare professionals feel familiar with their products and end up in using the products with the patients. The practice of conferences or meeting set up by pharmaceutical companies can be viewed as incentive when the accommodation, trips abroad, or banquets are provided. Moreover, it is questionable whether the information is given in all aspects; both downside and upside of the products or the products are presented only for their benefits since the information is given by the companies. Hence, the accuracy of information is questionable. Consequently, it can affect transparency and impair healthcare professionals' opinion on the companies' products.

In Thailand, there are legal provisions, self - regulations and voluntary code related to the area of relationship and behavior between pharmaceutical companies and healthcare professionals. In international level, there are various kinds of regulations in many levels such as international organization, membership organizations, European legal provisions, and national laws trying to enhance transparency and reduce conflicts of interest. On the aspect of disclosure, EFPIA Code on Disclosure of Transfers of Value is the self – regulation which contains disclosure duty towards its member companies operating in Europe. In France and United States, there has been an eagerness on the disclosure duty of pharmaceutical companies which leads to Law NO 2011 – 2012 Regarding the Reinforcement of the Safety of Medicinal and Health Products (Bertrand Act) and Physician Payment Sunshine Act (The Patient Protection and Affordable Care Act 2010) in both countries respectively. In Thailand, on the other hand, there is no specific legal provision on the disclosure of relationship between pharmaceutical companies and non – physician healthcare professionals. Hence, in order to enhance transparency, lighten public's concern about such relationship which can cause many downsides such as conflicts of interests, irrational drug use, loss of national budget, high priced drugs and et cetera, there should be a legal provision concerning such issue with the most comprehensive model used at present in order to contribute to the best result of transparency enhancement and conflicts of interest prevention.

## **2.RELATIONSHIP BETWEEN PHARMACEUTICAL COMPANIES AND NON – PHYSICIAN HEALTHCARE PROFESSIONALS**

Pharmaceutical Manufacturers pay large amount of money on drug promotion; sale representatives, samples, drug advertisement both on television, radio and publication media such as newspaper, including being a sponsor on events relating to education and conferences. In 2002, it has been found that around US\$21 billion paid on drug promotion. Nowadays, it is more vital to see the ways that drug promotion affects on drug prescribing and the use of medicines that resulting in increasing of money in the said execution. As it has been mentioned that in 2002, nearly US\$21 billion are paid on USA drug promotion<sup>1</sup>, the said sum of money is meagerly 30 times comparing with the money that national governments in many countries paid on informing about drug. In USA, there are more than 300,000 events arranging for physicians. Usually in developing countries, sale

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<sup>1</sup> Canadian Medical Association Journal (2003);169:699

representatives are almost solely drug information given by pharmaceutical companies. In those developing countries, there are big amounts of sale representative, for example, there might be one representative to every five physicians.<sup>2</sup>

Pharmaceutical industry is similar to other industries in the sense that companies aim at boosting their product sale and making the most profits which bring about various kinds of promotional methods. Using sale representatives is ones of those promotional methods in order to boost product sale by forming connection with healthcare professionals. Sale representatives are not the only promotional methods used by pharmaceutical companies, promotional methods can be provided in other means such as scholarship, conferences, trips, meals, seminars and et cetera. Those mentioned promotional methods have effects on attitude of healthcare professionals toward pharmaceutical companies' products which can bring about bias and affect the use of drugs which can damage patients' health. Since promotional methods can cause bias of healthcare professionals toward each product which can cause irrational drug use, bad effects to patients' health and loss in national expenditure. International organizations and government in many countries take an effort to intervene in such conduct by imposing both guidelines and legal provisions. In United States, in order to reduce conflicts of interests, Physician Payment Sunshine Act has been enacted in order to enhance transparency in the relationship between healthcare professionals and pharmaceutical companies, however, such Act aims only at physicians, hence, pharmaceutical companies take advantages of the law's loophole and aim at non – physician healthcare professionals in order to boost their product sale.

