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Medical Product Liability under the Consumer Protection Act 1999: Aims Unmet

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Abstract: Consumers, particularly patients are incapable to amass enough information of the complexity and high technology nature of medical devices and when injured, patients have difficulty in proving that the devices are defective. This study examines the legal status of medical devices under the Malaysian Consumer Protection Act 1999 (CPA 1999) and the compensatory system under part X of the CPA 1999 regarding product liability. The findings of this study show that although part X gives appropriate compensation for injury caused by faulty products, however patients are tossed into dealing with much heavier burden to prove under this part for medical devices compared to unrelated health products. This study attempts to show that the existing product liability provisions have several drawbacks which indicate that the provisions might have failed to achieve its aims and purposes. Therefore, it is the purpose of this study to examine those drawbacks and make suggestions in order to be able to assist patients in the process of claiming compensation.

Key words: Product liability, medical device, defective, consumer protection, Malaysia

INTRODUCTION

Basically, Malaysian Consumer Protection Act 1999 (CPA 1999) was designed to address an imbalance between the powerlessness of consumers and the strength of retailers and manufacturers. Consumer, the end-user of goods or products may bring an action against the manufacturer if it violates any provisions thereto which give right to the consumers to claim. Being a consumer, patient may bring an action against the manufacturer for compensation due to defective medical devices under the ambit of part X: Product liability if they sustain any injury or death. This part serves as a redress for the patient and according to Amin (2007), it is seen as part of the solution relating to unsafe products. However, 14 years has passed since the act had been enforced and not a single case has been reported in Malaysia. This is not an indication that there are no single incidents on faulty medical devices as medical devices are also subject to malfunction, failure and decay. Howells (1993) states that:

> Information on the exact number of product-related accidents is difficult to obtain because these can happen in any way to anybody, anywhere at any time. Unlike work accidents (which employers will record), there is no written record of product-related accidents and as many happen out of sight, there is doubtless countless which remain undisclosed. Also, the nature of the accidents vary from the minor (cutting a finger opening a sardine tin) to major catastrophe (witness the effects of the thalidomide drug).

Although, there are no legal reported cases in Malaysia, it is increasingly difficult to ignore the occurrence of injury due to defective medical devices. In the United States of America, Caldwell and Ann reported that in the 1970's, approximately 10,000 injuries from medical devices including 731 deaths and 513 of the death was due to defective heart valves alone. This study was done around 40 years ago and though cases go unreported, it is believed that the numbers have multiply ten folds. Recent figures from the United Kingdom Government's Medicines and Healthcare Products Regulatory Agency (MHRA) stated that dangerous medical equipment resulted in 184 deaths and 1197 serious injuries in England (Ellis, Rachel 28 April, 2007). It was reported that approximately 1400 patients injured due to defective medical devices, a rise of 100% from 2004-2007 and citing several incidents, such as patient died due to being trapped at the side of a defective bed rail and many went into hypoglycemic comas due to falsely high diabetic readings.

Unfortunately, there are no available statistics in Malaysia regarding this matter, however the Association of Malaysian Medical Industries (AMMI) reports that

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the consumptions of medical devices in the country is expected to grow to US$ 5877 million in 2010 from US$ 826 million 2009. This figure has increased from US$ 956 million in 2011 to the staggering amount of US$ 1.7 billion in 2012. Incidents have been reported of medical devices that have been withdrawn due to its defectiveness. In 2006, it was reported that contact lens solution was withdrawn immediately as many complained from 1st January, 2005 till February, 2006 (Shari, Izatun. 16 Mac 2006) that it caused fungal keratitis infection which damages the cornea that may lead to blindness and cataract. Hospitals were also reported using non-FDA approval stents in which these medical devices used are not registered with the Ministry of Health. The repercussion of this is can be disastrous as it leaves consumers, particularly patients compensation-less if sued under the provisions of part X of the CPA 1999. Most recent tragedy due to defective medical device was reported in 2011 in which 2 hospitals were found negligent due to faulty oxygen tank which caused a baby to suffer severe brain damage and paralyzed on the left side of her body (Shaharuddin, 2011). The cause of action taken by the family was under the law of negligence. It may be assumed that one of the factors for pursuing the claims under negligence is that the family may had better chance in obtaining compensation via tort rather than via product liability under the CPA 1999.

