

## MEDICAL DEVICES: LEGAL AND ETHICAL ASPECTS<sup>1</sup>

Carolyn Báez, Edwin J. Toledo and Marlenis Valentín<sup>2</sup>

**Abstract** – Biomechanics deals with design of health-improving artifacts that help people to deal with different kinds of diseases. Currently, biomechanical research is very advanced and considerable successful results have been found. However, the more advanced the research is, the more serious become the legal implications and concerns. Before inserting a device in a human body, awareness of the legal consequences must be raised to minimize possible litigation costs. This paper presents legal and ethical aspects in the field of biomechanics and the consequences of malpractice. Further, we will discuss the characteristics of general medical devices and the consequences, such as lack of biocompatibility, because of using these devices without considering the legal aspects that regulates them.

**Key Words** – Medical Devices; Medical Ethics; Medical Legal Aspects.

### INTRODUCTION

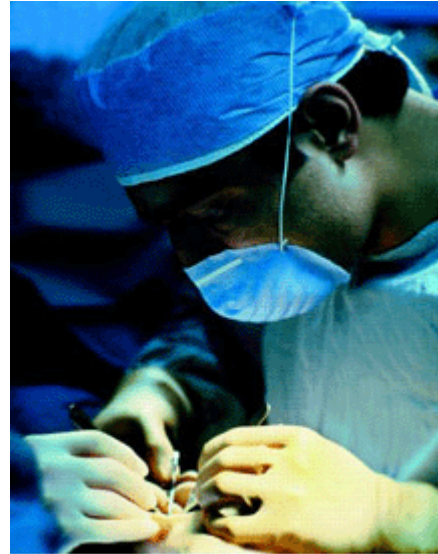
Biomaterials is a branch of biomedical engineering that deals with the material aspects of medical devices. The field involves any material such as metals, ceramics, plastics or polymers that is in contact with fluids, cells and tissues of the living body. A delicate concept like this is strictly regulated by the law, to avoid malpractice and life threatening situations. The law forces manufacturers and scientists to investigate materials for a medical device to avoid problems with biocompatibility. Incompatibility can lead to a possible legal action against the device manufacturers.

In 1998, a bill giving liability protection to manufacturers of medical devices took a big step forward. The Biomaterials Access Assurance Act of 1998 shields biomaterials manufacturers from liability suits as long as their products are safe and meets the specifications set by the device manufacturer. Medical Devices Associations claimed that the bill was needed because biomaterials suppliers were not selling the products to device manufacturers for fear of liability suits. Usually biomaterials suppliers are exonerated when included in suits against device makers. They still face the costs of fighting litigations.

The numbers in brackets refer to bibliography.

<sup>1</sup> This review article was prepared on May 12, 2005 for the course on Mechanics of Materials – 1. Course Instructor: Dr. Megh R. Goyal, Professor of Biomedical Engineering, General Engineering Department, PO Box 5984, Mayaguez, PR, 00681-5984. For details contact: [m\\_goyal@ece.uprm.edu](mailto:m_goyal@ece.uprm.edu) or visit at: [http://www.ece.uprm.edu/~m\\_goyal/home.htm](http://www.ece.uprm.edu/~m_goyal/home.htm)

<sup>2</sup> The authors are in alphabetical order.



**Figure 1.** Biomechanics scientists should investigate with care to avoid legal battles with patients [6].



**Figure 2.** Long debates have been held in U.S. Congress to discuss the Biomaterials Access Assurance Act [7].

Smaller medical devices developers, which are the companies that create newer and more innovative technologies, are concerned because they do not have the legal resources to battle legal actions against them.

## BIOMATERIALS ACCESS ASSURANCE ACT OF 1998 [8]

Public law 105-230 H.R. 872 was established on August 13, 1998 at the Second Session of the One Hundred Fifth Congress of the United States of America [8]. This act established rules governing product liability actions against biomaterials suppliers to medical device manufacturers. U.S. Congress found the following important details:

- Each year millions of US citizens depend on life-saving or life-enhancing medical devices, many of which are permanently implanted in the human body.
- A continued supply of raw materials and component parts is necessary for the invention, development, improvement, and maintenance of supply of the medical devices.
- The Federal Food, Drug, and Cosmetic Act established that manufacturers of medical devices are required to demonstrate that their products are safe and effective. They should demonstrate that the products are properly designed and have adequate warnings and instructions.
- The suppliers have been subjected to actions alleging inadequate design and testing of medical devices.
- Even though suppliers of raw materials and component parts have very rarely been held liable in such actions, such suppliers have ceased supplying certain types of raw materials and component parts for use in medical devices for a number of reasons, including concerns about the costs of litigation.
- Unless alternate sources of supply can be found, the unavailability of raw materials and component parts for medical devices will lead to unavailability of life-saving and life-enhancing medical devices.
- Because suppliers outside the United States refuse to sell their biomaterials for use in manufacturing certain types of medical devices, the prospects for development of new sources of supply for the full range of threatened raw.



**Figure 3.** The FDA is the government agency that regulates the use of medical devices [5].

- It is unlikely that the small market for biomaterials in the United States could support the large investment needed to develop new suppliers of such materials.
- Attempts to develop such new suppliers would raise the cost of medical devices.
- Courts that have considered the duties of the suppliers of raw materials and component parts have generally found that suppliers do not have a duty to evaluate the safety and efficacy of the use of a raw material or component part in a medical device or to warn consumers concerning the safety and effectiveness of a medical device.
- In order to safeguard the availability of a wide variety of life-saving and life-enhancing medical devices, immediate action is needed to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices and to provide procedures to dispose of unwarranted suits against the suppliers to minimize litigation costs.
- The states and their courts are the regulators of the system; however U.S. Congress must regulate in the national interest such as the issue of a threatened shortage of raw materials and component parts of life-saving medical devices and the issue of protection to assure the continued supply of materials for live-saving medical devices.

These findings by Congress were the motives for the creation of the Biomaterials Access Assurance Act of 1998, which pursued protecting suppliers to assure the continuous research and invention of new medical devices for people that suffer life-threatening diseases.

Congress established some definitions in the act between the two parts of a possible conflict, supplier and claimant. The **biomaterials supplier** means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant. It includes any person who has submitted master files to the Secretary for purposes of pre-market approval of a medical device or licenses a biomaterials supplier to produce component parts or raw materials. Congress defined **claimant** as any person who brings a civil action or on whose behalf a civil action is brought, arising from harm caused directly or indirectly by an implant, who claims to have suffered harm as a result of the implant.

The Biomaterials Assurance Act established some general requirements, applicability and preemption. In general, any civil action covered by the act, a biomaterials supplier may raise any exclusion from liability or make a motion for dismissal or for summary judgment. The act applies to any civil action brought by a claimant, whether in a Federal or State Court, on the basis of legal theory, for harm allegedly caused directly or indirectly by an implant. The act supersedes any state law regarding recovery for harm caused by an implant and any rule of procedure applicable to a civil action to recover damages for such harm only to



**Figure 4.** The Biomaterials Assurance Act was approved in 1998 by U.S. Congress [2].

the extent that the act establishes a rule of law applicable to the recovery of such damages.

This act that strictly regulates the legal aspects of the Biomaterials established liabilities to the suppliers of raw materials. In general, a biomaterial supplier shall not be liable for harm to a claimant caused by an implant unless such supplier is liable as a manufacturer of the implant, seller of an implant, for furnishing raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications.

The liability for manufacturers established that a biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the biomaterials supplier is the manufacturer of the implant. The biomaterials supplier may be considered the manufacturer of the implant if that allegedly caused harm to a claimant only if the biomaterials supplier is registered or was required to register with the secretary pursuant of the Federal Food, Drug and Cosmetic Act, and the regulations issued under such act. The liability for sellers established that a biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant only if the biomaterials supplier held title to the implant and then acted as the seller of the implant after its initial sale by the manufacturer or acted under contract as a seller to arrange for the transfer of the implant.

The liability for failure to meet applicable contractual requirements or specifications implies that a supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the claimant in an action shows by the preponderance of evidence, that the biomaterials supplier provided raw materials or component parts for use in the implant that either did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for supplying the product or failed to meet any specifications that were accepted, published and

provided by the biomaterials supplier to the person who contracted for such product.

## LEGAL ASPECTS IN BIOMECHANICS [1]

### Liability

Law is the compilation of rules by which society is governed. Biomaterials manufacturers are regulated under practice rules and laws. The three main reasons for which a manufacturer is responsible for personal injury caused by its product are: **negligence**, **strict liability**, and **breach of warranty**.

These three concepts are known as “theories of recovery” because an injured person cannot recover damages against a defendant unless he proves that the defendant owed him a legal duty and that the defendant breached that duty causing the plaintiff’s injuries. In the actuality federal and legislative action that would create a uniform federal liability product have been proposed and debated.

### Types of Liability

#### 1. Negligence

Legal actions against manufacturers occur mainly because of manufacturing defects of biomaterials, which can be dangerous inside a person. Negligence is the conduct and behaviors that do not obey the standards established by law and authorities. Malpractice is closely linked to it, but there are four reasons that comprise the negligence action.

- A person or business owes a duty if caring to another.
- The applicable standard of carrying out the duty was breached.
- As proximate cause of the breach of duty, a compensable injury resulted.
- There were compensable damages or injury to the plaintiff.

The idea of negligence law is that one should respond for injuries caused when acting below the standards of care established by law.

A plaintiff in a product liability action grounded in negligence must establish a breach of the manufacturer or seller’s duty to exercise reasonable care in the manufacture and preparation of the product. The manufacturer in particular must be sure that the product is free of any potentially dangerous defects. To avoid that, there is an obligation to exercise reasonable care in the inspection or testing of the product, the design of the product, or the giving of warnings concerning the use of the product. A manufacturer must exercise reasonable care even though he or she is just a part of the product’s production process that results in a finished product.

A product seller is normally held to a less strict standard of care than the manufacturer. This also applies to distributors and wholesalers.

## 2. Strict liability

Unlike the negligence lawsuit, which focuses on the defendant conduct, the strict liability suit focuses on the product. Strict Liability means that one, who sells a product in defective condition unreasonably dangerous to the user or consumer or to his property, is subject to liability for physical damage.

The critical focus on strict liability case is if the product is defective and dangerous. In the case of medical devices, a common standard is applied to reach that type of conclusion, the risk/benefit analysis. This analysis consists if the benefits of the device outweigh the risks attendant with its use.

## 3. Breach of warranty

A warranty action is contractual rather than tortious. It is based on representations, either express or implied, which a manufacturer or a seller makes about its product. The breach of warranty is alleged if there is:

- Breach of the implied warranty of merchantability.
- Breach of the implied warranty of fitness for a particular purpose.
- Breach of an express warranty.

Let us now define the types of warranty that could be used as reasons for legal battles.

Some warranties accompany the sale of an article without any express conduct on the part of the seller. These implied warranties are labeled the warranties of merchantability and of fitness for a particular purpose.

There are warranties implied in a contract for a sale, if the seller usually deals with those goods. At least, merchantable goods must:

- Pass without problem in the exchange under the contract description.
- Be fit for the stated purposes.
- Be within the variations permitted in the contract.
- Be correctly packaged, contained and labeled.

## Defects in Medical Devices

Defects are what courts find to be actionably wrong when the product leaves the seller. Courts distinguish between defectiveness and unreasonable danger. The following criteria is followed to determine if a product is defective:

- Consumer expectations.
- Presumed seller knowledge.
- Risk/benefit analysis.
- State of the art.
- Unavoidably unsafe products.