The situation in developing countries is quite similar in the sense that pharmaceutical companies also aim at physicians and healthcare professionals. In Thailand, promotional methods are also conducted by pharmaceutical companies targeting at healthcare professionals in various forms such as conferences, meals, product samples and et cetera.

Some might think that physicians are the only profession working in the process of drug use, however, there are other kinds of healthcare professionals in the process of drug and medical supplies use. For example, pharmacists play vital role in selection of drugs and medical supplies working in the committee form such as "Pharmacy and Therapeutic

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<sup>2</sup> Pauline Norris, Andrew Herxheimer, Joel Lexchin, Peter Mansfield, "Drug Promotion, What We Know, What We Have Yet to Learn – Reviews of Materials in WHO/HAI Database on Drug Promotion. World Health Organization and Health Action International"(2005)

Committee or PTC” which holds authority in setting policy in drugs and medical supplies selection. Hence, in order to bring the best result in transparency enhancement, physicians should not be the only professionals covered by the legal scope, non – physician healthcare professionals should also be included in the scope of covered recipients that pharmaceutical companies hold responsibility to disclose their interactions to the public.

### **3.LEGAL MEASURES CONCERNING TRANSPARENCY IN TRANSFER OF VALUE IN FOREIGN COUNTRIES**

Medical payment and transfer of value have been considered as a significant issue in public health in many countries. Therefore, there are various kinds of solutions to handle with such ethic concern, both non-legislative and legislative approach. In 1988, WHO issued Ethical Criteria for Medicinal Drug Promotion as a guideline that many countries can adopt.<sup>3</sup> In United States, the Pharmaceutical Research and Manufacturers of America or PhRMA which is representative organization of research-based pharmaceutical and biotechnology companies issued PhRMA Code on Interactions with Healthcare Professionals to be enforced among its member companies.<sup>4</sup> On the regulatory side in the United States, there is The Patient Protection and Affordable Care Act 2010 Section 6002 as known as Physician Payments Sunshine Act to control the sale promotion and relationship between pharmaceutical companies and healthcare professionals.<sup>5</sup> In Europe, there is EU Directive 2001/83/EC of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use which is enforceable among EU members.<sup>6</sup> On the self-regulation or voluntary side in Europe, EFPIA or European Federation of Pharmaceutical Industries and Associations issues EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations to be enforced among its member companies.<sup>7</sup> In France, there is the Decree No. 2011 – 2012 on the Strengthening of Health Protection for Medicinal and Health Products (aka the decree), such act is called Bertrand Act, which puts the duty to companies which are

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<sup>3</sup> WHO Ethical Criteria for Medicinal Drug Promotion 1988

<sup>4</sup> PhRMA Code on Interactions with Healthcare Professionals 2008

<sup>5</sup> Patient Protection and Affordable Care Act, Section 6002 (2010)

<sup>6</sup> EU Directive 2001/83/EC of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use (2001) L 311/67

<sup>7</sup> EFPIA European Federation of Pharmaceutical Industries and Associations “Who we are” <http://www.efpia.eu/about-us/who-we-are> accessed 25 January 2017

manufacturers or distributors of the products stated in Article L. 5311 – 1 of the French Code of Public Health to make disclosure concerning agreements and benefits made with the recipients.<sup>8</sup>

Since drugs and medical supplies are moral products which can cause great effects on humans' quality of life, unethical drug use is one of the top issues among others, guidelines and legal measures are imposed by international organizations, associations and countries. World Health Organization also raises concern about such issue by enacting WHO Ethical Criteria for Medicinal Drug Promotion 1988 as fundamental ethical standard to be applied in various levels. It can be used as a framework to be adapted into each country's measure.

Associations of professionals and business sectors in healthcare industry also concern about such issue by imposing their own ethical standards for their members. PhRMA Code on Interactions with Healthcare Professionals drafted by the Pharmaceutical Research and Manufacturers of America (PhRMA) to be used with its members which are R & D companies on the area of biotechnology. EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations is the Code governing EFPIA members which are pharmaceutical companies operating in Europe.

