REGULATING HEALTH RELATED TECHNOLOGIES AND MEDICAL DEVICES: WITH SPECIAL REFERENCE TO INDIA

Abstract

Medical law is made up of bits from a large number of different branches of law: criminal law, human rights law, tort law, etc. Indeed until recently law on medical devices and health related technologies was not recognized as a separate legal subject on its own. However it is now widely acknowledged there should be a separate legal regime of medical devices and health related technologies. Therefore it has been claimed in the academic research on medical law to find a space and to have a proper regulation to control negligence of doctors in using and product liability of manufacturers in marketing medical devices. Moreover various cases involving medical devices and law as applicable regarding use of medical devices and health related technology now in India has clearly proved as inadequate and demand a regulatory regime for safety and protection of patients.

I Introduction

MEDICAL DEVICES form an integral part of the health care sector. All surgical procedures involve the use of medical devices. It has been witnessed for a long time that there are a large number of incidents where a patient suffers as a result of a defective medical device or the result of negligence of the doctor in using of the device. However, the major dilemma lies with fixing the liability for the suffering of the patient. A surgically-implanted medical device often passes through a number of hands before ultimately reaching to the patient. There are a number of parties besides the manufacturer who may have to bear some responsibility for the patient's injuries. A physician generally implants a device which has been acquired by the physician, or a health care professional, or by the hospital from a distributor or the manufacturer. Moreover the application of a new technology in medical surgeries and treatment often leads to a lot of ambiguity as the doctors are not fully aware of the constraints of a particular technology, so whenever a patient suffers it becomes difficult to fix liability for it. However India still considers medical devices as drugs which lead to more uncertainties. Innovation is associated with every technology. The health sector cannot develop without innovation. Nevertheless innovation is faced with a lot of uncertainty, as it becomes difficult to fix liability.

II The conceptual issue

The author would like to introduce the topic with, Kenneth I. Shine's, a cardiologist experiences with medical devices.[1] The experience that had the most profound effect on him as a medical student was with Hufnagle valve,[2] a "birdcage" valve that was placed in the descending aorta in patients who had aortic insufficiency. It was placed in the descending aorta because at the time Hufnagle developed there was no technique to allow placing the valve directly into aortic position. Thus, it was done through a thoracotomy.[3] It did not affect the regurgitation[4] in the upper portion of the body, but only in the lower portion. What was remarkable about this device was that it made noise. It was located close to the trachea, and if the patient opened his mouth people across the room could hear the clicking. As long as the patient was in sinus rhythm,[5] they could tolerate the noise however when the patients developed atrial fibrillation,[6] which produced a random clicking that was highly disturbing to them. A patient under his care committed suicide because he could no longer tolerate the sound. Much progress has been made with prosthetic valves[7] since that time. The Hufnagle valve

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1 Karen B. Ekelman, *New Medical Devices Invention Development and Use* (National Academy Press, Washington D.C,1998).

2 Hufnagel's invention was a small plastic tube with a plastic ball in the middle which was "implanted quickly into the descending aorta using a non-suture technique" as there was no way at this time to maintain continuous blood flow to the body during surgery. Another drawback to this model, besides the mortality and cumbersome insertion, is that patients could hear the plastic ball bouncing around inside them, though sometimes it could be wrapped in silicone to muffle it. *Available at*: http://artificialheartvalve.umwblogs.org/antecedents/hufnagels-valve/ (last visited on Oct. 14, 2013).

3 Surgery to remove all or part of a lung involves making a cut on one side of the chest (thorax) during a procedure called a thoracotomy. Surgery that uses this approach avoids areas in the chest that contain the heart and the spinal cord. After the cut is made between the ribs, all or part of the lung is removed depending on the location, size, and type of lung cancer that is present. *Available at*: http://www.webmd.com/lung-cancer/lung-surgery-thoracotomy-for-lung-cancer (last visited on Sep. 20, 2013).

4 Regurgitation is the expulsion of material from the mouth, pharynx, or esophagus, usually characterized by the presence of undigested food or blood. *Available at*: http://en.wikipedia.org/wiki/Regurgitation_%28digestion%29 (last visited on Oct. 19, 2013).

5 In medicine sinus rhythm refers to the normal beating of the heart.

6 The human heart has two upper chambers and two lower chambers. The upper chambers are called the *left atrium* and the *right atrium* - the plural of *atrium* is *atria*. The two lower chambers are the *left ventricle* and the *right ventricle*. When the two upper chambers - the atria - contract at an excessively high rate, and in an irregular way, the patient has atrial fibrillation. *Available at*: http://www.medicalnewstoday.com/info/atrial-fibrillation/ (last visited on Oct. 14, 2013).

7 Signs and symptoms of prosthetic heart valve malfunction depend on the type of valve, its location, and the nature of the complication. It usually includes the following:· Acute prosthetic valve failure: sudden onset of dyspnea, syncope, or precordial pain. Acute aortic valve failure:

was an extraordinary contribution at the time that it was first implanted, but it had unexpected limitations. Development of medical devices depends on innovation that moves the field safely forward in a way that continually improves over time. Similarly innovation in technology is the implementation and commercialization of a product which gives improved performance and also delivers new and enhanced services to consumer.

The problem can be better understood if one looks into the very recent case of Johnson & Johnson[8] in which company had agreed to pay $ 2.5 billion (over Rs 15,000 crore) as compensation to around 8,000 U.S citizens who had sued the company after being fitted with its faulty hip implants.[9] It was revealed that the implant metals cobalt and chromium were leaving debris in the body which led to fluid accumulation in joints and muscles causing pain or discomfort and heightening chances of metal poisoning. However the scenario in the US contrasts gratingly with India. In India about 4,500 patients had received the implant and there is only one reported case against the company in consumer court. The patients are ignorant and have remained in the dark about the dangers the implant poses and the global outcry against it. A large number of patients have remained under pain or have gone for further surgeries unaware about the effects of the implant. This is the present scenario with regard to liability for medical devices. While a US litigant stands to gain an average compensation of Rs 15.6 crore under the plan besides the legal fees, the compensation issue has not even arisen in India. The company has only referred to bear costs of testing and treatment for reasons related to the recall, including revision surgery. The Maharashtra Food and Drug Administration (FDA) have now written to the CBI to take over the case. The FDA has also informed the Drug Control General of India (DCGI).