With the enormous production of highly technical and complex medical device usage as stated earlier, this study attempts to show that the existing product liability provisions have several drawbacks that might be unable to catch up with mass production as reported above. Therefore, it is the aim of this study to examine those drawbacks and make suggestions in order to assist the consumers, especially patients in, not only providing maximum protection but also be able to truly accommodate patients in process of claiming compensation.

STATUS OF MEDICAL DEVICES UNDER CPA 1999

Consumer when purchasing certain products is mostly unaware that it is a medical product or medical devices, such as treadmills, any exercise equipment or a simple product, such as cotton swab. According to Tolomco, Deborah E. (Vol. 1, No. 4; 117), there are products in which everyone recognizes it as a medical devices, such as crutches, x-ray machine, fetal cardiac monitors, hip joints (The New Zealand Herald, 14 Mac 2012; The New York Times, 28th December, 2011), implants, such as pace maker, heart valve (Sunday times 10 Mac 1985), breast implants, hip implants or basically all the devices used in connection with the patient in a hospital. Then there is readily accepted but non-apparent medical devices such as urine pregnancy test, band-aid, thermometers (The Telegraph, 15th June, 2012) or dental braces. Last category are those in which consumers are unaware that they are medical devices, such as heating pads to relieve muscle pain, pill boxes, manual and electronic toothbrush or tanning beds (Tolomeo and Clarke, 2008).

Contact lenses, for instance are medical devices that have been widely bought by many consumers without knowing that it is a medical device that needs prescription, especially coloured lense. Many young consumers, such as teenagers purchase these fashionable coloured lenses at any local stores nearby. What is the legal status of these medical devices under the CPA 1999? According to the definition of goods under section 3 of the CPA 1999, it is defined as goods which are primarily purchased, used or consumed for personal, domestic or household purposes. In the context of decided cases, several cases from various countries have held that medical devices are consumer goods as defined by their own consumer protection laws. For instance in the recent 2011 case of DJO Canada Inc. v. Schroeder (2011) SK. C Lexis 2456, the patient sued the manufacturer of a defective pain pump and seeks remedy under the Canadian CPA for breach of warranty. The court held that pain pumps, as a matter of clear first impression are goods ordinarily used for personal purposes within the ordinary meaning of the words found in the CPA definition of consumer product. The recent decision of Court of Appeal in Schroeder confirms that medical devices are goods under the CPA of Canada. For the purpose of CPA 1999, medical devices are goods as the consumers purchase the devices primarily for personal use.

PART X: PRODUCT LIABILITY

In the United Kingdom, history has shown in several decided cases the need for imposing strict liability for defective products in the Consumer Protection Act 1987 (CPA 1987). One of the important events which was said to be the piecemeal developments in product liability reform was the 1960's Thalidomide tragedy (Miller, 2004). This tragedy highlighted the need of product liability in the CPA 1987 as a form of providing redress of compensation to consumer due to defective product as torts has its own shortcomings. The children in the Thalidomide tragedy who suffered deformities had to claim under the ambit of tort as they had no locus standi

to claim in contract. Due to these shortcomings, European Community Directive particularly EC Directive on Product Liability (85/374/EEC) on 25th July, 1985 had been established. United Kingdom was a member state of the community hence implemented the directive in the CPA 1987 a strict liability provision for defective product under the ambit of part 1. The aims of the directive were to ensure consumer protection against damage caused to health or property by a defective product and to reduce the disparities between national laws (Delaney and van de Zande, 2001). It was an attempt to harmonize various member state laws regarding product liability and according to Howells (1993), it was not an easy task considering of different legal cultures but all these states had one common goal that is, to place the full cost of the harm caused by a product on its producer.

The enactment of the Malaysian CPA 1999 was greatly influenced by the CPA 1987 (Amin, 2007). Part X was introduced to CPA 1999 after the report of National Advisory Council and Consumer Protection (the Council) in 1992 which recommended that Malaysian existing law was insufficient to protect consumers for defective products. The existing laws which are negligence and the Contracts Act 1950 are unable to provide redress to consumers. The elements in negligent action, such as duty of care, breach of duty of care and injury are obstacles to the negligent claims. On the other hand, the Contracts Act 1950 emphasizes on the doctrine of privity. Part X of the CPA 1999 is trying to overcome these problems. However, how far part X of the CPA 1999 is successful in overcoming the problems is still questionable. Unfortunately in Malaysia, there is no reported case on part X. However, decided cases from other jurisdiction have shown that it is difficult for patients to establish a valid claim which will be discussed later.