Unethical drug promotion is one of the main concerns in the European Union as EU Directive 2001/83/EC of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use has been enacted in order to be a framework for EU member countries to implement into their own national laws.

In United States and France, unethical drug promotion is also one of important issues, United States Physician Payment Sunshine Act and Law NO 2011 – 2012 Regarding the Reinforcement of the Safety of Medicinal and Health Products or Bertrand Act of France share similar core idea to enhance transparency in interactions between pharmaceutical companies and healthcare professionals. Both legal provisions impose duty to pharmaceutical companies to disclose their interactions with healthcare professionals in order to shine the light to the public about such relationship, reduce conflicts of interests and enhance transparency. However, the said legal provisions contain different issue in the definition of "covered

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<sup>8</sup> Baker & McKenzie "Interactions between life sciences companies and health care professionals: can the French Sunshine Act push transparency so far?" (Baker & McKenzie France, 13 April 2012)

recipients". According to the US Physician Sunshine Act, scope of covered recipients consists of physicians and teaching hospitals, non – physician healthcare professionals are excluded from such scope, hence, pharmaceutical companies do not hold responsibility to disclose their interactions with non – physician healthcare professionals. Such narrow scope of covered recipients in the US Physician Sunshine Act has caused controversial issue concerning its loophole since pharmaceutical companies tend to use the loophole targeting promotional marketing methods at non – physician healthcare professionals instead which lead to the question that whether the law itself can bring the best transparency enhancement and conflicts of interests prevention. The France Bertrand Act, on the other hand, contains much broader scope of covered recipients than the US Physician Payment Sunshine Act. The scope of covered recipients in France Bertrand Act covers non – physician healthcare professionals such as pharmacists, assistants to physicians, nurses and et cetera, in this author's point of view, the France Bertrand Act tends to leave less loophole than the US Physician Payment Sunshine Act since conflicts of interests can also occur with non – physician healthcare professionals. Accordingly, The France Bertrand Act which imposes duty to pharmaceutical companies to disclose their relationship with non – physician healthcare professionals tends to be more effective in transparency enhancement and conflicts of interests prevention than the US Physician Sunshine Act.

#### **4.RELATED THAI LAWS IN HEALTHCARE SECTOR**

At present, existing legal provisions in Thailand healthcare sector consists of private organization self – regulation, ethical standard of public committee, code of conduct of administrative organization, ethical standards and regulations of government organizations and legal provisions, which will be explained in the following paragraphs.

PReMa Code of Practice for Ethical Channel 10<sup>th</sup> Edition 2016, issued by Pharmaceutical Research and Manufacturers Association (PReMa) which is a non – profit association for new medicine research and development companies. Most of its members are international and big pharmaceutical companies. The Code covers pharmaceutical companies' interactions with healthcare professionals. Violated members may face various kinds of sanctions such as fines and membership violation. The

Code contains no disclosure provision and does not contain enforcement over non – member pharmaceutical companies.<sup>9</sup>

Announcement of National Pharmaceutical System Development Committee concerning the Ethical Criteria on Thailand Medicinal Promotion B.E. 2559 is an ethical standard issued by National Pharmaceutical System Development Committee. The Ethical Criteria contains ethical standard on drug promotion regarding various players in healthcare industry such as healthcare professionals and pharmaceutical companies. It aims to be used as a framework to be implemented for players in healthcare sector. There is no sanction stated in such Ethical Criteria.<sup>10</sup>

The Medical Council Regulations on Medical Ethics Preservation B.E. 2549 issued by Medical Council which holds administrative power over medical practitioners, the said Regulations contain provisions concerning medical practitioners' interactions with healthcare professionals by prohibiting medical practitioners to accept money or any object which exceeds 3,000 Thai Baht. Such provision is enforced by filing complaint to Medical Council. The said Regulations contain sanction for violated medical practitioners.<sup>11</sup>