There is pure negligence in the “presume seller knowledge” mainly because it is a crime to market a product even knowing that the product is harmful or dangerous. The risk/benefit analysis is used to determine if there are defects in the design of a product. As mentioned before, this analysis focuses on comparing the risks and benefits that a product could bring to a patient.

Determine if a product is defective is not an easy task. To make a determination one has to consider the three types of product defects:

- Manufacturing of product defects.
- Design defects.
- Defective warnings or instructions.

Manufacturing defects are not easy to locate with direct evidence, a plaintiff must use circumstantial evidence and strong supportive evidences to prove that a medical device was defective. Evidence that can be considered are injuries from the use of the product, complaints from the performance of the product, defectiveness of other product units, etc.

For that reason, a manufacturer has to design its product to prevent any possible risk to the patient. A product that is defectively designed can be distinguished from a product with a manufacturing defect. The design problem involved any error in the planning of the product; the manufacture problem is a mistake occurring when the product is prepared. Failure of designing correctly a product is negligence. A wrongly design product will subject the manufacturer to strict liability. Product liability is divided in three categories:

- Cases with concealed danger.
- Failure to provide appropriate safety features.
- Construction of materials without adequate strength.

One frequently seen type of litigation is when the manufacturer or sellers forget to warn about potential dangers involved in the use of a certain type of medical device. These type of conflicts falls into the negligence category, because every regulation states that a manufacturer or seller who has the knowledge of a possible danger should warn the users of the consequences. Failure to do so is a negligence.

## DEVICE SAFETY [1]

The FDA and other regulatory agencies require that medical devices be safe and effective for their intended use. **Safety** is the most important aspect to consider in the design process of a medical device. A medical device should never function in a way that would cause harm to the patient. Following the basic safety standards implemented by FDA is the best way to assure the development of a safe product. A wrong product design without following the safety standards is an expressway to a lawsuit.

To design with safety, there are two aspects for considering. First, being sure of what harm could cause to a patient if a failure situation occurs. Think about what harm could be caused due to misuse. These possible situations must be analyzed carefully, specially the consequences of a device failure. Second, the liability assessment, the device creators must think about if all possible failures modes have been explored, designed and addressed. Courts are very strict when they investigate and find out that the companies had knowledge about unsafe conditions and do nothing about it.

A product is safe if its risks are considered and judged as acceptable. Even though sometimes all hazards cannot be eliminated, in the majority of times specific hazards can be totally eliminated from a product or system. System safety is a sub-discipline of System Engineering that applies scientific, management and engineering principles to ensure safety throughout the system cycle. Safety is defined sometimes as freedom from accident or losses. This definition concludes that any system that presents something risky is unsafe.

Usually some trials to eliminate risks often finish with risk displacements. Device Safety is relative because nothing is completely safe in every single condition. There are cases where a relatively safe material becomes hazardous progressively. The safety problems are evaluated during the examination of the product during its operational life and corrected when unacceptable hazards occur. In the examination the accidents are investigated, the causes are determined and corrective action begins. In some cases, one accident is sufficient to create a great loss in the product.



**Figure 5.** The Center for Devices and Radiological Health is the FDA subdivision that deals with the medical devices aspects [4].

**Table 1.** Hazard Analysis Probability Classification [1].

Classification Indicator	Classification Rating	Classification Meaning
1	Frequent	Likely to occur often.
2	Occasional	Will occur several times in the life of the device.
3	Reasonably Remote	Likely to occur sometime in the life of the system.
4	Remote	Unlikely to occur, but possible.
5	Extremely Remote	Probability of occurrence indistinguishable from zero.
6	Physically Impossible	Probability of occurrence is zero.

Every system, no matter its complexity, should be designed for a safe harmless state. Only few simple functions should be required to enter or preserve the safe states by terminating potential hazardous conditions. A vital part of the designing process is identifying these safe states. There are ways to identifying them such as radiation therapy, drug infusing, etc. In medicine it is usually sufficient to provide a simple safety system that disconnects the computer, achieves the safe state, and turn on the alarm when faults are discovered.

All biomaterials companies must have safety programs with procedures and expertise in formal hazard identification and analysis techniques. Also, several expected hazard mitigation controls should be implemented in any medical device system. An effective program includes the implementation of hazard analysis and awareness. Safety analysis begins when the product is planned and continues to be developed.

The Hazard Analysis Probability Classification (Table 1) is used to divide all biomaterials and medical devices according to their chances of becoming hazardous.

### Safety and Reliability

A safe system is one that does not present risk to people or equipment. Risks are measured in severity and probability. Safety is just about device failure and the hazards that it can provoke. The probability of failure of a device to meet its requirements is called **reliability**. A safe system is one in which damage to people or property does not happen, or when it does, the damage is minor. Slow damage potential means that a product can be considered safe.

### Safety and Liability

Avoiding legal liability is a primary goal. The impact of product liability judgments and the increase in insurance rates have been controversial. The new theories of liability

have increased the number of potential lawsuits and that there has been a trend toward punitive damage results. Medical devices have been focus of many mass actions that include thousand of cases brought against the producers of certain products. Product liability has increased the costs of doing business in some sectors of the medical device industry. As mentioned before the three most common reasons for which a manufacturer may be liable for personal injury caused by its product are: **negligence**, **strict liability** and **breach of warranty**. Those reasons are the most seen in federal and state courts.

The main idea of negligence law is that one should have to pay for injuries caused when acting below the standards establish by health law. This standard of conduct relates to a belief that centers on potential victims that have the right to be protected from unreasonable harm. Under the negligence theory, a manufacturer that does not exercise reasonable care or fails to meet the minimum standards of care in manufacture, handling or distribution of a product may be liable for any damages caused. Unlike the negligence legal actions that are based on the defendant conduct, in a strict liability suit, the focus is on the product. Strict Liability as mentioned before states that one who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property if the seller is engaged in the business of selling such a product, and it is expected to and does reach the user or consumer without substantial change in the business of selling such a product and it is expected to and does reach the user or consumer without substantial change to the condition in which it is sold. In a summary, the strict liability case is focused if the product is defective and unreasonably dangerous.

There is conflict in whether emotional distress alone is applicable in lawsuits, where there is no accompanying of physical injury. Courts have held that emotional distress without physical injury is applicable if the defendant' conduct is intentional. Safety will have an effect on the finances and reputation of the manufacturer.

### **BIOMATERIALS FOR COMMONLY USED MEDICAL DEVICES**

One commonly used definition of biomaterials is any material that is used to restore function of a body tissue and is continuously or intermittently in contact with body fluids. It is widely perceived that there will be significant advances in the development and use of biomaterials in the near future. In fact, many believe that biomaterials will soon become the dominant focus of materials research and that significant economic expansion will flow from this research. The very breadth of this field precludes a comprehensive, in-depth projection in all areas of biomaterials, which currently include orthopedic, cardiovascular, neurological, drug delivery, and other applications. Projected future applications include the use of microrobotic devices for disease detection, drug delivery, and neurological applications, for example. Gene therapy is also identified as an alternative approach to many of these same clinical problems. Some unanticipated

biomaterials-related events and changes will continue to occur; two such events will be described in the case studies to follow. In order to provide an overview of possible future directions in biomaterials, it is useful to focus on three-time frames:

1. The past: removal of tissues.
2. The present: replacement of tissues.
3. The future: regeneration of tissues.

Transplants or implants currently replace tissues. Transplants include autografts (as in vertebral fusion), homografts (human organ transplants), and heterografts or xenografts (tissues from other species). Implants are stabilized in the human body by cement, biological, or bioactive fixation techniques. Transplants have problems such as their availability, the need for immuno-suppressant drugs, and possible viral contamination. Today's implants have a variety of shortcomings related to their fixation, and, unlike living tissues, cannot self-repair or adapt to changing physiological conditions. Tissue regeneration has the potential for avoiding these problems associated with transplants and implants through the use of engineered tissues, regenerative bioactive materials, and gene therapy. Although the tendency toward regeneration rather than replacement of tissues is clearly the ultimate long-term objective, yet the incremental improvements possible to improve the processing and properties of the existing tissue-replacement materials have not been exhausted.

Another issue not typically addressed when considering the performance of biomaterials is the general area of information, which again can be usefully divided into three separate categories:

1. Information regarding the *in vivo* performance and performance limitations of biomaterials, including areas of current uncertainty and significant disagreement within and among the scientific, engineering, and medical communities.
2. Increased usage of information-storage and data-processing capabilities in implantable medical devices.
3. The potential utility, if any, of information technology (IT) processes such as data mining to improve the safety and efficacy of biomaterials.

Finally, no assessment of the future of biomaterials would be complete without examining the societal context in which new biomaterials or biomaterials fabrication processes are introduced. In essence this focuses on the kinetics of change as well as the thermodynamics of change, which is largely engineering and biological in origin. The Medical Device Amendments of 1976 require that all new biomaterials used in applications (or existing biomaterials used in new applications), which are life-sustaining or involve significant risks to patients must undergo pre-market approval (PMA) to establish their safety and effectiveness. The basic requirements are that

the material be biocompatible within the bodily environment in which it is used and that it perform its intended function safely and effectively in that environment. Clinical trials involving both animals and humans are typically part of the pre-market approval process. Biocompatibility testing of a new material is an extensive and expensive procedure that is undertaken only when significant performance increases in biocompatibility and/or functionality are anticipated. The tort liability litigation system also influences innovations in the use of biomaterials in that lawsuits involving not only biomaterial production defects but also materials selection or design defects are still possible even though the material has successfully undergone pre-market approval.

These regulatory and legal processes are traditionally described as stifling to innovation in biomaterials and medical devices; however, innovations have occurred in response to information concerning device and biomaterial deficiencies, which was generated by the regulatory and/or legal processes. A final influence on the continued use or substitution of biomaterials or fabrication processes is marketplace information. Manufacturers' sales representatives are constantly seeking information about deficiencies in their competitors' products and are not reticent about conveying this information to their current and potential customers. Several questions can be posed to address the processes of innovation and change in medical technology:

1. When and how does it become prudent to substitute a new, potentially safer and/or more effective biomaterial or biomaterial fabrication process for an older, perhaps less safe one?
2. How should physicians and engineers divide their efforts between new device development and surveillance of existing devices, particularly over the long term?
3. How should the normal information flow and decision making between physicians and engineers be influenced, if at all, by legal, regulatory, and risk management concerns, particularly in the case of new biomaterials or biomaterial fabrication processes?
4. What roles should physicians and engineer's play in formulating and communicating biomaterial risk information to patients; particularly risks associated with new biomaterials and biomaterial fabrication processes?

#### **THE FOOD AND DRUG ADMINISTRATION [1]**

Regulation of medical devices is intended to protect the consumer's health and safety by attempting to ensure that marketed products are effective and safe. Prior to 1976, the Food and Drug Administration (FDA) had limited authority over medical devices under the Food, Drug and Cosmetic Act of 1938. Beginning in 1968, U.S. Congress established a radiation control program to authorize the establishment of standards for electronic products, including medical and dental radiology equipment. From the early 1960s to 1975, concern over devices increased and six United States

presidential messages were given to encourage medical device legislation.

In 1969, the Department of Health, Education, and Welfare appointed a special committee to review the scientific literature associated with medical devices. The committee estimated that over a 10 year period, 10,000 injuries were associated with medical devices, of which 731 resulted in death. The majority of problems were associated with three device types:

- Artificial heart valves.
- Cardiac pacemakers.
- Intrauterine contraceptive devices.