The number of patient deaths linked to Implanted Cardiac Defibrillators (ICDs)[10] which are implanted in patients leads to a large number of adverse events. A dilemma

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Sudden death; survivors have acute severe dyspnea, sometimes accompanied by precordial pain, or syncope. Subacute valvular failure: Symptoms of gradually worsening congestive heart failure; they also may present with unstable angina or, at times, may be entirely asymptomatic. Embolic complications: Symptoms related to the site of embolization (e.g. stroke, myocardial infarction [MI], sudden death, or symptoms of visceral or peripheral embolization)· Anticoagulant-related hemorrhage: Symptoms related to the site of hemorrhage *Available at*: http://emedicine.medscape.com/article/780702-overview (last visited on March 3, 2013).

8 Editorial, "J&J to pay $ 2.5b for faulty hip implants" *The Times of India,* Dec. 4, 2013.

9 *Ibid.*

10 An implantable cardioverter defibrillator (ICD) is a small device that's placed in the chest or abdomen. Doctors use the device to help treat irregular heartbeats called arrhythmias. An ICD uses electrical pulses or shocks to help control life-threatening arrhythmias, especially those that can cause sudden cardiac arrest (SCA).SCA is a condition in which the heart suddenly

is raised with regard to safety of the patient and risk disclosure of the product for the medical device manufacturers[11]. Risks present in a medical device during clinical trial continue to be present even after the product is introduced in the market.

A case study has been conducted in the United Kingdom with regard to breast implants[12]. PIPS (Poly Implant Prothèse), are manufacturer of breast implants, had used a non-approved filter material which had threatened the life of many women. It was undetected by the UK Government and MHRA.[13] The investigation was hampered by wrong reporting of adverse events, as well as uncertainties about comparative data on similar products. The study carefully analyzed the role of MHRA and the reasons for such an incident. However, the MHRA conducted all tests and review of the PIP implant. It was due to the fraudulent manufacturer who after receiving approval for the breast implant changed it into a non-approved filter material which resulted in such incident. Even after having a very efficient mechanism the EU could not prevent such incident.

III Seeds of regulatory regime in health care

Seeds of liability for medical negligence originated in the common law principle which postulated that only the persons to whom the defendant owes a duty of care and the types of harm to which the duty extends have been considered. Today duty of care is concerned with whether or not a legal obligation to take care arises between persons. The logical progression from the duty of care issue standard of care was established through a series of judicial decisions. Similarly the complex history of liability for loss or injury caused by defective products is the result of gradual development and changing perception of the role of tort law. Liability for a failure to take care in the manufacture of a product causing personal injury originated in *Donogue*

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stops beating. If the heart stops beating, blood stops flowing to the brain and other vital organs. SCA usually causes death if it's not treated within minutes. *Available at*: http://www.nhlbi.nih.gov/health/health-topics/topics/icd/ (last visited on Dec.5, 2013).

11 Dianne M. Bartels, "Disclosing risks of new technologies: Ethical challenges for physicians, patients and Companies" 7 *Minnesota Journal of Science and Technology* 2005.

12 Poly Implant Prothèse (PIP) silicone breast implants. Review of the actions of the Medicines and Healthcare products Regulatory Agency (MHRA) and the Department of Health. *Available at*: https://www.google.co.in/search?q=Poly+Implant+Proth%C3%A8se+%28PIP%29+silicone+breast+implants.+Review+of+the+actions+ of+the+Medicines+and+Healthcare+products+Regulatory+Agency+%28MHRA%29+and+the+Department+of+Health+&ie=utf-8&oe=utf-8&rls=org.mozilla:en-US:official&client=firefox-&gws_rd=cr&ei=RA6jUuaEFoiOrQfk9oHQBA (last visited on Sep. 26, 2013).

13 Medicines and Healthcare products Regulatory Agency Agency. *Available at*: http:www.mhra.gov.uk/Howweregulate/Devices/ (last visited on Oct. 2, 2013).

v. *Stevenson*[14] and it has since been extended to include others involved in the lifecycle of products, including assemblers, repairers, testers, and certain suppliers. Thus actions are available to the purchasers of goods to users and bystanders. The classical common law stance towards faulty or useless goods was that of *caveat emptor* but in pursuance of UN Guidelines[15] legislature in most of the countries including India developed protection of rights of the purchasers or goods first by Sale of Goods Act, 1940 and presently by Consumer Protection Act, 1986 and US Medical Devices Act . Thus from a fault-based liability and the later development to a strict liability for the defects of products and ultimately the statutory liability governs the present issue of professional negligence or manufacture's negligence of products reaching to ultimate users or ultimate consumers. Therefore to investigate into the question of medical devices and liability arising out of defective medical devices may be looked through five stages:

1. Liability under common law
2. Liability under contract and Sale of Goods Act
3. Liability under Consumer Protection Act, 1986
4. Drugs and Cosmetics Act
5. Products Liability

Common law liability

Lord Atkin laid down the following principle in *Donoghue* v.*Stevenson:*[16]

> A manufacturer of products which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him with no reasonable possibility of intermediate examination and

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14 *Donoghue* v. *Stevenson* [1932] 1 All ER.