Ministry of Public Health issues the Ministry of Public Health Regulation on the Administration of Drugs and Medical Supplies in Government Sector and Organizations under Ministry of Public Health B.E 2557 to be used as a main framework on drugs and medical supplies managements for organizations under the Ministry of Public Health. Such Regulation sets broad and general guidelines with a set of secondary Notifications of Ministry of Public Health on further specific issues. Using as general framework, there is no penalty stated in such Regulation.<sup>12</sup>

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<sup>9</sup> PReMa Code of Practice for Ethical Channel 10<sup>th</sup> Edition 2016

<sup>10</sup> ประกาศคณะกรรมการพัฒนาระบบยาแห่งชาติ เรื่อง เกณฑ์จริยธรรมว่าด้วยการ

ส่งเสริมการขายยาของประเทศไทย พ.ศ. ๒๕๕๙ (Announcement of National Pharmaceutical System Development Committee concerning the Ethical Criteria on Thailand Medicinal Promotion B.E. 2559)

<sup>11</sup> The Medical Council Regulations on Medical Ethics Preservation, B.E. 2549

<sup>12</sup> ระเบียบกระทรวงสาธารณสุขว่าด้วยการบริหารจัดการค้านยาและเวชภัณฑ์ที่มิใช้ยาของส่วนราชการและหน่วยงานในสังกัดกระทรวงสาธารณสุข พ.ศ. ๒๕๕๗ (The Ministry of Public Health Regulation on the Administration of Drugs and Medical Supplies in Government Sector and Organizations under Ministry of Public Health B.E. 2557)

The Notification of the Ministry of Public Health on the Ethical Standard concerning the Procurement and the Promotion on Drug Sale and Medical Supplies B.E. 2557 is a standard practice used for organizations under Ministry of Public Health which aims to enhance transparency in such organizations. It contains good practices for related parties on drug promotion issue such as prescribers, healthcare professionals, pharmaceutical companies, sale representatives. Hospitals and organizations under Ministry of Public Health hold duty to implement such Notification into their own standard practice. However, since it only aims to be guideline, there is no penalty stated in such Notification.<sup>13</sup>

The Notification of the Ministry of Public Health concerning the Practice in Drugs and Medical Supplies Management by Committee, Co – Committee or Sub – Committee B.E. 2557<sup>14</sup> aims to be a guideline for the management in each type of drugs and medical supplies to be managed efficiently and with good governance. It sets standard for drugs and medical supplies management of organizations under Ministry of Public Health in 4 levels which are organization level, district level, and medical supplies management, there is no penalty in the Notification.<sup>15</sup>

Related provision in Thai Criminal Code which consists of the provisions related to the offense against official and misconduct of the government officers. Although being convicted by criminal charges are considered grave since it has high penalty such as imprisonment, the relationship between healthcare professionals and pharmaceutical companies is questionable whether it is considered the violation of Criminal Code since

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<sup>13</sup> ประกาศกระทรวงสาธารณสุขว่าด้วยเกณฑ์จริยธรรมการจัดซื้อจัดหาและการส่งเสริมการขายยาและเวชภัณฑ์ที่มิใช่ยาของกระทรวงสาธารณสุข พ.ศ. ๒๕๕๗ ลงวันที่ ๓๐ ตุลาคม พ.ศ. ๒๕๕๗ (The

<sup>14</sup> Notification of the Ministry of Public Health on the Ethical Standard Concerning the Procurement and the Promotion on Drug Sale and Medical Supplies B.E. 2557 on 30<sup>th</sup> October B.E. 2557)

<sup>15</sup> ประกาศกระทรวงสาธารณสุขว่าด้วยแนวทางการบริหารจัดการด้านยาและเวชภัณฑ์ที่มิใช่ยาโดยคณะกรรมการหรือคณะกรรมการร่วมหรือคณะกรรมการย่อย พ.ศ. ๒๕๕๗ (The Notification of the Ministry of Public Health concerning the Practice in Drugs and Medical Supplies Management by Committee, Co – Committee or Sub – Committee B.E 2557)

the nature of such relationship can be claimed to build good relationship and for academic purpose.<sup>16</sup>