These activities culminated in passage of the Medical Devices Amendments of 1976. Devices marketed after 1976 are subject to full regulation unless they are found substantially equivalent to a device already on the market in 1976. By the end of 1981, only about 300 of the 17,000 products submitted for clearance to the FDA after 1976 had been found not substantially equivalent.

#### **History of Device Regulation**

In 1906, the Food and Drug Administration enacted its first regulations addressing public health. While these regulations did not address medical devices, they did establish a foundation for future regulations. It was not until 1938, with the passage of the Federal Food, Drug and Cosmetic Act (FFC&C) that the FDA was authorized, for the first time, to regulate medical devices. This act provided for regulation of adulterated or misbranded drugs, cosmetics and devices that were entered into interstate commerce. A medical device could be marketed without being federally reviewed and approved.

In the years following World War II, the FDA focused much of the attention on drugs and cosmetics. Over the counter drugs became regulated in 1961. In 1962, the FDA began requesting safety and efficacy data on new drugs and cosmetics.

By the mid-1960s, it became clear that the provisions of the FFD&C Act were not adequate to regulate the complex medical devices of the times to assure both patient and user safety. Thus, in 1969, the committee was formed to examine the problems associated with medical devices and to develop concepts for new regulations.

In 1976, with input from the committee, the FDA created the Medical Devices Amendments to the FFC&C Act, which were subsequently signed into law. The purpose of the amendments was to assure the medical devices were safe, effective and properly labeled for their intended use. To accomplish this mandate, the amendments provided the FDA with the authority to regulate devices during most phases of their development, testing, production, distribution and use. This marked the first time the FDA clearly distinguished between devices and drugs.

In 1978, with the authority granted the FDA by the amendments, the Good Manufacturing Practices (GMP) were promulgated. The GMP represents a quality assurance program intended to control the manufacturing, packaging, storage, distribution and installation of medical devices. This regulation was intended to allow only safe and effective devices to reach the market place. It was this regulation that had the greatest effect on the medical device industry. It allowed the FDA to inspect a company's operations and take action on any noted deficiencies, including prohibition of device shipment. Recent regulations specific to medical devices are the Medical Device Reporting (MDR), the Device Reconditioner Rebuilder and the Safe Medical Devices Act.

## Device Classification

A medical device is any article or health care product intended for use in the diagnosis of disease of other condition or for use in the care, treatment, or prevention of disease that does not achieve any of its primary intended purposes by chemical action or by being metabolized.

From 1962, when U.S. Congress passed the last major drug law revision, and first attempted to include devices, until 1976 when device laws were finally written, there were almost constant congressional hearings. Testimony was presented by medical and surgical specialty groups, industry, basic biomedical sciences, and various government agencies, including all the FDA. All of the viewpoints and arguments that we hear today were proposed, and considered in public discussion. Nearly two dozen bills were rejected as either inadequate or inappropriate.

The committee concluded that the many inherent and important differences between drugs and devices necessitated a regulatory plan specifically adapted to devices. They recognized that some degree of risk is inherent in the development of many devices, so that all hazards cannot be eliminated; that there is often little or no prior experience on which to base judgements about safety and effectiveness; that devices undergo performance improvement modifications during the course of clinical trials; and that results also depend upon the skill of the user.

Therefore, they rejected the drug-based approach and created a new and different system for evaluating devices. All devices were placed into classes based upon the degree of risk posed by each individual device and its use. The Pre-Market Notification Process (510k) and the Pre-Market Approval Application (PMAA) became the regulatory pathways for device approval. The Investigational Device Exemption (IDE) became the mechanism to establish safety and efficacy in clinical studies for PMAAs.

## Class of Devices

### 1. Class I devices

Class I devices were defined as not life sustaining, their failure poses no risk to life, and there is no need for

performance standards. Basic standards, however, such as premarket notification (510k), registration, device listing, good manufacturing practices and proper record keeping are all required. Nonetheless, The FDA has exempted many of the simpler Class I devices from some or all of these requirements. Examples are:

- Tongue depressors.
- Stethoscopes.

### 2. Class II devices

Class II devices were also defined in 1976 as not life sustaining. However, they must not only comply with the basic standards for Class I devices, but must meet specific controls or performance standards. Premarket notification is documentation submitted by a manufacturer that notifies that the FDA that a device is about to be marketed. It assists the agency in making a determination about whether a device is substantially equivalent to a previously marketed predecessor device. As provided for in Section 510k of the Food, Drug and Cosmetic Act, the FDA can clear a device for marketing on the basis of premarket notification that the device is substantially equivalent to a pre-1976 predecessor device. The premarket notification of 510k process was designed to give manufacturers the opportunity to obtain rapid market approval of these noncritical devices by providing evidence that their device is substantially equivalent to a device that is already marketed. The device must have the same intended use and the same or equally safe and effective technological characteristics as a predicate device.

Class II devices are usually exempt from the need to prove safety and efficacy. The FDA, however, may require additional clinical or laboratory studies. On occasion these may be as rigorous as for and IDE in support of a PMA, although this is rare. The FDA responds with an order of concurrence or nonconcurrence with the manufacturer's equivalency claims.

The Safe Medical Device Act of 1990 and the Amendments of 1992 attempted to take advantages of what had been learned since 1976 to give both the FDA and manufacturers greater leeway by permitting down classification of many devices, including some life supporting and life sustaining devices previously in Class III, provided that reasonable assurance of safety and effectiveness can be obtained by application of special controls such as performance standards, post market surveillance, guidelines, and patient and device registries. Some examples are:

- Infusion pumps.
- Surgical drapes.

### 3. Class III devices

Class III devices were defined in 1976 as either life sustaining or life supporting so that their failure is life threatening. These devices almost always require a PMAA,

a long and complicated task fraught with many pitfalls that has caused the greatest confusion and dissatisfaction for both industry and the FDA.

The new regulations permit the FDA to use data contained in four PMAs for a specific device, that demonstrate safety and effectiveness, to approve future PMA applications by establishing performance standards or actual reclassification. Composition and manufacturing methods which companies wish to keep as proprietary secrets are excluded. Advisory Medical panel review is now elective.

However, for PMAAs that continue to be required, all of the basic requirements for Class I and II devices must be provided, plus failure mode analysis, animal tests, toxicology studies and then finally human clinical studies, directed to establish safety and efficacy under an IDE.

It is necessary that preparation of the PMA must actually begin years before it will be submitted. It is only after the company has the results of all of the laboratory testing, pre-clinical animal testing, failure mode analysis and manufacturing standards on their final design, that their proof of safety and efficacy can begin, in the form of a clinical study under an IDE.

At this point the manufacturer must not only have settled on a specific, fixed design for his advice, but with his marketing and clinical consultants must also have decided on what the indications, contraindications, and warnings for use will be. The Clinical Study must be carefully designed to support these claims.

Section 520 of the Federal Food, Drug, and Cosmetic Act, as amended, authorizes the FDA to grant an IDE to a researcher using a device in studies undertaken to develop safety and effectiveness data for that device when such studies involve human subjects. An approved IDE application permits a device that would otherwise be subject to marketing clearance to be shipped lawfully for the purpose of conducting a clinical study. An approved IDE also exempts a device from certain sections of the Act. All new significant risk devices not granted substantial equivalence under the 510k section of the Act must pursue clinical testing under an IDE. Some examples are:

- Replacement heart valves.
- Silicone gel-filled breast implants.
- Implanted cerebella stimulators.

### **Registration and Listing**

Under section 510 of the Act, every person engaged in the manufacture, preparation, propagation, compounding or processing of a device shall register their name, place of business and such establishment. This includes manufacturers of raw materials, licensed practitioners, manufacturers of devices for use solely in research or teaching, warehousemen, manufacturers of veterinary devices, and those who only dispense devices, such as pharmacies.

Upon registration, the FDA issues a device registration number. A change in the ownership or corporate structure of the firm, the location, or person designated, as the official correspondent must be communicated to the FDA device registration and listing branch in 30 days. Registration must be done when first beginning to manufacture medical devices and must be updated yearly.

Section 510 of the Act also requires all manufacturers to list the medical devices they market. Listing must be done when first beginning to manufacture a product and must be updated every 6 months. Listing includes not only informing the FDA of products manufactured, but also providing the agency with copies of labeling and advertising.

Foreign firms that market products in the United States are permitted but not required to register, and are required to list. Foreign devices that are not listed are not permitted to enter the country.

Registration and listing provides the FDA with information about the identity of manufacturers and the products they make. This information enables the agency to schedule inspections of facilities and also to follow-up on problems. When the FDA learns about a safety defect in a particular type of device, it can use the listing information to notify all manufacturers of those devices about that defect.

### **The 510k Process**

#### **1. Determining substantial equivalency**

A new device is substantially equivalent if, in comparison to a legally marketed predicate device:

- Has the same intended use.
- Have different technological characteristics as the predicate device.
- Have different technological characteristics and submitted information that does not raise different questions of safety and demonstrates that the device is as safe and effective as the legally marketed predicate device.

#### **2. Types of 520k's**

There are several types of 510k submissions that require different formats for addressing the requirements. These include:

- Submissions for identical devices.
- Submissions for Equivalent but not identical devices.
- Submissions for complex devices or for major differences in technological characteristics.
- Submissions for software controlled devices.

The 510k for simple changes, or for identical devices should be kept simple and straightforward. The submission should refer to one or more predicate devices, it should contain samples of labeling, it should have a brief statement of equivalence, and may be useful to include a chart listing similarities and differences.

The group of equivalent but not identical includes combination devices where the characteristics or functions of more one predicate device are relied on to support a substantially equivalent determination. This type of 510k should contain all of the information listed above as well as sufficient data to demonstrate why the differing characteristics or functions do not affect safety or effectiveness.

Submission of some functional data may be necessary. It should not be necessary, however, to include clinical data. Preparing a comparative chart showing differences and similarities with predicate devices can be particularly helpful to the success of this type of application.

Submissions for complex medical devices or for major differences in technological characteristics is the most difficult type of submission; since it begins to approach the point at which the FDA will need to consider whether a 510k is sufficient of whether a PMAA must be submitted.

This key is to demonstrate that the new features or the new uses do not diminish safety or effectiveness and that there are no significant new risks posed by the device. In addition to the types of information described above, this type of submission will almost always require submission of some data, possibly including clinical data.

As a general rule, it often is a good idea to meet with FDA to explain why the product is substantially equivalent, to discuss the data that will be submitted in support of a claim of substantial equivalence, and to learn the FDA's concerns and questions so that these may be addressed in the submission. The FDA's guidance documents can be of greatest use in this type of submission.

## 2. 510k format

The actual 510k submission will vary in complexity and length according to the type of device or product change for which substantial equivalency is sought. A submission shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. All submissions shall contain the following information:

- Submitter's name, address, telephone number, a contact person, and the date the submission was approved.
- Name of the device, including the trade or proprietary name, if applicable, the common or unusual name, and the classification name.
- An identification of the predicate or legally marketed device or devices to which substantial equivalence is being claimed.

- A description of the device that is the subject of the submission, including an explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device such as device design, materials used, and physical properties.
- A statement of the intended use of the device, including a general description of the diseases or conditions the device will diagnose, treat, prevent, cure or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the predicate or legally marketed device identified above, the submission shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device and why the differences do not affect the safety or effectiveness of the device when used as labeled.
- A statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device identified above.