Elements of product liability and hurdles for patients in seeking compensation: As, researchers can see the enactment of CPA 1987 was to implement the directive of the council of the European Communities (the directive). Study 4 of the directive of No. 85/374/EEC states that the injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage. It is the requirement of the directive for the claimant to prove:

- The product is defective
- Injury
- Causal relationship between the defect and injury

In the case of Piper v. JRI (Manufacturing) Ltd. (2006) EWCA Civ. 1344, the plaintiff sustained injuries and claimed that implant of hip prosthetic was defective product under section 2 of the CPA 1987 and defendant was strictly liable as the producer. This case demonstrates that the fundamental element of defect and injury and the causal link must be proved by the plaintiff. The same requirements are adopted under part X of the CPA 1999. By virtue of section 68 of the CPA 1999, the person injured by a defective product must prove the damage, defect and causal relationship between them. Studies have shown that these requirements impose huge hurdles to the claimant, particularly patients to prove its case which will be discussed.

The product is defective: The first challenge of the claimant is to prove that the medical devices are defective. Fairgrieve and Howells (2007) states that defect is at the core of the strict liability regime under the directive. A finding of defectiveness is a necessary precondition of liability and hence compensation. In the case of A and other v. National Blood Authority and Anor (2001) 3 All ER 289, the court held that the advantage of this approach for the individual is that liability turns on the existence of a defect alone. A medical product is defective when the claimant expected the medical device to be safe and it turned out to be unsafe. There are several decided cases such as, Foster v. Biosil (2001) 59 BMLR 178, Richardson v. LRC Products Ltd 59 BMLR 185 and Australia Carey-Hazell v. Getz Bros and Co. (Aust) Pty Ltd. (2004) FCA 853 in which the courts explicitly stated that the claimant must prove not only the defect but how the defect occurred. Decided cases have shown, especially medical devices are difficult to prove such as in the case of XYZ and Ors v. Schering Healthcare Ltd. & Ors (2002) EWHC 1420 which involved 10 epidemiologists regarding contraceptive pill, Multiple Claimants v. Sanifo-Synthelabo Ltd. and Anor (2007) EWHC 1860 which involved a medicine taken during pregnancy and Peterson v. Merck Sharpe and Dohme (Australia) Pty Ltd. (2006) FCA 875 which involved side effect of a defective medicine named Vioxx. These cases have shown that the court have declined claimants claim for compensation of defective medical devices because the claimant failed to discharged its burden of proof regarding its defectiveness. How does a patient to prove that the medicinal products are defective as required under the regime of strict liability?

In order to prove defect, the provisions of section 67 (1) and (2) must be read together. A product is defect if the safety of the product is not, such as a person is generally entitled to expect taking into account all relevant circumstances but not limited to circumstance, as per listed (Morris v. Alcon Laboratories (Australia) Pty

Ltd. (2003) FCA 151). However, in trying to interpret section 67(2) what the consumer are entitled to expect is the safety level of external and internal features of the medical device (Fairgrieve and Howells, 2007). The expectation test is not referred to the expectation of an individual but the expectation of the public at large (A v. National Blood Authority (2001) 3 All ER 289). Grubbs (2007) in his studies stated that the determination of defectiveness has to be taken not from the viewpoint of the individual but rather from the standpoint of society.

Applying this provision in the context of medical devices, the expectation element is actually beyond what a claimant or the public at large can expect. Logically, consumers will expect that all medical devices purchased are safe from defects otherwise they would not have purchased it. Medical devices and medicinal products are primarily obtained via prescription of a doctor. Patients rely on these prescriptions as it is a form of instruction from the physician in order to heal or alleviate pain of their patients. The paternalism of a doctor still dominates when it involves illness that patients are clueless about. Hence, any recommendations of their doctors are generally relied and expected to be safe and assume that the medical device has abided strict regulations imposed by Medical Device Act 2012 or sales of Drugs Act 1952. It is this general expectation of the patients that when the medicines are put into circulation, it is safe as it has passed the mandatory clinical trials, various tests and regulations.

In deciding this element, decided cases, such as above have accepted expert witness as evidence on behalf of the claimant to prove what constitutes a defect. Nevertheless, the requirement of the law is that the safety level of a product is to be assessed by the public at large in this particular case, the general public that uses the medical device. When assessing the expectation test, can the expert witness substitute their expectation on behalf of the general public when clearly knowledge-wise, the general public are not at par with them? The reason behind accepting expert witness is to assist the court in dealing with complicated and technical issues of medical devices which clearly the court is unfamiliar with. The role of expert witnesses is to explain to the court the nature of a medical device, its functions and how it is said to cause injury and not to be accepted as giving evidence on behalf of the claimant. The testimonies of expert witnesses tend to slant their testimony to their party's advantage. Assuming expert witnesses give evidence pertaining to the defectiveness of the highly technical and sophisticated medical device, it still does not serves the purpose as it is extremely challenging for the judge to digest and amass all these data and to evaluate upon it. Piles of documents would be trawled back and forth from one expert witness to another which would create more confusions and difficult to decide.

In fulfilling this expectation test, the court may have to evaluate what the general public (patients) expects in the level of safeness regarding medical device. The question is what does the general public knows or has common knowledge about the safeness of a medical device? According to Masters (2006), consumer expectation test is based on the ordinary consumer with ordinary knowledge common to the community is a surrogate for the community of non-expert consumers (purchasers) of a product. Masters further stated that the ordinary consumer is not making assessment on the basis of his or her individual knowledge but on the basis of what the community mutually knows about the product. This entails another problem, as the consumption of medicine and usage of medical devices are only confined to a particular community that uses that medical device. Although, it might be an advantage for the claimant, as the numbers are small compared to general public using normal products but the disadvantage despite the number of demand of the medical devices is difficult to evaluate when the human body reaction to these medical devices differs from each patients in the community. According to Miller (2004) and Khoury (2007), other factors that makes it equally difficult to claim for defective medical device is because it takes years to even notice the adverse effect of a medical device (such as the case of thalidomide). Besides according to Khoury (2007), it poses a heavy burden upon the claimant to draw the line between an injury caused by the medical device itself, allergies from the device or interaction with other medicines, food or over dosage. In addition, such difficulties may be accentuated where a person has taken several different products for separate conditions or a series of similar products from different manufacturers for one condition.

Therefore, it is evident from decided cases above that this element serves as a great hurdle for the patient in proving the defectiveness of a medical device. The expectation test is a challenge proves to be unfair for the patients in the court of law. However, these challenges do not end here as the patient must also prove the injury sustained was caused by the defective medical device as discussed.

Injury and causal relationship: After enduring the burden of proving the defective product, the second and third element that patient has to prove is damage and that the damage has been caused wholly or partly by a defect in

the product (section 68 of CPA 1999). The difference between negligence and strict liability is that in a pursuit of negligence it must be proved that the breach of duty caused the harm. In strict liability under the CPA 1999, consumer must prove that the defect of product caused the damage (Dan Pustaka and Yusoff, 2007). This shows that prove of causation in negligent is to assign blame and strict liability is much more concerned with the behavior of the product (Rosem, 1977). Thus, the onus of proof lies on the consumer to prove on the balance of probabilities that the defect in the medical device had caused injury and damage.

According to the European Commission, Green Paper on liability for defective products, proving damage is caused by a defect in a product might be a severe burden on the claimant when such proof turns out to be technically complicated (Miller, 2004). In the case of Multiple Claimants v. Sanifo-Synthelabo Ltd. and Anor (2007) EWHC 1860 the claimant was born to mother who took defective epileptic drugs during pregnancy that caused permanent disabilities. The claimant sued under Council Directive (EEC) 85/374, Article 6. The court rejected the claim and held that it is complicated litigation giving rise to apparently difficult legal and scientific questions. Although, the subject matter is defective drug, the nature of product relates to the healthcare of the consumer similar to medical devices. In the case of XYZ and Ors v. Schering Health Care Limited and Ors (2002) EWHC 1420 ten epidemiologists of expert evidence for a period of three months were called to give evidence. The claimant sought for compensation due to defective third generation oral contraceptives. The court had difficulty in deciding the issue of causation. The case of Multiple Claimants v. Sanifo-Synthelabo Ltd. and Anor and XYZ and Ors v. Schering Health Care Limited and Ors indicate that to prove causation is not an easy task for the patient.