Drug Act B.E. 2510 contains provisions concerning drugs and drug advertisements. The Act contains committee body which holds authority in medicinal issues drug committee administrative power such as granting permission on drug manufacturer. There is penalty for violation of this Act.<sup>17</sup>

At present, there are two legal provisions concerning procurement of government supplies which are Regulation of Prime Minister's Office on Procurement B.E. 2535<sup>18</sup> and Procurement and Management of Government Supply Act B.E. 2560, the Procurement and Management of Government Supply Act was published on Thailand Royal Gazette on 24<sup>th</sup> February 2017<sup>19</sup> and shall be taken into effect on 23<sup>rd</sup> August 2017, which the former Regulation of Prime Minister's Office on Procurement shall soon to be replaced by such Act. Procurement and Management of Government Supply Act governs broader scope of organizations such as independent organizations and state enterprises. These two legal provisions on procurement show that the process of drug and medical supply selection is not limited only for physicians but there are other officers working in such process.

Since this part mainly explains on Thai laws in such related matters, the analysis shall be in the following part.

## **5.COMPARATIVE ANALYSIS OF THAI AND FOREIGN LAWS**

Irrational drug use, unethical drug promotion and conflicts of interests between healthcare professionals and pharmaceutical companies have been major concerns in international level. Thailand, although there are legal provisions and self – regulations addressing those concerns, irrational

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<sup>16</sup> English Version of Thai Criminal Code B.E. 2499 <<http://library.siam-legal.com/thai-criminal-code>> accessed on 29 June 2016

<sup>17</sup> Drug Act B.E. 2510

<sup>18</sup> ระเบียบสำนักนายกรัฐมนตรีว่าด้วยการพัสดุ พ.ศ. ๒๕๓๕ (Regulation of Prime Minister's Office on Procurement B.E 2535)

<sup>19</sup> พระราชบัญญัติการจัดซื้อจัดจ้างและการบริหารพัสดุภาครัฐ พ.ศ.๒๕๖๐ (Procurement and Management of Government Supply Act B.E 2560)

drug use caused by unethical drug promotion continues. In foreign countries, there have been efforts in shining the light in the interactions between healthcare professionals and pharmaceutical companies which the US Physician Payment Sunshine Act and France Bertrand Act impose duty of disclosure on pharmaceutical companies. However, the US Physician Payment Sunshine Act might be too narrow in the means of covered recipients which covers only physicians, leaving other healthcare professionals out of scope and pharmaceutical companies take such loophole to conduct their promotion on other non – physician healthcare professionals. France Bertrand Act, on the other hand, covers much wider range of healthcare professionals with non – physician healthcare professionals included. In Thailand, although there are various legal provisions and guidelines which address that unethical drug promotion occurs in our country, there is no solid legal provision concerning disclosure of relationship between healthcare professionals and pharmaceutical companies. At present, drug consumption in Thailand has been skyrocketed, the rise of drug consumption in Thailand is caused by unethical drug use which is harmful for Thai people's health. One of the main roots causing irrational drug use is influence that pharmaceutical companies have toward healthcare professionals. The study by Dharmniti Internal Audit Co., Ltd. has found that parties which are the cause of rise of unnecessary drug consumption in government officers is not caused by physicians only but also non – physician healthcare professionals who are related in the drug use such as auditors and pharmacists.<sup>20</sup> Considering those mentioned foreign legal provisions and current situation in Thailand, this author sees the opportunity to bring foreign laws as models for better transparency in the industry that will help reduce irrational drug use and contribute positive effects to Thai patients as a whole.

