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The Actuary and the Medical Device Industry

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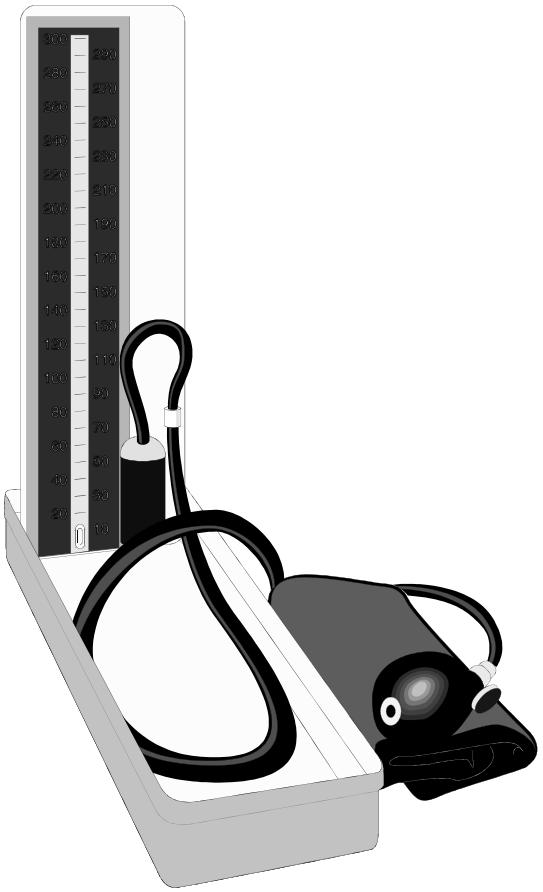

Traditionally, actuaries have been involved in the medical device arena in estimating the potential in implementing new technologies, as either savings in provider costs or as in reductions in utilization, as it relates to a provider network or carrier plan. Such analyses provide valuable justification in using or disregarding new technologies. These tend to be post-development analyses. Actuaries, however, are well-versed in risk management techniques, and an actuary who becomes involved in the device development process could assist in designing the market analysis model, integrating the cost analysis model and measuring the associated risk severity outcomes. This would ultimately help the firm avoid wasting valuable resources, mainly time and capital investment.

It is well known that the medical device and pharmaceutical industries are among the most regulated industries, primarily overseen by the FDA. While on the surface such regulation may impede new technologies, it is needed primarily to ensure patient safety and validate the efficacy of new technologies. By understanding the regulatory environment and the developer's perspective, insight can be gained as to how an actuary can provide added value in the development, production and marketing processes.

The Regulatory Environment

The FDA classifies medical devices in terms of the regulatory control necessary to achieve product safety and efficacy. These regulatory controls are called the General Controls. Any medical device that is marketed in the United States is regulated under these controls. Regulations under the General Controls include but are not limited to:

- Adulteration and Misbranding—Upon FDA approval, the medical device cannot be marketed with substandard components.
- Regulation and Listing—The FDA requires device manufacturers to register each year.
- Pre-market notification, (510k)—The FDA must be notified by the manufacturer at least 90 days before introducing a medical device. The FDA initially classifies all new devices as class III, the most stringent classification. Upon a petition approval, a device may be reclassified as either a class I device or a class II device, (see below for class descriptions).
- Banning—The FDA has the authority to ban any hazardous or fraudulent device.
- Reporting Requirements—Manufacturers must establish, maintain and provide any information that assures FDA compliance. For example, any adverse effects to the patient must be reported should the device cause injury or death.

The FDA medical device classifications under which the General Controls apply are summarized below:

- Classification I—Medical devices with minimal risk, non-life threatening.
- Classification II—Medical devices requiring performance standards such as:
- Establishing use, functioning and labeling of device.
- