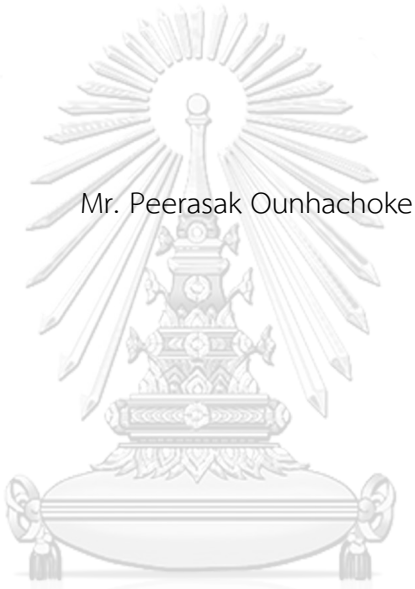
Malfunctioned Pacemaker and Business Operator's Liability in US, EU and Australia: Implication for Thailand

Mr. Peerasak Ounhachoke



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ความรับผิดทางแพ่งของผู้ประกอบการเกี่ยวกับเครื่องปรับจังหวะการเต้นของหัวใจ กรณีสินค้าชำรุดบกพร่องในสหรัฐอเมริกา สหภาพยุโรป และออสเตรเลีย: นัยต่อประเทศไทย

นายพีระศักดิ์ อุณหโชค

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญานิติศาสตรมหาบัณฑิต
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By	Mr. Peerasak Ounhachoke
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Thesis Advisor	Professor Dr. Sakda Thanitcul

Accepted by the Faculty of Law, Chulalongkorn University in Partial Fulfillment of the Requirements for the Master's Degree

.....Dean of the Faculty of Law

(Assistant Professor Dr. Pareena Srivanit)

THESIS COMMITTEE

.....Chairman

(Mr.Charnnarong Praneejit)

.....Thesis Advisor

(Professor Dr. Sakda Thanitcul)

.....Examiner

(Lecturer Dr.Natchapol Jitirat)

พีระศักดิ์ อุณหโชค : ความรับผิดทางแพ่งของผู้ประกอบการเกี่ยวกับเครื่องปรับจังหวะการเต้นของหัวใจ กรณีสินค้าชำรุดบกพร่องในสหรัฐอเมริกา สหภาพยุโรป และออสเตรเลีย: นัยต่อประเทศไทย (Malfunctioned Pacemaker and Business Operator's Liability in US, EU and Australia: Implication for Thailand) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: ศ. ดร. ศักดา ธนิตกุล, 154 หน้า.

ปัจจุบัน เครื่องกระตุ้นหัวใจหรือเครื่องมือแพทย์ที่ฝังในร่างกายมนุษย์กำลังมีบทบาทสำคัญกับวงการแพทย์ของประเทศไทย เนื่องด้วยเครื่องกระตุ้นหัวใจหรือเครื่องมือแพทย์ที่ฝังในร่างกายมนุษย์เหล่านี้เป็นสินค้าประเภทหนึ่งที่ผ่านกระบวนการผลิตเช่นเดียวกับสินค้าอื่นๆ จึงย่อมมีโอกาสชำรุดบกพร่องเกิดขึ้น ซึ่งอาจทำให้เกิดความเสียหายต่อผู้บริโภคมากกว่าสินค้าประเภทอื่น เนื่องจากตามลักษณะการใช้งาน เครื่องกระตุ้นหัวใจถูกฝังในร่างกายของผู้ป่วยซึ่งมีปัญหาเกี่ยวกับจังหวะการเต้นของหัวใจผิดปกติ ดังนั้นความชำรุดบกพร่องของเครื่องกระตุ้นหัวใจจึงอาจส่งผลกระทบร้ายแรงต่อผู้ป่วยจนถึงขั้นเสียชีวิต

วิทยานิพนธ์ฉบับนี้จึงมีวัตถุประสงค์เพื่อศึกษากฎหมายที่เกี่ยวข้องในประเทศไทยที่จะนำมาปรับใช้กับกรณีข้างต้น พัฒนาการของการปรับใช้กฎหมาย กล่าวคือ กฎหมายว่าด้วยสัญญาซื้อขาย กฎหมายลักษณะละเมิด พระราชบัญญัติคุ้มครองผู้บริโภค และพระราชบัญญัติสินค้าไม่ปลอดภัย วิเคราะห์ถึงความเหมาะสมและปัญหาที่เกิดจากการปรับใช้ รวมถึงศึกษามาตราการการควบคุมเครื่องมือแพทย์ในประเทศไทยที่ถูกกำหนดไว้ในพระราชบัญญัติเครื่องมือแพทย์ วิเคราะห์ถึงข้อดีข้อเสีย โดยศึกษาเปรียบเทียบกับมาตรการการควบคุมเครื่องมือแพทย์ของประเทศสหรัฐอเมริกา

นอกจากนี้ วิทยานิพนธ์ฉบับนี้ยังค้นคว้าเกี่ยวกับกรณีศึกษาที่เกี่ยวข้องกับประเด็นเครื่องกระตุ้นหัวใจชำรุดบกพร่อง ที่เกิดขึ้นในประเทศสหรัฐอเมริกา สภาพยุโรป และประเทศออสเตรเลีย พิจารณาแนวทางการตัดสินของศาล เหตุผลเบื้องหลัง การตีความกฎหมาย ตลอดจนการนำมาปรับใช้กับการตัดสินของศาลไทย พิจารณาถึงความเหมาะสมระหว่างความรับผิดที่ผู้ประกอบการสมควรได้รับและการคุ้มครองผู้บริโภคที่ได้รับความเสียหาย สุดท้ายนี้ ผู้เขียนมีวัตถุประสงค์ที่จะชี้ให้เห็นปัญหาเกี่ยวกับการชำรุดบกพร่องของเครื่องกระตุ้นหัวใจที่มีแนวโน้มจะเกิดขึ้นในประเทศไทยในอนาคตอันใกล้ เพื่อให้ทุกฝ่ายที่เกี่ยวข้องเตรียมพร้อมรับมืออย่างเหมาะสมและเป็นธรรม

สาขาวิชา กฎหมายธุรกิจ ลายมือชื่อนิสิต .....

ปีการศึกษา 2560 ลายมือชื่อ อ.ที่ปรึกษาหลัก .....

5786372734 : MAJOR BUSINESS LAW
KEYWORDS: PRODUCT LIABILITY, PROPERTY DAMAGE, DEFECTIVE PRODUCT, / PACEMAKER / CONSUMER PROTECTION

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At the present time, for the purpose of healthcare, pacemakers and other implantable medical devices are playing a significant role. However, the severity of level of damage arising from a malfunctioning pacemaker may be higher when compared with other simple products because when taking into consideration the characteristics and purpose of a pacemaker, it was normally implanted into a patient's body to control an abnormal heartbeat rate; therefore, a malfunctioned pacemaker may potentially cause harmful consequences, and in the worst scenario, death.

From the abovementioned issue, the aspects of this research focused on the evolution of the laws and regulations in Thailand in relation with defective products including but not limited to Product Liability Act B.E. 2551 (2008), moreover, the medical devices control system of Thailand defined in the Medical Devices Act B.E. 2551 (2008) in comparison with the United States were examined. In addition, this research referred to the judicial decisions on a malfunctioned pacemaker in the United States, the EU and Australia, their background reasons, interpretation and implications for Thailand. This study also examined what would be the most suitable solution for a Thai Court in regard with imposing a liability to an entrepreneur and the balance of consumer protection and social utilities. Finally, the author would like to mention the potential occurrences and issues of a malfunctioning pacemaker in Thailand for all related parties and stakeholders to be prepared for confronting this situation appropriately and equitably.

Field of Study: Business Law Student's Signature .....

Academic Year: 2017 Advisor's Signature .....

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CHAPTER 1 Introduction

1.1 Background

At present, Thailand has been classified by the World Bank as one of the "Upper-middle-income economies", or ranked as the 86th wealthiest country in comparison with all countries around the world.[1] Thus, this implies that the buying capacity of the Thai people has increased.

In the aspect of healthcare, in relation with the economic growth of Thailand, Thai medical services have also been substantially improved. Research conducted by the World Bank further demonstrated that the life expectancy at birth of the Thai population was 72.2 years old in 2005; however, this increased to be 74.2 years old in 2014.[2] This development has occurred because medical technology has significantly improved and because of the purchasing of high-level medical equipment or related necessary accessories to cure, remedy and save the life of patients. Thus, good healthcare is in demand by the Thai people.

Presently, the majority of high-level medical apparatus used in Thailand are unable to be manufactured in the country, so they are imported from other countries,

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[1] The World Bank, "Country and Lending Groups," accessed 13 February, http://data.worldbank.org/about/country-and-lending-groups#Upper_middle_income.

[2] "Data of Thailand," accessed 13 February 2016, http://search.worldbank.org/all?qterm=Thailand&title=&filetype=.

which have the efficiency to produce them. In 2017, a total of US$ 5.6 billion of medical equipment was imported into Thailand. From that amount, the Thai healthcare industry imported medical equipment valued at US$ 1.5 billion from Japan, US$ 1 billion from China and US$ 682.2 million from the Unites States of America, respectively[3], including but not limited to a significant amount from Malaysia and Switzerland.

A pacemaker is the one of the significant devices, which cannot be produced in Thailand, so they are imported into the country from many other countries around the world.

A pacemaker is a small medical device that is implanted into the patient's chest or abdomen to control an irregular heartbeat, which is slower than 60 beats per minute, as well as a faster or unusual rate by using electrical pulses that are triggered to prompt the heart to beat at a usual rate.[4]

Pacemakers are also used to treat arrhythmias. During an arrhythmia, the heart can beat too fast, too slow, or with an irregular rhythm; consequently, the heart may not be able to pump enough blood to the body[5]. The symptoms and effects of

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[3] World's Richest Countries, "Top Thailand Imports from the World," accessed June 2, 2018, http://www.worldsrichestcountries.com/top_thailand_imports.html.

[4] Lung and Blood Institute National Heart, "Pacemakers," accessed June 2, 2018, https://www.nhlbi.nih.gov/health-topics/pacemakers.

[5] Medtronic, "What Is Pacemaker," accessed June 2, 2018, http://www.medtronic.com/us-en/patients/treatments-therapies/pacemakers.html.

arrhythmias include shortness of breath, fatigue, or unreasoned fainting. Severe arrhythmias can damage the body's vital organs and may even cause loss of consciousness, including, but not limited to, death.

For the person who requires a pacemaker, a doctor will implant the device under the skin on the chest, just under the collarbone linking it to the patient's heart with tiny wires.[6]

With regards to Thailand, cardiovascular diseases, including arrhythmias, are a critical public health issue. In 2013, 54,530 people in total died from a form of these diseases; in the other words, six people died each hour from cardiovascular diseases.[7] Therefore, a pacemaker and other cardiac devices are becoming a significant factor for resolving this problem.

However, because Thai people, now, are still unable to produce or develop a pacemaker by themselves, but have imported from many countries; such as, the US, EU, China and Japan, the standard of each pacemaker, in comparison, may not be the same because of the technology and quality of manufacturing of each country, the differences in the manufacturing processes including the quality of the raw materials,

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[6] American Heart Assosiation, "Answers by Heart," accessed Jan 16 2018, http://www.heart.org/HEARTORG/Conditions/More/ToolsForYourHeartHealth/Answers-by-Heart-Fact-Sheets_UCM_300330_Article.jsp#.WxLmw7sh05s.

[7] Chatchai Nokdee, "Heart Decease Is Killing 6 Thai People Per Hour," *Thairath*, Sep 29 2014; ibid.

as well as, the differences of the applicable laws and regulations, which were used and enforced to control the standard of pacemakers in that particular country.

In some countries, for example, the US, rigorous regulations regarding every aspect of medical devices have been imposed on their manufacturers and importers. Alternatively, in some countries in which the technology and system for quality control of medical devices have not been imposed strictly and appropriately, the standards of their medical devices, including pacemakers are controlled just by the approval of documents, without any scientific check or approval from a professional technician or accredited organization.

As a consequence, there is a significant issue if, unfortunately, some pacemakers which were imported into Thailand were defective products. Thus, this is a serious problem because normally a pacemaker is implanted in the patient's body. This would therefore mean that defective products would be given to a person with heart disease. As such, instead of sustaining life, the defective pacemaker may cause severe adverse effects to that patient.

In order to resolve this problem, the government sector needs to impose stronger regulations for the control standards and safety of pacemakers, including, but not limited to other medical devices to guarantee public safety. Therefore, this research would demonstrate the current Thai regulations regarding medical devices,

the strengths and weaknesses which need to be added or revised, in comparison with universal standards, as well as medical device rules and regulations of the US.

In addition to the medical device control systems, it is necessary to know about the current Thai legislation in connection with defective products; for example, contract of sales, torts, Product Liability Act, Consumer Protection Act, Medical Devices Act, as well as protecting and curing consumers who were affected by defective pacemakers. Some people may believe that the afore-mentioned legislations could be used and applied to resolve this issue. However, in reality, cases in this category have never happened in Thailand, as almost all product liability cases in Thailand were filed and ended at the Consumer Protection Board (CPB). Moreover, the details of the case and the amount of compensation have never been disclosed to the public[8]. Consequently, the Supreme Court of Thailand has never passed down a sentence for a case regarding a defective pacemaker; however, this research intends to examine foreign cases, as well as the court's suggestions and final decisions. Furthermore, there are many other interesting issues; for example, what should a Thai court decide if in the case that there was a reasonable risk of failure of the pacemaker but it was not

[8] Kowit Somwaiya, (paper presented at the How to avoid product liability claims: effective risk management strategies' (seminar of Product liability law, Risk & Crisis Proactive Strategies Preventive measures), Sukhumvit, Bangkok, 2016).

possible to prove that a particular patient's pacemaker was defective without removing it[9]?

Many significant cases in the US, EU and Australia will also be explained in this research and the experience, decisions, background reasons, concepts, interpretation, burden of proof could be adopted if similar situations were to happen in Thailand. Additionally, the author would attempt to discover the best strategy to protect and preserve the right of the consumer, public safety and balance of social utilities at the same time.

1.2 Research Objectives

1. To examine the strengths and weaknesses of current Thai legislation in connection with product liability laws, especially in the case of malfunctioned pacemakers, that is contract of laws, tort laws, Consumer Protection Act, Product Liability Act and Medical Devices Act.

2. To examine the strengths and weaknesses of the control system of medical devices in Thailand, relevant laws, regulations and current practices.

3. To examine the medical device control system of the US in comparison with Thailand and the possibility of implications.

4. To investigate case studies regarding malfunctioned pacemakers in the US, EU and Australia, relevant laws and regulations of each case, interpretation of legislations in

[9]*Courtney V. Medtel Pty Limited*, (2003).

comparison with Thailand, and decisions together with the concepts and background of these decisions, as well as implications for Thailand.

5. To examine the best strategies to protect consumers from a malfunctioned pacemaker, implications to other similar medical devices, and balancing social utilities provided by the business sector.

1.3 Scope of the Research

This thesis scope will cover current Thai legislation in relation to product liability laws, in the case of a malfunctioned pacemaker which would bind and obligate business operators, contract of sales, tort laws, the Consumer Protection Act, Product Liability Act and Medical Devices Act, as well as rules and regulations in accordance with the medical device control system in Thailand in comparison with the US. In addition, this thesis' scope would involve the cases of malfunctioned pacemakers arising in the US, EU and Australia.

1.4 Research Hypothesis

For pacemaker business operators that have imported and distributed defective pacemakers or devices which may be at an additional risk for failure, strict liability shall be obligated and applied, for the best remedy and benefits of innocent consumers. In the aspect of the policy of the business sector, which conducts operations regarding pacemakers or medical devices that have to be implanted into a patient's body, they should be enforced to have a product liability insurance,

especially for a pacemaker, for ensuring compensation that affected consumers would be entitled. In addition, rigorous rules and regulations for controlling the standards and safety of medical devices in the US should be adopted into Thailand.

1.5 Research Procedures

1. To conduct a documentary research on the current Thai legislation in relation to product liability, in the case of malfunctioned pacemakers including the contract of sale principle, torts, Consumer Protection Act, Product Liability Act and Medical Devices Act, including, but not limited to related rules and regulations of the medical device control system in Thailand.

2. To collect data and conduct interviews experts, related governmental officers/agents, business operators/agents or by joining seminars or debates regarding product liability laws in Thailand.

3. To conduct comparative studies with the cases of malfunctioned pacemakers in the US, EU and Australia.

4. To conduct analytical studies on all information mentioned above and with current contemporary practices of Thailand for making a guideline and suggestions.

1.6 Benefits of the Research

1. To recognize and make aware the problem of malfunctioned pacemakers, types of cases and prepare to deal with them.

2. To realize the strengths and weaknesses of current Thai legislation in relation to product liability, in the case of malfunctioned pacemakers and to imply, as a guideline, experiences from malfunctioned pacemaker cases in the US, EU and Australia for application of Thai laws.

3. To recognize the strengths and weaknesses of the current medical device control system of Thailand and to adopt a rigorous medical device control system, rules and regulations of the US to be utilized in Thailand and improve it.

4. To know the customer's rights and business operator's liability in case of a malfunctioned pacemaker or medical devices that have to be implanted into the patient's body and to initiate a policy for the business sector to have product liability insurance for pacemakers and similar medical devices to ensure compensation would be awarded to consumers.

CHAPTER 2 Evolution of laws and regulations in relation to unsafe products in Thailand

In exchanging items, the sale of goods is the first normal and very simple transaction in society. This is started by a simple relationship in which the seller produces goods to sell to the buyer who is the end user. When the problem of defective products arises, it is therefore easy to find out and enforce the seller to be the responsible party.

However, these transactions have rapidly grown from the past to the present together with the market scale. The complexity of the relationship between contractors, buyers, sellers, manufacturers, importers and exporters affects the sale of goods in the same way. The products are manufactured in a huge quantity, so the manufacturer through the seller may not make a second sale to the buyer. However, in the case the goods or products were found to be defective and damage was done to the buyers or consumers, then it would be difficult to know which party or parties would be liable; moreover, the damage may not be limited to only a small group of consumers.

To uphold the rights of consumers, laws and regulations are the significant factors that impose duties, methods including but not limited to liabilities, as well as solutions and compensation. With regards to the range of unsafe or defective product

issues, there are numerous laws and regulations used for these cases including a contract of sale, torts, Consumer Protection Act, and so on. However, as those laws and regulations could not be adapted and applied for effectively resolving the issue of defective products, the Product Liability Act was drafted and enacted especially for this case.

In this chapter, the author will discuss about the evolution and improvement of laws and regulations in Thailand, from the past to the present-day, which have been adopted for defective products, in this case, especially, malfunctioning pacemakers. Those laws or regulations have some weaknesses for enforcement on the cases or cannot be adopted appropriately in some situations. Therefore, the author would demonstrate their limitations and reasons which affect those laws or regulations from being enforced efficiently resulting in the exploitation of the rights of the consumer.