510k summaries for those premarket notification submissions in which a determination of substantial equivalence is based on an assessment of performance data shall contain the following information in addition to that listed above:

- A brief discussion of the nonclinical tests and their results submitted in the premarket notification.
- A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety and/or effectiveness data obtained with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence.

## PMA Application

Pre-market Approval (PMA) is an approval application for a Class II medical device, including all information submitted with or incorporated by reference. The purpose of the regulation is to establish an efficient through device review process to facilitate the approval of PMAs for devices that have been shown to be safe and effective for their intended use and that otherwise meet the statutory criteria for approval, while ensuring the disapproval of PMAs for devices that have not been shown to be safe and effective or that do not otherwise meet the statutory criteria for approval.

### 1. The PMA process

The first step in the PMAA process is the filing of the investigational device exemption (IDE) application for

significant risk devices. The IDE is reviewed by the FDA and one accepted, the sponsor can proceed with clinical trials.

## 2. Contents of a PMAA

Section 814.20 of 21 CFR defines what must be submitted in an application, including:

- Table of contents.
- Name and address.
- Application procedures.
- Summary.
- Complete device description.
- Reference to performance standards.
- Nonclinical and clinical investigations.
- Justification for single investigator.
- Sample of device.
- Proposed labeling.
- Environmental assessment.

The summary should include intentions of use, a device description, a description of alternative practices and procedures, a brief description of the marketing history, and a summary of studies. This summary should be of sufficient detail to enable the reader to gain a general understanding of the application. The PMAA Must also include the applicant's foreign and domestic marketing history of a third party marketing the same product.

The description of the device should include a complete description of the device, including pictorial representations. Each of the functional components or ingredients should be described, as well as the properties of the device relevant to the diagnosis, treatment, prevention, cure or mitigation of a disease or condition.

The principles of the device's operation should also be explained. Information regarding the methods used in, and the facilities and controls used for the manufacture, processing, packing, storage, and installation of the device should be explained in sufficient detail so that a person generally familiar with current good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device.

To clarify which performance standards must be addressed, applicants may ask members of the appropriate reviewing division of the Office of Device Evaluation or consult FDA's list of relevant voluntary standards of the Medical Devices Standards Activities Report.

## Investigational Device Exemptions (IDE)

The purpose of the Investigational Device Exemptions regulation is to encourage the discovery and development of useful devices intended for human use while protecting the public health. It provides the procedures for the conduct of clinical investigations of devices. An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with a performance standard or having marketing clearance.

## Good Laboratory Practices (GLP)

In 1978, FDA adopted Good Laboratory Practices rules and implemented a laboratory audit and inspection procedure covering very regulated entity that conducts nonclinical laboratory studies for product safety and effectiveness. The GLP's were amended in 1984.

The GLP standard addresses all areas of laboratory operations including requirements of a Quality Assurance Unit to conduct periodic internal inspections and keep records for audit and reporting purposes, Standard Operating Procedures (SOPs) for all aspects of each study and for all phases of laboratory maintenance, a formal mechanism for evaluation and approval of study protocols and their amendments, and reports of data in sufficient detail to support conclusions drawn from them. The FDA inspection program includes GLP compliance, and a data audit to verify that information submitted to the agency accurately reflects the raw data.

## Good Manufacturing Practices (GMP)

FDA is authorized to promulgate regulations detailing compliance with current good manufacturing practices. GMPs includes the methods used in, and the facilities and controls used for, the manufacture, packing, storage and installation of a device. The GMP regulations were established as manufacturing safeguards to ensure the production of a safe and effective device and include all the essential elements of a quality assurance program. Because manufacturers cannot test every device, the GMPs were established as a minimum standard of manufacturing to ensure that each device produced would be safe. If a product is not manufactured according to GMPs, even if it later shown not to be health risk, it is in violation of the Act and subject to FDA enforcement action.

The general objectives of the GMPs, not specific manufacturing methods, are found in Part 820 of the Code of Federal Regulations. The GMPs apply to manufacture of every medical device. The proposed new GMP regulations, scheduled to be released in 1996, gives FDA the authority of examine the design area of the product development cycle for the first time.

## Design Control

The FDA has the authority of covering design controls in their inspections. Design control concepts are applicable to

process development as well as product development. The extent is dependent upon the nature of the product and processes used to manufacture the product. The safety and performance of a new product is also dependent on an intimate relationship between product design robustness and process capability.

### **The FDA Inspection**

The FDA's power to inspect originates in Section 704 of the Federal Food, Drug, and Cosmetic Act. This program allows FDA officials to inspect any factory, warehouse, or establishment in which medical devices are manufactured, processed, packed or held, for introduction into interstate commerce. The FDA is permitted to enter any vehicle used to transport or hold regulated products for import or export. Every FDA inspector is authorized by law to inspect all equipment that is used in the manufacturing process. Investigators may examine finished and unfinished devices and device components, containers, labeling for regulated products, and all documents that are required to be kept by the regulations, such as device master records and device history records.

### **MEDICAL DEVICE REPORTING REGULATION [3]**

On July 31, 1996, the new Medical Device Reporting (MDR) regulation became effective for user facilities and device manufacturers. This document describes the current provisions for device manufacturers.

The MDR regulation provides a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goals of the regulation are to detect and correct problems in a timely manner. Although the requirements of the regulation can be enforced through legal sanctions authorized by the Federal Food Drug & Cosmetic (FFD&C) Act, FDA relies on the goodwill and cooperation of all affected groups to accomplish the objectives of the regulation.

The statutory authority for the MDR regulation is section 519(a) of the FFD&C Act as amended by the Safe Medical Devices Act (SMDA) of 1990. The SMDA requires user facilities to report:

- Device-related deaths to the FDA and the device manufacturer;
- Device-related serious injuries to the manufacturer, or to FDA if the manufacturer is not known; and
- Submit to FDA on an annual basis a summary of all reports submitted during that period.

The SMDA requires FDA to issue regulations requiring distributors to report device-related deaths, serious injuries and reportable malfunctions. On September 1, 1993, FDA published a final MDR reporting regulation for distributors,

including provisions for importers that became effective on October 1, 1993. In addition, the SMDA requires distributors and manufacturers to certify to FDA the number of MDR reports filed or that no reports have been filed.

The user facility reporting section of SMDA became effective on November 28, 1991. Device manufacturers should familiarize themselves with the user facility requirements and read the guidance document entitled, "Medical Device Reporting for User Facilities." Since 1984, domestic manufacturers have been subject to the MDR regulation if they were required to register their establishment with the FDA. The new MDR regulation eliminates this link with registration. All manufacturers of finished medical devices and components which are ready for use, including foreign manufacturers, are now subject to the requirements of the MDR regulation, despite registration status.

To carry out the reporting provisions of SMDA, FDA published a tentative final rule in the Federal Register (FR) on November 26, 1991, proposing to implement reporting regulations for users and distributors. In addition, the tentative final rule proposed to amend the existing 1984 MDR reporting regulation for manufacturers.

On June 16, 1992, President Bush signed into law the Medical Device Amendments of 1992 (Public Law 102-300; the Amendments of 1992), amending certain provisions (section 519 of the FFD&C Act) that relate to the reporting of adverse events. The primary impact of the 1992 Amendments on MDR reporting was to define certain terms and to establish a single reporting standard for user facilities, manufacturers and distributors.

The final MDR regulation for user facilities and manufacturers, published in the Federal Register on December 11, 1995, addresses the comments received by FDA on the November 29, 1991, tentative final regulation and the changes mandated by the Amendments of 1992.

Significant changes for manufacturers from the 1984 MDR regulation include:

- Different time frames for reporting.
- Use of standardized reporting forms.
- Removal of unanticipated temporary impairments.
- New definitions.
- Addition of an FDA disclaimer.
- Requirement for foreign manufacturers to have a U.S. Designated Agent for reporting MDR events to FDA.

## Changes Affecting the MDR Regulation

The FDA began to receive comments regarding the regulation, following publication of the December 11, 1995, final rule on Medical Device Reporting for manufacturers and user facilities.

The FDA staff subsequently met with industry representatives to discuss their concerns about the new regulation.

Following these discussions, FDA decided to place all or portions of three specific parts of the regulation into abeyance. This means that FDA has revoked/stayed, or delayed these parts from going into effect. Therefore:

- Foreign manufacturers are not required to have a U.S. Designated Agent.
- There is no requirement to submit distribution information. This means that manufacturers do not fill out data elements 15 and 16 only of the baseline report.
- A foreign manufacturer is fully subject to the medical devices reporting requirements. If a foreign manufacturer already has a USDA, they may forward medical device reports through this agent until further notice. However, if a foreign manufacturer chooses to employ a contact in the United States (U.S.) to forward reports to FDA, FDA views this person as if he or she is an employee of the foreign firm. The FDA explains these decisions in the Federal Register (FR) notices summarized below.
- The FDA encourages foreign firms to register with FDA by completing a Form FDA 2891, "Initial Registration of Device Establishment."

## Modernization Act Changes

### 1. Distributors

Distributors of medical devices are no longer required to report device related adverse events involving death, serious injury and malfunction to the FDA and/or the device manufacturer.

Instead, distributors must keep records of complaints and make the records available to FDA upon request.

### 2. Annual certification requirement

Repeals the requirement for manufacturers, importers and distributors to submit an annual certification, Form FDA 3381, to FDA certifying whether any adverse event reports were filed during the previous year and, if so, the number filed.

### 3. User facilities

The user facility semi-annual reporting requirement has been changed to annual reporting. The annual report will now be due on January 1 of each year. User facilities may continue to use the current semi-annual user facility report form, FDA 3419, until a revised one is issued by FDA.

The identity of user facilities that are submitting MDR reports is protected from disclosure except in connection with:

- Certain actions brought to enforce device requirements under the FFD&C Act.
- A communication to a manufacturer of a device that is the subject of a report to FDA of death, serious illness or injury, or other significant adverse experience.

In this FR notice, the FDA changed the MDR requirements as follows:

- The effective date of the annual certification provision of the MDR regulation for manufacturers and distributors was stayed.
- Annual certification provisions for manufacturers were stayed to allow FDA to address industry concerns. The FDA repropose this provision as described below.
- The existing requirement for distributors to annually certify was revoked. It was also repropose, so that manufacturers and distributors would be treated the same regarding certification; and
- The U.S. designated agent requirements for foreign manufacturers were stayed.

In addition, foreign manufacturers, as of July 31, 1996, have a responsibility to comply with all remaining medical device reporting requirements. The original medical device reporting regulation that became effective on December 14, 1984, defined a manufacturer required to submit MDR reports, as any person FDA required to register under 21 CFR Part 807. Since foreign manufacturers are not required to register, the December 1984 regulation was not applied to them.

The new medical device reporting regulation, published December 11, 1995, no longer defines a manufacturer as a person whom FDA requires to register under 21 CFR Part 807. Under section 803.3(n), a manufacturer is defined as any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure(s). Accordingly, foreign manufacturers fit within the new definition of manufacturers that FDA requires to submit MDR reports.

Therefore, as of July 31, 1996, all manufacturers, including foreign manufacturers, are subject to all requirements of 21 CFR Part 803 including, but not limited to:

- The requirements for written MDR procedures.
- MDR event files.
- Individual adverse event reports.
- Five-day MDR reports.
- MDR baseline reports.
- MDR supplemental reports.