15 The development of consumer protection regime is very recent and may be traced to the Bill of Consumers Rights wherein the recognition of consumer rights commenced at the international level. This bill has provided recognition to four important rights of the consumers, viz. (i) the right to safety; (ii) right to be informed; (iii) right to choose; and (iv) the right to be heard. These rights of the consumers were further strengthened by passing of resolution by UN General Assembly on April 9, 1985, wherein general guidelines were issued by the United Nation General Assembly which included: (i) physical safety, (ii) protection and promotion of consumer economic rights, (iii) standards for the safety and quality of consumers goods and services , (iv) measures enabling consumers to obtain redress, (v) measures relating to specific areas like, food, water and pharmaceuticals; and (vi) consumer education and information programmes.

16 *Supra* note 14 at 599 .This is sometimes referred to as narrow rule. The wider rule about the duty of care in general such as you must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbor. An American Court had anticipated this by 16 years: *MacPherson* v. *Buick Motor Co.* (1916) 111 N.E. 1050.

> with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in an injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care.

In *Andrews* v. *Hobkinson*[17] the principle of *Donoghue* v. *Stevenson*[18] has been extended from manufacturers to include repairers,[19] fitters[20] and assemblers.[21] Mc Nair J held that the defendant was guilty of negligence in failing to make the necessary examination, or atleast in failing to warn the plaintiff in *Carroll* v. *Fearon*.[22] The manufacturer's duty extends to taking steps concerning dangers which are discovered only after the product has gone into circulation.[23] Similarly a mere distributor maybe under a duty to make inquiries or carry out an inspection of the product and if it is dangerous for some reasons of which he should have known, his failure to warn of it will then amount to negligence.[24] Prescription drugs will commonly have untoward side effect upon a minority of users and a manufacturer will normally fulfil his duty by giving adequate warning to the prescribing physician. However if the physician fails to heed the warning his default may properly be regarded as the sole cause of injury to the patient.[25]

The Post Junior Book case,[26] reveals a general pattern of restriction on the reach of negligence law and an attempt to keep separate the spheres of tort and contract law is discernible. There is much discussion of the practical impact of placing upon the manufacturer the liability for defects of quality and it must be borne in mind that if the claimant is a purchaser of the article and the usual chain of contractual indemnities

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17 [1957] 1 QB 229.

18 *Supra* note 14.

19 *Stennett* v. *Hancock* [1939] 2 All E.R 578.

20 *Brown* v. *Cotterill* [1934] 51 T.L.R.21

21 *Howard* v. *Furness–Houlder Argentine Lines* Ltd [1936] 2 All ER 296.

22 [1998] P.I.Q.R. P.416

23 *E.Hobbs* v. *Baxenden Chemical Co* [1992] 1 Lyod's Rep.54; *Hamble Fisheries Ltd v Gardner* [1999] 2 Lyod's Rep.1; *Hollis* v. *Dow Corning* (1996) 129 D.L.R.(4th) 609. See also Carroll v Fearon [1998] P.I.Q.R.P416.

24 *Chaudhury* v. *Prabhakar* [1989] 1 W.L.R.29 (gratuitous agent inspecting property liable to principal, though a duty of care was conceded).

25 *Hollis* v. *Dow Corning* (1996) 129 D.L.R.(4th) 609 it was held that in such a case the manufacturer cannot escape liability by giving evidence tending to show that the doctor would not have passed the information on. That would leave the claimant in the position of failing against the doctor (who is not negligent because he received no warning) and against the manufacturer. See *Tettenborn* [2000] L.M. &C.L.Q.333.

26 In *Junior Books* v. *Veitchi* [1983] 1 AC 520 at 534. Lord Fraser thought that the claimant in tort could be in no better position than the purchaser from the manufacturer. Perhaps these problems laid passing of consumer protection law because common law principle has little room for bargaining and judicial control of exemption clauses between the manufacturer and the intermediary.

functions fully it is the manufacturer who carries responsibility even if he is not negligent. The liability under Sale of Goods Act is created between the buyer and seller. Therefore certainly creation of a direct liability from manufacturer to consumer might raise formidable difficulty. For example, what would be the effect of exclusion or limitations of liabilities in the contract between the manufacturer and the intermediary that is the seller and some more remote persons in the distribution chain.

Liability under contract and Sale of Goods Act

Products are typically acquired by customers under contracts of sale or supply. The seller or supplier is often a retailer who sells to a consumer or trade buyer. The retailer will probably himself been a buyer, having bought the goods under a contract of sale or supply from the producer or a distributor.[27] However it is to be conceived that the ultimate consumer usually buys it directly from the manufacturer under a contract, so that it will be the producer who has contracted to sell or supply to these parties. There may be express terms in the main contract of sale or supply which make promises as to some features of the goods. The express conditions may also provide with remedies in case the goods are defective or has developed faults as a result of wear and tear. The consumer under a contract regime usually gets remedy for repair, replacement, refund, compensation or some other remedy. The promises as to the goods or as to the remedies are provided under the so-called 'extended warranty' contracts which exist between the seller or supplier and the buyer or between the manufacturer and the buyer. Guarantee and extended warranty usually exists along with the main contract of sale or supply. An extended warranty is usually paid while a guarantee is usually not paid. The most significant contractual responsibility in relation to goods comes from the implied terms as to description, quality and fitness for particular purpose.[28] In the instance of breach of contract the buyer will always be able to claim damages. In some cases the buyer has also been provided the right to reject the goods and terminate the contract. When this right arises in contract other than sale it is only lost when the buyer knows of the problem and still affirms the contract. However in contract of sale when the right arises it can be lost by the acceptance of the goods. This usually happens by lapse of time.[29]

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27 Geraint Howells and Andrew Grubb(ed.), *The Law of Product Liability* 47 (LexisNexis Butterwoths, Britain, 2nd ed., 2007).