In an Australian case of Carey-Hazell v. Getz Bros and Co. (Aust) Pty Ltd. (2001) FCA 703, the claimant brought an action for defective prosthetic heart valve. Plaintiff claimed that the heart valve was not reasonably fit for purpose and the defect had caused injury as per section 75AD under the Part V of Trade Practice Act 1974. The provision provides for the liability of manufacturers and importers for defective goods. Sub-section (c) states that because of the defect, an individual suffers injuries and followed by sub-section (d) the corporation is liable to compensate the individual for the amount of the individual's loss suffered as result of the injuries. Unfortunately, the court had to determine the issue of limitation of commencing this action as the defendant raised the issue of time-barred. Nevertheless, this case has shed a light that the law also requires the proof of causation of defective medical devices before the claimant may be entitled to his claim.

In another, Australian case of Morris v. Alcon Laboratories (Australia) Pty Ltd. (2003) FCA 151, the patient sued the manufacturer due to defective lens that was implanted in her eyes. She pled that the lens was not safe as persons generally entitled to expect as per section 75AC Part VA Trade Practices Act 1974. The court held that in relation to the onus of proof, the court noted that it was for the applicant to determine what evidence she views was sufficient to establish liability for defective lens. In Bright v. Femcare Ltd. (2000) FCA 742, the applicant was one of the women who went through sterilization procedure in which the respondent was alleged to use a defective filshie clip. Filshie clip was to be applied in women's fallopian tubes to prevent pregnancy. The applicant claimed that the medical device failed to properly close, causing loss and damages. The court held had struck out the applicant's statement of claim stating that it was inadequate, incomplete and embarrassing as the applicant must prove defective of the device and the injury sustains and not damages or loss.

There are wide ranges of medical devices which involve purchasing small, minimal risk devices to those that are life-saving and high-risk devices. In the case of Foster v. Biosil (2001) 59 BMLR 178, a claimant sought compensation for injury caused by a ruptured breast implant. The court rejected the claimant whom failed to prove it was defective. In rejecting the claim, the court held that the claimant had to indicate a specific defect and identify how it had occurred, such as whether it is a design or manufacturing fault. In A v. National Blood Authority (2001) All ER 289, 114 claimants brought action under the CPA 1987 claiming that they suffered hepatitis C from blood transfusion. Surprisingly Burton J held that blood devices were defective and defendants were liable. It was a turning point in the history of product liability and it was a successful attempt by Burton J to put a halt in the irresponsible conduct of the manufacturer producing defective products.

Defences under part X: There are several situations in which the patient will not be able to succeed in claiming compensation, even though the above elements have been painfully proven by the patient. The CPA 1999 has stipulated several provisions under section 72 which gives the manufacturer a way out of strict liability. Although, medical devices are constantly developing and improvising for the benefit of the patient but it takes time to discover any side effect or defect. Hence, the provision

that has been widely used by manufacturer to their advantage is sub-section (d): That the scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question may reasonably be expected to discover the defect if it had existed in his product while it was under his control. It is known as development risks under Article 7 (e) of the directive. This provision set as an escape clause for the manufacturer. In order for this subsection to operate, the burden is reversed onto the manufacturer to prove that although there is a defect on the medical device, the defect was due to the lack of scientific and technical knowledge, at the time the medical device was put into circulation and was unable to discover it sooner (Multiple Claimants v. Sanifo-Synthelabo Ltd. and Anor (2007) EWHC 1860 QB). Burton J in A and others (2001) 3 All ER 289 Para (50) had discussed this particular provision at length. The defendant claimed that it was impossible to identify the agent causing hepatitis C when the infected blood was supplied to the claimants. The question that was taken into consideration was:

> The question is, thus whether in order to take advantage of the escape clause, the producer must show that no objectively assessable scientific or technical information existed anywhere in the world which had identified and thus, put producers potentially on notice, the problem or whether it is enough for the producer to show that although existence of the defect in such product was or should have been known, there was no objectively accessible information available anywhere in the world which would have been enabled a producer to discover the existence of that known defect in the particular product in question.