In addition, the regulations that are now in effect, and will remain in effect during the stay, permit foreign manufacturers to:

- Register their companies using Form FDA 2891, "Medical Device Establishment Registration".
- Submit premarket notifications [510(k)s].

These regulations also require foreign manufacturers to list their devices on Form FDA 2892, medical "Device Listing".

#### **4. Second notice, federal register, July 23, 1996: Medical device reporting; certification and U.S. Designated Agents (USDA); Proposed rule.**

In this FR notice, FDA repropose the annual certification requirements for manufacturers and distributors. The proposed annual certification changes:

- Eliminate the current certification statement.
- Substitute a new certification statement that states that the certifying official has.
- Read the MDR regulation.
- Made certain that the manufacturer has established an MDR reporting system.
- Determined that a certain number of reports, or no reports, have been submitted.
- Provide flexibility by allowing firms to identify the certifying agent for annual certification, rather than

requiring the certifying agent to be the Chief Executive Officer or the President of the company.

#### **5. Third notice, federal register, July 31, 1996: Baseline reports, stay of effective date.**

In this FR notice, FDA placed into abeyance, or stayed, the effective date of the provision of the MDR regulation that relates to part of the baseline reporting requirement [21 CFR 803.55(b)(9) and (10)]. Therefore, at this time, FDA will not require any manufacturer to submit denominator data requested in Part II, Items 15 and 16 only on Form FDA 3417, "Baseline Report." Instead, FDA will initiate a demonstration project to evaluate denominator data. At the completion of this project, FDA will either lift the stay, retain it, or repropose these specific requirements.

#### **6. Fourth notice, federal register, March 20, 1997: Medical device reporting; Annual certification; Final rule.**

In this FR notice, FDA amended its medical device manufacturer and distributor certification regulations to allow manufacturers to designate more than one certifying official, each of whom would sign a certification statement for his or her identified organizational component or site; and to amend the certification statement to minimize concerns relating to liability from unintentional reporting errors and indicate that the certifying official is making the certification statements, to the best of his/her knowledge and belief.

This action was taken to help FDA carry out its public health protection responsibilities relating to medical devices. This action provides reporting entities with greater flexibility in the certification process while reducing the regulatory burden. This amendment is effective on May 19, 1997, and replaces the requirement that was stayed on July 23, 1996.

### **ETHICAL ASPECTS [9]**

In a society where new technology is constantly being invented, medical devices are evolving at a fast pace. The use of complex and sophisticated equipment to monitor patient and diagnose disease are more and more routine in hospitals and clinics. New discoveries in the material science field have led to the improvement in implant devices such as pacemakers, artificial grafts, and artificial organs. Armed with these technological advances, physicians and engineers are able to save more lives and improve the quality of living.

However, these new technologies have raised new debates and discussions on morality and ethical issues. Approval and regulation of medical devices, as well as patient's rights and informed consents are just a few of the many issues stirred up by these new developments. This section discusses some of the issues and concerns dealing with

medical ethics as well as regulation of medical devices. It also talks about some cases that involved medical device failure, and some of the government's attempts to reduce failure.

### 1. Issues and concerns

As most people know, putting new medical technologies on the market requires repeated clinical tests follow by animal and human tests. Finally the device is approved by the government agency such as the Food and Drug Administration (FDA). In order to fully test the effectiveness of these devices, animal and human testing is necessary at some point.

Due to sheer increases in the volume of biomedical research, problems associated with human experimentation gain in importance. This need raises very complicated questions about balancing the patient's right against the overall benefits. On the one hand, human life is precious and needs to be considered a high priority. On the other hand, the new technology could potentially have large social benefits.

In order to ensure the risks of physical and emotional injuries are at a minimum, every clinical study is required to meet comprehensive guidelines and regulations before moving to human experimentations. In addition to the regulations, a patient's rights during a human trial study should be properly protected. The concept of "informed consent" has emerged as a way to control this issue. Under informed consent, patients need to be informed of every aspect of the study, as well as the potential risks involved.

### 2. Medical device regulation

The first step in medical device regulation is to clearly define all the related terms and categories. A medical device is defined as any equipment used to treat, diagnose, or prevent disease. It can range from very basic equipment such as needles and syringes to complex devices such as X-ray machines and MRI scanners. In the case of clinical studies where the device has not yet been approved, a series of steps needs to be taken. In the US, the Food and Drug Administration (FDA) is responsible for the regulation of these devices.

For the new device to be used on human subjects, first an investigational device exemption (IDE), which allows an unapproved device to be used in a research study, needs to be approved by the FDA. After the approval, the devices are then divided into two categories: significant risk and insignificant risk. Devices that pose significant risks include implants and artificial organs. Devices such as glasses and teeth-braces are qualified as insignificant risk devices. Research study that involves devices with significant risk cannot process until the procedure is approved by an institutional review board (IRB) and the FDA, which is based on the informed consent forms.

In the UK and Europe, the devices are divided up into three categories: low risk (category I) and high risk (category II and III). With a low risk device, the manufacturer is allowed to self-inspect the product. Government agencies, such as the Medical Device Agency (MDA), then inspect the manufacturer for requirements.

The control of high-risk devices is done through Notified Assessment Bodies. This is an organization composed of agencies from different countries in Europe. The Bodies inspect the design of the device, as well as checks the experiment protocol involving the device. Once the device has been approved by one country, it can be used in all of the countries that are members of the Notified Assessment Bodies.

Although the regulations are very detailed and comprehensive, they still need to be constantly updated to keep up with the advancement of technology. In recent years, the continue reuse of disposable medical device has caused the FDA to refine its regulations on medical devices. In an effort to reduce costs, many hospitals and clinics in the US are reusing the medical devices after cleaning and sterilizing, despite their "single-use" designation. While the device's safety was backed by experts in the medical field, growing public concerns led to new regulations imposed by the FDA. In 2000, the FDA classified many reused medical devices into low, moderate, and high risk categories. It also requires that any facilities that use these devices must reprocess them using the same standard for new equipment (Anonymous, 2002a). With the evolution of medical technology, it is imperative that the regulations are up to date to minimize accidents.

### 3. Medical device failure

Despite all the precautionary steps in an effort to keep accidents from happening, medical device failure is inevitable. This is seen especially in clinical research where new technology is used without approval, and risk can be high and costly.

In the case of a 51-year-old veteran who got a fully implanted artificial heart, the device failure cost him his life. This gentleman was the fifth patient who agreed to test this break-through technology. Although he showed remarkable recovery after the surgery, He suffered strokes and other complications during the next nine months and was pronounced brain dead. His wife sued the Abiomed Inc., the maker of the heart, on the grounds of being misinformed about the risks. The lawsuit brought media coverage locally but was ultimately won by Abiomed Inc. because the gentleman had signed a 15-page informed consent. Abiomed Inc. later altered the design of the heart to reduce the chances of stroke.

For this gentlemen and his wife, not treating the informed consent as an important step when trying an unproven medical device had a tragic consequence. Companies that develop these new devices are obligated to provide

information on potential risks, and patients are also obligated to fully understand the study that they are involved in. Only with the efforts of both sides of the study can an ethical controversy be avoided.

## **RECOMMENDED GUIDELINES FOR REUSABLE MEDICAL DEVICES**

### **1. Background**

Attention must be given to the reuse of medical devices. Contaminated and unsafe medical devices pose a potential source for cross-contamination, infection and injury to patients and personnel. Strict guidelines are needed to standardize the process of reusing medical devices. The guidelines are intended to assist institutions and endoscopy units in the development of their specific needs. Providing the best possible care is the ultimate mission of each healthcare institution and the professionals who staff it. An integral component of delivering quality care is instrumentation. Most endoscopy procedures are performed on an outpatient basis. The volume of procedures scheduled each day is often high. Whether that schedule can be met and each patient given high quality care is dependent on device reliability and safety.

The reuse of critical and semi-critical devices has become a common practice in many institutions. The reuse of medical devices is a practice undertaken primarily for economic reasons as a means to maximize the effective usage of a particular nondisposable device. Only the devices labeled reusable can be reused.

Due to this concern the authorities decided to establish some guidelines and recommendation for reuse of reusable medical devices.

### **2. Recommendations for reuse**

All reusable medical devices must be placed into three categories:

1. Critical.
2. Semi-critical.
3. Non-critical.

The process for reuse, resterilizing and reprocessing is determined by the category in which the medical device is classified.

### **3. Issues to consider to meet performance standards**

- Strict adherence to the manufacturer's instructions for reprocessing.

- Clinically proven device.
- Inspect upon opening package.
- Necessity to perform multi-step cleaning process and high level disinfection/sterilization process.
- Ensure adequate backup inventory.
- Establish protocol for reprocessing.
- Establish protocol for inspection and repair.
- Establish training and retraining protocols for staff.
- Establish institutional policy/standards to determine maximum number of use for the device.

Preventing patient infection means that the device must be free of contamination. Preventing injury means that the device must function according to specifications without degradation of parts that might become dangerous to the patient or staff. Perhaps the most significant risk of injury from product degradation is the fraying of electrical sheaths due to reprocessing plus normal wear and tear during procedures. This is difficult to monitor even with close inspection. The potential of injury to the patient may be significant.

### **4. Issues in Reuse**

#### **a. Risk of infection**

- Thorough cleaning is the most integral part of reprocessing. Concern is expressed regarding mechanical parts being difficult to clean, and that porous material, such as plastic, may absorb contaminants and chemicals.
- Most manufacturers recommend steam sterilization. Gas is excellent in sterilizing provided the equipment is free from all blood and other organic materials. The item should be dry because the presence of saline or water may form a poisonous chemical in the presence of gas. With the elimination of chlorofluorocarbons (CFCs), which are required for most gas sterilizers, institutions are switching to other technologies. Check manufacturer's label for reprocessing.
- High level disinfection may be appropriate for semi-critical devices, but the effect on functionality must be assessed.
- Personnel performing the reprocessing of the item are at risk if being exposed to body fluids and/or cleaning, disinfection or sterilization products. Personnel must

follow the Health and Safety recommendations outlined in infection and control Guidelines.

#### **b. Medical device integrity**

It is necessary to assess what effect the high level disinfection or sterilization process will have on the integrity and functionality of the device. The number of reuses should be based on manufacturer guidelines.

#### **c. Cost-effectiveness**

Institutions should consider the following; cost of labor, supplies and machine use, storage, quality assurance programs, overhead, possible additional liability insurance and possible increase in price of an item if fewer are used. There are also protocol development costs and educational costs to consider.

#### **d. Legal issues**

The manufacturer's labeled information on care and usage of reusable products must be adhered to. When infections occur or injuries take place due to an instrument selected and maintained by the institution, there is a potential for significant legal liability. Instruments that are continually reprocessed can increase that risk.

Disposal of the instrument after its useful life must be performed according to institutional and governmental regulations.

Liability may be avoided or reduced if a reasonable standard of care can be demonstrated, including the adherence to established hospital guidelines on reuse.

#### **e. Ethical issues**

Must the patient be informed that the instruments/devices being used for their procedure is a reusable device? Is this part of an informed consent?

Usually, specific consent is not obtained from the patient. The risk of the procedure in general is described to the patient in the same manner whether it is a new or reusable device.

It has been suggested that internal procedures must be developed, approved by the Board of Directors, and that hospital policy must become public policy. The debate revolves around the social responsibility of stakeholders to society and to individuals.