28 Chris Willett, "The Role of Contract Law in Product Liability" in *The Law of Product Liability ibid.*

29 *Ibid.*

Liability for medical devices which are considered as products is usually regulated under Law of Contract, 1872; Sale of Goods Act, 1930; negligence under law of torts and Consumer Protection Act, 1986. It has been observed that contract-based remedies offer many advantages for the buyer as compared to negligence action under law of torts. If the seller supplier or manufacturer makes a contractual promise he has to ensure that the goods have attained a certain standard or that they will be repaired or replaced if they break down. The promisor is not saved from being in breach simply because he did not owe a duty of care to the consumer or because he was not negligent. Moreover if a seller or supplier is in breach of the implied terms, the buyer does not need to establish that the breach was as a result of negligence of the seller or supplier.[30] The contract remedies are more generous as compared to the provisions existing under Consumer Protection Act, 1986. The limitation for a contract based regime is the narrow conception of contract upon which it is based. Even where a buyer has bought from a retailer it is arguable that this is often done in reliance upon the reputation that the manufacturer has established with regard to the specific product.

In India in a contract there are certain stipulations or warranties between the manufacturer and the buyer, any deviation from the stipulations gives rise to liability. The buyer is given protection under section 16 of the Sale of Goods Act, 1930. Under other laws, a product may be considered defective if: (i) an implied warranty or condition as to the quality or fitness for any particular purpose for the product is breached; or (ii) the seller fails to fulfill its fundamental obligation under a contract; in which case no term of the contract can relieve the seller of its respective fundamental duty; or (iii) the statutes governing specific goods require certain specific compliances like branding, labeling *etc*., then, any breach or non-compliance of such requirements. Further, the standards by which a product may be deemed to be defective also depends upon the terms and conditions of the contract along with any warranties or guarantees.

Liability under Consumer Protection Act

Protection and interest of consumers is important in a welfare state. In this context the development of consumer rights and consumer movements became one of the most important pressures for law reform. In the United States, U.K and India liability for negligence was overtaken by law reform in favour of consumer. According to the Supreme Court, the redressal mechanism established under the Consumer Protection Act, 1986 is "not supposed to supplant but to supplement the existing judicial system".[31] The Supreme Court also explained the object and philosophy of the Consumer

30 *Supra* note 27 at 8.

31 Gurjeet Singh, *The Law of Consumer Protection in India: Justice Within Reach* 63-64(Deep and Deep Publications, 1996).

Protection Act, 1986 in the landmark case of *Lucknow Development Authority* v. *M.K. Gupta*[32] The apex court has made the following important observations: [33]

> In fact the law [the law of consumer protection] meets the long felt necessity of protecting the common man from such wrongs for which the remedy under ordinary law for various reasons has become illusory . . . The importance of the Act lies in promoting welfare of the society by enabling the consumer to participate directly in the market economy. It attempts to remove the helplessness of a consumer which he faces against powerful business, described as, 'a network of rackets' or a society in which, producers have secured power to 'rob the rest' and the might of public bodies which are degenerating into store house of inaction where papers do not move from one desk to another as a matter of duty and responsibility and for extraneous considerations leaving the common man helpless, bewildered and shocked.

The liability under Consumer Protection Act also extends to goods and services.[34] The doctors and surgeons come under the purview of services. The Consumer Protection Act, 1986 has served as a viable and quasi-judicial institutions by resolving even the most critical and complex disputes which have arisen in due course. As per the Consumer Protection Act, 1986, a consumer is:

i) Any person who fulfils the terms of a contract[35] and purchases a good[36]for which he has paid/partly paid/ has promised to pay/ has partly promised to pay under any system of deferred payment.

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32 (1993) 1 CTJ 929 (SC). It may be appropriate to mention here that the judgment handed down by the apex court in this case is no doubt the second judgment delivered by the Supreme Court of India in relation to the Consumer Protection Act, 1986, but for all intents and purposes this was the first one on the interpretation of the various provisions of the 1986 Act. The earlier judgment of the Supreme Court in the matter of *Common Cause* v. *Union of India* (1993) 1 CTJ 678 (SC) was only in the nature of direction to the governmental authorities to establish the district consumer disputes redressal forums and the state consumer disputes redressal commissions and to provide the infrastructural support. For more details, see: S.S. Kumar, "Supreme Court on Consumer Protection" *Consumer Protection and Trade Practices Journal* 213-217 (Vol. 1, 1993).

33 *Lucknow Development Authority* at 933.

34 S. 2(0) of The Consumer Protection Act,1986(Act 68 of 1986) provides that "service" means "service of any description which is made available to potential users and includes the provision of facilities in connection with banking, financing, insurance, transport, processing, supply of electrical or other energy, board or lodging or both, [housing construction,] entertainment, amusement or the purveying of news or other information, but does not include the rendering of any service free of charge or under a contract of personal service".

35 S.2 (h) of The Indian Contract Act, 1872(Act 9 of 1872).

36 S. 2 (i) of The Consumer Protection Act, 1986(Act 68 of 1986).

ii Any person who hires a service[37] or who is the beneficiary of a service for which he has paid/partly paid/ has promised to pay/ has partly promised to pay under any system of deferred payment.

On the contrary, there have instances where it has been established that whenever any service or good is provided free of charge and there is any misadventure arising from the transaction, then no relief would be granted under the Consumer Protection Act, 1986.[38] If it could be proved that the said service was a gratuitous act on the part of any medical institution or a medical professional and no consideration was transferred between the parties then services rendered would not constitute 'service' as defined in section 2(1) (o) of the Act.

In the year 1995, the Supreme Court of India in the case of *Indian Medical Association* v. *V.P. Shantha,*[39] held that if any service was provided a medical professional or a hospital in exchange for consideration then said service would be covered under the purview of the Consumer Protection Act, 1986 thereby allowing the patient to seek redress as a consumer in case of any dispute.