The court had rejected the defence stating that the authority had the scientific knowledge that the blood could be contaminated and could cause an infection and was liable towards the claimant. In the case of Scholten v. Sanquin Blood Supply Foundation (Ware and Castle, 2005), the plaintiff who contracted HIV due to blood transfusion claimed against the defendant for supplying defective blood in 1996. The foundation had conducted several HIV test before using the blood which gave negative results. The last test that the foundation used has not been approved by relevant authority at the time of operation. The foundation raised the defence of development risks and the court agreed by stating that it had not been able or required, to use the new test at the time of the transfusion. The court in the case of Multiple Claimants v. Sanifo-Synthelabo Ltd. and Anor (2007) EWHC 1860 QB (as per the facts set above) held that the issue of development defence should be tried together with the question of liability and causation to avoid prolong of the trial. The court held that the onus is upon the defendant to prove its defence of development risk.

There are other defences such as the defective medical devices supplied were not put into circulation (section 72 (1) (b) CPA1999). There was an attempt to raise this defence in a case of Veedfald v. Arhus Amtskommune CMLR 39 (2002) by the hospital which prepared a kidney transplantation using defective fluids. This caused the kidney to be damaged and cannot be used. The hospital argued that the kidney had not been put in circulation. The court rejected the hospital's defence and stated that this defence had to be construed rigidly in order to give maximum protection to the consumer. Another defence is that the medical devices were defective after the product was put into circulation by the producer (section 72 (1) (c) CPA 1999). The producer bears the onus to prove that the defect was caused by a third party intervention or that the defect that injured the patient was caused within the supply chain. This defence definitely poses difficulty for the patient in succeeding their claim, especially when the manufacturer relies on the argument that medical devices have been tampered by third party intervention such as the doctors or medical staffs who uses the device during surgery or treatment. The consequence of this matter is clearly the patient would be left uncompensated and these shortcomings should be addressed seriously.

TOWARDS A WORKABLE SOLUTION

The findings of this article have shown that there are no decided cases that patients are able to claim compensation without going through all these hurdles as stated above. The existing product liability law, particularly CPA 1999 indicates that due to these burdensome elements, patients are reluctant to proceed to court and claim for their rights to compensation. The consequence is severe because as the medical device industry in Malaysia increase significantly over the years, it is feared that the manufacturers would not be brought to justice and the vulnerable patient would not be compensated and bears the financial burden. These results are consistent with those of other studies, such as done by Hall and Schneider (2008) which states that:

> We do not imagine that courts can solve the problems of healthcare finance. But, we believe that courts can and should shield patients from

> the cruelest consequences of the new market. Sickness, fear and ignorance make patients inherently vulnerable. When patients must be consumers, their vulnerability deepens as they find themselves trapped in a market that starves them of information, alternatives and leverage, a market that precludes prudent choice.

In addressing the issue of proving a defective medical device, studies in the United States by Rosenn (1977) highly recommends the seriated trial (4 phase trial) proposed by the Carnegie-Melon study. This study suggests that liability can be imposed rationally only if the court thoroughly understands the product. This is achieved by first determining and focusing on the critical issue of the medical device's behavior before moving on to the issue of causation and evaluation of damages if causation has been proven. Expert witness will be called at this early stage and can act as a technical arm of the court in defining and analyzing the precise, technical issues, assist in establishing minimal levels of evidence both theoretical and physical (Rosenn, 1977). In analyzing the Carnegie-Melon study, it does not eliminate the problems that the patients face in dealing with burden of proof under the strict liability system. What is boiled down is that this system must prove the causal link between the defect and the injury sustained. This can be seen in the case of Schick v. Boehringer Ingelheim (Canada) Ltd., (2011) O.J No. 1381 in which the plaintiff claimed that the drug Mirapex was defective and caused Impulse Control Disorders (ICD). The court held that the issue of causation should be framed as is Mirapex defective or unfit for the purpose for which it was intended? The burden is upon the plaintiff to prove the drug was defective on the balance of probabilities. According to Khoury (2007) in analyzing the element of causation in medical product liability stated:

> Under the traditional rules of evidence and causation, a plaintiff having to deal with the above uncertainties may be doomed to failure. There are studies which suggested creating health courts (Mello *et al*., 2006) and three tier consumer disputes redressal machinery, such as consumer forums, however the core of the problem that needs to be addressed is not the forum of adjudicating the matter but the procedure in determining the liability, i.e., burden of proof.