## 6.CONCLUSION AND RECOMMENDATIONS

Pharmaceutical products are merit goods which can effect greatly on both national level and patients' health, therefore, rational drug use is the critical factor to save our nation budget spent on drugs and protect patients' benefit. However, due to the competition in the industry, pharmaceutical

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<sup>20</sup> บริษัท ตรวจสอบภายในธรรมนิติ จำกัด “เปิดกลโงค่ายา ค่ารักษาพยาบาล สูงกว่า หมื่นล้าน” ๑๐ กุมภาพันธ์ ๒๕๖๐ (Dharmniti Internal Audit Co., Ltd “Corruption in Cost of Medical Care, losing more than Millions Thousands” 10 February 2017) <https://dir.co.th/th> accessed 24 July 2017

companies have to carry various methods in order to boost their circulation, hence, there are many kinds of promotions provided to people in the circle of drug and medical supply use such as conferences sponsored by pharmaceutical companies, sponsored overseas trips or even small souvenir, these mentioned examples to build the relationship by pharmaceutical companies' sale representatives for the said reason to boost the circulation, can contribute to conflicts of interest, lack of transparency and irrational drug use. However, conflicts of interest between pharmaceutical companies and healthcare professionals might not limit only between pharmaceutical companies and physicians.

Since there is no provision concerning the disclosure of agreements, benefits, payments and transfers of value in Thailand self – regulations, voluntary codes and legal provisions, moreover, self – regulations and voluntary codes do not contain strong legal enforcement or some are hard to be enforced, the author's preliminary suggestions are to draft specific provisions concerning the disclosure of the transfer of benefits, agreements and payments pharmaceutical companies made with healthcare professionals. The author believes that having specific legal provisions on such disclosure will acknowledge the consumers about their physicians and healthcare professionals' relationship with pharmaceutical companies, such disclosure will also raise awareness and public concern on the point of transparency and reduce conflicts of interest which affect consumer's health and cause irrational drug use. According to Alfonso case in USA, it shows that conflicts of interest not only occur between physicians but also other kinds of healthcare professionals. Therefore, it indicates that the United States version of Physician Payment Sunshine Act has its loophole in leaving non – physician healthcare professionals out of the scope of disclosure. Moreover, in Thailand, the process of drug selection and procurement is not limited only for physicians. Thus, using the model that limits only physicians is not the best way to prevent conflicts of interest and enhance transparency. Hence, this writer believes that the better way to prevent conflicts of interest and reduce irrational drug use is to include non – physician healthcare professionals in the definition of covered recipients by choosing Law NO 2011 – 2012 Regarding the Reinforcement of the Safety of Medicinal and Health Products or Bertrand Act as a model for Thai legislation since Law NO 2011 – 2012 is a legal provision with strong legal enforcement which will carry more effective outcome than voluntary code that has lax enforcement. Moreover, it contains wide range of covered recipients, including pharmacists and other non – physician healthcare professionals, which fulfills the loophole left by United States version of Physician Payment Sunshine Act.

The scope of covered recipients using Bertrand Act as a model should be extended to cover non – physician healthcare professionals in order to cover more staffs working in the line of drugs and medical supplies use to have better transparency enhancement. The scope should cover wider range such as physicians, dieticians, dentist, pharmacists, nurses, assistant to healthcare professionals, medical students and et cetera. Moreover, it should cover healthcare professionals associations, medical student associations, foundations in healthcare sector and et cetera. The scope of companies holding duty of disclosure should be pharmaceutical companies and drugs and medical supplies manufacturers in Thailand. The threshold of benefits and platform of disclosure can further be made by law. The disclosure principles should be made by amending Drug Act B.E. 2510, the responsible body should be the existing Drug Committee. The punishment such as fines, warnings or even license suspension can further be made by law.

Although this writer believes that only disclosure might not be enough to distinguish good and advantageous support on finance from the ones that arouse conflicts of interests and form inappropriate relationship. However, enhancing transparency on these kinds of relationships will be a good opportunity to prevent the forming of improper relationship and avoid the costs of healthcare which may rise as an inessential and extravagant ones causing by conflicts of interests.