#### **f. Summary of issues in reuse**

There is a high volume of endoscopic procedures performed in many institutions. For both the patient's safety

and the financial health of the institution, it is important that these procedures be performed reliably, safely and efficiently.

Most of the devices used in endoscopic procedures are classified as critical or semi-critical. The threat of potentially life threatening malfunction can lead to patient/staff injury or needless prolongation of the procedure.

Reusable devices provide assured first-use performance. After that, a series of steps must be performed to ensure that they are properly reprocessed and provide acceptable performance during subsequent procedures.

It is important that each institution be fully aware of the issues involved in device selection. Institutions that choose to reuse devices need to validate the sterility and integrity of the reprocessed devices, and have in place detailed protocols to include mechanisms for ongoing evaluation and quality assurance monitoring.

### **MEDICAL MALPRACTICE**

When illness or injury forces the patient to see a physician or go to the hospital, patient can generally be assured that the doctor's years of experience and training will result in excellent treatment of your ailment.

But in truth, physicians are only human and as such, errors are always possible. Medical malpractice occurs when a negligent act or omission by a doctor or other medical professional results in damage or harm to a patient.

Negligence by a medical professional could include an error in a diagnosis, treatment, or illness management. If such negligence results in injury to a patient, a case could arise against the doctor if his or her actions deviated from generally accepted standards of practice; against the hospital for improper care, such as problems with medications, sanitation or nursing care; or against local, state or federal agencies that operate hospital facilities.

Medical malpractice laws are designed to protect patients' rights to pursue compensation if they are injured as the result of negligence. However, malpractice suits are often complex and costly to win. While theoretically, one can seek compensation for any injury caused by negligence, regardless of its seriousness, time and money make it unrealistic to sue for an injury that is minor or resolves quickly. Therefore, if one believes that he or she has a medical malpractice claim, it is important to consult with an attorney who can help determine whether a claim is worth pursuing.

#### **1. Theories of liability in malpractice cases**

Most medical malpractice cases proceed under the theory that a medical professional was negligent in treating the

patient. To establish medical negligence, an injured patient, the plaintiff, must prove:

- The existence of a duty owed by the health care professional to the plaintiff (for example, a doctor/patient relationship).
- The applicable standard of care, and the health care professional's deviation from that standard, which is deemed a breach of the duty owed the patient.
- A causal relationship between the health care professional's deviation from the standard of care and the patient's injury.
- Injury to the patient.

One of the most important aspects of a medical malpractice action is establishing the standard of care to be applied to the health care professional. Medical professionals are often heard to refer to medicine as an art, rather than a science, and although errors in judgment may result in injury to a patient, not all medical errors are actionable as negligence.

To find a medical professional legally at fault, it must be shown that his or her conduct fell below a generally accepted standard of medical care. To establish the standard to be applied, a plaintiff must present the testimony of another medical expert, qualified in the same area of medicine as the defendant, indicating what standard, or level of care, is commonly met by those recognized in the profession as being competent and qualified to practice. The plaintiff will have to present expert testimony not only as to the applicable standard of care, but establishing that the defendant failed to meet this standard.

Another element of in medical malpractice actions, causation, is sometimes challenging to establish. Specifically, the plaintiff must show that his or her health care provider's deviation from the applicable standard of care resulted in his or her injury. This is challenging because sometimes, the health care provider's deviation from the standard of care may not have caused the plaintiff's eventual injury, and vice versa.

If an injured patient does not know exactly what caused his or her injury, but it is the type of injury that would not have occurred without medical negligence, he or she might be able to invoke a legal doctrine known as "res ipsa loquitur," which shifts the burden of proof to the health care professional, to show that he or she was not negligent.

## **2. Negligent prescription of medications or medical devices**

A medical professional may be held liable for the negligent prescription of a medication or medical device if he or she ignored the manufacturer's instructions, or prescribed an

incorrect medication or dosage, which resulted in injury to the patient. In some cases, a pharmaceutical manufacturer may be liable where a drug caused a patient injuries, but only if the manufacturer failed to warn of potential side effects or dangers of the drug. In most cases, the prescribing physician is considered a "learned intermediary," which means that because of his or her superior medical knowledge, and the fact that he or she has been given adequate information from the manufacturer, he or she is in the best position to determine whether a particular drug or device is appropriate for a patient. Thus, the physician has the primary duty of advising the patient of the risks and side effects of a medication or medical device he or she prescribes.

## **3. Informed consent**

In many situations, the failure to obtain a patient's "informed consent" relative to a procedure or treatment is a form of medical negligence, and may even give rise to a cause of action for battery. Although the specific definition of informed consent may vary from state to state, it means essentially that a physician (or other medical provider) must tell a patient all of the potential benefits, risks, and alternatives involved in any surgical procedure, medical procedure, or other course of treatment, and must obtain the patient's written consent to proceed.

## **4. Breach of contract or warranty**

Although doctors very rarely promise specific results from procedures or treatments, in some cases they do, and the failure to produce the promised results may give rise to an action for breach of contract or breach of warranty. For example, a plastic surgeon may promise a patient a certain result, which result may be judged more easily than other types of medical results, simply by viewing the patient. Similarly, if a patient is not satisfied with the outcome of a procedure, and the physician had guaranteed or warranted a certain result, the patient may attempt to recover under a theory of breach of warranty.

## **5. Legislation affecting malpractice actions**

Due to the power and resources of the health care industry, many states have passed legislation making it more difficult to bring and prevail in medical malpractice actions. In most states today, physicians and hospitals are protected by legal limits, called "caps," on the amount of damages and attorneys' fees that can be awarded in malpractice suits. Also, most states have a two-year time limit for filing malpractice actions, unless extraordinary circumstances affect the case.

## **6. Certificate of merit**

One obstacle plaintiffs in many states may have to overcome before they can even file a malpractice action against a health care professional is the requirement that

they file what is commonly known as a "certificate of merit." In order to file a certificate of merit, a plaintiff will first have to have an expert, usually another physician, review the relevant medical records and certify that the plaintiff's health care provider deviated from accepted medical practices, which resulted in injury to the plaintiff. The plaintiff's attorney then files the certificate of merit, which confirms that the attorney has consulted with a medical expert and that the plaintiff's action has merit.

## 7. Potential defendants

Several types of health care professionals can commit medical malpractice. In the case where a hospital employee commits malpractice, the hospital itself may be held liable under the legal doctrine of "respondeat superior." Under this theory, an employer may be held liable for the negligent acts of its employee if the employee was acting within the scope of his or her employment when the negligent act or omission occurred.

This doctrine is very important to plaintiffs in medical malpractice cases, because it helps to ensure that there will be a financially responsible party to compensate an injured plaintiff.

In some situations, commonly involving attending physicians working in hospitals, health care providers are considered independent contractors rather than employees, which makes the doctrine of "respondeat superior" inapplicable. What this means is, if a doctor or other health care professional an independent contractor, and commits malpractice while treating a patient in a hospital, the hospital cannot be held liable for the doctor's negligence. However, the hospital can be held liable for its own negligence, for example, in granting attending privileges to an unlicensed or incompetent physician.

## FREQUENTLY ASKED QUESTIONS IN MALPRACTICE

Medical malpractice is the failure to meet the standard of care required by the profession for the medical practice area in question. A medical professional may be a doctor, a nurse, a medical technician, or other health care provider. Medical malpractice involves hospitals, clinics, doctors, nurses, nursing homes, and virtually every other type of health care provider and facility. Medical malpractice cases are time sensitive, so the claimant wants to contact an attorney immediately.

### 1. Does a bad outcome always mean that medical malpractice has occurred?

No. The duty of a medical professional usually is not the duty to cure or to guarantee a good outcome from treatment. The duty is to provide medical care according to accepted standards in the community or, in the case of a specialist, accepted standards in that medical specialty.

Since a medical professional may have a different duty of care if a specific guarantee of a particular result is given to the patient, most doctors require a written consent to surgery or other invasive procedures. The issue in a medical malpractice case is whether the health care provider caused damage by a breach of the standard of care for the procedure in question.

### 2. What are some examples of medical malpractice?

Medical malpractice may arise from failure to provide adequate medical care, the failure to properly diagnose a medical condition, or the failure to properly treat a medical condition. Examples include failure to properly diagnose a patient's disease or injury resulting in improper or delayed treatment, improperly prescribing a drug, failing to inform the patient of available treatments, continuing a treatment that has been shown to be ineffective, or failing to provide material information to a patient.

Some types of injuries are considered "negligence per se" because the particular type of injury could not have occurred without the negligence of someone involved in the patient's treatment. For example, if a medical instrument is left inside the patient's body following an operation, negligence usually may be assumed without further proof.

### 3. How soon should I contact a lawyer?

Generally, and with many exceptions, claims for medical malpractice must be settled or a lawsuit filed within two years of the last act of negligence by the defendant. The statute of limitations changes with the facts of your case and can be different for children, when a death has occurred or when a foreign object is left inside the body.

The fact that different limitations of time can apply to the potential case illustrates the need to speak to a qualified attorney as soon as possible to help you address the statute of limitations issue and to conduct the necessary medical and legal investigation required.

Claims for medical malpractice require a considerable amount of time to conduct an appropriate medical and legal investigation. Accordingly, if one believes that one has been the victim of medical malpractice, it is best interest to seek legal advice immediately.

### 4. What kinds of damages are recoverable in a medical malpractice case?

Usually there are two types of damages available in a medical malpractice case: actual damages and punitive damages. Actual damages include the cost of additional medical treatment, lost wages, lost future earning capacity, and pain and suffering caused by the injury.

Punitive damages are usually only available if the person who caused the harm acted intentionally, willfully, or

recklessly in causing the harm. In some cases, an award of punitive damages may be many times the amount of the actual damages, especially if the actions of the person found responsible for the harm are considered particularly wrongful.

When a physician fails to properly treat a medical condition and the negligent act or omission is the cause of a new or aggravated injury to the patient, one may have a valid medical malpractice case. The negligence in medical malpractice cases can occur in a variety of situations.

### **MEDICAL MALPRACTICE IN PUERTO RICO**

Malpractice is the lack of knowledge or practice that a person must have at work. This concept includes forms of guilt, negligence and imprudence.

First of all, in a case of malpractice, the lawyer cannot determine if there is a possibility to conduct a lawsuit because they do not know about medical regulations and ethics. For that reason, a lawyer should contact a legal medical consultant who must completely know everything about the branch of medicine involved in the conflict.

The consultant evaluates the case considering the regulations and medical ethics. With this evaluation, the lawyer proceeds to conduct the lawsuit using the suggestions and specifications made by the consultant.

Article 1802 of the Puerto Rican Civil Code, is the only law that regulates medical malpractice. The law establishes that it is "the obligation when harm is done due to negligence". (31 L.P.R.A. sec. 5141). It stipulates that somebody because of action or omission causes harm to other, involving guilt or negligence, is obligated to repair the harm caused.

Concurrent imprudence from the accused don't exime him or her from responsibility, but it cause an indemization reduction. (Amendment on 1956, law 28)

#### **1. Process to follow in a malpractice lawsuit in Puerto Rico**

No matter the case, this legal process applies to every lawsuit.

- The client/patient is evaluated to determine the current situation that he or she is going through.
- After evaluating the client/patient, the lawyer determines if there is medical malpractice.
- The lawyer requests the medical file of the client.
- The lawyer legally evaluate if the case is in the lawsuit terms, for example, some lawsuits have a time limit to be started.