Amendments should be made pertaining to this matter in the provisions of strict liability under part X of the CPA 1999. Thailand for instance, on 21 February, 2009 the Unsafe Product Liability Act, B.E. 2551 2008 (the PLA 2008) came into force. This piece of legislation is somewhat different from other product liability laws as it deviates from the other product liability laws. In part X of the Malaysian CPA 1999, like any other countries that adopt the 85/374/EEC Directive, plaintiff bears the burden of proving the device is defective. Thailand, on the other hand has a method of its own in determining liability. The Product Liability Act 2008 shifts evidentiary burdens in product liability claims. According to section 5 PLA 2008, every entrepreneur is liable to the injured person for the damage caused by the unsafe products (section 5 of the PLA 2008). The injured person has to prove that the injury was due to that defective product (section 6 of the PLA 2008) but the burden of proving that the product is defect is upon the entrepreneur. This means that evidentiary burden shifts to the manufacturer as required under section 7 (1):

> An entrepreneur shall not be liable for damages caused by the unsafe products if he can prove that such products are not unsafe products.

On the outset, this seems to be a fair legislation as, in the context of manufacturer of medical devices carries the burden of proving that its product is safe instead of patient having to prove how the product should work. This provision is supported by the Consumer Case Procedures Act B.E 2551 in which section 29 provides:

> For any issue in dispute that needs the proof of facts concerning production, assembly, design or contents of goods, provision of service or any acts which facts are considered by the court as being within the exclusive knowledge of the party who is the business operator, the burden of proof of such issue shall be borne by the party who is the business operator.

In order to bring manufacturer of medical devices to justice, it may be a good initiative for the CPA 1999 to amend the provisions under the part X in reversing the burden of proof. Logically, manufacturer are the best party to prove that medical device are not defective, as they possess all the data and information of the product they created and at least half the burden is upon the manufacturer to prove their case. These initiatives may be the key in solving this matter as it alleviates the hurdles faced by consumers, especially patients in dealing with highly technical and sophisticated medical device.

Another, suggestion is amending the Sales of Drugs Act and Medical Device Act 2012 by including strict liability provisions as per the law of Germany. Germany has enacted a special regime of strict liability mainly for

pharmaceutical product such as Pharmaceutical Act 1976 (Maurer, 2006). In this act, it created a strict liability for injuries or death caused by defective pharmaceutical product which includes all products which are either used or consumed to prevent, recognize, cure and soothe any disease, suffering or other bodily harm (Phamarceutical Act 1976 paragraph 2). However, these amendments should be coupled by providing a proper venue, such as health courts or health tribunals in which consists of judges whom has thorough knowledge in medical field. This should reduce the amount of time in assessing and evaluating the evidence of expert witnesses on defective medical device.

CONCLUSION

All medical devices pose direct risk of injury or even death to patient when used. What makes medical device different from any other product is that most normal product does not carry or may have minimal risks to users whereas medical device when used, risks are attached based on the complexity of the device itself. It is used to heal, alleviate pain or cure illness, a direct contact to a person's body, therefore the risk of injury and death are imminent. Medical implant devices for instance are surgically implanted in the human body and pose unique dangers as it is a foreign object which possesses potential cause to injury and death by interacting with the body's natural chemistry (Ware and Castle, 2005). Part X CPA 1999 provides compensation to patient if the medical devices used are defective and caused injury. The provisions are strict liability in nature which means in order for these provisions to operate, the patient must prove defect, injury and the causal link of defective medical device and the injury sustained, in order for the manufacturer be liable. However, in the context of medical devices it is not easy as it seems. From the discussion earlier, it can be gathered that when a personal injury or wrongful death lawsuit arise from the use of defective medical devices, it inevitably presents complex, legal and technological issues that needs to be dealt with before the court of law. Decided cases from other jurisdictions above have shown that in order for the patient to claim compensation under this provisions, the patient has been cast the burden of proving those complex legal and technological issues. The drawbacks and shortcomings that have identified above therefore assists in the understanding of the current CPA 1999, especially product liability cases involving defective medical devices will certainly put a heavy toll upon the patient to succeed in its claim. These factors may contribute to the fact that till date there are still no reported cases on this matter. Based on the analysis above, an inference could be drawn that part X CPA 1999 has failed to respond the need of patients in providing a workable and viable civil claim against the manufacturer of defective medical device, thus the aims of these provisions of the law are clearly unmet. It is certainly a lacuna that deserves special attention by the legislature in order to ensure the sovereignty of patient as consumer in the global era.

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