## REFERENCES

### Book

Canadian Medical Association Journal (2003);169:699

Norris, Pauline, Andrew Herxheimer, Joel Lexchin, and Peter Mansfield. “Drug Promotion, What We Know, What We Have Yet to Learn – Reviews of Materials in WHO/HAI Database on Drug Promotion, World Health Organization and Health Action International” (2005) <<http://apps.who.int/medicinedocs/en/d/Js8109e/3.2.html>> accessed 15 July 2016

### Laws

#### English

“Code of Practice for Ethical Channel” (10th Edition, 2016) Pharmaceutical Research & Manufacturers Association (PReMA)

English Version of Thai Criminal Code B.E. 2499 <<http://library.siam-legal.com/thai-criminal-code>> accessed on 29 June 2016

EU Directive 2001/83/EC of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use (2001) L 311/67

Patient Protection and Affordable Care Act, Section 6002 (2010)

PhRMA Code on Interactions with Healthcare Professionals 2008

The Medical Council Regulations on Medical Ethics Preservation, B.E. 2549 (2006)

WHO Ethical Criteria for Medicinal Drug Promotion 1988

#### Thai

ประกาศกระทรวงสาธารณสุขว่าด้วยเกณฑ์บริยธรรมการจัดซื้อจัดหาและการส่งเสริมการขายยาและเวชภัณฑ์ที่มิใช่ยาของกระทรวงสาธารณสุข พ.ศ. ๒๕๕๗ ลงวันที่ ๓๐ ตุลาคม พ.ศ. ๒๕๕๗

(The Attachment of Notification of the Ministry of Public Health on the Ethical Standard Concerning the Procurement and the Promotion on

Drug Sale and Medical Supplies B.E. 2557 on 30th October B.E. 2557)

ประกาศกระทรวงสาธารณสุขว่าด้วยแนวทางการบริหารจัดการด้านยาและเวชภัณฑ์ที่มิใช่ยาโดยคณะกรรมการหรือคณะกรรมการร่วมหรือคณะกรรมการย่อย พ.ศ. ๒๕๕๗

(The Notification of the Ministry of Public Health concerning the Practice in Drugs and Medical Supplies Management by Committee, Co – Committee or Sub – Committee B.E 2557)

ประกาศคณะกรรมการพัฒนาระบบยาแห่งชาติ เรื่อง เกณฑ์จริยธรรมว่าด้วยการส่งเสริมการขายยาของประเทศไทย พ.ศ. ๒๕๕๘

(Announcement on Ethical Criteria on Thailand Medicinal Promotion B.E. 2559 issued by National Pharmaceutical System Development Committee)

พระราชบัญญัติการจัดซื้อจัดจ้างและการบริหารพัสดุภาครัฐ พ.ศ. ๒๕๖๐ (Procurement and Management of Government Supply Act B.E. 2560)

พระราชบัญญัติยา พ.ศ. ๒๕๑๐ (Drug Act B.E. 2510)

ระเบียบกระทรวงสาธารณสุขว่าด้วยการบริหารจัดการด้านยาและเวชภัณฑ์ที่มิใช่ยาของส่วนราชการและหน่วยงานในสังกัดกระทรวงสาธารณสุข พ.ศ. ๒๕๕๗ (The Ministry of Public Health Regulation on the Administration of Drugs and Medical Supplies in Government Sector and Organizations under Ministry of Public Health B.E. 2557)

ระเบียบสำนักนายกรัฐมนตรีว่าด้วยการพัสดุ พ.ศ. ๒๕๓๕ (Regulation of Prime Minister's Office on Procurement B.E. 2535)

Electronics Media

Baker & McKenzie “Interactions between life sciences companies and health care professionals: can the French Sunshine Act push transparency so far?”(Baker&McKenzieFrance,13April2012)

<<http://www.lexology.com/library/detail.aspx?g=44eeeadc-6a49-4c46-8a8e-df6d776dabde>> (accessed 15 February 2017)

## Other Materials

บริษัท ตรวจสอบภายในธรรมนิติ จำกัด “เปิดกล้องค่ายา ค่าวัสดุพยาบาลสูงกว่า หนึ่งล้าน”

๑๐ กุมภาพันธ์ ๒๕๖๐ (Dharmniti Internal Audit Co., Ltd “Corruption in Cost of

Medical Care, losing more than Millions Thousands” 10 February2017)

<<https://dir.co.th/th>>)(accessed 24 July 2017)