2.1 Contract of Sales

In the beginning, a small sized market of sale where there is a simple transaction between the seller and the buyer are under a contract of sales. In this case seller and manufacturer always same person, thus there is no issue, the seller should be responsible for defective products. However, market size in present day is very huge and complex. Seller may not the same person with manufacturer.

These principles of sale have been defined in the Thailand Civil and Commercial Code, Sections 453-520. In this case, the author would demonstrate some provisions in relation to defective products, and the liability for defects.

Usually, a contract of sale is private and individual. Both parties can make and arrange their agreements mostly in the way that they desire; nevertheless, in minor issues whereby there is a need for conformity, the imposition of laws is required. Therefore, normally, if a buyer found a defect, the seller would be liable in which both parties would agree either by word or in writing. However, there would be greater clarity and no sense of doubt if they made their sales contract in writing. Although, in some cases, the buyer and seller did not make their agreement in writing, so the liabilities would be in accordance with the respective laws.

The seller would be liable for a defective product and if that defect had an adverse effect on the product's value or normal usage or purpose, which was agreed upon in the sales contract by both parties regardless of the recognition of that defect by the seller; in other words. The seller would be liable even if he/she knows or did not know about that defect.[10] However, there are three exceptions which the seller is able to avoid liability as follows:

[10] Civil and Commercial Code of Thailand.

i. The buyer knew of the defect at the time of sale or should have realized it if the buyer exercised such care which should be expected from an ordinary person.

ii. At the time of delivery, the defect could be obviously detected and was accepted voluntarily by the buyer without any conditions being made.

iii. The product was sold in the process of a public auction.[11]

Thus, there is no explanation given by the Thai contract of sales principle for the definition of liabilities in relation to a defective product. The seller has to provide a replacement with new products without any defect or repair of that defective product with his/her own expenses[12]. In some cases, the buyer is entitled the right to terminate that sales contract because the provision of a defective product was deemed as a breach of contract[13], so the seller has to return the full amount of the price of that product.

Based on the contract of sale, it can be concluded that in the case of a defective product, the solution is that the buyer as the consumer would receive a

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[11] Ibid.

[12] Ph.D. Pataichit Aekjariyakorn, *Explanations of Contract of Sales, Exchange and Give* (Winyuchon, 2005; repr., 5).

[13] *2830/2522*, (2522 B.E.).

replacement of a new product, a repair of the present product, or receive a full refund of the price. As such, those solutions would focus on the property's value.[14] However, in some cases, the damage is not limited only at the perspective of the product, it may extend to the life or health of the consumer, and other properties, for example. Replacing or refunding only the price of that defective product may not be considered as reasonable and fair damages for the affected party.

In the case of a defective pacemaker, the buyer as the patient who was implanted with a defective pacemaker into his/her body has the right to claim to the seller to replace it with a new pacemaker without any defect or pay the price of that pacemaker in accordance with the sales contract. However, a defective pacemaker may cause personal injury or, unfortunately, result in death to the patient, which was damage beyond the cost of that product. In this case, this would be obviously seen as being unfair to the patient; for instance, a malfunctioning pacemaker may cause unconsciousness and permanent disabilities to the patient, so, any physical and mental injuries should not be resolved fairly by replacing the defective product with a new one or providing a refund of its price. Hence, the principle of the contract of sale and obligations in which the debtor should be responsible to the creditor by focusing on the product and prices would not be seen as appropriate for this case.

[14] *Explanations of Contract of Sales, Exchange and Give*.

In conclusion, in Thailand, there are many obstructions of enforcement of the contract of sale to redeem the rights of the consumer who was affected by a defective pacemaker.

The initial obstruction is starting legal litigation in other countries that would be a disadvantage to the buyer. This was because most recently all business sectors had imported pacemakers from other countries, which meant that the seller had no domicile in Thailand. In accordance with international law, sovereignty, jurisdiction including the decisions and orders of a Thai court had no effect in other countries. Therefore, this would be a difficult situation for the buyer to start legal action against a seller located in other countries. Moreover, consumers are not familiar about the applicable laws and regulations of other territories including but not limited to, many legal processes, which they are not intimate with, as well as the huge costs and long period of time that they would have to spend, as well as the difficulty of gathering the necessary evidence in other countries.

The second obstruction would be if there was no contract of sale between the buyer and importer. Importers are the people or organizations who should be responsible for any problems relating to the sale of a product because they created this risk. However, a contract cannot impose obligations arising under it to any person

who is not a party; this principle is called “The Privity of Contract”[15]. In fact, the patient makes a contract with the pacemaker’s seller; such as, the hospital or clinic; he/she does not buy the pacemaker directly from the importer. As such, in the case of a defective pacemaker, the patient could sue the hospital, but not the importer. In the other words, the sales contract would not affect a third party who is not involved with that sales agreement, only the seller and the buyer.[16] Therefore, the contract of sale could not be used effectively for addressing this problem, as the importers have no liability under the contract of sale.

The third obstruction would be the damages and/or compensation under the principle of obligations, which does not cover the real damage incurred by the buyer. The definition of damages and/or compensation which the buyer is able to claim from the seller who delivers the defective products would only be limited for the replacement and the cost of those products. As the author has already mentioned, the seller only has to repair that defect or replace the old product with a new one, which has no defect as well as to refund the cost. However, if the pacemaker was defective while in the patient’s body, damages and/or compensation would not cover the cost of the operation for the removal of the defective pacemaker from the

[15] Sankalp Jain, "Rule of Privity of Contract: Study in English and Indian Context," (2014).

[16] N Andrews, "Privity of Contract: The Impact of the Contracts (Rights of Third Parties)," *The Cambridge Law Journal, 60(1), 200-224* (2001).

patient's body and implanting a new one; moreover, nor would there be any recompense for the cost of the hospital, any costs in connection with the lack of opportunities, cost for bodily and mental injuries, being disabled including but not limited to, in the worst scenario, death. That is an unfair situation for the buyer, as the customer.

For the three main reasons mentioned above, the author summarized that the contract of sale and principle of obligation under Thai laws and regulations are lacking in the preservation of the rights of the buyer, the affected party.

2.2 Tort

A tort is another path to claim damages or return to the status quo by the affected party. Imposing a liability on a person who commits a tort is called an act of law. This means that these liabilities do not come from the contract or agreement by both parties, but legislations. Therefore, the affected party who has suffered from a defective product is able to sue the manufacturer or the seller directly regardless of any relationship between the buyer and manufacturer.

In Thailand, the main concept of a tort is defined as a person who commits an illegal act to injure or harm the life, body, health, liberty, property or any right of others

intentionally or negligently shall be considered as a person who commits a tort and has to pay damages or compensation for that act.[17]

Hence, from the aforementioned concept, there are four factors which the injured person has to prove:

1) An illegal action has to have been committed. To interpret the word "act", not only action by movement, an inaction or ignorance may be deemed to be an act if that act should have been conducted because it is defined by laws or agreements. "Illegal" means that act, which does not comply with the respective laws. Therefore, an illegal act means the actions including but not limited to an inaction or ignorance, which does not comply with the relevant laws.

2) That act was done intentionally or negligently. An intentional act means the person who acted knew or realized that that act would cause damage to others, but the actor did not need to know or realize the kind of damage which would be incurred; for example, in the case of a pacemaker, the seller intended to sell a defective pacemaker to a distributor even though the seller knew that the device had a defect. Then that seller would be considered as the person who committed a tort; nevertheless, the

[17] *Civil and Commercial Code of Thailand*.

damage arising from that defective pacemaker would not be taking into consideration as the condition for an intentional act.

For a negligent act, this refers to an action, which was committed unintentionally; however, without exercising such care which should be expected from an ordinary person under such condition and circumstances, or the person could exercise such care but did not do so sufficiently.[18] For example, in selling a product without carefully checking it, the seller would have no intention to damage the consumer, but sufficient care was not properly exercised.

3) The damages were occurred against things defined by laws that provide life, body, health, liberty, property or any right. Moreover, it has to be certain kind of damage.

4) There was causation between the action and the result. This would only be provided that the damage occurred from a cause, which was committed directly by a tortfeasor. If there was no cause, the damage would not occur. In other words, that action would have a substantial role in causing the damage. In addition, a reasonable relationship between the cause and result (damage) would need to be taken into consideration. The cause would have to be a "proximate cause", which could be evaluated by a foreseeable situation. If the damage occurred could not have been reasonably

[18] *Criminal Code of Thaialand*.

anticipated, the proximate cause shall not be established; therefore, there would be no causation between the action and the damage thereby that act would not be considered as a tort.[19]

The affected party, as the plaintiff, would have to prove the four factors mentioned above completely to the court for claiming damages. If one or more of those factors were not proven or demonstrated, the defendant would be free from the liability of the torts.

In sales practices, all business sectors, manufacturers and sellers normally do not have any intention to damage the consumer. The damage usually arises from issues; such as, negligent manufacturing, design or warning. As a consequence, based on tort, the case of the damage in connection with a defective product done by negligence would not be considered as the intention of the business sector. Hence, the consumer would usually find a way to prove negligence.

However, there is an exception that the plaintiff would not need to prove all four factors. Firstly, if the damage occurred from the violation of any laws or provisions, which were purposed for the protection of others, the person who committed that damage would be deemed to be in fault[20]. Therefore, if the plaintiff could prove that the damage arising from the breach of laws, which was aimed to protect others; such

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[19] W.J. Stewart, "Collins Dictionary of Law," (2006).

[20] *Civil and Commercial Code of Thailand*.

as, the violation of the Consumer Protection Act, and the damage was a result from that breach, the defendant would be deemed as the tortfeasor who committed the torts intentionally or negligently, and there would be a burden of the defendant to defend itself. It should be noted that, in this case, the plaintiff would not need to prove about the intentional or negligent act of the defendant.

In the part of damages or compensation based on the torts, the court would be entitled to have the power to determine the way or amount of damages, which would be subject to the situation and the gravity of those torts.[21] The methods of compensation include the replacement of the property which was damaged by that tort, paying the costs of that property, including but not limited to, any involved damages.

Thus, it can be seen that the definition of damages is rather broad, and all actual damages would be determined by the court. In practice, all damages, which could be calculated in the form of money, monetary damages, would in reality be conducted. In addition, any damages which were not considered monetary damages; such as, damage of liberty, reputation or from suffering could be claimed by the enforcement of torts[22]. Moreover, damages for the future would be covered as well.

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[21] Ibid.

* However, in the practice of the Thai court, sadness or disappointment are not the cause to claim damages, which is based on torts.

Adapting to the scope of this research, in comparison with the contract of sales, there are many advantages of torts. The first is that the affected party (the patient) would be able to use torts to resolve the problem regarding the legal relationship between the importer of a pacemaker and the patient. Furthermore, the definition of damages has been extended to not only includeabout property. As such, related damages could be claimed by the enforcement of torts, Section 438.

Alternatively, there are disadvantages which could happen if the affected party used the torts as a weapon to contend against the other party in a defective product case. These are as follows:

1) There is difficulty to prove the act by the plaintiff. Due to the burden of proof according to the act of the tortfeasor, in the case of a defective product, the plaintiff would have to find out if that manufacturer, as the defendant, intended to produce those defective products or produce the products negligently. The problem is how could the plaintiff do this successfully if the products were manufactured by complicated processes or a high level of technology, including but not limited to specific knowledge which has not been easily understood; moreover, the information of the components or manufacturing processes were almost in the possession of the manufacturer, as the defendant. For this issue, specialists and huge costs, as well as, a long

period of time would be needed. As such, it would be difficult and unfair for the plaintiff to gather evidence and prove this factor of the tort.

2) Sometimes, actual damages may not arise because of a defective product since certain damage is a factor that activate the effects of torts, but, in some cases, a defective product may cause damage in the future. Consequently, uncertain damage, or damage which is going to potentially occur are not considered as the damage in the definitions of a tort. For example, one of the pacemakers in a specific lot were implanted into a patient's body. Then, a few years passed, and it was announced that some pacemakers in that specific lot might fail without warning because they were manufactured with faulty raw material, which may adversely affect the human body; moreover, there would be no way to identify the defect unless it was removed[23] from the patient's body. Therefore, patients who used the pacemakers in that specific lot would have a potential risk of receiving an unexpected effect from a defective pacemaker. Therefore, the patient would suffer from anxiety while that pacemaker was inside his/her body. In addition, there would be the expense for having a check-up or surgery to remove the suspected pacemaker from the body although the pacemakers in some patients' bodies may not be defective. In a tort, when the damage has not yet occurred, then a tort is

[23] *Courtney V. Medtel Pty Limited*.

irrelevant. Even if those damages mentioned above occurred, they would not be directly linked with the action of the actor because it would not be exactly known if the suspected pacemaker was defective or not. Hence, the mental damage and the damage arising from the elimination of the risk of failure may be interpreted in a way that they should not be resolved by a tort because there would be no actual defective product and no certain damage arising directly from a defective product.

In conclusion, torts benefit the consumer if the four necessary factors were proven by the plaintiff; such as, creating and connecting a relationship between the consumer and the importer (or the distributor) and extending the definition of damages, not only damages about property, but also other related damages. However, due to the factors of the tort which would have to be proven, this would be a difficult circumstance for the plaintiff, especially, proving the intentional or negligent acts of the defendant by the reasons of the difficulty and complexity of that act (manufacture); moreover, all important information possessed by the defendant may be concealed, in particular in the case that there was uncertain defective damage that may be not be covered under the torts.

2.3 Consumer Protection Act B.E. 2522 (1979)

This act was drafted and made effective for protecting the customer, who is defined as someone who acquires goods or services for direct use or ownership. This

act imposed many regulations to control the standard and safety of the products in the market including, but not limited to, labeling and advertising to safeguard consumers' interests, and eliminate goods that are hazardous to life and property. With regards to information, consumers have the right to be informed of the details of the products regarding the price, quality, quantity, warning, risk, etc. they desire to buy. This act imposes rules and duties on the manufacturers; such as, to disclose all necessary information to the public accurately and to advertise the products and services in good faith. Moreover, this act has some functions, which support and facilitate affected consumers to sue a disreputable manufacturer easily, timely and economically.

In summary, according to the scope of this research about defective products, the following issues benefit the customers under the Customer Protection Act B.E. 2522 (1979):

1) This act categorized the group of people who sell or distribute the goods or products to the consumers, as a "business person", which means the seller including, but not limited to, the manufacturer or importer for the sale or re-sale of goods in the market. This broad definition is advantageous consumers to accuse someone to take responsibility regarding defective products regardless of the direct legal relationship between the customers and those people. Moreover a "business person" under the Thai

Consumer Protection Act also includes a person who renders services and operates an advertising business as well.[24]

As such, this is a clear statement, which insists that the customers who suffer from defective products are entitled to the right to receive a solution.[25]

2) The establishment of the organization, the "Office of the Consumer Protection Board (OCPB)", which has a role to directly help and support customers.[26] The powers of the OCPB are, for example, to consider complaints from consumers who received damages resulting from the acts of the business person, to issue or publicize information about any goods and services which may potentially cause damage, to start legal proceedings regarding the infringement of consumers' rights, including but not limited to, proceed and manage goods or products, which may be harmful to consumers.[27]

3) There are particular steps for dealing with harmful products[28] in accordance with the powers of the OCPB to start some processes for resolving issues about the products, which have a potential risk to be hazardous. These are as follows:

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[24] *Consumer Protection Act of Thailand*.

[25] Ibid.

[26] Ibid.

[27] Ibid.

[28] Ibid.

3.1) The kind of product includes the product, which is reasonable to believe that it would cause damage or be harmful to the customer. This means that there is no necessity for certain damage to occur. This knowledge would be useful for the consumer because it would be illogical if the consumers have to wait for the occurrence of the damage first to begin any process. Then, there is a step for 'protection', as sometimes damage cannot be perfectly resolved, so protection is better.

In opposition with a tort, certain damage may be required, but it would not be practical to protect the damage.

3.2) When there is reasonable cause to suspect that any product may be harmful, the Board has the right to proceed with that product by ordering the business sector to test or verify the quality and standard of safety of such product. If, without any logical reason, nothing or no delay was done by the business sector, the OCPB has the right to conduct this by itself with the expense of that business sector.

3.3) For the test or verification mentioned above, if the result was that the products could be harmful to consumers, and that harm could

not be prevented effectively by the requirement of this act[29] or under any other laws, the OCPB would have the following powers:

i. to prohibit the sale of such products,

ii. to order the business sector to modify the goods in accordance with the conditions imposed by the OCPB,

iii. to order the business sector to destroy such products, in the case that the products cannot be modified or there is a doubtful situation that the business sector would keep the goods for sale at the expenses of the business sector.

3.4) For an urgent and necessary case, if the Board has the reason to believe that any product may be potentially harmful to consumers, the OCPB shall have the power to prohibit the sale of such products for the time, until the test or verification (mentioned in Item 3.2) has been completed. This prohibition would be published in the Government Gazette.

Therefore, it can be seen that to operate the power mentioned in Item 3.3), the OCPB would not have to wait for the result of the test or verification mentioned

[29] Ibid. *Section 30: Goods which are manufactured for sale by the factories under the law on factories and goods, which are ordered or imported into the Kingdom for sale shall be label-controlled goods.

in item 3.2) for prohibiting the sale of the suspected products. Nonetheless, the OCPB has the right to prohibit the sale of such potential products immediately if there is any reason to believe that harm is going to be occurred from the suspected products. Consequently, this is another method of protection that is beneficial for the customer.

3.5) A legal proceeding for affected customers would be initiated or coordinated by the OCPB. In case the breach of consumers' rights were found by the OCPB itself and it is appropriate to start legal action in the case that the OCPB had received the complaints from the consumers who were infringed on their rights and the institution of such legal actions is required and it would be beneficial to many consumers, the Board would have the power to appoint "a consumer protection official[30]" to have the duty to start civil and criminal proceedings in court against any business sector who commits that error. In addition, in accordance with the legal proceedings, the consumer protection official would have the power to claim property or damages for the affected consumers, and all costs and fees in order to proceed with any lawsuits would be exempted. Therefore, there is a function to help the customer who is impoverished and inexperienced about the law.

[30] A public prosecutor with the approval of the Director-General of the Department of Public Prosecutions, or an officer of the Consumer Protection Board whose qualification is not below a Bachelor of Laws degree.

3.6) Furthermore, for any performance in accordance with this act, the authority[31] would have the powers as follows:

i. to collect or take the products in reasonable quantities as samples for testing or verification without cost.

ii. to search and seize the products, its packaging, label or other documents, which do not conform with this act for the purpose of initiating the lawsuits against the business sector, which was reasonably suspected of committing a violation of this act,

iii. to enter any place in order to inspect as well as to examine any related documents and equipment of a business sector in the case that there is a reason to suspect that a violation under this act has been committed,

iv. to issue a summons to any person to give a statement or submit necessary documents and evidence for the consideration of the authority.[32]

[31] The authority means a person appointed by the Minister for the execution of this Act, defined in Section 3, Consumer Protection Act B.E. 2522 (1979).

[32] *Consumer Protection Act of Thailand*.

The powers mentioned above are the factors to accomplish the purposes of this act, which is protecting customers from harmful products.

The scope of the author focuses on the power of collecting evidence, as this is an advantage for the customers because all forms of evidence or information would be mainly in the possession of the manufacturers. The OCPB has many powers; such as, seizing any suspected product and entering a suspected place for gathering necessary information. Moreover, for the products manufactured by complicated processes and technology; such as, a pacemaker, when any defect was found, the manufacturer would be the best person who would know about the actual causes, and it would be conceivable that consumers would not know about those causes. If the cause of the defect could not be proved; therefore, it would be unable to prove the negligent act of the manufacturer which is a necessary fact of the tort. Adversely, the manufacturer could claim or deny that guilt freely because the consumers do not know the facts; thus, it would be seen as unequal for consumers.

Therefore, those mentioned problems have been resolved by this power of the authority; in other words, in the appropriate situation, the authority could issue the summons to call any business sector for giving significant information or to provide important evidence relating to the consumer cases to the authority. As such, this step would help consumers to clarify the cause of the defect.

3.7) Finally, this act imposes punishments, including but not limited to, criminal penalties in case of the violation of this act. For example, "Any person who obstructs or fails to render facilities or submit representation or deliver documents or evidences to the authority, that person shall be liable to imprisonment and/or a fine"[33], in other cases, any business sector who sells a product which has been prohibited by the OCPB because those products may be harmful to consumers, that person shall be liable to imprisonment and/or a fine also[34]. These liabilities and penalties would influence the business sector to comply with this act and be aware to manufacture or distribute their products. As a consequence, this is also an advantage for all customers' rights.

It seems to be beneficial for customers because they have specific laws and regulations to control, manage, and resolve the problems about defective products, as well as help, support and facilitate consumers in case of starting lawsuits, but there are some disadvantages which have occurred according to the enforcement and execution of the Consumer Protection Act B.E. 2522 (1979) as follows:

In practice, the processes under this act were done too slowly to protect the customers from harmful products. Even if the legislations were defined, the efficiency of the enforcement is an important factor to be considered. For Thailand, the

[33] Ibid. Section 45

[34] Ibid. Section 56

enforcement has not been rigid; moreover, the relevant processes have been performed too slowly. A real example is a "scientific blowing balloon case"[35], which was an unsafe product.

There was suspicion that one of the components of the blowing balloon was "ethyl acetate (EA)", a dangerous substance for people to consume into their body, especially in this case, mainly children. While children are blowing the balloon by using a tube, there was the unavoidable situation of them inhaling EA into their body. The result is it creates an irritation of the respiratory system and causes dizziness. If the consumers took too much EA into their body in the long term, it would affect the nervous system causing inactiveness, losing consciousness, losing the ability to breath, and in the worst case, death.[36] Therefore, in 1992, the scientific blowing balloon was prohibited to be sold for a temporary period and the OCPB ordered the Ministry of Science and Technology and Ministry of Public Health to check and verify the components in the scientific blowing balloon and finally found that EA was a component. This verification process took a total of 13 years, so in 2005, the scientific blowing balloon was announced as having harmful products and was prohibited from being sold. However, after that announcement, the blowing balloon was still found in

[35] Luke Nottage and Sakda Thanitcul, *Asean Product Liability and Consumer Product Safety Law* (Winyuchon publication house, 2016).

[36] Pollution Control Department of Thailand, "Material Safety Data Sheet(Msds) Information Center," accessed 15 May 2018, http://ohs.sci.dusit.ac.th/wp/?p=743.

small shops or peddlers in front of schools or grocery stores in flea markets.[37] Therefore, the tardiness of all processes and the enforcement of laws are the significant problems which affect the safety of consumers.

Additionally, almost all cases regarding defective or unsafe products were ended at the mediation step and unfair results would potentially happen. According to the steps for legal proceedings, the mediation step would be arranged for both parties of the affected customer and the business sector before starting the inquisition by the court, so to negotiate in order to reach a compromise and end that case. This is good for the court system because there is a way to end the case which is faster than taking all the steps of a legal proceeding. However, for cases regarding defective products, negotiation is seen as unfair for the customers because the manufacturers or business sector side have more influence to receive the benefit from negotiation; such as, more information in their possession, better lawyers, etc. For these reasons, mediation would be more beneficial for the manufacturer not the affected customer. Compensation resulting from the mediation may also not be worthy in comparison with the real damages arising from defective products. Despite unfair mediation and compensation, those results have generally been accepted by customers because they realize that they are unable to contend and win the case.

[37] Nottage and Thanitcul, *Asean Product Liability and Consumer Product Safety Law*.

Another weak point of unfair negotiation is normally the manufacturer would not accept its guilt, all processes, including the negotiation would be concealed as secret, then, the significant information; such as, the name of the defective product, cause of damage, methods to protect and/or resolve that damage would not be published. On the other hand, if the case was brought to the court and all the steps proceeded as usual, due to the principle of the transparency of the trial, significant information could be accessed by the public for a decision by the court. In the case that this involved popular products in a certain market, reporters or journalists could help to disseminate the information to society, so, the people would realize and acknowledge the problem of that defective product, and find the way to protect themselves. However, for the manufacturer, they would improve and resolve the problem for maintaining their business. Moreover, due to the court's decision and public pressure, compensation would be awarded for the affected customer to resolve the damage. These benefits would occur to the affected customer and society in the case that the defective product case was brought to court. Unfortunately, no benefits would be mentioned or be provided if private and unfair negotiation between the manufacturer and the affected customer was conducted.

Under the Consumer Protection Act B.E. 2522 (1979), there is no direct definition of the relationship between the manufacturer and the customer. This act mainly defines the relationship between the government and the business sector; for

example, the duties and powers of the OCPB for controlling the manufacturer regarding its defective products, rules and regulations which the manufacturer must abide by, and the benefits that the OCPB will provide to affected customers when the case occurs, but there is no direct and clear legal relationship between the manufacturer and customer. Moreover, the party who is entitled to receive damages under this act is only the buyer, tenant, hirer under a hire – purchase contract, or the party who obtains a product or service through his/her payment or compensation only; it does not include the end customer.

Furthermore, there is no provision about the civil liability defined in this act; there is only criminal liability.

Under the Consumer Protection Act, there are no obvious regulations or steps for initiating the measures to protect the customer. As such, to introduce those measures, the provisions defined in this act usually left the OCPB (and its officers) to consider whether the situation was appropriate to initiate the measures or not; if they decided that it was suitable, these measures would be engaged. However, in practice, those measures have rarely been utilized because the officers have no confidence in making a final decision. The words, ‘proper’ or ‘suitable’, which are the condition for initiating legal steps, are subjective for each person to analyze and decide, so for the same situation, some people may decide in different ways. For the manufacturer, it is sure that engaging those legal measures would cause disadvantages to their business, so

even if there were small or large problems, they would consider that it would not be necessary to introduce those measures by claiming that this is not a great problem, or it is not dangerous, or it can be resolved easily; therefore, in the view of the manufacturer, legal measures should not be engaged. In addition, manufacturers consider themselves to be better than consumers as they can influence the authority to believe them because, in almost all cases, the manufacturer is more popular, influential and knowledgeable than consumers. They could state that the products were invented and manufactured by themselves, the information is in their hands, so they have an advantage for predisposing the authority, or giving information partially, or concealing information which would be a disadvantage to themselves.

Moreover, not only explicit conditions for initiating legal measures for protecting affected customers, the authority also has no confidence to activate legal measures against the manufacturer because of the incidence of criminal law, which may adversely affect the authority, as any authority that uses his/her power inappropriately, then that authority would be liable.[38]

The authority who wrongfully exercises or does not exercise any of his/her duties to damage any person including but not limited to infringe anyone's right, would be punished.[39] In the case of this research, the interpretation of the word 'suitable' is

[38] *Criminal Code of Thaialand*. Section 157

[39] Ibid.

an ambiguous condition to engage the legal steps of the Consumer Protection Act. This is because the actions may be interpreted as exercising its duties to damage or discredit the manufacturer. The chances to be punished would affect the authority for making his/her decision to engage legal measures of the Consumer Protection Act, but in practice, they are rarely utilized.

Therefore, the lack of information and knowledge by the consumer including, but not limited to some unclear provisions for initiating the necessary steps under this act which may be adversely interpreted and provide punishments to the authority, the legal measures of the Consumer Protection Act which is an implement for helping affected customers have been utilized and rarely used in practice; therefore, unfairness still occurs to the consumer. Consequently. The Consumer Protection Act cannot effectively resolve the problem of defective products.

2.4 The Product Liability Act B.E. 2551 (2008)

It has been assumed that the Product Liability Act B.E. 2551 (2008) was drafted for resolving problems arising from defective products. As the author previously mentioned, because of ineffective legal measures of the contract of sales, torts and Consumer Protection Act B.E. 2522 (1979), which could not provide fairness to consumers, after many improvements of the original draft since the year 2000 by using

the 1985 European Economic Community (EEC) Directive as a model law[40], the Thai government announced the Product Liability Act B.E. 2551 (2008).

2.4.1 Background

First of all, it is necessary to know and understand the reasons why Thailand needs the Unsafe Goods Liability Act.

The Product Liability Act was created to resolve the problem of the legal relationship between the consumer and the manufacturer. In the case of a small social size, the relationship between the buyer and seller is not complicated, as the manufacturer and the seller is usually the same person; therefore, if the product is defective, the buyer can directly sue the seller. Unfortunately, at the present time, the market is so complicated, a manufacturer is a different party to the seller, so there is no relationship between the buyer and manufacturer. As such, the manufacturer has no liability under the contract of sale in accordance with the Privity of Contract. Nevertheless, the Product Liability Act defined a word 'entrepreneur', which included the manufacturer into its meaning. Hence, it can be concluded that the Product Liability Act has made a legal link between the affected customers and the manufacturer.

[40] Legal office of senate secretary office, "Minutes of the Council of State Office on the Liability of Damage Arising from Unsafe Product Act, Documents for Deliberating the Bill on the Liability for Damage Arising from Unsafe Product " (2007).

Moreover, nowadays, products are manufactured in huge amounts in a short time, and those products are distributed in abundance, so, the laws and regulations for control are required. The Product Liability Act is the direct instrument for dealing with this circumstance by imposing a strict liability, which is a liability without fault, to the business sector. Then, the business sector will realize their potential liabilities, quality of its manufacturing, and the product will be indirectly improved.

The Product Liability Act can also help the affected customers about their burdens of proof. Nowadays, everybody has to admit that the products have been improved, invented and manufactured by high and complicated technology, which is different from the past. The buyer cannot effectively use his/her knowledge and carefulness to select a good product when buying. As such, torts under the fault theory and the principle, 'Caveat Emptor', which defines that the buyer has the duty to use his/her carefulness, are not fair for this case. If not, there are many chances that the consumer is unable to prove the case and obtain a resolution. In addition, due to the high level of technology used in manufacturing, the consumer cannot prove the negligence of the business sector as well as find any causation, or relationship between the negligent action by the business sector and/or damage because they are unable to understand those complicated functions or components for proving that the damage occurred from its defect. Therefore, the Product Liability Act imposes the duty of proving to the entrepreneur instead of the consumer. This means that if the

consumer was damaged from a defective product, the consumer has no duty to prove the negligence of the other party, but the entrepreneur, knowing the procedure and its functions wholly, who is the best person that can protect or prevent any harm or damage, has a duty to prove that the product is not unsafe or prove that the damage arose by the mistake of the consumer themselves; such as, the consumer already knew that the product was unsafe or the damage occurred from inappropriate or incorrect use or storage in which there are instructions for the use and storage, or a warning or related information of that product was already defined correctly and clearly by the entrepreneur.[41]

2.4.2 Definition of Products

Products under this act mean any kind of moveable properties manufactured or imported for sale including agricultural products and electricity[42], excluding which products were specified in the Ministerial Regulations. Agricultural products refer to products from any form of agriculture; for example, farming, animal husbandry, scale insect breeding, etc.

In conclusion, the products covered by this act are only moveable properties, excluding real property; such as, land and component parts.

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[41] Sakda Thanitcul, *Explanation and Various Court Decisions: Product Liability Law* (Winyuchon publication house, 2010).

[42] *Product Liability Act of Thailand.* Section 4 "Product"

The manufacturing or importation of those products are another important condition whereby the product, which was created naturally is not covered by this act.

Finally, the products are purposed for sale, without any condition of quantity.

"Sell" means to distribute, dispense, give or exchange for business purposes, so obtaining a profit is not a condition for consideration because the actions done for business purposes are not necessarily for profit; such as, giving the products for free to promote a market and reputation[43]. Moreover, any return from the activities for business purposes is not only limited to money. In summary, the real purpose of that activity has to be considered carefully whether it is for business purposes or not.

Additionally, it is stated that a service is not included by this act.

In the case of this research, a pacemaker, as a product distributed in Thailand by importation, has been definitely included as a product under this act.

2.4.3 Definition of Damage

Damage in accordance with this act means damage caused by unsafe products that includes damage to life, the body, health, hygiene, mind or property, but does not include damage to such unsafe product itself.[44]

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[43] Ibid. Section 4 "Sell"

[44] Ibid. Section 4 "Damage"

Moreover, the section additionally defined “Mental damage” which means torture, pain, anxiety, phobia, sorrow, shame including, but not limited to, other similar types of mental damages.[45] This demonstrates that definitions of “damage” covered by the Product Liability Act are different and broader than the damage covered by the contract of sales.

2.4.4 Definition of Unsafe Products

The Act defined an unsafe product means products which cause or may cause damage either by:

i. its manufacturing defect arising from, for example, human error, malfunctioned machine, failure of quality control, misspecification or

ii. its design defect means nonconformity of shape, building, form including, but not limited to, formula and proportion, or

iii. by having no instructions, preservation, warning, caution or related information about those products or incorrect or unclear information mentioned in Item 3.[46]

[45] Ibid. Section 4 “Damage”

[46] Ibid. Section 4 “Unsafe Product”

For consideration, if that product can be categorized into any one of the four kinds mentioned above, it would be deemed as an unsafe product under this act.

However, for making a consideration about unsafe products under this act, at the end of its definition, the reasonable expectation of the people is an important condition; on the other hand, its nature, or usual usage and storage must be reasonably expected by the public.

However, there is an interesting point that an unsafe product under this act is not necessarily causing any damage first. If there was some reasonable potential that a product may cause damage, that product would also be defined as being an unsafe product under this act. For for example, in the case of this research about a pacemaker, if there was an announcement from the manufacturer that informed customers, who are patients who implanted with those pacemakers in their bodies that some of those pacemakers may malfunction while in usual usage without a warning signal because of a manufacturing defect, this would mean that all those pacemakers would be deemed as an unsafe product under the Product Liability Act of Thailand, even if some of those pacemakers would never malfunction in the future, or the patient has not yet been damaged by a malfunctioning pacemaker.

2.4.5 Definition of an Entrepreneur

As previously mentioned, an entrepreneur was defined as one of the following people:

i. Manufacturer or hirer,

ii. Importer,

iii. Seller of goods, in case, a manufacturer, hirer or importer cannot be identified,

iv. The person who uses the name, trade name, trademark, mark or the person who demonstrates in any way, which can be considered reasonably as the manufacturer, hirer or importer.[47]

It is clear that the definition about the person who is involved with an unsafe product is not limited only to the seller or manufacturer anymore, an importer or people who act like an agent or distributor of an unsafe product would also be considered as an entrepreneur under this act.

In case of a pacemaker, distributed in Thailand by importation, the actual manufacturer of the pacemaker is a foreigner; thus, it is a difficult situation whereby an injured person is going to sue those manufacturers; however, the importer of an

[47] Ibid. Section 4 “Entrepreneur”

unsafe pacemaker would be the person who would be sued and liable in accordance with the definition of entrepreneur under this act.

2.4.6 Party who is entitled to file a lawsuit

Not only an affected person, but also the Consumer Protection Board or associations and foundations certified by the Consumer Protection Board under the Consumer Protection law are entitled to file a law suit against an entrepreneur for damages on behalf of the affected person.[48] This is one of the benefits of this act provide to the customer because those organizations mentioned, who are able to commence the case, are professional in regards to the legal steps more than an affected person.

2.4.7 Burden of proof

Normally, in accordance with the torts, a person who brings case to court has the burden of proving in regards to the intention or negligence of the other party for manufacturing or importing such unsafe product, and the affected party's life, body, health, hygiene, mind and property was damaged from that product. As the author mentioned above, it is difficult for an affected party to prove because, nowadays, products are created or manufactured by complicated scientific procedures and technologies. If the affected party was unable to prove his/her case and he/she loses;

[48] Ibid. Section 10

therefore, in the case of the liability of an unsafe product under this act, the burdens mentioned before would be excluded from the affected party.

The Thai Product Liability Act defined that all entrepreneurs shall be jointly liable to the affected person for the damage caused by unsafe products, which have been sold to the affected person no matter whether the damage was intentionally or negligently caused by the entrepreneur.[49] The author would like to point out that for damages caused by an unsafe product, the entrepreneur has to be liable without the consideration of intention or negligence of that entrepreneur. In the other words, the entrepreneur's intention or negligence would not be a necessary factor for consideration under this act, which means the entrepreneur would be liable without its actual mistake. This is called "Strict liability", or liability without fault.

In the theory of fault, normally, the person who was blamed for committing any fault has to prove his/her fault fairly including, but not limited to, his/her intention. For fairness, people who would be liable, affecting their rights and liberty must be proved that they actually committed that fault by their intention or negligence. This was improved to be the principle of torts whereby a person who blames others has to prove the following four factors:

i. Actions or omissions of that person were done,

[49] Ibid. Section 5

ii. Intention of negligence for committing that fault of that person,

iii. Causation between actions and consequences,

iv. Damage arising from that fault.

All four factors are needed to prove for implying the liability to that person. However, for the principle of strict liability, intention or negligence, the feeling or thinking of the actor, are not the requirement in regards to the burden of proof anymore.

The reasons behind this concept of law, “strict liability”, which the entrepreneur may be liable without fault are as follows:

The scope of the laws on the results and consequences (product) mainly, not on the mind or thought of the actor (entrepreneur) due to the limitations and restrictions to know and prove the actor’s mind and intention; such as, in the view of manufacturing products and complicated method of production.

It should be fair to believe that the entrepreneur is the best person who can solve the causes of that damage. The entrepreneur has a duty to use his carefulness to manufacture a product distributed to the market.

Ignorance of intention or negligence of the entrepreneur for proving their fault is a benefit of the affected person because it is difficult, unfair and may be impossible to do so. However, this does not mean nothing cannot be done, the affected person

still has other factors to prove for implying the liabilities to the entrepreneur. As such, the Thai Product Liability Act imposes the factors which would be proved by the affected person, or its representatives as follows:

i. The product is involved with the entrepreneur,

ii. The affected person was damaged and the damage was occurred from that product (causation),

iii. The product was used or stored as usual.[50]

If all of the three factors were clearly proved by the affected person, the liabilities of this act would be implied to the entrepreneur, unless, at least one of the exceptions of those liabilities defined in this act was proved by the entrepreneur which the author will discuss next as the “exception clauses from the liabilities of the entrepreneur”.

2.4.8 Liabilities

Liabilities implied to the entrepreneur under this act are civil liabilities, or compensation.

An entrepreneur in the meaning of this act would be liable jointly to the affected person in connection with the damage arising from the unsafe product and that unsafe product was sold to the consumer without any condition of intention or negligence of the entrepreneur.

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[50] Ibid. Section 6

Therefore, the entrepreneur would be liable jointly, that means, when two or more entrepreneurs are jointly liable each would be individually liable for the whole debt or obligation they have together. As such, the affected person would be entitled to sue or any one of them for the full amount of its loss.[51] This is a benefit of the affected person provided by this Act.

Moreover, this act does not prohibit an affected person to sue for compensation in accordance with a tort.[52] In addition to the aforesaid compensation, the court has the power to consider to reward additional kinds of compensation.

As mentioned before by the author, civil liabilities under this act come with the compensation for the affected person, as he/she can claim the damages based on the torts. Furthermore, the court is given the power to determine other compensation as follows, in accordance with the Thai Unsafe Goods Liability Act:

Compensation of mental damage resulting from bodily, health or hygiene damage of such affected person; moreover, in the case the affected person died, its spouse parents or heirs would be entitled to receive this compensation.

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[51] Practical Law Thomson Reuters, "Joint Liability," accessed 25 April 2018, https://uk.practicallaw.thomsonreuters.com/0-200-1390?transitionType=Default&contextData=(sc.Default).

[52] *Unsafe Goods Liability ActProduct Liability Act of Thailand*. Section 11

Punitive damages would be claimed to the entrepreneur by the court in the case that the entrepreneur has manufactured, imported or sold a product which:

i. has been known to be an unsafe product by that entrepreneur, or

ii. was not known because of severe negligence of that entrepreneur itself,

iii. has been known to be an unsafe product after the completion of manufacturing, import or sale by the entrepreneur, and there was no suitable or necessary method or procedure for resolving the problem, or protecting the customer from damage.[53]

The court is entitled to determine the punitive damages as its sole reasonable discretion; however, punitive damage shall be limited at two times of the actual amount of the damages. In addition, many factors and circumstances for consideration of the court to determine the damages have been defined at the end of Section 11 of the Act; for instance, severity of damage which the affected person suffered, the awareness or knowledge of the entrepreneur regarding the danger of that product, the period which the entrepreneur concealed the facts regarding the danger of the product, the action was done by the entrepreneur after knowing that the product was unsafe, an advantage or benefit gained by the entrepreneur, financial status of the entrepreneur, the mitigation, an action done by the entrepreneur for reducing the

[53] Ibid.

severity, seriousness, or pain of the affected person, including but not limited to, causation of the damage involved by the affected person itself.

2.4.9 Exception clauses from liabilities

In the case the affected person or its representative succeeded in proving the factors mentioned above, this does not mean the entrepreneur has to be immediately implied in the liabilities of this act. Although the entrepreneur is unable to prove or use its intention or negligence for defending itself in regard to an unsafe product, the entrepreneur is still entitled to prove at least one of three following exceptions, which if successful in proving these exceptions would release the entrepreneur from the liabilities under this act:

Such product is not unsafe; thus, it should be fair that if that product was safe and not dangerous, the entrepreneur should not be liable.[54]

The affected person has already been aware or known that the product was unsafe.[55] If the customer accepts to willingly take the risk of an unsafe product, the liabilities should not be imposed on the entrepreneur.

The damage was caused by incorrect usage or storage when the correct and clear instructions or directions of usage or storage of that product including relevant

[54] Ibid. section 7(1)

[55] Ibid. section 7(2)

information about the product was appropriately provided by the entrepreneur.[56] If damage occurred from a mistake or fault of the customer when the entrepreneur has executed everything suitably to avoid the occurrence of damage, liability should not be implied on the entrepreneur.

These clauses of exception can show that the entrepreneur would be released from liability if the product was not defective, and in the case that the damage was occurred by the customer's mistake.

2.4.10 Prescription

The claim for damages under this act is barred by prescription after three years from the date that the damage and entrepreneur who would be liable was known by the affected person or after ten years since the date that unsafe product was found.[57]

In case that damage occurred to the customer's life, body, health or hygiene resulting from an accumulation of the substance in the affected person's body or in the case that time is required for the appearance or symptom of the damage; in other words, the damage has not happened suddenly, then it takes some period of time for showing, the affected person or its representative who are entitled to make a lawsuit have the right to claim the damages barred by prescription after three years from the date of that kind of damage; moreover, the entrepreneur who would be liable was

[56] Ibid. section 7(3)

[57] Ibid. section 12

known by the affected person or after ten years from the date that the kind of s damage was known by the affected person.

Therefore, it can be concluded that different kinds of damage have not been ignored by this act even if the damage which potentially takes some period of time for showing its symptom. Thus, this is a benefit for the injured person.

Moreover, in practice, the entrepreneur usually make a negotiation between both parties, mainly, for reducing the damages. Normally, this usually takes a long period of time. Another reason is when the case has just been publicized, and society focuses on the result. If the result was delayed by some court procedures, calling of evidence, including but not limited to, negotiations for reducing the damages, people may forget and not concentrate on a fair result. More importantly, the period of time given by the laws to claim the damages would be wasted and the right would eventually be barred by the prescription as the author mentioned above. However, from the effect of this Act, the prescription period would be legally suspended until the termination of the negotiation for reducing the damages made by either party.[58] This also protects the affected person from the influence of the entrepreneur.

As a consequence, it can be clearly seen that the Product Liability Act was drafted with the function for assisting customers or the affected party in the case of damage arising from an unsafe product, which is much better when compared with

[58] Ibid. section 13

the contract of sale or torts. Many points defined in Unsafe Goods Liability Act; for example, the burden of proof, strict liability, broad interpretation, compensation, punitive damages as well as individual prescription have been drafted to apply with the case efficiently and for the purpose of a fair result for the affected party.

However, in the case of a pacemaker, the Product Liability Act may not be perfectly applied with the damage arising from a malfunctioned pacemaker in some aspects. For instance, the normal use of a pacemaker is implanted in the human body, the proof of unsafety or its defect is definitely different and not able to be done in a simple way in comparison with other products; as such, occasionally, an operation is potentially needed for that proof. The necessary use of a pacemaker is more important in comparison with other products, as it is related to the medical reasons, saving life, then the severity of damage which may arise from a malfunctioned pacemaker is surely much greater when compared with other products. Therefore, the intensity of quality control, enforcing and interpretation of the related laws should be greater.

CHAPTER 3 Regulations of medical devices control in Thailand and the United States

In the first chapter of this study, the author informed about the evolution of the relevant laws and provisions, which have to be applied for the cases of defective or unsafe products. In this chapter, the author will discuss about the measures for the importation of pacemakers into Thailand in comparison with the United States (US), the beginning checkpoint to prevent potential consequences in each territory.

3.1 Pacemaker

A pacemaker is a little device to help controlling irregular heart rhythms that is placed in the patient's chest. This device uses electrical pulses to stimulate the heart to beat at a normal rate. However, for a medical definition, a pacemaker is actually a nature system of human body that sends electrical impulses to the heart in order to set the heart's rhythm; therefore, the pacemaker can be a normal "natural" pacemaker of the heart, or in case of heart decease, natural pacemaker was abnormal, it is an electronic device used for taking place. However, it may be malfunctioned, unsafe product.

The natural pacemaker of the heart is called the "sinus node", one of the major elements in the cardiac control system that affects the heartbeat rate. This

system generates electrical impulses and conducts them throughout the muscle of the heart prompting the heart to pump blood.[59]

An artificial pacemaker, which the author is focusing, is a device that was invented to regulate the heart's rhythm when the natural pacemaker cannot work properly, pacemakers, as medical device, are used to treat arrhythmias, which are problems with the rate or rhythm of the heartbeat. During an arrhythmia, the heart can beat too fast, too slow, or with an irregular rhythm.[60] Irregular electrical signaling is a root cause of arrhythmias. Pacemakers use or create low-energy electrical pulses to cure this abnormal occurrence.

A pacemaker consists of many components such as a computerized pulse generator, a battery and leads with sensors at their ends, which are called electrodes, the battery gives power to the generator. The leads connect the generator to the heart. The electrodes detect the heart's electrical activity and send data through the leads to the computer in the generator. If the heart's rhythm is abnormal, the computer will

[59] MedicineNet, "Pacemaker Definition and Facts," accessed 14 November 2017, https://www.medicinenet.com/pacemaker/article.htm.

[60] American Heart Assosiation, "About Arrhythmia," accessed 11 October 2017, http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/About-Arrhythmia_UCM_002010_Article.jsp#.WxOtWLsh05t.

conduct the generator to send electrical pulses that travel through the leads to reach the heart.[61]

Placing a pacemaker requires minor surgery for it to be implanted into the body. The surgery can be done regularly in a hospital or special heart treatment clinic. Overall, pacemaker surgery is generally safe. However, the following problems may occur: bleeding, swelling, bruising, or infection in the area where the pacemaker was placed, blood vessel or nerve damage, a collapsed lung, also bad reaction to the medicine used during the procedure.[62]

The patient receives a regular check-up doctor about every three months to see that the pacemaker is operating as required. Over time, a pacemaker can stop working because many reasons, for example, its wires get dislodged or broken, its battery gets weak or fails including but not limited to, other devices have disrupted the pacemaker's electrical signal.[63]

For battery replacement, pacemaker batteries last between five and 15 years, but on average for about 6 to 7 years depending on how active the pacemaker is. The doctor will replace the battery in the same time with the generator before the battery

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[61] Florida Hospital, "Components of a Pacemaker/Icd," accessed April 15, 2017, https://www.floridahospital.com/pacemaker/components.

[62] Ibid.

[63] Dizon J. Reiffel JA, "Cardiology Patient Page: The Implantable Cardioverter-Defibrillator: Patient Perspective," (2002).

starts to run down. Replacing the generator and battery requires less involved surgery than the original surgery to implant the pacemaker; nevertheless, the pacemaker wires may also need to be eventually replaced.[64]

Currently, Importation is the only way for having a pacemaker in Thailand. No one has manufactured them yet in the country. The measures for importing a pacemaker were defined in the Medical Devices Act B.E. 2551 (2008) because it has been categorized as a "medical device".

3.2 Definition of a Medical Device

The Medical Devices Act B.E. 2551 (2008) was developed from the Medical Devices Act B.E. 2531 (1988). Several sections were added for effectiveness.

According to the Medical Devices Act of Thailand, a "medical device" is defined as an instrument, apparatus, machine, appliance, implant, in vitro reagent, product, software, or others intended by the manufacturer to be used, alone or in combination or assembled with other items, for any of the following specific purposes:

i. device for practice within the related areas; such as, healing arts, medical, nursing and midwifery, dental, medical technology, physical therapy and veterinary;

[64] Ibid.

ii. diagnosis, prevention, monitoring, treatment, alleviation or cure of human or animal diseases;

iii. diagnosis, monitoring, treatment, alleviation or cure of human or animal injury;

iv. investigation, replacement, remedy, modification, or support of the anatomy or of a physiological process of a human's or animal's body;

v. supporting or sustaining the life of human beings or animals;

vi. control of the conception or promotion of human or animal fertility;

vii. aid or compensation for the disabled or handicapped human beings or animals;

viii. providing information for medical or diagnostic purposes by means of an in vitro examination of specimens derived from the human's or animal's body;

ix. disinfection or sterilization of a medical device;

A medical device under this act also included equipment or a component part of an instrument, apparatus, machine, product or object of those devices mentioned above;

Moreover, the Thai Minister of Public Health can define any instrument, apparatus, machine or product to be under the meaning of a medical device under this Act[65].

In conclusion, the definition of a medical device given by the Thai Medical Devices Act is so comprehensive. Not only are instruments for medical purposes; such as, healing, cure, diagnosis, and sustaining life included, but also their component parts as well as instruments. However, medical devices exclude instruments that have the main purpose relating to pharmacological, immunological or metabolic processes.

3.3 The related parties of medical devices control in Thailand

3.3.1 Minister of Public Health

This act defined that the Minister of Public Health shall have the duty and control of the execution of this act and shall have the power to appoint officials, issue Ministerial Regulations, issue notifications and determine other necessary activities to accomplish the purposes of this act including but not limited to imposing the relevant fees for execution of activities in accordance with this act.[66]

[65] *Medical Device Act of Thailand*. Section 4

[66] Ibid. Section 5

3.3.2 Medical Devices Committee

The “Medical Devices Committee” will be established legally under this act, which is composed of the following group of people:

i. the Permanent Secretary of the Ministry of Public Health as Chairperson;

ii. Directors and representatives of relevant departments or organizations in Thailand who are involved in controlling medical devices as members;

iii. qualified members appointed by the Minister, nine to 11 people; such as, medical practitioner, nursery and midwifery practitioner, dental practitioner, first-class veterinary practitioner, representative of an association or foundation having an objective relating to the promotion or support of medical facility operations, and representative of an association or operator having the objective of manufacturing, importing or sales of medical devices,

iv. The Deputy Secretary-General designated by the Secretary-General shall be a member and secretary, and the Director of

the Medical Devices Control Division, Food and Drug Administration, shall be a member and assistant secretary.[67]

It can be seen that the Medical Devices Committee is a group of people who have knowledge and special experience in the medical field; therefore, this committee would play important roles in this act to control the quality and standard of medical devices in Thailand.

3.3.3 Grantor

The grantor of this Act is the Secretary-General of the Food and Drug Administration or a designated person who is entitled to provide permission or the rights of importation, manufacture and sale to a "Licensee"[68] in compliance with the regulations in this act.

3.3.4 Licensee

A licensee is a person who obtains licenses from the grantors under this act, in case of a juristic person, a person who was appointed or designated by the juristic person to operate its business shall also be included.

[67] Ibid. Section 7

[68] Ibid. Section 4

3.4 Importation Control

3.4.1 Application for the Certificate of Establishment

This act gives the definition of import as to bring or order an item into the Kingdom of Thailand[69]. Consequently, the ways which the medical devices were brought into the territory shall all be interpreted as imported whether by air, sea or ground. Moreover, a number of medical devices do not require any consideration; therefore, it should be noted that any purpose of importation is not an issue of concern.

For being a legal importer under this act, that person who intends to manufacture or import a medical device shall register his/her establishment with the grantor.[70] An application for registration of an establishment in accordance with the rules, procedures and conditions shall be done in accordance with the Ministerial Regulations.

There are some forms and attached documents defined by the Medical Device Control Division which are needed; such as, process demonstration form, requesting form, map of the establishment and nearby buildings, interior layout of that establishment including but not limited to personal documents proving that the applicant is legitimate; for example, copy of the company's registration issued by the

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[69] Ibid.

[70] Ibid. Section 15

Department of Business Development, Ministry of Commerce, applicant's photograph, applicant's identification card, and medical certificate. Moreover, a fee is required to be paid.[71]

An interesting point for the establishment's registration is there is an appendix form which the applicant needs to complete the common name and Universal Medical Devices Nomenclature System (UMDNS). As such, the applicant must provide details of all the medical devices that he/she intends to import or sell.

The applicant can be an individual person or juristic person. The qualifications of the applicant were also imposed including having residence in Thailand, no status of bankruptcy, and one qualification which is important for import control is that the applicant must have a place for the manufacturing or importing of medical devices.[72]

There are some regulations for receiving approval imposed by the Ministry of Public Health about the place for importation that includes the equipment or instruments, which would be used for the storage of medical devices. The place for storage of medical devices has to be clean, and have suitable and enough light, as well as good ventilation. There must be a sufficient number of equipment or

[71] Food and Drug Administration of Thailand, "Forms, Rules, Processes and Conditions for Registration of Establishment, in Regard with Importation of Medical Device," (B.E. 2552).

[72] *Medical Device Act of Thailand*. Section 16

instruments for the storage of each category of the medical devices, which must be stored separately and systematically.[73]

Within a period of not more than 15 days, all processes must be completed by the grantor, so the Certificate of Establishment would be issued for the applicant.

However, obtaining a Certificate of Establishment for the importing and selling of medical devices in accordance with Section 15 of Medical Devices Act is not sufficient for making the importation. The Certificate of Establishment is just one of many requirements.

3.4.2 Application for a Certificate of Medical Devices Importation

After the applicant has completed the necessary processes and received the Certificate of Establishment, there are the prohibitions for importing or the sale of medical devices in Thailand as defined in the Notification of the Ministry of Public Health No. 34 B.E. 2549 (2006) whereby if the applicant does not comply with these rules and regulations, the importation will not be considered legal. Thus, the final part of the process, the applicant will receive after accomplishing all the steps in accordance with that notification is a “Certificate of Medical Devices Importation”.

The Notification of the Ministry of Public Health No. 34 B.E. 2549 (2006) issued by the Ministry was made and published before the Medical Devices Act B.E. 2551

[73] Ministry of Health, "Notification, the Establishment for Medical Device Importation," (B.E. 2552).

(2008), so, the laws and regulations which were imposed previously should be revoked. However, all Ministerial Regulations or Notifications issued under the Medical Devices Act B.E. 2531 (1988) being effective before the day this act comes into force, would continue to be in force insofar as they were not contrary to or inconsistent with the provisions of this act until the latest issuance of the Ministerial Regulations or Notifications under this act were completed.[74]

In conclusion, now, there are no Ministerial Regulations or Notifications which prohibit the importing or sales of medical devices issued by any Ministry or authorized organization by using the power of the Medical Devices Act B.E. 2551 (2008), so, Notification of the Ministry of Public Health No. 34 B.E. 2549 (2006) issued by the Ministry would continue to be in force.

The Notification of the Ministry of Public Health No. 34 B.E. 2549 (2006) would lead the applicant to obtain the "Certificate of Medical Devices Importation", as the author mentioned, it has to be used together with the "Certificate of Establishment" in accordance with Section 15, Thai Medical Devices Act B.E. 2551 (2008).

Furthermore, there are medical devices which were prohibited for importation and sale[75] as follows:

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[74] *Medical Device Act of Thailand*. Section 129

[75] "Notification No.34: Medical Device, Prohibition for Sale and Importation," ed. Thai Ministry of Health (B.E.2549).

i. Medical device which has a name, type, category or any aspect that has been prohibited or banned for sale in the manufacturer's or owner's country;

ii. Medical device which has no Certificate of Free Sale (CFS) issued by the manufacturer's country to show to an authority at checkpoints imposed by the Food and Drug Administration of Thailand (Thai FDA). Moreover, the contexts defined in that CFS have to comply with the regulations imposed by the Thai FDA.

On the other hand, a "free sale" is a required document which has to be submitted to the authority appointed by the Thai FDA.

3.4.2.1 Thai Regulations for the Certificate of Free Sale

The Certificate of Free Sale (CFS) means a certification that the products are approved for unrestricted sale in the country of origin.[76] It can be issued by:

i. the original country's government, or

ii. state organization, which is certified by that government;

iii. private sector.

[76] Global Negotiator, "Dictionary of International Trade, Certificate of Freesale," accessed May 20 2018, https://www.globalnegotiator.com/international-trade/dictionary/certificate-free-sale/.

For the importation of medical devices into the Kingdom of Thailand, the qualifications required for a CFS as follows:

i. The CFS has to be issued by a government organization of the manufacturer's country or private organization, which was certified by its government.

A free sale, which was issued by a private company without the certification of its government is not acceptable.

ii. That CFS has not expired. In case the expiration date was not found, that CFS must not have been issued more than two years from the issuance date.

iii. The following details have to be defined in the CFS:

- Name of the manufacturer, composer or packing company and its address;

- Name of that medical device, which has to specify its type, size, code, and so on. In case of a difference between the trading name of the medical device used in the country of origin and the name which was intended to be used in Thailand, the same has to be approved.

- Messages or documents which show that the medical device has been sold in the manufacturer's country. In case there was no sale of that medical device in the manufacturer's country because it is unnecessary, a certificate of origin from that country is required together with the CFS issued by the owner's country or country in which that medical device has been sold.[77]

For the medical device which was manufactured, composed or packed by any country which has been a member of the European Union, and the EU directive in regard with medical devices has been complied, as well as the 'EC' mark was given, an importer can use the EC certificate or EC Declaration of Conformity instead of a CFS.

In case that there is no sale of that medical device in the manufacturer's country, but it has been sold in the US, Canada, Japan, Australia or the EU group of

[77] Food and Drug Administrarion of Thailand, "Regulations: Certificate of Free Sale for Importation of Medical Device, and Exceptional Medical Device, Demonstrating against the Authority at Fda Checkpoints " (B.E. 2550).

countries, the CFS in those countries above are replaceable including the Certificate of Manufacture (COM) and explanation letter for its necessity.[78]

In conclusion, together with other attachments, a CFS is a requirement for the importation of medical devices into Thailand.

However, the CFS alone is not enough for some medical devices, which are a potential risk to humans, or by the reason of consumer protection defined by the Thai FDA. For this group of medical devices, a "certificate of the quality of the manufacturing system" issued by the government of the manufacturer's country of organization certified by that government is also required.

The following medical devices were categorized as those which might be a risk for human use[79]:

i. Implant products;

ii. Devices which were derived from tissue;

iii. Sterile products;

iv. Radiological instruments both for diagnosis and therapy;

[78] Food and Drug Administration of Thailand, *Manual for Application of Certificate of Medical Device Importation: In Case of General Medical Device, Exception from Section 6(1)(2) in Accordance with Thai Medical Device Act B.E. 2551* (B.E. 2559).

[79] Section 5 in the Regulations issued by the Thai FDA on 26 March B.E. 2550

v. In vitro-diagnostic products for:

- Blood group test: ABO system;
- Diagnostic agents; for example, HIV infection, hepatitis infection, HTLV infection, biochemical tests: Glucose, lipid profile, liver function test, Creatinine, pregnancy test, drug abuse, hormones and cardiac markers;
- Disinfectant solutions for medical devices;
- Restorative material and orthodontic products.

According to the regulations of the Medical Devices Control Division of Thailand, the certificate of the quality of the manufacturing system has to state Good Manufacturing Practices (GMP) or Quality Management System (QMS), or similar systems which have been approved by the Thai FDA. The in demand QMS for Thailand is ISO 13485, which was created especially for controlling the quality of medical devices.

The certificate of the quality of the manufacturing system has to be shown to the authority at the food and drug checkpoints before importing into Thailand.

However, there are exceptions from the conditions defined in Items 2) and 3) above. This means if that medical device is not prohibited for sale in other countries,

a CFS and/or certificate of the quality of the manufacturing system is not necessary for the following medical devices:

i. Medical device, its components, equipment, and installment which cannot be used separately, has to be used together with or for the purpose of repair.

ii. Medical device, its components, equipment, and installment which shall be used for the purpose of manufacturing a medical device or drug that has been permitted in Thailand.

iii. Medical device which shall be manufactured for the purpose of export.

iv. In a suitable amount, a medical device which shall be used for a specific reason, education, analysis, and/or test for checking the quality and standard.

v. Medical device which was imported for technicians to repair and then sent back, or a medical device which was exported for repair then will be imported back into the Kingdom.

vi. Medical device which will be donated to a state organization that has its purpose of protection, investigation, healing or rehabilitation of disease and ailment, or to be given to the Thai

Red Cross Society, or to any charity which has been permitted by the Thai FDA.

vii. Medical device which will be used by a state organization that has its purpose of protection, investigation, healing or rehabilitation of disease and ailment.

viii. Medical device which can show its efficiency, standard, quality and safety approved by the Thai FDA.[80]

In summary, unless a medical device is exempted as defined in Section 27, Thai Medical Device Act B.E. 2551 (2008) and/or the group of medical devices as defined in the notification issued by the Thai FDA, or if having a Certificate of Free Sale (CFS) for importing medical devices, or for the importation of specific medical devices without a CFS for demonstrating to a authority at food and drug checkpoints, the applicant has to apply for a Certificate of Establishment to define his/her place for conducting the business of importing and selling the medical device, under Section 15, Thai Medical Devices Act. After that, the Certificate of Medical Devices Importation in accordance with Notification No. 34 of the Ministry of Public Health B.E. 2549 (2006) has to be obtained by the applicant also by submitting the CFS and/or the certificate of the quality of the manufacturing system issued by the state organization of the

[80] "Notification No.34: Medical Device, Prohibition for Sale and Importation."

manufacturer's country or any organization certified by the government of that country.

3.4.3 Application for an Import License and Specification Declaration: Special medical devices

In some situations, the Certificate of Establishment and Certificate of Medical Devices Importation are not satisfactory for the Thai FDA for the importing of a medical device. This is because according to the Thai Medical Devices Act, for some kinds of medical devices, the importer has to apply for a "license"[81] or make a "specification declaration".[82]

For the conditions and purposes of the control of medical devices and consumer protection in Thailand, the Minister, through the advice of the Committee, has the power to prescribe by notification for some medical devices to obtain a license or make a declaration necessary for the importation or sale.

At present, in accordance with the notifications issued by the Ministry of Public Health, there are two groups of "special medical devices", which are subject to the conditions of obtaining a license and making a specification declaration as follows:

i. Medical devices which have to apply for a license:

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[81] *Medical Device Act of Thailand*. Section 17

[82] Ibid. Section 19

- Condoms;
- Examination gloves;
- Surgical gloves;
- HIV test kits;
- Contact lens;
- Human blood bags.[83]

ii. Medical devices which have to make a declaration:

- Sterile disposable syringes;
- Sterile disposable insulin syringes;
- Physiotherapy products;
- Alcohol detectors;
- Silicone breast prostheses implants;
- Topical equipment or instrument used as a breast enhancer;
- Amphetamine test kits for urine (by immunochromatography).[84]

[83] Ibid. Section 6(1)

[84] Ibid. Section 6(2)

For each category of the medical devices mentioned above, there was a particular notification issued by the Thai Ministry of Public Health. Each notification defined an individual instructions with regards to the import, manufacturing and sale of that respective medical device.

Therefore, all importers have to first apply for a Certificate of Establishment. Then, after that:

(1) if the medical device they desire to import or sell is a “general medical device”, that importer has to apply for a Certificate of Medical Devices Importation by submitting the relevant documents, Certificate of Free Sale, and other attached documents. In some cases, if there was a medical device which may be a potential risk for human usage; such as, implantable medical device, a certificate of the quality control of manufacture is also required.

(2) If the medical device they desire to import or sell is a “special medical device”, that importer has to apply for a license or make a specification declaration. Each category of the special medical device has its particular notifications issued by the Thai Ministry of Public Health that has imposed particular regulations; thus, the importer or seller has to comply with those regulations individually.

In the case of this research for the pacemaker, the importer who has qualified for establishment, has to apply for a Certificate of Establishment, and Certificate of Medical Devices Importation as a "general medical device" by submitting the CFS; however, for the application for the Certificate of Medical Devices Importation, the importer has to submit not only a CFS, but also a certificate of the quality of the manufacturing system because the pacemaker was categorized as an implantable medical device which might be a risk for human use, an "implant product".

Because of the term "general medical device", no notification mentioned specifically about the pacemaker, so there was no requirement for an importation license or specification declaration.

3.5 Sales Control

The sale of medical devices in Thailand does not have many regulations in comparison with importation. Normally, a medical device can be sold freely unless it comes under the following two restrictions:

3.5.1 Medical devices prohibited for sale under Notification No. 34 issued by the Ministry of Public Health

These restrictions are the same as those for the prohibition for importing:

i. Medical device which has been prohibited for sale in the manufacturer's or owner's country cannot be sold in Thailand.

ii. Medical device which has no CFS issued by the manufacturer's country to show to the authority at checkpoints imposed by the Thai FDA. Moreover, matters defined in that CFS must comply with the regulations imposed by the Thai FDA.

iii. Medical device which has a potential risk for humans, or by the reason of consumer protection defined by the Thai FDA, or the "certificate of the quality of the manufacturing system" issued by the government of the manufacturer's country or an organization certified by that government is required.

3.5.2 Medical devices that require a Sales License

For the purpose of the control of medical devices and consumer protection, the Minister, through the advice of the Committee, has stipulated that in order to sell some medical devices the applicant must submit an application for a sales license.[85]

There are three types of medical devices, which have been defined that require a "sales license":

i. HIV test kits and relating kits;

ii. Blood bags;

[85] Ibid. Section 6(3)

iii. Viscous substances which shall be used for ocular surgery.[86]

Some documents are needed for applying for a sales license; such as, a map of the place of sale, place of storage and nearby buildings, layout of those places in the actual ratio, which is able to show the suitable partition of the area and installment of any equipment or tools used for storage and preservation of the quality of the medical device.[87]

In summary, if the seller desires to sell medical devices, which are not HIV test kits and related kits, blood bags, or viscous substances that shall be used for ocular surgery categorized as medical devices which require a sales license, the seller is able to sell the devices freely.

There are, however, some exceptions for the application for a sales license as follows:

i. Medical devices which require an importation license,

ii. Medical devices which require a specification declaration.

These medical devices can be sold the same as they were subject to a sales license.

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[86] Food and Drug Administration of Thailand Medical Device Control Division, *Manual: Application for Identification of Medical Device* (B.E. 2559).

[87] Thai Ministry of Health, "Ministerial Regulation: Application and Issuance of Medical Sale License, May 28, 2012," (2555 B.E.).

The reason was those medical devices were already checked and verified in accordance with Notification No. 34 of the Ministry of Public Health; in the other words, the CFS and important related document were submitted to the authority. Consequently, those medical devices should be safe for sale.

In the case of the sale of a pacemaker in Thailand, because there is no single particular individual or company that is manufacturing a pacemaker in Thailand now, so the importation regulation defined above is required. After that, the sale of a pacemaker can be done without a sales license.

3.6 Manufacturing Control

3.6.1 Application for the Certificate of Establishment

As same as every activities in relation with medical device, business sector has to apply for Certificate of Establishment. The full details were described in 3.4.1) above.

3.6.2 Application for a Manufacturing License and Specification Declaration

The step is similar to importation of Medical Device, for manufacture of some specific medical devices, the business sector has to apply for a Manufacturing License or make Specification Declaration.

The lists of medical devices which are under requirement of Manufacturing License or Specification Declaration process, are the same with the list of Importation as follows:

i. Medical devices which have to apply for a license:

- Condoms;
- Examination gloves;
- Surgical gloves;
- HIV test kits;
- Contact lens;
- Human blood bags.

ii. Medical devices which have to make a declaration:

- Sterile disposable syringes;
- Sterile disposable insulin syringes;
- Physiotherapy products;
- Alcohol detectors;
- Silicone breast prostheses implants;
- Topical equipment or instrument used as a breast enhancer;
- Amphetamine test kits for urine (by immunochromatography).

3.7 Control Exceptions

There are eight categories of medical devices as follows which are not required to comply with Section 15 (Certificate of Establishment for Import and Manufacture),

Section 17 (Importation License in accordance with the Notification issued under the power of Section 6(1)), Section 19 (Specification Declaration in accordance with the Notification issued under the power of Section 6(2)) and Section 24 (Sales Certification in accordance with the Notification issued under the power of Section 6(3)):

(1) the manufacture, import or sale of medical devices by organizations certified by the government in connection with functions about disease prevention, diagnosis and treatment, or rehabilitation, and the Thai Red Cross Society;

(2) the manufacture of a medical device only for sterilization in a medical facility under the law on medical facilities;

(3) the manufacture and sale of a medical device, which has been manufactured by a medical professional or public health practitioner for a particular patient or animal;

(4) the sale of a medical device, for which a medical facility or medical and public health practitioner has obtained a license or specifications declaration receipt, for a particular patient or animal;

(5) the manufacture or import of medical devices in an amount necessary for personal use, use as a sample, exhibition or use in a study, research, analysis or quality and standard test;

(6) the import of a medical device, which is an accessory or assembling part for the manufacture of a medical device or the import of a medical device for a particular patient or animal;

(7) the manufacture of a medical device for use as an export sample;

(8) the manufacture or import of a medical device in accordance with the rules, procedures and conditions notified by the Minister upon the advice of the Committee.[88]

3.8 Other Controls

Under the Thai Medical Devices Act, for the control of the importation and sale, there are many regulations which have been imposed for the purposes of quality and standard control of medical devices.

3.8.1 Notification issued by the Ministry of Public Health

Under Section 6, in the opinion of the author, there is a main section which imposed the control methods of medical devices in Thailand whether for importation, sale or manufacturing purposes. The Minister, through the advice of the Committee, shall have the power to prescribe notifications as follows:

(1) medical devices for which a manufacturer or importer must obtain a license,

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[88] *Medical Device Act of Thailand*.

(2) medical devices of which a manufacturer or importer must declare the specifications,

(3) medical devices for which a seller must obtain a license,

(4) the standards of medical devices that a manufacturer, importer or seller must comply;

(5) quality systems for the manufacture, import or sale of medical devices;

(6) standards of the containers and use of containers, as well as materials prohibited to use as containers of medical devices that a manufacturer, importer or seller must comply;

(7) medical devices which require a controller in the manufacturing, importing or selling, as well as qualifications, number and duties of a controller;

(8) medical devices which require a technological assessment in order to ensure that the use of such medical devices are suitable and corresponds to the health problems of the public, as well as the socio-economic conditions of the country;

(9) medical devices which must be sold only to a consumer having a prescription issued by a medical and public health practitioner;

(10) medical devices which must be sold only to medical facilities or medical and public health practitioners;

(11) medical devices of which the manufacture, import or sale are prohibited;

(12) medical devices of which direct sales or direct marketing under the law on direct sales and marketing are prohibited;

(13) medical devices which must display data on the shelf lives, warnings, prohibitions or use cautions on the labels or accompanying documents,

(14) medical devices which must provide a record of the patients using such medical devices, as well as rules, procedures and conditions for the registration of patients using such medical devices;

(15) rules, procedures and conditions for the use of medical devices in clinical research;

(16) rules and procedures for the transport, safekeeping and destruction or disintegration of medical devices;

(17) designation of a place within the Kingdom as a checkpoint for the inspection of imported or exported medical devices;

(18) medical devices exempted from compliance with certain control measures under the Act and the exempted measures.[89]

It was clear that notifications of Sections 6(1), 6(2) and 6(3) were issued as the author mentioned before. Section 6(11) can be compared with Notification No. 34 of the Ministry of Public Health under the Thai Medical Devices Act B.E. 2549 (2006), which defined the medical devices which were prohibited for importation and sale only, so, the prohibition of manufacturing was not mentioned.

Unfortunately, 18 portals for the issuance of notifications for the quality control of medical devices have not been wholly activated. This means Thai medical device control is not strong enough, so the government sector should impose and issue all the regulations above as soon as possible.

3.8.2 Duties of the importer and seller of medical devices

The licensee cannot operate or store other medical devices other than those that have been registered.[90] However, there are some exceptions as follows:

i. temporary storage permitted by the grantor,

ii. direct sales to a medical and public health practitioner;

iii. assembly for the installation of medical devices.

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[89] Ibid. Section 6

[90] Ibid. Section 40

Moreover, the manufacturer, importer and seller shall perform the following matters:

(1) control and supervise operations pertaining to conforming with the quality system;

(2) provide a controller for the manufacture, import or sale of medical devices to supervise such person's total compliance;

(3) keep records of the manufacture, import or sale of medical devices to be made available for inspection by an authority and reporting to the grantor;

(4) report abnormal functioning of a medical device or undesired result occurring to a consumer as well as report steps taken to resolve such results to the grantor regardless of whether the result occurred in the country or outside of the country;

(5) provide a signboard indicating the place of manufacture, place of import, place of sale or place of storage of medical devices to be displayed in a conspicuous location;

(6) display the Certificate of Establishment, importation license or Specifications Declaration in a conspicuous and noticeable location at the place specified in each certificate;

(7) provide technical documentation confirming that one's medical device meets the required quality, standard, efficiency and safety to be examined or submitted to an authority upon request.[91]

3.8.3 Recognition or certification of the medical devices' quality and standard made by a foreign entity

In the case where there is a foreign regulation or international agreement about the standard, efficiency, safety of a medical device or regulation in relation to the import of medical devices, the Thai FDA may enter into an agreement with the foreign agency in relation to the recognition of inspections or certifications of medical devices or medical device establishments conducted by such foreign agency, regardless of whether the foreign agency is a state or private agency.[92] This panel of recognition is purposed for the adoption of a higher standard of safety of the medical device. However, the consideration to enter to any international agreement or adopt an internal regulation of each country has to be made reasonably and carefully for the purpose of safety, not for convenience or expedience.

Some experts believe this panel of recognition would be rarely activated.

[91] Ibid. Section 41

[92] Ibid. Section 35

3.8.4 Control of labeling

For the manufacture, import or sale, a medical device's label and related documents must not contain false or exaggerated statements. A label and related documents would be provided by the seller in connection with the certificates under this act.[93] A licensee would display the shelf life, warning, prohibited uses or cautions on the label or accompanying document.

3.9 Classification of Medical device in Thailand

Medical devices are classified into two types, in vitro diagnostic (IVD) and Non-IVD.[94] Each type is classified into four subclasses from Class I, a small risk of harm, to Class IV, a high risk of harm. There are some criteria for classification, and those people who want to know can make an application to Thai FDA to obtain a result.

IVD means device intended by the manufacturer for using outside the living organism examination of specimens derived from the human body including any blood or tissue donation, solely or principally to provide information for diagnostic, monitoring or compatibility purposes, concerning a physiological or pathological state or a congenital abnormality, This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus, whether used

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[93] Ibid. Section 44

[94] Food and Drug Administration of Thailand Medical Device Control Division, "Criteria of Medical Device Classification," (B.E. 2558).

alone or in combination[95], for example HIV test kits, Pregnancy self-testing, Blood glucose self-testing. There are 4 classes as follows:

- Class I Low Individual Risk and Low Public Health Risk

  Examples: Clinical Chemistry Analyzer, prepared selective culture media

- Class 2 Moderate Individual Risk and/or Low Public Health Risk

  Examples: Vitamin B12, Pregnancy self-testing, Urine test strips

- Class 3 High Individual Risk and/or Moderate Public Health Risk

  Examples: Blood glucose self-testing, Rubella

- Class4 High Individual Risk and High Public Health Risk

  Example: HIV Blood diagnostic[96]

It should be noted that the kind of people who usually use IVD medical device is individual that does not have formal training in a specific field or discipline.