Liability under Drugs and Cosmetics Act 1940 and Drugs and Cosmetics (Amendment) Bill 2013

Medical devices in India are regulated under the definition of drugs provided under the Drugs and Cosmetics Act, 1940. This lead to a lot of uncertainties so the Central Government set up a committee under the chairmanship of R.A. Mashelkar,

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37 S. 2(o) of The Consumer Protection Act, 1986(Act 68 of 1986).

38 *Dr. S Venkataraman* v. *M. Chandrasekharan* (1995) 2 C.P.R. 482 ("Services rendered by a doctor employed in the hospital, run by Voluntary Health Services were without consideration and hence any person availing such services was not constituted as consumer under The Consumer Protection Act, 1986").

39 (1995) SCC (6) 651.

40 See s.3 of The Drugs and Cosmetics Act 1940 (Act 23 of 1940): (i) "3 all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including, preparations applied on human body for the purpose of repelling insects like mosquitoes; (ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of 3[vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette; (iii) all substances intended for use as components of a drug including empty gelatin capsules; and (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;".

then Director General of Council of Industrial Research in the year 2003 to provide suggestions for improving the regulation of drugs in India. The department related parliamentary standing committee suggested in the year 2008 that a separate chapter for the purpose of establishing a "Central Drug Authority" be added to the Drugs and Cosmetics (Amendment) Bill of 2007.[41] It would provide for a financially self-sustaining regulatory body specifically dealing with administration of medical devices.[42] It has been observed by the committee that it was neither feasible nor desirable to disband all existing entities and create a centrist structure like the USFDA in India. Though the committee agreed with many provisions of the Drugs and Cosmetics Amendment Bill, 2007 it recommended various suggestions with regard to medical devices. It recommended the establishment of a "Central Drug Authority" and "Centralized Licensing" in India.[43] The Ministry of Health and Family Welfare has withdrawn the Drugs and Cosmetics (Amendment Bill), 2007 which was pending in the Rajya Sabha, in favour of a new amendment bill.[44] The new bill to amend the Drugs and Cosmetics (Amendment) Bill, 2013 has been introduced in the Rajya Sabha on 29th August, 2013. This is an initiative taken by the government to remove medical devices from the category of drugs and give them a new classification, as well as create new regulations for them. The new bill contains a revised approach towards "centralized licensing" with regard to seventeen categories of critical drugs. The new bill has also provided for a separate chapter IIA for the purpose of "Import, Manufacture, Sale, Distribution and Export"[45] of medical devices under the proposed section 7B to 7N. The bill has provided definitions for medical devices and manufacturer.

Product liability

The term product liability is more often related to tortuous rules aimed at ensuring that products are safe. Product liability is often treated as being synonymous with strict product liability. Undoubtedly the introduction of strict liability has been an important landmark in the development of this area of law, however, it is important

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41 Parliament Of India, Rajya Sabha, Department-Related Parliamentary Standing Committee On Health And Family Welfare Thirtieth Report On Drugs And Cosmetics (Amendment) Bill-2007. *Available at*: http://www.prsindia.org/uploads/media/1188536330/scr1226998041_Drugs_and_Cosmetics__ Amendment__Bill_ 2007.pdf (last visited on Nov. 8, 2013).

42 *Ibid.*

43 *Id.* at 12.

44 *Available at*: http://www.ficci.com/ficci-in-news-page.asp?nid=7292 (last visited on Sep.18, 2013).

45 *Supra* note 41 at 12.

to remember that existing contractual and tortuous liability for misrepresentation, breaches of implied quality conditions and negligence remain available and continue to be invoked in practice. The strict liability system is in addition to existing heads of liability and the wise litigant would frequently combine a claim in strict liability with a claim in contract or negligence.

A bar to the development of tort liability was the rule that there should be no liability for the lack of due care in the absence of contractual relationship.[46] In the latter half of the nineteenth century this rule began to be circumvented. The courts were prepared to impose liability, notwithstanding the absence of a contract, for articles dangerous in themselves',[47] and in two important cases, *George* v. *Skivington*[48] and *Heaven* v. *Pender,*[49] liability for products was imposed without categorizing them as inherently dangerous. In 1932 the most reasonable product liability case of all, *Donoghue* v. *Stevenson,*[50] placed a general duty of care on all manufacturers derived from the famous neighbor principle.

English product liability law then remained fairly stable until the recent reforms provoked by the EC Product Liability Directive. Elsewhere in Europe, French was developing a form of strict liability based primarily on contract law, but also in tort on the basis of the producer's control of product design. In Germany the courts were using the technique of reversing the burden of proof to develop its tort liability for products.

In *Baxer* v. *Ford Motor Co*[51] liability for a misrepresentation that a windscreen was shatterproof was said to rest not on a contractual obligation, but on the wrongful act of delivering an article that was unsafe because it lacked qualities the manufacturer had represented it as having.

The main leap in US tort law came in the 1960s when it was recognized that the development in contract law made it artificial to still treat such cases as contractual. A principle of strict product liability was laid down by Traynor J in *Greenman* v. *Yuba Power Products*[52] and the American Law Institute adopted 402A of the Restatement (Second) of Torts (1965), which provided that:

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46 *Winterbottom* v. *Wright* (1842) 10 M & W 109.

47 *Longmeid* v.*Holliday* (1861) 6 Exch 761.

48 [1869] LR 5 Exch 1.

49 [1883] 11 QBD 503.

50 *Supra* note. 14

51 168 Wash 456, 12 P 2d 409 (1932) (Supreme Court of Washington).

52 59 Cal 2d 57, 27 Cal Rptr 697, 377 P 2d 897 (1963) (Supreme Court of California).

> One who sells any products in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property….