- The client is referred to a legal medical consultant, who must know about the medicine branch involved in the case.
- The lawyer submit the client's medical file to the consultant, and he certify if it is or not medical malpractice.
- If there is medical malpractice, the lawsuit begins by informing the accused people and insurers with the necessary proves.
- The consultant presents a complete report with the reasons because medical malpractice is applied.
- The report is given to the claimant and insurers; it is used in the defense.
- Finally, a negotiation begins, if no agreement is reached, the case is brought to courts.
- In court, the claimant present proves. The accused people defend their position with evidence that could confront the claimant's evidence.
- The judge solves the case.

#### **2. Sample Case**

A young man had a leg fracture after falling off a horse. The doctors implanted a thin metal rod from the knee to the ankle. Later, the patient had limitation to extend the joint of the right knee more than ninety degrees; he experienced severe pain. Another doctor evaluated the patient, and he found out that the metal rod was cut one inch longer than supposed, which caused problems to the patient. Finally, the rod was removed.

The complaints and limitations of the patient were not heard nor taken care of. The doctor could have solved the problem by ordering a suitable x-ray that allowed finding the invasion of the rod. This was the cause of the continuous pain that the patient suffered. The patient's family began a lawsuit against the hospital, accusing them of medical negligence. This case is not solved; it is paralyzed because the hospital had bankruptcy.

#### **NEGLIGENCE IN BIOMATERIALS: PATH TO LACK OF BIOCOMPATIBILITY**

Possible effects of biomaterials on the living environment due to a lack of blood compatibility are thrombogenicity, and the induction of hemolysis. In addition, the biomaterial must not be carcinogenic, immunogenic, antileukotactic or mutagenic. In turn, the environment should not cause degradation or corrosion of the biomaterial that would result in loss of physical and mechanical properties. No synthetic material will be completely harmonious or inert with the living environment; however, materials do have different levels of inertness.

There are many factors which influence implant biocompatibility such as implants size, shape, material composition, and surface wettability, roughness and charge. For a material to be deemed biocompatible, any adverse reactions, which may ensue at the blood/material or tissue/material interface, must be minimal, while resistance to biodegradation must be high. This requires a biomaterial to interact as a natural material would in the presence of blood and tissue. Implantable materials should not:

- Cause thrombus formations.
- Destroy or sensitize the cellular elements of blood.
- Alter plasma proteins.
- Cause adverse immune responses.
- Cause cancer.
- Cause teratological effects.
- Produce toxic and allergic responses.
- Deplete electrolytes.
- Be affected by sterilization.

If an implant material cause one of these problems, and the creators knew about it, a negligence lawsuit would be imminent. Legal problems because of biocompatibility issues are frequently seen on courts.

### RECOMMENDATIONS

U.S. Congress and FDA should consider taking action against unfair and unjustified legal battles. Meanwhile, medical devices companies should do excellent and complete investigations to avoid legal problems that could affect this important industry. Millions of people depend on medical devices, conscience and care is vital to keep this industry functioning.

### SUMMARY

Legal and Ethical Aspects during the planning, development, and distribution of medical devices are very important, because not every kind of material can be implanted in the human body. Health complications could lead to lawsuits because of negligence, strict liability or breach of warranty. Manufacturers must be careful about legal and ethical aspects before releasing a medical device to the market.

### ACKNOWLEDGEMENTS

We thank the suggestions and advice by:

- Dr. Megh Raj Goyal
- Dr. Héctor Rosario
- Lcdo. Anibal Acevedo Rivera

### BIBLIOGRAPHY

1. Fries, Richard C. 1997. *Reliable Design of Medical Devices*. 1<sup>st</sup> Edition. New York City, NY. Marcel Dekker, Inc.
2. <http://www.cnn.com/HEALTH/9604/28/cancer.gene.congress.lg.jpg>  
[Photo of U.S. Congress]
3. <http://www.fda.gov/cdrh/index.html>  
[Information of the Medical Device Regulation]
4. <http://www.fda.gov/cdrh/images/homepg/c-d-r-h.gif>  
[Logo of Center for Devices and Radiological Health]
5. [http://www.fda.gov/graphics/mastheadart/centers/fda\\_mast\\_01.gif](http://www.fda.gov/graphics/mastheadart/centers/fda_mast_01.gif)  
[Logo of FDA]
6. <http://www.me.umn.edu/dmd/2003%20Logos/surgery.gif>  
[Photo of Surgery]
7. [http://www.senate.gov/visiting/resources/graphic/medium/dome\\_at\\_night.jpg](http://www.senate.gov/visiting/resources/graphic/medium/dome_at_night.jpg)  
[Photo of U.S. Capitol]
8. <http://www.thomas.loc.gov/cgi-bin/query/z?c105:H.R.872>:  
[Information of Biomaterials Access Assurance Act]
9. The Center for Professional Advancement. 2005. *Ethical Issues in Medical Devices*. Handout. East Brunswick, New Jersey. CfPA.

### GLOSSARY

**510k process:** Process in which a device is classified as substantially equivalent if, in comparison to a legally marketed predicate device: has the same intended use, have different technological characteristics as the predicate device or have different technological characteristics and submitted information that does not raise different questions of safety and demonstrates that the device is as safe and effective as the legally marketed predicate device.

**Biocompatibility:** The body's reaction to a certain type of implant introduced in the body.

**Biomaterials:** A branch of biomedical engineering that deals with the material aspects of medical devices.

**Biomaterials Assurance Act of 1998:** Public law established on August 13, 1998 at the Second Session of the One Hundred Fifth Congress of the United States of America. This act establish rules governing product liability actions against raw materials a bulk component suppliers to medical device manufacturers and for other purposes.

**Biomaterials Supplier:** An entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant.

**Breach of Warranty:** Representations either express or implied, which a manufacturer or a seller makes about its product

**Claimant:** Any person who brings a civil action or on whose behalf a civil action is brought, arising from harm caused directly or indirectly by an implant, including a person other than the individual into whose body, or in contact with whose blood or tissue, the implant is placed, who claims to have suffered harm as a result of the implant.

**Class I Devices:** These devices are defined as not life sustaining, their failure poses no risk to life.

**Class II Devices:** Class II devices are defined as not life sustaining. However, they must meet specific controls or performance standards.

**Class III Devices:** Devices defined as either life sustaining or life supporting so that their failure is life threatening.

**FDA:** Government subdivision in charge of the Food and Drug regulations.

**Hazard Analysis Probability Classification:** Resource used to classify devices in terms of their probabilities of became hazardous after implanting them.

**Investigational Device Exemptions:** Regulation that encourage the discovery and development of useful devices intended for human use while protecting the public health

**Medical Malpractice:** Failure to meet the standard of care required by the profession for the medical practice area in question.

**Medical Device Reporting Regulation:** The MDR regulation provides a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices

**Negligence:** Negligence is the conduct and behaviors that don't obey the standards established by law and authorities.

**PMA Application:** Pre-market Approval is an approval application for a Class II medical device, including all information submitted with or incorporated by reference.

**Predicate Device:** Original Device, used for comparison in the 510k process.

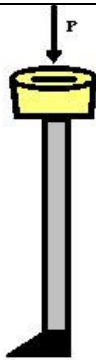
**Reliability:** Probability of failure of a device to meet its requirements.

**Safety:** Freedom from accident or losses.

**Strict Liability:** One who sells a product in defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical damage.

## APPENDIX I: NUMERICAL EXERCISES

### TENSION, COMPRESSION AND SHEAR



A person receives a prosthesis that will substitute the victim's calve lost in a car accident. The person weighs 125 pounds. The prosthesis is made of aluminum with Modulus of Elasticity of 11,400 ksi, diameter of 3 inches.

Determine:

- A) Axial Stress.
- B) Elongation of the initial length is 2 ft.

### SOLUTION

a) Determine axial stress:

Load on each leg:

$$P = 125/2 = 62.5 \text{ lb}$$

Area:

$$A = (\pi/4)d^2$$

$$A = (\pi/4)(3\text{in})^2$$

$$A = 7.06 \text{ in}^2$$

Axial stress:

$$\sigma = P/A$$

$$\sigma = -62.5\text{lb}/7.06\text{in}^2$$

$$\sigma = -8.85 \text{ psi}$$

b) Determine elongation:

Strain:

$$\sigma = E\varepsilon$$

$$-8.85\text{psi} = 11,400 \times 10^3 \varepsilon$$

$$\varepsilon = -7.77 \times 10^{-7}$$

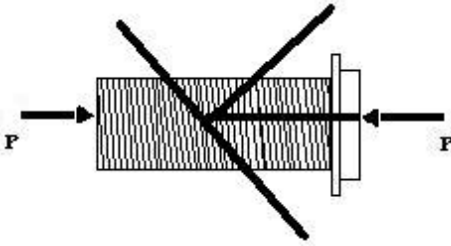
Elongation:

$$\varepsilon = \delta/L_0$$

$$-7.77 \times 10^{-7} = \delta/2\text{ft}$$

$$\delta = -1.55 \times 10^{-6} \text{ ft (shortening)}$$

## AXIALLY LOADED MEMBERS



After a serious fracture in the elbow, a person gets the fracture corrected with a turnbuckle with diameter of 0.5 in that receive an axial load of 4 pounds.

- Determine the axial stress.
- Determine the stress acting on the inclined section at an angle of  $30^\circ$ .
- Determine the stress acting at an angle of  $60^\circ$ .
- Draw the stress the stress diagram.

### SOLUTION

a) Determine axial stress:

Area:

$$A = (\pi/4) d^2$$

$$A = (\pi/4)(0.5\text{in})^2$$

$$A = 0.196 \text{ in}^2$$

Axial Stress:

$$\sigma_x = P/A$$

$$\sigma_x = -4\text{lb}/0.196 \text{ in}^2$$

$$\sigma_x = -20.4 \text{ psi}$$

b) Determine stress at  $30^\circ$ :

$$\sigma_\theta = (\sigma_x/2)(1 + \cos 2\theta)$$

$$\sigma_\theta = (-20.4/2)(1 + \cos 2(30^\circ))$$

$$\sigma_\theta = -15.3 \text{ psi}$$

$$\tau_\theta = -(\sigma_x/2)(\sin 2\theta)$$

$$\tau_\theta = -(-20.4/2)(\sin 2(30^\circ))$$

$$\tau_\theta = 8.834 \text{ psi}$$

c) Determine stress at  $60^\circ$ :

$$\sigma_\theta = (\sigma_x/2)(1 + \cos 2\theta)$$

$$\sigma_\theta = (-20.4/2)(1 + \cos 2(60^\circ))$$

$$\sigma_\theta = -5.1 \text{ psi}$$

**PROBLEM 2 CONTINUED:**

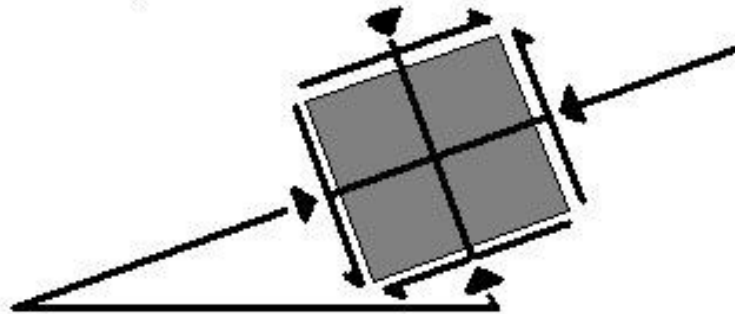
$$\tau_{\theta} = -(\sigma_x/2)(\sin 2\theta)$$

$$\tau_{\theta} = -(-20.4/2)(\sin 2(60^\circ))$$

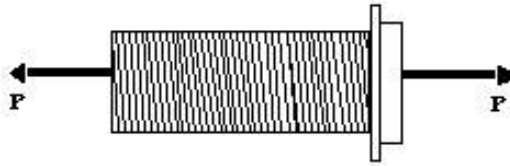
$$\tau_{\theta} = 8.834 \text{ psi}$$

d) Draw the stress diagram:

(All values are in psi)



## AXIALLY LOADED MEMBERS



After an operation, a person has a stainless steel turnbuckle in an elbow that receives a load of 8 pounds and the initial length is 3 inches. The diameter of the turnbuckle is 0.5 inches. Modulus of elasticity is 11,400 ksi.