There are some criteria which are the factor to classify IVD device into 4 classes such as intended uses and indications defined by the manufacturer, users (normal person or healthcare professional), the impact of the result to the individual and/or to public health[97], for example, HIV test result significantly impacts for individual and

[95] *Asean Agreement on Medical Device Directive*.

[96] Food and Drug Administrarion of Thailand, "Notification: Classification of Ivd Medical Devices," (B.E. 2558).

[97] Medical Device Control Division, "Criteria of Medical Device Classification."

social, the result has to be made by the testing device accurately, HIV test kits shall be classified into Class IV, High individual risk and high public health risk.

Non-IVD means the medical device other than IVDs. They are classified into 4 classes also, as follows:

- Class I Low Risk,

  examples: Surgical retractors, tongue depressors
- Class II Low-moderate Risk,

  examples: Hypodermic Needles, suction equipment
- Class III Moderate-high Risk,

  examples: Lung ventilator, bone fixation plate
- Class IV High Risk,

  examples Heart valves, implantable defibrillator, pacemaker[98]

The rules which were used for consideration of classification of non-IVD medical device into these classes are, for example, duration of device contact with the body, degree of invasiveness, whether the device delivers medicinal products or energy to the patient[99].

[98] Food and Drug Administrarion of Thailand, "Notification: Classification of Non-Ivd Medical Devices," (B.E. 2558).

[99] Medical Device Control Division, "Criteria of Medical Device Classification."

Nevertheless, there are no regulations of control defined for each class or subclass. The regulations of control can be found for each individual category of the medical device instead; for example, a condom has been classified into Class III (non-IVD). This is because there were regulations to control the condom, but there were no regulations for all the Class III devices. On the other hand, the pacemaker was classified into Class IV, the most harmful risk device; however, there are no regulations to control the pacemaker or any specific Class IV medical device.

3.10 Medical Devices Control in the US

As the author previously mentioned, a study about medical devices control in Thailand would be conducted in comparison with US, the largest medical devices market[100], so, there are important factors of the US to control the quality of medical devices.

3.10.1 Reorganization of a foreign regulatory

For importing medical devices into the United States (US), the one significant point is that the FDA of the US shall not recognize any compliance with other foreign regulatory bodies or approval of any country. The importer must comply with the

[100] Parul Chansoria, "How to Import Medical Devices into the United States " accessed 12 May 2018, https://www.linkedin.com/pulse/how-import-medical-devices-united-states-parul-chansoria.

applicable US regulations before, during, and after importing products into its territory. As such, the product must only meet the FDA regulatory requirements.[101]

There is a difference between the Thai regulations in accordance with Notification No.34 of the Ministry of Public Health which accepts the approval of the medical device's standard and safety of other countries by requesting a Certificate of Free Sale. Alternatively, the US does not accept any certificate or approval from any country unless the standard and quality of the medical device met the applicable US regulations imposed by its FDA.

3.10.2 Categorization of the importer and manufacturer

In regard with the regulations of the US FDA, there are three categories of importers and manufacturers as follows:

I. Domestic establishment which has a person or juristic person in the US or its territories.

II. Initial importer, which is any importer who furthers or supports the marketing of that medical device from a foreign manufacturer to the

[101] US Food and Drug Administration, "Importing into the U.S.," accessed 11 May 2018, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/ucm050126.htm.

person who makes the final delivery or sale of the medical device to the ultimate consumer or user in the US.

III. Foreign Manufacturer or Foreign Establishment has to appoint a US agent.[102]

In case of a Foreign Establishment, they have to appoint someone to be responsible for the relevant matters about imported medical devices including, but not limited to, assist the US FDA in communications with the Foreign Establishment, such as answering the questions of medical devices, making appointment of inspections and, significantly, if the US FDA cannot contact the Foreign Establishment directly, the FDA may contact or provide information or documents to the US agent instead, and such action shall be deemed legally that US FDA already provided those information or documents to the Foreign Establishment. Moreover, the rules and regulations have been imposed on a foreign body more than a Domestic Establishment and Initial Importer.

3.10.3 Classification of medical devices

In accordance with the US FDA regulations, classifications have been made for approximately 1,700 different generic types of medical devices. Each of these generic

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[102] "U.S. Agent," accessed 11 May 2018, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053196.htm.

types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of that medical device.[103] The classification is based on the risks associated with the use of the device with Class I being the lowest risk and Class III the highest risk. The three classes are as follows:

i. Class I : General Controls

These are devices that may cause minimal potential risk of harm to the user.

ii. Class II : General Controls and Special Controls

These are devices that generally present a moderate risk of harm to the user. The special control is called a premarket notification 510(k).

iii. Class III : General Controls and Premarket Approval

These are devices that sustain or support life, are implanted, or present a potential high risk of illness or injury. Examples of Class III devices include implanted pacemakers.[104]

General controls apply to all classes of the medical devices. The US FDA desires for regulating the medical devices to assure their safety and effectiveness. General

[103] "Classify Your Medical Device," accessed October 18, 2017, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm.

[104] Ibid.

controls include but are not limited to provisions that relate to the establishment's registration and device listing.[105]

Some medical devices may be considered as "exempt". This means that the importer or manufacturer would not be required to submit a premarket notification and obtain a FDA clearance before marketing the device in the U.S.; however, exemption was assigned for a medical device in Class I and Class II only. A medical device in Class III would not be exempted.

Therefore, it is sure that a pacemaker would be classified as Class III in accordance with the regulations of the US FDA.

3.10.4 Intensive details of medical devices

Each medical device provided accurate details. According to Title 21 of the Code of Federal Regulations (CFR), Parts 862-892, the US FDA has classified and described most types of medical devices marketed in US. For each of the device, a general description, intended use, the class where the device belongs, and requirements for marketing those devices in the US were given.

An example of the details of medical device, a pacemaker.

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[105] "The 510(K) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(K), Guidance for Industry and Food and Drug Administration Staff," ed. US Department of Health and Human Services (2014).

Subpart D--Cardiovascular Prosthetic Devices Sec. 870.3610 Implantable pacemaker pulse generator.

(a) Identification. An implantable pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device is used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders. This device may include triggered, inhibited, and asynchronous modes and is implanted in the human body.

(b) Classification. Class III (pre-market approval).

(c) Date PMA or notice of completion of a PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 20, 2012, for any implantable pacemaker pulse generator device that was in commercial distribution before May 28, 1976, or that has, on or before September 20, 2012, been found to be substantially equivalent to any implantable pacemaker pulse generator device that was in commercial distribution before May 28, 1976. Any other implantable pacemaker pulse generator device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.[106]

[106] *Code of Federal Regulations* 21CFR870.3610

This control makes no questions for the importer and consumer. They know exactly what medical device they desire to use, import, distribute including which class that medical device was classified and what required processes the importer and manufacturer have to do before marketing. Everything was clear, as there is a strong standard.

3.10.5 Premarket Notification 510(k)

The importer and manufacturer who want to market the medical device in the U.S., intended for human use must submit a Premarket Notification 510(k) to the US FDA unless the device is exempted. Before marketing the medical device, letter issued by the US FDA shall be received by the applicant, which states that the medical device is “substantially equivalent” and the order of permission that the medical device can be marketed in the U.S. is called a “510(k) Clearance”.[107]

For the purposes of safety and effectiveness of the medical device, the applicant must compare the new device to at least one similar legally marketed medical device for making and supporting their substantial equivalence claims. The legally marketed device where the equivalence is approved is known as the "predicate", or medical devices recently cleared under 510(k) are often selected as the

[107] Ibid. 21CFR807.87

predicate. By providing relevant information to the US FDA, the determination of equivalence is usually made within 90 days.

For the requirement of the demonstration of substantial equivalence in comparison with another legally marketed medical device, substantial equivalence can be deemed that the new device is potentially safe and effective as the predicate. There are two conditions mainly used for consideration:

i. The same intended use as the predicate, and the same technological characteristics as the predicate;

ii. The same intended use as the predicate, and in the case of any difference of technological characteristics, it does not raise different questions of safety and effectiveness; moreover, the information submitted to the US FDA demonstrates that the device is at least as safe and effective as the legally marketed device.[108]

Generally, a Premarket Notification 510(k) must be done by many kinds of applicants; such as:

i. domestic manufacturers;

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[108] "What Is Substantial Equivalence," accessed https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

ii. Specification developers who develop the specifications for a finished medical device, but the medical device has been manufactured under contract by another firm or entity. The specification developer submits the 510(k), not the contract manufacturer;

iii. Packers who make important labeling changes or whose operations significantly affect the device;

iv. Foreign establishment.[109]

However, for the exemption of a Premarket Notification 510(k), the US FDA has exempted almost all Class I devices.[110] If a medical device falls into a general category of exempted Class I devices, a premarket notification application and FDA clearance is not required before marketing the medical device in the US.

It was seen that for all medical devices which were exempted, those names and their details were defined clearly for avoidance of hesitation.

For medical devices classified as Class II under the US FDA regulations, these medical devices were also exempted, but the total amount of devices was less than Class I. Even though they were annotated as "II" after their name, the Class II devices were not exempted from good manufacturing practices (GMP), the requirements for quality

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[109] "The 510(K) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(K), Guidance for Industry and Food and Drug Administration Staff."

[110] *Code of Federal Regulations*

systems contained in applicable international standards, primarily, the International Organization for Standards (ISO).[111]

Nevertheless, as mentioned before, medical devices classified as Class III would not be exempted because of the potential risk in regards to the safety of the end customer.

3.10.6 Premarket Approval (PMA)

All devices classified as Class III are subject to premarket approval (PMA) requirements. Premarket approval by the US FDA is a required process of the scientific review to ensure the safety and effectiveness.

The purpose of the classification of the medical device into three classes is there is a necessity to realize the degree of control to assure that the various types of medical devices are safe and effective. Medical devices in Class III were treated as a group of medical devices which may cause a potential adverse risk about safety and effectiveness. A Class III medical device was defined as a medical device which supports or sustains human life or is of substantial importance in preventing the impairment of human health, or in that medical device presents a potential,

[111] Ibid.

unreasonable risk of illness or injury.[112] In other words, a medical device would be classified as Class III when that medical device cannot be classified as Class I and Class II because the applicant was not able to provide sufficient information to assure that general controls, substantial equivalence in comparison with other legal medical devices in the US market for Class I, or, performance standards, GMP requirements, for Class II. Therefore, many regulations imposed by the US FDA shall be regulated for this class of medical devices including, but not limited to, Premarket Notification 510k and also the Premarket Approval application.[113]

The applicant is usually the person who owns the rights, or has authorized access to the data and other information of the medical device to be submitted in support for this approval. Generally, the applicant is the creator, developer or the manufacturer who really knows that medical device well. If the applicant does not reside or have a place of business within the US, the Premarket Approval must be done by an authorized representative who does.[114]

The Premarket Approval is based on the consideration by the US FDA. The significant factor which will be used for consideration is sufficient valid scientific

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[112] "Pma Approvals, General Information," accessed Oct 18, 2017, https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.

[113] *Us Food, Drug, and Cosmetic Act*. Section 515

[114] *Code of Federal Regulations* 21CFR814.20 (a)

evidence to assure that the medical device is safe and effective for its intended use. In an acceptable case, the applicant would receive a private license as permission to market the device.[115]

According to US FDA regulations, a 180-day period was imposed to review the PMA[116] and make a determination; however, the review time is normally longer.

For approving or denying a PMA, the FDA advisory committee may review the PMA at a public meeting and provide a recommendation and result to the applicant. After that, the PMA result is published on the Internet announcing the data on which the decision is based. The American people can access the website to check which medical device was approved or not.

A medical device that fails the PMA cannot be marketed in the US.

3.10.7 Medical Device Reporting (MDR)

The requirements for Medical Device Reporting (MDR) is for manufacturers, importers, and distributors. Those must report any deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summarized annual reports.[117] These reports help the US FDA to

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[115] "Pma Approvals, General Information".

[116] *Code of Federal Regulations* 21CFR814.42

[117] Ibid. 21CFR803.1

protect the American public's health by ensuring that medical devices are not degrade, contaminated or misbranded and are effective and safe for their normal use.

In the case of a manufacturer or importer, they must report any deaths and serious injuries that a medical device has or may have caused or contributed to, and must report certain medical device malfunctions, as well as establish and maintain adverse event files within 30 calendar days of becoming aware of an event.

It should be noted that a "device user facility" also has a duty to report. A device user facility is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician's office. User facilities must report a suspected medical device-related death, as well as in the case of a medical device-related serious injury to the manufacturer, or to the FDA if the medical device manufacturer is unknown. Annual reports must be made by the device user facility to the FDA by the first day of each calendar year.[118] The MDR can be made and sent by electronic format.[119]

[118] Ibid.

[119] "Mandatory Medical Device Reporting Requirements," accessed https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

CHAPTER 4 Judicial decisions on malfunctioned pacemakers in the United States, EU and Australia

This chapter will provide examples of cases that have occurred in the US, EU and Australia. The significant issues of those cases can be used to adopt legal proceedings with regards to medical devices control in Thailand, as well as an interpretation of the provisions of the Product Liability Act B.E. 2551 (2008) by a Thai court including, but not limited to, the opinion of the author that some parts of this act should be revised.

4.1 US Case: Medtronic vs. Lohr

4.1.1 Parties

Lora Lohr as the Plaintiff.

Medtronic Inc. as the Defendant (Pacemaker Manufacturer).

4.1.2 Facts

In 1987, a “Medtronic Model 4011 pacemaker” was implanted into the heart of the Plaintiff[120] in which that pacemaker was manufactured by the Defendant “Medtronic Inc.” Three years later, the pacemaker failed because of a defect in the

[120] "Summary of Medtronic Inc V. Lohr, S. Ct 518 U S 470 [1996]," accessed May 15, 2018, https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

lead resulting in a complete heart block. Emergency surgery was required for her case. The doctor stated that the defect was in the lead causing the failure.

The Plaintiff filed a law suit in a Florida state court alleging negligence, as Medtronic had breached its duty to use reasonable care in the design, manufacture, assembly, and sale of the subject pacemaker, as well as strict liability.

The Defendant transferred the case to a federal district court, claiming according to the Preemption Doctrine, that under the Medical Device Act 1976, federal laws preempted the state common law claims (Florida state laws); in other words, the claims made by Lohr were prohibited and barred by federal provision.

The preemption doctrine refers to the concept that federal law is the supreme law of the land.[121] A higher authority of law will displace the law issued by a lower authority when the two authorities come into conflict. In the US, when state law and federal law conflict, federal law displaces, or preempts, state law. Preemption applies regardless of whether the conflicting laws come from legislatures, courts, administrative agencies, or constitutions.[122] Thus, a federal court may require a state to stop certain activity which may interfere with, or is in conflict with, federal law. The provision about preemption in relation to this case, defined that no state and local

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[121] *U.S. Constitution* Article VI, Supremacy Clause

[122] Robert S. Adler and Richard A. Mann, "Preemption and Medical Devices: The Courts Run Amok " (1994).

requirements or political subdivisions of a state could establish or continue in effect with respect to the medical devices intended for human use any requirement which is different from, or in addition to, any requirement applicable under this chapter to the device.[123]

Focusing on the difference between those provisions, the Plaintiff claimed that the pacemaker was defective by negligence under a tort of Florida, but the Defendant argued that the pacemaker was safe because it had substantial equivalence in accordance with the Premarket Notification 510(k), under the Medical Device Amendments (MDA) of 1976.

As a pacemaker is classified in Class III of medical devices, which may cause a high adverse risk for the safety of the user, normally, the processes of both a Premarket Notification 510(k) and also Premarket Approval (PMA) have to be done before marketing. However, the pacemaker in this issue was marketed before the date which the Medical Device Amendments (MDA) were in effect.

The medical devices that were in commercial distribution before May 28, 1976, the date the Medical Device Amendments were enacted, were exempted from the Premarket Approval process. After the Medical Device Amendments became law, the classification of devices was determined and by the US FDA committee. Eventually all

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[123] *Us Food, Drug, and Cosmetic Act*. Section 360(k)

Class III devices required a PMA. However, pre-amendment Class III medical devices[124] required a PMA only after the US FDA published a regulation calling for submissions of a Premarket Approval.

As a consequence, the Medical Device Amendments of 1976, as federal law, permitted the Defendant to market the pacemaker into the market with the condition of a Premarket Notification 510(k) and the Defendant's pacemaker had substantial equivalence. Therefore, the Defendant argued that there was no need to comply with any other regulations which was different from, or in addition to, any requirements applicable under the Medical Device Amendments of 1976 to the device. Federal laws should pre-empt Florida state laws.

The district court eventually held that Lohr's causes of action were federally pre-empted and dismissed the entire action. The Court of Appeals concluded that reversing and affirming in part, Lohr's negligent design claims were not pre-empted, but that their negligent manufacturing and failure to warn claims were. Both parties sought a final decision by the United States Supreme Court.

[124] Pre-amendment medical device means the medical devices that was in commercial distribution before May 28, 1976, the date the Medical Device Amendments were enacted.

4.1.3 Issues

Do the “Substantial Equivalence” granted by Medical Device Amendments of 1976 as federal laws, pre-empt a state common law, negligence action of an allegedly defective medical device?

4.1.4 Decisions

The MDA does not pre-empt the common law claims asserted by the plaintiff. A state law will be pre-empted only if the MDA has promulgated a relevant specific requirement.[125] The court allowed the lawsuit about the defects in the pacemaker's design and also allowed the lawsuit to proceed on the claims of defects in its manufacturing and failure to warn.

The general duties of design, manufacturing and labeling are not the type of requirements that the court envisioned for federal rules. Preemption occurs only where a particular state requirement threatens to interfere with a specific federal interest. State requirements must be related to the medical devices and “different from or in addition to” federal requirements.[126] Medtronic’s pacemaker was not required to take any particular form for any specific reason by state torts. The US FDA’s

[125] Kenneth T. Sigman, "Medtronic, Inc. V. Lohr: Bad Medicine for Manufacturers of Unproven Medical Devices," Volume 47, no. Issue 2 Winter 1998 (1998).

[126] Longwell & Assosiates Nancy E. Isaac, Attorneys Serveing the Healthcare Industry, "Defining the Domain of Medical Device Preemption," accessed 5 May 2017, http://fdclaw.com/cases/devicepreemption/.

substantially equivalent determination alone does not state which can be specified or enforced; in other words, Premarket Notification 510(k) was not a specific requirement imposed by the MDA as federal law. When there was no such requirement, in this case, under federal law, the Florida torts could not be interpreted as "different from, or in addition to" in comparison with federal rules as mentioned above.

4.1.5 Background reasons

If the court intended the Medical Device Amendments of 1976 to pre-empt state law, it can be assumed that the preemption would be done by that language; however, the court's intention is discerned from the language of the statute. The structure and purpose of the statute as a whole would be needed for consideration.[127]

Therefore, it is certain that the federal government would play a role in health protection. If the court adopted the preemption, this would mean that the court intends to preclude state courts from affording consumers any form of protection from injuries resulting from a defective medical device, so the manufacturers would receive complete immunity from design defect liability suits. As such, this would be seen to be opposite to the court's intention to enact more stringent safeguards for the people.

The Premarket Notification 510(k) process emphasizes on the substantial equivalence of a device, not ensuring the safety. Lohr mentioned that the Premarket

[127] *Medtronic V. Lohr 518 U.S. 470*, (1996).

Notification 510(k) process focused on equivalence, not safety, and provided little protection to the public.[128] In fact, in accordance with this process, a recently launched medical device was compared with another medical device already marketed requiring only compliance with the substantial equivalence or general standards, which are the lowest level of protection.

In comparison with the Premarket Approval and Premarket Notification 510(k) for a Class III medical device at that time, around 1976, for Premarket Approval, this required about 1,200 hours and required the device to be tested by a panel of experts for safety and effectiveness while the Premarket Notification 510(k) only required about 20 hours and raw data to make a decision and support the assertion that the device had "substantial equivalence".

From this case, the issue that needs to be significantly noted is the standard of safety of the medical device. For importing, sale or distribution in one's own territory, when comparing between the US and Thailand, has some conditions to allow those medical devices to be distributed in Thailand. In the opinion of the author, the US has the strongest regulations with regards to consumer protection, which refers to medical devices in the case of this research, but there is a failure about the purpose. It can be stated that Premarket Notification 510(k) would not be sufficient to protect and ensure the safety standards for the people. In accordance with the Premarket Notification

[128] "Defining the Domain of Medical Device Preemption".

510(k), there is only a requirement of submitting the relevant documents and the condition of “substantial equivalence” to compare a new medical device with a marketed medical device, so there is the condition for the actual guarantee of safety. In comparison with Thailand, Thai FDA accepts “free sale” from foreign country, there is sure that acceptance does not provide sufficient standard of safety.

4.2 US Case: Riegel v. Medtronic

4.2.1 Parties

Charles Riegel as the Plaintiff

Medtronic as Defendant

4.2.2 Facts

For this case, there was not pacemaker, but “Balloon Catheter”. During Riegel's angioplasty, his surgeon used the balloon catheter to dilate his coronary artery, unfortunately, the catheter burst causing extreme complications. Riegel sued the manufacturer, Medtronic, for negligence in the design, manufacture, and labeling of the device under state (New York) tort laws.[129]

The balloon catheter is classified as Class III device in US as same as a pacemaker. however, in comparison with Lohr case mentioned above, Medtronic’s catheter received premarket approval (PMA) In 1994, but Medtronic’s pacemaker in Lohr case was not received PMA (was deemed as substantial equivalence)

[129] *Riegel V. Medtronic, Inc.*, (2008).

Surely, the Defendant defensed itself by preemption doctrine, MDA 1976 as federal laws bar state common laws in case of confliction. PMA approval granted by US FDA as federal regulation prohibits New York tort laws because it was different from or in addition to regulations imposing by PMA.

4.2.3 Issue

Should preemption doctrine be triggered and implemented in this case or not?

4.2.4 Decisions

In 2008, the US Supreme court reversed its decision from Lohr case. The MDA preempted state common law claims for defective devices. Riegel's negligence and strict liability claims based on New York's requirements were different from, or in addition to the federal requirements (PMA).

4.2.5 Background reasons

The court gave the reasons that this time the balloon catheter had passed the PMA, a very strong process focusing on safety and effectiveness. It determines that device offers a reasonable assurance of safety. But in Lohr's case, the device had passed the premarket notification 510(k) focusing on equivalence, which never been formally checked for safety or its efficacy. The state regulations are considered as the difference, which may interfere the consistency of the federal regulations. As a consequence, it is illogical if a state tort requires higher safety but less effectiveness than a PMA model. In addition, the court thought about the cost-benefit theory; more

lives would be saved by a device along with its greater effectiveness rather than adverse risks.[130]

4.3 Marmol v. St. Jude Medical center

4.3.1 Parties

Delio Marmol as Plaintiff

St. Jude Medical center as Defendant

4.3.2 Facts

The medical device in this case is Implantable Cardiac Defibrillator (ICD) which is classified under US FDA's regulations as Class III, high-risk medical device as same as the pacemaker. The fact is the Rita leads was granted PMA approval already before marketing. In 2009, the ICD was implanted into Marmol. In 2010, St. Jude as developer and manufacturer, published a "Dear Doctor" letter stating that the Riata leads, a lead of those ICDs, were vulnerable to insulation abrasion. The recall order was made by US FDA.[131]

Then, in 2011, St. Jude recalled them, citing insulation failure, experiencing premature erosion of the insulation surrounding the electrical conductor wires attached to the ICDs. The manufacturer eventually stopped selling the Riata lead in issue. But by the time the manufacturer did so, more than 227,000 of the units had

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[130] Ibid.

[131] *Marmol V. St. Jude Medical Center and Pacesetter, Inc.*, (2015).

been distributed worldwide with as many as 80,000 still implanted in patients even a year later.[132]

In April 2012, Marmol alleged that he began to sustain unnecessary electrical shocks from his ICD unrelated to his condition and that he was informed by his doctor that his Riata lead had been recalled by the FDA[133]., therefore, Marmol made an effort to have his replaced, unfortunately his surgery was unsuccessful and the implanted ICD could not be removed.

Marmol as Plaintiff asserted the claims under Florida law for negligent manufacturing defect, and failure to warn. The defendants sought to dismiss Marmol's claims by the preemption notion again, manufacturing defect and failure to warn claims were preempted under MDA, moreover, the Defendant also contended that no private action could be brought for violations of FDA requirements under Florida law.

4.3.3 Issue

Should preemption doctrine be triggered and implemented in this case or not?

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[132] PLLC Pollard, "Cardiac Icd Product Liability Claims Dismissed as Preempted," accessed May 17, 2018, https://www.pollardllc.com/personal-injury/cardiac-icd-product-liability-claims-dismissed-as-preempted/.

[133] Inc. LEAGLE, "Marmol V. St. Jude Medical Center," accessed March 16, 2018, https://www.leagle.com/decision/infdco20150925h89.

4.3.4 Decisions

In 2015, the court decided that Florida law does not permit a private action to enforce violations of FDA requirements. There was the same with Lohr case and Riegel case, if state tort laws (in the case Florida) were different to or in addition to federal laws or regulations (in this case, PMA imposing by MDA 1976), those state laws shall be no effect. It seems that the Florida laws asserted by Plaintiff shall be considered as different from or in addition to PMA. However, it was interesting that the Plaintiff stated a notion of "parallel claim" based on violations of the PMA specifications or federal regulations which is able to survive from preemption. It means that the defective Rita lead in this case may occur from the failure to comply with PMA rules done by the Defendant. Nevertheless, the court did not answer and conclude the notion of parallel claim. Even if the Plaintiff could properly allege a sufficient reasons, the court insist that the Florida law does not permit a private action to enforce violations of FDA requirements.[134]

4.3.5 Background reasons

It was clear from Riegel case and Marmol case that, in this recent period, US Courts' decision has the purpose of protecting the business sector and maintaining the consistency of the PMA more than consumer protection.

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[134] *Marmol V. St. Jude Medical Center and Pacesetter, Inc.*

4.4 EU Cases: AOK Sachsen-Anhalt and Die Gesundheitskasse vs. Boston Scientific Medizintechnik GmbH

4.4.1 Parties

AOK Sachsen-Anhalt and Die Gesundheitskasse are the Plaintiff (hereinafter referred to as "AOK and Die") and Boston Scientific Medizintechnik GmbH is the Defendant (hereinafter referred to as "Boston Scientific").

It should be noted that these were joint cases C-503/13 and C-504.[135]

4.4.2 Facts

This case was a dispute between Boston Scientific, a company established in the United States, which manufactures and sells as a worldwide producer and seller of medical devices implantable in the human body[136]; such as, pacemakers, cardioverter defibrillators, versus two insurance companies, AOK and Die, which devolved the right of claim from injured people, who were damaged from a defective product manufactured by Boston Scientific. Those people, as patients, had the pacemakers removed and were covered by insurance. The insurance companies then sued Boston Scientific to pay the costs of the surgery necessary for the replacement.

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[135] *Boston Scientific Medizintechnik Gmbh V Aok Sachsen-Anhalt – Die Gesundheitskasse, C-503/13 and C-504/13*, (2015).

[136] Ibid.

For this first case, C-503/13, after the implantation of the pacemakers manufactured by Boston Scientific for the patients, on July 22, 2005, recommendations concerning the series of those pacemakers were issued by Boston Scientific, which indicated that the quality control system had established that a component utilized to hermetically seal those pacemakers may experience a gradual degradation. That defect could lead to premature battery depletion resulting in loss of telemetry and/or loss of pacing output without warning.[137] Boston Scientific recommended physicians to consider replacing such pacemakers for the patients.

From that recommendation, the pacemakers previously implanted in two patients, who both had medical insurance cover with AOK, were replaced in September and November 2005, respectively. After that, the pacemakers were destroyed without any expert opinion or analysis about their functioning.

AOK brought this case to the Stendal local court (Amstgericht Stendal) to seek an order that Boston Scientific pay compensation in respect of the costs relating to the implantation of the original pacemakers, including the cost of removal.

In the meantime, in connection with Case C-504/13, Boston Scientific's recommendation letter was issued in June 2005 in regard with the implantable cardioverter defibrillators stating that its quality control system had established that

[137] Ibid. Paragraph 14

the functioning of implantable defibrillators might be adversely affected by a defect in one of its components, which could limit the device's therapeutic efficacy. It was apparent from the scientific analysis carried out that a magnetic switch in those defibrillators might remain stuck in the closed position. As such, treatment of ventricular or atrial arrhythmias would be inhibited. As a consequence, any cardiac dysrhythmia that could be potentially fatal would not be recognized by the defibrillators and no life-saving shock would be given to the patients.[138]

Therefore, it can be concluded that these two notification letters issued by Boston Scientific had the same significant point that in the same group of its products, there was a potential risk or chance of each product being defective.

On March 2, 2006, as a result of the notification mentioned letter above, the implantable cardioverter defibrillator implanted in one of the users, who was covered for insurance purposes by Die, was prematurely replaced. After that, Die started the lawsuit at the regional court (Landgericht Düsseldorf) requesting Boston Scientific to reimburse the costs incurred in respect of the patient's treatment, and the cost of the operation to replace the implantable cardioverter defibrillator.

Boston Scientific appealed for both cases, as these two cases were joint situations because of similar issues.

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[138] Ibid. Paragraph 19-20

4.4.3 Issues

Firstly is the issue about the interpretation of the defective product. A product in the form of a medical device implanted in the human body; such as, a pacemaker or implantable cardioverter defibrillator should automatically be considered as defective if the products were in the same group which have a significantly increased risk of failure but a defect has not been proved and detected.

The second issue is, in the case the first issue was affirmed, does this cover the cost of a surgical operation to replace that individual product and other relevant costs and reimbursement that constitute damages for personal injury in accordance with its applicable product liability law or not. It should be noted that the operation for replacement is not a direct result of the defect because the defect has still not occurred.

4.4.4 Decisions

Those issues are involved with the applicable Product Liability Act, Council Directive 85/374/EEC of July 25, 1985. Article 6 of this Directive, which was used for the interpretation of a defective product, defined that a product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

i. the presentation of the product;

ii. the use to which it could reasonably be expected that the product would be put;

iii. the time when the product was put into circulation.[139]

The problem of the first issue is those pacemakers (and defibrillators) have not yet been really defective, but there was just a warning that products belonging to the same group or forming part of the same production series may have a potential increased risk. As such, is possible or not to classify such products as defective without any need to make sure that the products in question have such a defect.[140]

The court has to make an interpretation of the phrase in Article 6, a product is defective when "*it does not provide the safety which a person is entitled to expect"*, and so, that assessment must be carried out in regard to the reasonable expectations of the public. The intended purpose, the objective characteristics of the product, and the specific requirements of the group of users would be the factors for consideration. Not only for its suitability for use, but also the lack of the safety which the public, not to a specific user, is reasonably entitled to expect.

In particular, in respect of medical products, especially pacemakers and defibrillators which were implanted into a patient's body, the Court specified that it

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[139] *Directive 85/374/Eec* Article 6

[140] *Boston Scientific Medizintechnik Gmbh V Aok Sachsen-Anhalt – Die Gesundheitskasse, C-503/13 and C-504/13*.

had to consider their functions and the vulnerable situation of the patients. Hence, the patients are entitled to expect particularly high safety requirements for those medical devices.

Therefore, the Court decided that where it is found that products belonging to the same group of the same production series; such as, pacemakers and implantable cardiovascular defibrillators, have a potential defect, it is possible to classify all the products in that group or series as defective without any requirement to show that the products in question are defective[141]; in other words, regardless of whether the products at hand are in fact defective.

For the second issue, after the products in question were defined as defective, could the damages from the replacement of those products from the patient's bodies and other relevant costs be claimed or not. The possibility to claim the damages is the damage occurred by the replacement would be legally interpreted as "damage caused by death or by personal injuries" which was stated in Article 9, Directive 85/374/EEC.

In accordance with Article 1, the manufacturer shall be liable for damage caused by a defect in his/her product, and Article 9 requires manufacturers to

[141] Rouse Magazine, "Eu Court Says It Is Possible to 'Infer' a Device Is Defective," accessed 25 Mar 2018, https://www.rouse.com/magazine/news/eu-court-says-it-is-possible-to-infer-a-device-is-defective/.

compensate for “damage caused by death or by personal injuries”. Moreover, causal relationship between defect and damage has to be proved by that injured person.[142]

In comparison, there is no question if the damage arose from the operation to remove the actual defective products from the patient’s body, but, in this case, there was an operation for removing the pacemaker which still had not caused any damage. In that case, the Court decided that the costs relating to the replacement of such pacemakers, including the costs of the surgical operations, constituted damage within the meaning of “damage caused by personal injuries”; therefore, under Article 9 of Directive 85/374, Boston Scientific was liable.

Boston Scientific itself recommended that those implantable medical devices were recommended to be replaced because of additional potential risks when an operation was necessary to prevent that harm or eliminate the defect product from the patient’s body. Therefore, that would be reasonable to eliminate any harmful consequences. Causal relationship can be settled reasonably between the Plaintiff and the defect, so an operation for removal was necessary to prevent the risk of failure in connection with the defective products.[143]

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[142] *Directive 85/374/Eec* , Article 4: The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.

[143] ALTALEX Annemieke Lippes, "Boston Scientific Medizintechnik Is Liable for the Costs of Operations to Replace Potentially Defective Pacemakers," accessed May 16,

It can be seen that the term “damage” can be broadly interpreted by reference to the purpose and general scheme of the rules where it belonged. Because the product liability laws were created for the purposes of protecting consumer health, ensuring that the consumer would be reimbursed or compensated what they lost from the effect of defective products. Consequently, such replacement is necessary to restore the level of safety which a person is entitled to expect.

4.4.5 Background reasons

There may be some opinions about this case that the interpretation of “defective products” was too broad; however, the Court interpreted this case by considering the objective of the Product Liability Directive as trying to achieve a fair balance between the allocation of risks in modern technological production between consumers and manufacturers[144], so such a broad definition of a “defective product” simplifies the burden of proof for the consumer. Hence, a plaintiff would only have to

2018, http://www.altalex.eu/content/boston-scientific-medizintechnik-liable-costs-operations-replace-potentially-defective.

[144] Barend Van Leeuwen and Paul Verbruggen, "Resuscitating Eu Product Liability Law? Contemplating the Effects of Boston Scientific Medizintechnik Gmbh V. Aok Sachsen-Anhalt and Betriebskrankenkasse Rwe (Joined Cases C-503/13 and C-504/13)," (2015).

allege the “potential defect” in products of the same series and not the defect in the individual product. [145]

This is a difficult situation that consumers are able to protect themselves effectively from the risk arising from products manufactured with high and complex technology, in this case pacemakers. In fact, for all cases, no manufacturing process is perfect; some mistakes will always happen; however, the manufacturer is in the best position to minimize it and to prevent damage at the lowest cost. Therefore, there is one preventive function imputing liability to the person who, has created the risk by manufacturing a defective product.

Pacemakers and implantable cardioverter defibrillators are not just any simple products, but a medical device. In the EU, a pacemaker was classified in Class III which corresponds to the most critical devices for which explicit prior authorization regarding conformity is required for them to be placed into the market.[146]

4.5 Australia Case: Courtney vs. Medtel

4.5.1 Parties

Kevin Glynn Courtney as the Plaintiff (A pacemaker was implanted in his body).

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[145] Nicolas Carbonnelle, "Medical Device Liability Update " accessed May 16, 2018, https://www.twobirds.com/en/news/articles/2015/global/life-sciences-newsletter-june/medical-device-liability-update.

[146] the rules in Annex IX to the Directive 90/385,

Medtel Pty. Limited as the Defendant (distributor of the pacemaker).

4.5.2 Facts

Mr. Courtney, a 70-year-old man, was implanted with a Tempo pacemaker in July 1999, imported and distributed by Medtel. On June 5, 2000, a hazard alert was issued by the Therapeutic Goods Administration, government body in relation with healthcare in Australia, for a batch of Tempo pacemakers manufactured by Pacesetter Inc. incorporated in California, USA. The hazard alert warned that the particular batch of pacemakers had an increased risk of early battery depletion and affected some 1,048 people in Australia. While it was acknowledged that only a small percentage of the pacemakers would actually malfunction; however, it was not possible to determine whether a particular pacemaker was actually defective without taking it out of the patient, so it could be tested outside the patient's body.[147]

A batch of pacemakers was imported and distributed by the Defendant in which some of the pacemakers were subsequently found to be at greater risk of early battery depletion due to the type of solder used in their manufacture. [148]

However, after removing the pacemaker from the Plaintiff's body, the fact was, his pacemaker were found to be functioning normally. Nevertheless, the Plaintiff brought an action against the Defendant for compensation by reason of its supplying

[147] *Courtney V. Medtel Pty Limited*.

[148] Ibid.

goods, a batch of pacemakers that were not of merchantable quality, or reasonably suitable for the purpose for which they should be received and used.

This case was brought to court by class action. Six hundred and sixteen people were classified into the following three groups:

Group I: those whose pacemakers remained in their body notwithstanding the hazard alert;

Group II: those whose pacemakers had been removed and, on examination, were found to be functioning abnormally; and

Group III: those whose pacemakers had been removed and, on examination, were found to be functioning normally. (Mr. Courtney was in this group)[149]

4.5.3 Issues

Were the Defendant's pacemakers of merchantable quality under the laws of Australia or not. In particular, in the case of the Plaintiff, his pacemaker was still not defective when it was in his body and also, after removing, it was found to be functioning normally.

[149] Peter O'Donahoo, "Pacemaker Payout," (2003); ibid.

4.5.4 Decisions

Under the laws of Australia, a manufacturer has a special expanded meaning to include not only the actual manufacturer of the goods but also a corporation which:

i. holds itself out to the public as a manufacturer;

ii. applies its name or brand to the goods;

iii. permits someone to promote the goods as those of the corporation; or

iv. imports the goods where the actual manufacturer has no presence in Australia.[150]

In the case of the Defendant who imported the pacemaker in question, so, the Defendant was interpreted as the manufacturer under Australia's applicable laws.

In the territory of Australia, the manufacturer is liable to compensate the consumer or other person for the loss or damage when the goods are not of merchantable quality[151], then, the consideration of "merchantable quality" has to be done legally.

Goods of any kind are of merchantable quality if they are suitable for the purposes why they are commonly bought, as it is reasonable to expect any description applied to the goods by the manufacturer, moreover, the price of the goods defined by the

[150] *Trade Practice Act*. Section 74A(4)

[151] Ibid. Section 74D(1)(d)

manufacturer may be also considered.[152] Thus, it can be seen that “merchantable quality” would be considered by the notion of legitimate public expectation the same as the EU.

The Defendant stated that, according to the hazard alert as mentioned before, the Defendant was able to show that only a small percentage of statistical probability of premature failure but, the Court considered that the expectations of the reasonable consumer could not be measured and applied against only specialist opinion or technical knowledge of the manufacturer, instead, the Court supported the argument of the reasonable consumer.[153]

For "The purpose commonly bought", regarding the purpose, the Court said that is not only the individual subjective purpose in acquiring the goods, but a broader enquiry regarding the normal use of the goods.[154] It was clear enough that the common purpose of the pacemaker was to maintain a regular heartbeat for patients, however, according to the hazard alert, there was additional risk that would adversely affect the normal use of the pacemaker, which is a sensitive device.

The Court opined it was necessary to make a consideration of the expectations of a reasonable consumer in the circumstances, and thought that they would expect

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[152] Ibid. Section 74D(3)

[153] Susan Yee-Kong, "Heartening News," accessed Febuary 13, 2018, http://www.findlaw.com.au/articles/261/heartening-news.aspx.

[154] *Courtney V. Medtel Pty Limited*.

the pacemakers would not be manufactured by any material that may create a substantially higher risk of premature failure than the pacemakers in general, in this case with a yellow spool solder. Given that each of the pacemakers subject to the harmful alert had an additional risk because of the materials used in the manufacturing process, thus, the Court finally concluded that none of the pacemakers in that batch under a hazard alert were suitable for the purpose of restoring and maintaining normal heartbeat rate as was reasonable to expect by public[155]; in other words, they were not merchantable quality. In addition, it was not necessary for any of those pacemakers to be actually defective. It was sufficient if those pacemakers were subject to the hazard alert and consequently the additional risk, then they would not be legally classified as merchantable quality under Australia's Product Liability laws, so then they would be defective products. Even if, in the case, any of them are able to prove their function to be normal without any defect after removal from the patient's body, they would still be considered as defective or unsafe products, as a hazard alert was issued.

4.5.5 Background reasons

The Court of Australia pointed out the interesting criteria about the ordinary risk of random failure. It was explained that, in reality, each manufactured product always has a chance of failure. This is normal and unavoidable, and it can be called "background failure rate", which is regular for all business operations.

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[155] Ibid.

However, in this case, all pacemakers in the same series were subject to the hazard alert, which was manufactured by a yellow spool solder causing an additional risk of premature failure, over and above the background risk of failure. Therefore, the pacemakers were subject to a significant "superadded" risk of premature failure by reason of the materials used in the manufacturing process, so the Court concluded that the products were not of merchantable quality.[156]

[156] Amanda Turnill, "Australia: Liability for Manufacturers Who Supply Unmerchantable Goods - a Novel Statutory Cause of Action Available to Australian Plaintiffs," (2015).

CHAPTER 5 Foreign judicial decisions and implication for Thai court

The study focused on the weaknesses of the medical devices control system in accordance with the relevant regulations in Thailand in comparison with the modern and stringent standards and regulations, which were imposed to control the quality and safety of medical control in the US. In addition, from the case studies of the US, EU and Australia, the lessons and experiences about court decisions, interpretations, background reasons and any other related concepts could be adopted as a guideline for Thailand in many aspects as follows:

5.1 Regulatory Regime of Medical Devices Control in Thailand

From the stringent regulations of the US FDA, in the opinion of the author, the following points with regards to Thailand should be improved.

5.1.1 Recognition of the Certificate of Free Sale (CFS) certified by other countries and the document system

At present, the Certificate of Free Sale (CFS) of other countries was used as an important condition for importing medical devices into Thailand. This means that if that medical device could be sold in other territories, it was safe and could also be sold in Thailand. There is insufficient logic for the guarantee of the standard of safety. Medical devices, which were permitted to be sold do not mean they are safe. For example, from the Lohr case the author mentioned in Chapter 3.1, her pacemaker was

found to be defective even if her pacemaker was permitted for sale in the US with the condition of a Premarket Notification 510(k) which compared a new medical device with a permitted medical device in their market. As such, it can be seen that the approval by comparing medical devices in the same territory still cannot guarantee the safety of that product, so, a guarantee of the safety of a medical device by comparing a medical device in a different territory using a CFS should not be a set standard.

According to the concept of the US, that country denies accepting permission for the sale of medical devices from other territories unless they have complied with US regulations. This principle should be adopted in Thailand for the improvement of safety standards.

Moreover, the approval for importation and sale by a document system does not ensure the quality and safety standards of the medical device. Documents can ensure in some levels, but not all because the documents could be falsified, counterfeit or illegally duplicated. In addition, the issuance of the documents was sometimes made with the negligence of authority or an adverse influence. Therefore, if documents are used as one condition to approve everything, there is a potential risk of the standard of safety. It cannot be denied that a document system for approval is still necessary because of the huge number of applications; however, in some particular cases; for example, medical devices like a pacemaker which have to be

implanted in the human body should be treated on a strict basis with a scientific process and observation.

5.1.2 Categorization of stakeholders

According to the US regulations, applicants who are involved in activities regarding medical devices are categorized into three groups: local applicants, promoters, and foreign bodies/organizations. Each group has differently imposed regulations. For example, foreign bodies/organizations have to appoint an agent as the legal contact between the US FDA and the foreigner; promoters who influence others for being involved in activities about medical devices in US territory have the duties of reporting of significant information; such as, reports of deaths, serious injuries and malfunctions.

Categorization of the related parties into subgroups is a functional concept which Thailand should adopt to impose the necessary processes.

5.1.3 Classification of medical devices and legal consequences

This is a necessary requirement that all countries should undertake. Therefore, the classification of medical devices into particular groups and imposing of regulations for each group suitably its critical. In Thailand, as previously mentioned, medical devices were separated into four groups through detailed criteria; unfortunately, there is no legal consequences of each particular group. This means a medical device in all groups would have the same standard for importing or sale. As a consequence,

Thailand should follow the regulations set by the US; for example, a pacemaker was classified in Class III in which the Premarket Notification 510(k) and Premarket Approval (PMA) were acquired legitimately.

5.1.4 Intensive data and access of data

In the US, all types of medical devices are required to provide their details, data, and specifications by law, and they are published on the US FDA's website, which is very easy to access. This is a simple situation for applicants or the related parties to participate and follow. Thus, it would be beneficial if Thailand could also do so.

5.2 Interpretation of a Defective Product

As seen from the EU and Australian cases, the defective product should be broadly interpreted. Not only the actual defect, as in some particular cases, the product can be determined to be defective even if the actual defect does not occur. In the EU and Australian cases, the pacemakers, which were subject to a notification of harm or hazard alert, were finally concluded to be a defective or unsafe product and not merchantable quality even though they were not really defective. The reasons given by the Court were they were not suitable for the public's expectation to buy and use. A pacemaker should be expected to be a product which has a very low adverse potential risk because it has to be implanted into the human body and used to maintain heart disease, or sustain the patient's life. Therefore, any additional risk is not acceptable. Hence, even if the pacemakers are not actually defective or in the

case the manufacturer is able to prove that after removal from a patient's body, that the pacemaker was not defective, those pacemakers with an additional adverse risk would be legitimately determined to be defective products for the purposes of consumer protection.

In the Product Liability Act of Thailand, defective product definitions were imposed as a product that causes or may cause damage, regardless of its manufacturing defect, design defect, or by a mistake of labeling. There are differences between the provision of Thailand and provisions of the EU and Australia. For the EU, the "expectation of the public" is the factor of determination of a defective product; on the other hand, for Australia, they consider about "merchantable quality". Thus, it can be learned from the cases of the EU and Australia that many concepts were adopted for the interpretation of those terms; such as. The characteristic of the product, target group of the end user, severity of that potential damage, etc.

Therefore, those notions above should be adopted for the interpretation of a "product which may cause damage" in accordance with Section 4, Unsafe Goods Liability Act. Pacemakers which are subject to a notice of harm or hazard alert should be interpreted and covered by the meaning of "product that may cause damage". It is reasonable if a Thai court, as its sole decision, used this criteria as a guideline, reference or background reason for the explanation in its judgement, including but not limited to, the involved person who experiences a similar situation in Thailand also.

However, the broad interpretation of a defective product above should be conducted appropriately. The regime of consumer protection and the social utility of products should be balanced. If a broad interpretation was applied to all categories of products, it would not be fair for the manufacturer, but just for some particular products, which require a high standard and safety for its purpose and normal use; such as, a pacemaker, but also other implantable medical devices should be applied for this regime.

If this regime was applied improperly, this could result in an adverse effect; such as, the market price of the product would be increased, so the consumer would be disadvantaged by this adverse effect. Furthermore, the entrepreneur may not want to operate business because they would be concerned about encountering a law suit or compensation. Therefore, if no business was conducted for medical devices, the development of healthcare in Thailand would become stagnant resulting in patients having no high technical medical device to cure or sustain their life.

5.3 Interpretation of damage

In EU and AUS cases that the pacemakers was interpreted as defective product in whole group of same series because they carried additional risk of failure, however, at last, those pacemaker had not been proved as actual defective product. In fact, the patient decided to remove them from their body eventually, even if they was suspected as defect. An issue is the removal pacemaker in question out of patient

body, constitutes damage under product liability principle or not. It should be noticed significantly that the pacemaker in question have not defect actually, so, there was no any direct damage from any defect.

The court decisions of EU and AUS were made in the same way. The removal or explantation of suspected pacemaker constitute damage because of those steps are necessary to do for eliminate harmful risk or restore level and standard of safety, prevent adverse consequences even if they are not direct damage from the defect.

The meaning of damage was extended by the court for the purpose of consumer protection, not only direct damage from the defect, but also in direct damage from any step to prevent the harm or restore level of safety are included to be a meaning of damage. In this case, the author agree with this broad interpretation. There is necessary to do simply and reasonably if the potential of defective pacemaker was in your body, the removal is better than doing nothing.

5.4 Analysis and Recommendations

According to the cases in this study, a Thai court could adopt those experiences, decisions and background reasons if similar facts occurred in Thailand. However, the interpretation of the civil law system and purpose of customer protection balanced with the social utilities provided by the business sector are factors which are necessary for consideration.

These cases can be categorized into two groups as follows:

5.4.1 The pacemaker is actually defective.

For this case, it was found that the pacemaker in question was defective after removal from the patient's body, and the patient directly suffered from certain damage arising from that defective pacemaker.

Consequently, there would be no question that the patient would be entitled to the right to sue the entrepreneur in accordance with the Product Liability Act in Thailand; however, the entrepreneurs may claim one of three exceptions for avoiding liability.

It is almost impossible for an entrepreneur to assert exception about the improper use or storage by the patient because, in order to use a pacemaker, the pacemaker was implanted into the body by a medical professional, so there is no issue or suspicion about the normal usage or storage.

In addition, there is the issue of the exception about the patient had already known about the defect of the pacemaker beforehand. The patient cannot definitely know or realize that a pacemaker was defective or not functioning due to the high level of technology. Furthermore, in practice, the patient was in a condition that they had no option to choose, or check the quality of the pacemaker before being implanted into the body. Thus, the entrepreneur cannot assert this exception.

The potential remaining exception is the pacemaker is not an unsafe product. The entrepreneurs can claim that they already did the best thing for ensuring the

quality of that pacemaker because they received permission for importing and selling the pacemaker legally by the Thai FDA. Moreover, they already submitted a “Free Sale”, which was considered by the Thai FDA that a pacemaker is freely sold in the country of origin, especially, if that pacemaker had been sold legally in a country that has stringent about medical devices control; such as, a Premarket Approval for Class III medical device in the US, so, it can be deemed that a pacemaker is not an unsafe product.

Moreover, in comparison with the trend of the US courts’ decision, the manufacturers have been protected by state torts if the process of a Premarket Approval was done correctly.

This is the point to consider that a pacemaker which was permitted to be imported and sold by the Thai FDA and subject to a CFS issued by the original country is an unsafe product or not. As such, it is unavoidable that, for a pacemaker as a high-level product, the best way for ensuring and guaranteeing its quality and standard of safety is the method of acceptance or recognition of permission to sale in another territory because the Thai FDA may not have the efficiency and specific knowledge to do that. The entrepreneur may use this reason to defend itself that the medical device which has already been approved by the Thai FDA along with a CFS is not an unsafe product.

However, for the civil law system, a Thai court has to interpret the laws and provisions by letter literally and its purpose.[157] Thus, an unsafe product means the product that causes damage. If that pacemaker actually caused damage, it would have to be logically considered as an unsafe product even if it was permitted legally to be imported and sold by any organization. In addition, the purpose of product liability is consumer protection, and to impose liability on the entrepreneur, the person who created the adverse risk even if there was no mistake done by the entrepreneur itself at all.

In comparison with US court decisions, the business sector has been protected from state product liability laws occasionally by the reason of the Preemption Doctrine, federal laws, bar state laws. It seems unfair for the damaged party, but there are background reasons as follows:

1. The US has very strong regulations for controlling Class III medical devices with a "Premarket Approval (PMA)". They believe that a PMA is stronger than a state product liability law, so it should be maintained. If the court decided that state laws are able to prevail the PMA, then the PMA would be meaningless for the enforcement and consistency issue.

[157] *Civil and Commercial Code of Thailand*. Section 4

2. The US believes that the importation and distribution of a pacemaker and other Class III medical devices have advantages more than disadvantages. A pacemaker can save or sustain life rather than kill.

Those reasons above should be considered by a Thai court. For the reason of benefits, the author agrees that a Class III medical device is necessary for medical sector at the present time. However, the author disagrees with the reason of preemption because the Thai legal system has no federal law and state law, only civil law, not common laws. Additionally, the Thai medical control system is not strong enough, as the relevant authorities and government sector still do not have sufficient proficient experts and tools for the verification and certification of the standard and safety of medical devices. This is especially so for the importation of high-risk medical devices from a country which has no set standards, as well as the Thai FDA will give permission for importation by acceptance of CFS issued by other countries which are so many different standards of safety. Therefore, the Thai people were put at a higher risk than the American people, so the product liability laws should definitely not be interpreted in the way of the exemption of the liability for the entrepreneur. It should maintain its purpose, which is consumer protection.

5.4.2 Pacemaker was not actually defective, but had the additional risk to fail

This type can be found in the EU case where the pacemaker in question could not be proved exactly if it was defective or not. For a particular situation, while the

pacemaker was in the patient's body, there was a "hazard alert" issued from the business sector side or government that the pacemaker had a chance to be defective or experience failure and suggest that it should be replaced. That alert affected the patient badly. Finally, an operation for replacement was arranged. The questions are if that pacemaker is an unsafe product or not and should the damage in connection with the operation be legally constituted or not, and should the costs of the operation be claimed from the manufacturer or not.

The answers were made clear by the EU and Australian courts whereby the pacemaker in question was considered as a defective product wholly in the same series. The reason was the device carried an additional risk for failure. All pacemakers have an ordinary risk to fail, as it is the nature of a product; one million pieces produced, one of them may be defective, therefore this is an unavoidable fact. Nevertheless, the pacemaker which was subject to a hazard alert, other than ordinary risk, also carried an additional risk to fail. This means, in total, it has a higher harmful risk. In considering the type of product, the pacemaker is a product used for sustaining life and implanted into the patient's body. Its functions are related to the human heart; therefore, the pacemaker shall be expected to have absolute safety. Carrying an additional risk should not be acceptable for a patient who was in a position that is difficult to avoid the risk.

For Thailand, the court's decision for this case should be the same as the EU and Australia although after removal is the pacemaker defective or not. The business sector should not be exempted from any liability because of the exception of "it is not an unsafe product". The condition of "unsafe" should be determined while the device was in the patient's body or before distribution into the market, not after the removal. The criteria which were applied to extend the definition of unsafe product by the foreign courts should be applied and considered by Thai court also. They can be concluded as follows:

1. Additional risk of failure, other than ordinary risk
2. Expectation of public, not specific users
3. Characteristic of product, normal use
4. Target group of consumer, capacity and condition for prevent or avoiding the risk

5.4.3 Parallel functions for customer protection

Imposing liabilities under Product Liability Act to entrepreneur side and stringent regulations for medical device control are necessary equally. When the entrepreneurs realize that they are going to be liable for any defective pacemaker or defective medical device without any exception given by the court, they will find out the way to reduce a harmful risk as much as possible, such as, a consideration for selection of the original country where has high standard of safety in regard to

manufacture of medical device for making importation into Thailand for avoiding liability. This can help the consumers to get better standard of medical devices indirectly. However, even if the entrepreneur side try their best to reduce the harmful risk, but it is unavoidable some consumers may get damage from ordinary risk of failure, nevertheless, the remedy from the Product Liability Act can be help wholly or partial for innocence customer. This is reasonable that the entrepreneur side should be responsible for this even if they did not commit any fault, but there is undeniable that the ordinary risk was created by them. The profit arising from their business should be portioned for remedy those innocence victims.

However, remedies under Product Liability Act may be not enough for some kinds of damage, such as permanent disability or death, therefore, the preventive function is significantly required. It means there is unacceptable if the entrepreneur side can put the defective products or harmful risks into market without any control.[158] The control system of standard of safety in relation with medical device in Thailand needs some improvements. The model should be the control system of US. Firstly, Thai FDA should set up rigorous regulations for high-risk medical device (Class IV). Recognition of approval from other countries should be done carefully. Training experts or specialists about medical device and providing necessary tools for

[158] Kenneth W. Simons, "Tort Negligence, Cost-Benefit Analysis, and Tradeoffs: A Closer Look at the Controversy," (2008).

verification and check the quality of medical device have to be improved also. Then, strong preventive regulations will reduce the number of defective medical devices.

In conclusion, strict enforcement of Product Liability Act imposing liability to the entrepreneur side and stringent control regulations in relation to medical device are indispensable for Thailand. Both functions need to be triggered and implement harmoniously as parallel functions for the greatest protection of safety.

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APPENDIX

VITA

Mr. Peerasak Ounhachoke, was born on October 18th, 1989, Bodindecha (Sing Singhaseni) School, for Middle and High school. He graduated Bachelor's degree of from Thammasat University, Faculty of Laws in 2012 and continued Master's degree at Business Laws program, Faculty of Laws, Chulalongkorn University in 2014.