The most important categories are manufacturing design and failure to warn/ instruct about defects. [53] A standard product is one which is and performs as the producer intends. A non-standard product is one which is different, obviously because it is deficient or inferior in terms of safety, from the standard product: and where it is harmful characteristic or characteristics present in the non-standard product, but not in the standard product, which has or have caused the material injury or damage.

. IV Medical device regulation: the design

According to World Health Organization Medical Device Regulation, "Medical devices include everything from highly sophisticated computerized medical equipment down to simple wooden tongue depressors".[54] An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.[55] Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means. Medical devices include a wide range of products such as medical gloves, bandages, syringes, contact lenses, disinfectants, X-ray equipment, surgical lasers, pacemakers, dialysis equipment, baby incubators and heart valves.[56]The Global Harmonization Task Force(GHTF) was adopted in 1992 which included European Union, United States, Australia, Japan, and Canada[57] which provided for a uniform regulatory mechanism and also in order to amplify the access to safe, effective, and clinically beneficial medical technologies across the globe.[58]

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53 Thus as cars become safer, drivers might drive faster and closer to one another. *A* v. *National Blood Authority* [2001] 3 All ER 289.

54 World Health Organization Medical device regulations. Global overview and guiding principles. Geneva. *Available at*: http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf (last visited on May 7, 2012).

55 Information document concerning the definition of the term "medical device. Global Harmonization Task Force, 2005. *Available at*: http://www.ghtf.org/documents/sg1/sg1n29r162005. pdf (last visited on Mar. 29, 2011).

56 *Id.* 56 at 14.

57 About GHTF, *available at*: http://www.ghtf.org/about/ (last visited on Sep.9, 2013).

58 *Ibid.*

International efforts in designing health care law

The initiative for ensuring minimum standards of healthcare traversing geo-political and economic diversities has been enunciated by means of international conventions and agreements trying to address this long felt need. Article 12 of the Covenant on Economic, Social and Cultural Rights, 1966, has provided that the states parties to the present covenant would recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health which essentially include[59] the creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The Geneva Declaration (as amended at Sydney) 1968, enjoins a duty on the doctors to discharge their professional duties carefully and deligently.[60] The Declaration of Tokyo, 1975 prohibits a doctor from indulging in torture and other cruel, inhuman or degrading treatment." The Declaration of Oslo, 1970 regulates performance of therapeutic abortion." The Declaration of Helsinki 1975 and the European Convention on Human Rights and Biomedicine 1997, enjoins compliance of certain requirements before subjecting any person to therapeutic or non-therapeutic research.[61]

The World Health Assembly Resolution 60.29 on Health Technologies has given recognition to medical devices with regard to prevention, diagnosis and rehabilitation. The WHA resolution 60.29 on health technologies emphasizes the role of medical devices and health technologies in healthcare, as well as their current suboptimal contribution to health outcomes:[62]

> [U]nderstanding that health technologies and in particular medical devices, represent an economic as well as technical challenge to the health system of many member states, and concerned about the waste of resources resulting from inappropriate investments in health technologies that do not meet high priority needs, are incompatible with existing infrastructure, are irrationally or incorrectly used, or do not function effectively.

WHO's strategic plan for 2008-13 is to ensure improved access, quality and use of medical products including medical devices; this recognizes medical devices as a tool to improve health care across the globe.

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59 International Covenant on Economic, Social and Cultural Rights, Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 Dec. 1966 entry into force 3 Jan. 1976, in accordance with art. 27, *available at*: http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx (last visited on Sep. 10, 2013).

60 Mason and McCall Smith, *Law and Medical Ethics* 252(London, 1983).

61 *Ibid.*

62 Innovative Technologies that address global health concerns, *available at*: http://whqlibdoc.who.int/hq/2010/WHO_HSS_EHT_DIM_10.12_eng.pdf (last visited on July 10, 2013).

V Issue of liability for using medical devices

Medical devices serve the main purpose of prevention, correction and rehabilitation from disease. As a result of uncertainty associated with technology it usually faces a lot of resistance before it is accepted. The challenge faced is between over regulation and adequate regulation. Research has also revealed that innovation was mostly conducted by doctors rather than manufacturers as they were more responsive to the needs of the patients being treated. Surgical innovation, developed in surgical suites or stimulators is one of the major ways by which innovation in medical devices is developed. Tortious liability, product liability and medical malpractice usually deal with medical device innovation. However, It has been noted that tortuous liability with regard to medical device innovation poses a great hindrance to it as a doctor, researcher or manufacturer is held liable if they have shifted from the safety related custom or industrial custom. There is no incentive provided in medical technology with regard to innovation. Thus a doctor usually tries to avoid liability by following the existing technology for treatment.

A doctor usually tries to avoid liability by following the existing technology and practice of treatment. There are two legal pathways followed in surgical innovation which include the medical practice pathway and the human research pathway. Medical practice pathway allows for retrospective redress of the injury suffered by a patient through tort liability.[63] The human research pathway on the other hand involves prospective review and oversight. It also allows for retrospective redress of injury through legal sanctions and tort liability.[64] Innovative surgery does not fit comfortably in either the practice pathway or the research pathway. The practice pathway views innovations retrospectively through the lens of malpractice, examining and judging deviations from standards of care that are generally accepted by the medical community.[65] An innovation in medical devices can be considered to be a marriage between technological opportunity and medical demands. Tort cases are capricious, unaccommodating to scientific evidence and many times failed to compensate the injured patients. It requires a more robust background of facts about efficacy and safety of medical devices.

An innovation in medical devices can be considered to be a marriage between technological opportunity and medical demands. Regulation with regard to innovative

63 Anna C. Mastroianni, "Liability, Regulation And Policy In Surgical Innovation: The Cutting Edge Of Research And Therapy" 16:2 *Journal of Law-Medicine* 20 (2006).

64 *Ibid.*

65 David H. Spodick, "Numerators without Denominators: There Is No FDA For the Surgeon" 232 *JAMA* 35 (1975).

medical devices is cumbersome, slow and costly. Tort cases are capricious, unaccommodating to scientific evidence and failure to compensate the injured patients. It requires a more robust background of facts about efficacy and safety of medical devices.

One of the major similarities between law and medicine is that no one can predict with certainty its outcome. However some aspects have very well been identified, firstly, judges are not experts in medical science. They have to base their judgment on testimonies of other doctors which may be influenced by various factors. The judges base their decisions on such opinions. Doctors who are negligent should obviously be penalized yet one should bear in mind that doctors too can make errors of judgment.

The medical profession has been commercialized at a very high level yet it remains one of the most important and essential aspect of the society. The Consumer Protection Act by including medical profession within its ambit has proved to be a double-edged sword for a doctor.[66] The Act is tried to protect patients from every kind of medical malpractice yet there are still so many incidents reported with regard to medical negligence. A doctor should give more importance to excellence in the treatment and patient care and not to the rapid globalisation and commercialization which have engulfed our society today.

It has been observed that except India most countries have specific laws related to medical devices, in fact in India medical devices are also considered as drugs as provided under the Drugs and Cosmetics Act, 1940. The basic framework of the legislations with regard to medical devices is very similar. One of the essential criteria for medical devices is classification of medical devices. The classification is usually made according to the risk which is associated with the medical device, the intended purpose for the device by the manufacturer and the device's indications for use. It has also been observed by the authors that United States has the most efficient mechanism to regulate medical devices. The US Food and Drug Administration's Centre for Devices for Radiological Health (USFDA/CDRH) governs the regulatory regime of medical devices in the United States. With an efficient regulatory mechanism in the United States it is much easier to bring an action against a manufacturer or doctor in case a patient suffers as a result of defective medical device as compared to the other countries. India is still in process of developing a legislation specific to medical devices.

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66 Juthika Debbarma, Neha Gupta, N K Aggarwal, "Consumer Protection Act - Blessing or Curse to Medical Profession?" 12 *Delhi Psychiatry Journal* (2009).

VI Judicial attitude in application of medical devices in India

The authors have attempted to make a trend analysis of few cases where medical devices have been used. In the case of *Mohd. Abrar* v. *Dr. Ashok Desai*[67] the appellant had suffered a comminuted fracture and was fixed with an external fixator. He complained that the external fixator was inferior and defective and the rings and steel rods were rusted, yet this issue has not been raised further in this case. The patient had suffered from gangerene which could have resulted to some extent from the rusted rods. His left leg below the knee was amputated. It was held that the doctor was not liable as it was difficult to draw a thin line between negligence of the patient, the quantum of his contribution and other causes which gave rise to the onset of gangrene and absence of care on the part of the doctor . Thus it can be mentioned that the quality of the external fixator was not raised in this case. In this case it was held that "the medical practitioner would be liable only where his conduct falls below that of a reasonably competent doctor".

In the case of *Kailash Hospital & Research Centre* v. *Prem Tandon*[68] the complainant suffered an accident and surgery was done and a rod was placed in the leg of the complainant. It was the case of the complainant that after five months, the complainant was examined by the doctor wherein it was found to be alright and he was advised free movement but when he started moving, the rod put by surgery was broken. After that another surgery was done to remove the old rod and place a new one by another doctor. The National Commission held that it is a well-settled proposition of law that, a specific case of medical negligence has to be made out by the complainant, and, the onus of proof is on the complainant to prove this medical negligence by an 'expert-opinion'. The onus is on the complainant, to prove, that as to 'what the Doctor should have done which he did not do, or, what the Doctor did not do what

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67 Decided on Apr. 8, 2011, *available at*: http://164.100.72.12/ncdrcrep/judgement/00110408095905696FA1252006.htm (last visited on Aug. 6, 2013). Similar cases related to medical devices *Mehernosh Kersi Khambatta S/o Kersi Minocher Khambatta, By Faith Parsi, By Occupation Ex-Employee of Tata Iron and Steel Company Limited* v. *Venkatrama Nursing Home,* decided on Dec. 6, 2012 *available at*: http://ncdrc.nic.in/judgements.html and *Smt.Leela Deviv. Dr. Shatrughan Ram & Anr,* decided on Aug. 24, 2012, *available at*: http://ncdrc.nic.in/judgements.html (last visited on Oct.21, 2013) and *Vikram Singh* v. *Dr.Santosh Kumar Sharma*, decided on Nov. 18, 2011, *available at*:http://ncdrc.nic.in/judgements.html (last visited on Oct.17, 2013) no negligence of the doctor has been established. The negligence of the manufacturer has also not been discussed in these cases.

68 *D*ecided on Jan. 7, 2010, *available at*: http://ncdrc.nic.in/judgements.html (last visited on Oct. 20, 2013).

he ought to have done?' Admittedly, no opinion of any 'expert' had been led in this case by the complainant. In this case though it was observed that the rod which was implanted was broken within five months, yet there was no issues raised as to the quality of the implant. Though the patient had started movement on the advice of doctor, yet the reason for the broken implant was attributed to of his movement as held by the National Commission. The doctor in this case was not held liable as onus of proof was on the complainant and he had failed to do so.

In another case of *Dr. Naveen Agrohi* v. *Shri Parvas*[69] the complainant had suffered injuries in an accident and fractured his right leg. The doctor operated upon the leg and implanted a rod/plate in it. After the operation, the complainant complained of severe pain in his leg. The doctor took the x-ray of the leg after four days and told that the bolts used for fixing the rod/plate had loosened. The doctor again operated the leg and replaced the bolts. On the day of discharge the complainant complained of the pain in the leg, but the doctor assured him that it would subside gradually, but the pain persisted. When he went to the doctor and complained of the severe pain, he took the x-ray of the leg and told that the bolts had broken due to extra tightening of the plate. The National Commission held that a doctor cannot be held negligent if he has performed the operation according to standard norms and medical practice, but thereafter patient had not taken due care of himself as per the instructions and advices given by the doctor. In this case the doctor was not held liable as the reason for his condition was due to his fall and not following the instructions of the doctor. In the case though it was evident that the bolts had broken and there was negligence of the doctor in fixing it yet no compensation was given to the complainant.

In the case of *Cather* v. *Catheter Technology Corp*[70] the patient was suffering from colon cancer. He checked into the hospital for implantation of Groshong catheter in his chest for purposes of chemotherapy treatments. Before the implantation the nurse discussed with him about the precautions to be observed after implantation and he also signed a consent form which stated that he had been advised "as to the nature of the proposed procedure(s), attendant risks involved, and expected results." However after the operation he did not follow the prescribed precaution and performed heavy exercise which led to separation of the catheter in two pieces. A further surgery was performed to remove it. After one month he started having chest pains and was admitted to the hospital. He was later diagnosed as suffering from pneumonia, possible embolism, venous thrombosis, and colon cancer. He also experienced problems with his left leg, and doctors who had examined his leg report stated that blood clots have

69 Decided on May 7, 2013, *available at*: http:/ncdrc.nic.in/judgements.html (last visited on Oct.13, 2013).

70 753 F.Supp. 634 [1991].

developed in the area. After few months he instituted the suit against Catheter Technology Corporation (CTC), the manufacturer of the Groshong catheter. In his suit, he asserted breach of warranty, negligence, and strict liability claims against CTC. The court concluded that plaintiff had failed to raise any genuine issue of fact regarding the strict liability claims for defective design or manufacture. Moreover before the operation he had signed a consent form which clearly stated about the risks involved. To recover under a theory of breach of warranty, plaintiff must prove, among other elements, that the goods were unfit for their normal use at the time of sale and that the plaintiff incurred injuries that were proximately caused by the defective nature of the goods. Thus in this case there was no breach of warranty. In order to recover on a theory of strict liability it must be established that: (1) "That the defendant placed a product on the market that was in a defective condition and unreasonably dangerous for its intended use; (2) the plaintiff was using the product in a manner that was reasonably foreseeable; and (3) the defective condition was the proximate cause of the injury to Plaintiff". Thus it was clearly established in this case that there was no liability of the manufacturer. This case had provided with a well developed legal reasoning which can be applied in cases related to medical devices. The reasoning adopted by the court was fair, just and reasonable.

Contract the Indian cases with in the case of *Richard Mckasson* v. *Zimmer Manufacturing Company Et A*[71] rods had been implanted in plaintiff's left femur which broke. The stainless steel rod in question was designed for insertion into a fractured bone to provide support and stabilization during the healing process. Plaintiff remained in a wheel chair for approximately six months after surgery, and was then permitted to place partial weight on the affected leg, first while using a single crutch and, later, a cane. In this case the liability was fixed on the manufacturer on the basis of strict liability and he had to pay compensation to the plaintiff for the loss suffered by him. It was observed in this case that the breaking of the rod resulted in his disability.

After making an analysis of few of the above mentioned cases it is evident that there is a clear distinction between the approach led by the judiciary in dealing with cases of medical devices in India and United States. It is found that in some cases in India the patient had suffered injury due to a broken rod, screw or pin yet in none of the cases there was any question of liability of the manufacturer. In fact there was no link established between the defect and the damage. Though in few cases there was an issue raised with regard to the quality of implant but the patient was not able to prove the liability of the manufacturer. Infact, there is no application of the concept of "misbranded", "adulterated", "spurious" under the Drugs and Cosmetics Act, 1940 which can have application for medical devices also. The only issue raised in most of the cases is the liability of the doctor in using the device. The principle of law applicable

71 299 N.E.2d 38.

in most of the cases was laid down in the case of *Jacob Mathew* v. *State of Punjab*[72] wherein it was held that:

1. Mere deviation from normal professional practice is not necessarily evidence of negligence.
2. Mere accident is not evidence of negligence
3. An error of judgment on the part of a professional is not negligence per se.
4. Simply because a patient has not favorably responded to treatment given by a physician or a surgery has failed, the doctor cannot be held liable *per se* by applying the doctrine of *res ipsa loquitur*.

While in most of the cases in the United States whenever a patient has suffered as a result of a broken or defective device the manufacturer has been held liable. There is no issue raised with regard to the liability of the doctor in cases of medical devices unless it was related to implantation of the medical device. In most of the cases action has been brought for negligence, strict liability and breach of warranty. Thus it can be clearly observed that the law is well developed in the United States. In India the concept of strict liability can be very well applied in cases dealing with medical devices where liability shall be fixed on the manufacturer in case of a defective medical device.

VII Conclusion

With the commercialization of medical profession patients have been conferred with various rights. The authors have observed in the various national legal regime that medical services are usually "patient –led". It has also recognized the various rights of patients. The link between medical law and medical ethics leads to a lot of legal issues and dilemma. The court with regard to cases of medical negligence usually would not give an order which is unethical but legal. The doctors have various moral obligations towards a patient, however a breach of it wouldn't make him liable. A doctor may breach a contract for not treating a private patient, but there might be a purely ethical reason for such breach. However the court while dealing with such controversial issues has given a significant role to the ethical issues. To conclude with the observation of Hoffman LJ, in a case concerning the treatment of a patient: "The decision of the court should be able to carry conviction with the ordinary person as being based not merely on legal precedent but also upon acceptable ethical values.[73]

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72 (2005) 6 SCC 1.

73 *Airedale NHS Trust v. Bland* [1993] 1 All ER 821, 850.

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