- A) Determine the elongation.
- B) Determine strain energy density.
- C) Determine strain energy.

### SOLUTION

a) Determine Elongation:

Area:

$$A = (\pi/4) d^2$$

$$A = (\pi/4)(0.5\text{in})^2$$

$$A = 0.196 \text{ in}^2$$

Elongation:

$$\delta = PL/AE$$

$$\delta = (8\text{lb})(3\text{in})/(0.196 \text{ in}^2)(11,400 \times 10^3 \text{psi})$$

$$\delta = 1.07 \times 10^{-5} \text{ in}$$

b) Strain Energy Density:

$$U = P^2L/2AE$$

$$U = (8\text{lb})^2(3\text{in}) / 2(0.196 \text{ in}^2)(11,400 \times 10^3 \text{psi})$$

$$U = 4.30 \times 10^{-5} \text{ psi}$$

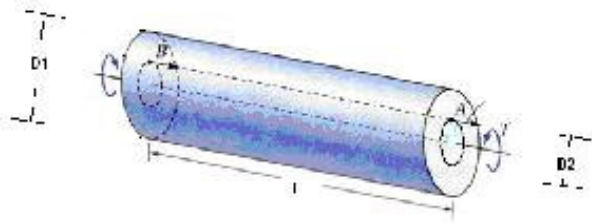
c) Strain Energy:

$$U = P\delta/2$$

$$U = (8\text{lb})(1.07 \times 10^{-5} \text{in})/2$$

$$U = 4.28 \times 10^{-5} \text{ lb-in}$$

## TORSION



A circular stainless steel tube of 15 inches of length with inside diameter of 0.6 inches and outside diameter of 1.0 inches will be installed around the humerus. Before implanting it, the device is subjected to torsion by torques applied at A and B for investigation purposes.

When the torque is 100 lb-in, determine the maximum shear stress, the total angle of twist and the maximum shear strain. Shear modulus of elasticity for steel is 11300 lb-in<sup>2</sup>.

## SOLUTION

a) Polar Moment of Inertia:

$$I_p = (\pi/32)(D_1^4 + D_2^4)$$

$$I_p = (\pi/32)(1^4 + 0.6^4)$$

$$I_p = 0.111 \text{ in}^4$$

b) Maximum Stress:

$$\tau_{\max} = Tr/(I_p)$$

$$\tau_{\max} = (100\text{lb-in})(0.5\text{in})/(0.111\text{in}^4)$$

$$\tau_{\max} = 450.4 \text{ lb-in}^2$$

b) Total angle of twist:

$$\Phi = TL/GI_p$$

$$\Phi = 100\text{lb-in}(15\text{in})/(11300 \text{ lb-in}^2)(0.111)$$

$$\Phi = 1.19 \text{ rad or } 68^\circ$$

c) Rate angle of twist:

$$\Psi = \Phi/L$$

$$\Psi = (1.19)(15\text{in})$$

$$\Psi = 0.079 \text{ rad or } 4.54^\circ$$

d) Maximum shear strain:

$$\Psi_{\max} = (.5\text{in})(1.19\text{rad})$$

$$\Psi_{\max} = 0.595$$

## APPENDIX II: CASE STUDY IN MEDICAL MALPRACTICE

### Medical File: Expert's opinion

The patient received trauma in the right leg after falling off a horse. He was evaluated, handled and treated in the emergency room. Later, orthopedic specialists evaluated and installed a plaster during a closed reduction.

The patient was evaluated again. He was intervened to implant a metal rod to the intramedular and a plaster. After removing the plaster, he is sent to physical therapy. They found out that the patient has limitation to extend the joint of the right knee more than ninety degrees and that he experiences a severe pain.

The patient did not improve. Before the negativity of the orthopedist in charge of the case, the patient decided to ask his primary doctor to request a second opinion for the case.

Another orthopedist demonstrated that indeed there was limitation of the extension of the right joint of the knee with pain and that the x-ray demonstrated that the intramedular rod has approximately one inch within the joint. He recommended that the rod be removed. Four months after the operation, another specialist removed the rod.

The complaints and limitations of the patient were not heard nor taken care of. The doctor that evaluated him initially could have solved the problem that this patient suffered with simply ordering a suitable x-ray that allowed finding the invasion of the rod. This was the cause of the limitation of the movement and the continuous pain that the patient suffered.

The contempt to the postoperative condition of this patient is of the whole responsibility of the doctor that evaluated, handled and treated the patient. An attitude like this separates this facultative of the recognized standards of the medicine practice in the Commonwealth of Puerto Rico.

### Lawsuit

To the honorable court appears the part plaintiff by conduit of its legal representative who subscribes and very respectfully he exposes, he alleges and he asks for:

1. Personal data of the young person (they are not possible to be put in).
2. Important information of the young person (they are not possible to be put in).
3. On July 15 2002, the plaintiff fell off a horse and his right leg was broken.
4. The doctor A took care of him in the hospital A.
5. The doctor A did not operate him; he plastered just the leg and sent him to his house.

6. The injury of the plaintiff was a serious one and entailed greater treatment.
7. After a month, the fracture did not heal and they put a metal rod to him in the leg.
8. The rod turned out to be one inch longer than it should be and it affected the leg and its movement.
9. The young plaintiff had to be evaluated in another hospital B by this condition.
10. Later another doctor B removed the rod.
11. The patient was sent to take therapies that did not improve the patient.
12. Neither the Hospital A nor the orthopedists took part in this situation and allowed it to continue acting negligently.
13. At the present times the plaintiff continues with impediments in the leg to walk.
14. The parents have had to be with the plaintiff, taking him to all their appointments and buying medicines to him and incurring additional expenses.
15. In addition they have had lost of income, sufferings and anguishes.
16. The plaintiff has had loss of income, lost in the capacity to generate income, physical sufferings and mental anguishes.
17. All the expenses are considered in \$450,000.

By everything that we asked this honorable court to declare with place the present demand condemning the demanded ones to pay the amount of \$450.000 more expenses and honoraria of the lawyer.

### Defendant's Answer to the Lawsuit

To the honorable court appears the hospital A by conduit of its legal representative who subscribes and very respectfully exposes, alleges and solicits:

1. What is alleged in the first paragraph of the demand is refused by lack of sufficient information to make a responsive allegation.
2. The allegation in the second paragraph of the demand is refused because the form in which it is written up. It is accepted that the person appearing operates under this name in this place.
3. What is alleged in the third paragraph of the demand is refused by lack of sufficient information to make a

responsive allegation. Of the allegation in this paragraph it is accepted that the patient had gone to the emergency room because of a fall of a horse thus had suffered the injuries that arise from the medical examination that was made to him.

4. The received information is believed and the allegation in the fourth paragraph of the demand is accepted.
5. The allegation in the fifth paragraph does not require a responsive allegation of the defendant. To require a responsive allegation of the defendant, what is alleged in the fifth paragraph of the demand is refused by lack of sufficient information to make a responsive allegation.
6. What is alleged in the sixth paragraph of the demand is refused by lack of sufficient information to make a responsive allegation.
7. What is alleged in the seventh paragraph of the demand is refused by lack of sufficient information to make a responsive allegation.
8. What is alleged in the eighth paragraph of the demand is refused by lack of sufficient information to make a responsive allegation.
9. What is alleged in the ninth paragraph of the demand is refused by lack of sufficient information to make a responsive allegation.
10. What is alleged in the tenth paragraph of the demand is refused by lack of sufficient information to make a responsive allegation.
11. What is alleged in the eleventh paragraph of the demand is refused by lack of sufficient information to make a responsive allegation.
12. Of the allegation in the twelfth paragraph of the demand, it is accepted only and exclusively that the hospital A and the Doctor A where those who provided the treatment to the young plaintiff. The rest of the allegations in this paragraph are refused.
13. What is alleged in the thirteenth paragraph of the demand is refused by lack of sufficient information to make a responsive allegation.
14. What is alleged in the fourteenth paragraph of the demand is refused by lack of sufficient information to make a responsive allegation.
15. What is alleged in the fifteenth paragraph of the demand is refused by lack of sufficient information to make a responsive allegation.
16. What is alleged in the sixteenth paragraph of the demand is refused by lack of sufficient information to make a responsive allegation.

17. What is alleged in the seventeenth paragraph of the demand is refused by lack of sufficient information to make a responsive allegation. If this court determines that it requires a responsive allegation the allegation in this paragraph is refused and affirmatively alleges that the demanded quantity to repay the supposed damages undergone by the plaintiff part turns out to be too exaggerated and unreal.

#### **Affirmative defenses**

1. Cause of action of the plaintiff's part is prescribed. Facts alleged in the demand, as established the plaintiff's part the negligence in their day, had happened to the fault and negligence of third people for who the defendant part is not responsible.
2. The damages supposedly undergone by the part plaintiff are exaggerated, speculative and they do not keep proportion with the magnitude from the damages really undergone by the plaintiff part.
3. A causal relation between the damages supposedly undergone by the plaintiff part and the performances or negligent omissions imputed by the defendant part does not exist. For such reason they cannot be compensated in right.
4. The plaintiff part has not given fulfillment to his obligation to mitigate damages.
5. The treatment offered to the plaintiff was given and offered to him by the hospital A, the doctor A and the associates, employees and/or independent contracts of this organization. For such reason are these, if exist some negligent act, whom must respond to the plaintiff by the damages supposedly suffered.
6. The medical treatment as well as the hospitable offered to the patient enjoys of a presumption to its favor, in order that was used a reasonable degree of well-taken care of and the treatment was adapted and corresponding to the norm applicable to the hospitable institutions of Puerto Rico.
7. The here defendant part reserves the right to formulate those affirmative defenses that arise from the discovery of proof tests.

In merit of all the exposed, to this honorable court it is asked that it misestimates the demand against the defendant part condemning in his consequence the plaintiff part to the payment of the costs, expenses and honoraria of lawyer.

#### **Informative motion: Request of paralyzation**

The hospital A by conduit of its legal representative who subscribes and very respectfully exposes, alleges and asks to the honorable court that:

1. The hospital has taken refuge in the protection that offers the federal law of bankruptcies.

2. As part of the procedure under protection of the referred legislation, an order of automatic paralyzation has been sent for all process followed against this institution in any forum.
3. Being pending the present case before the consideration of the honorable court, we ask for the immediate paralyzation of the process as far as the hospital until the court of bankruptcies tells.

In merit of the exposed, of this honorable and respectful court is asked to take reason from it and accept the dispositions.

The case became paralyzed without an answer of the court to the demands and until the day of today it continues paralyzed.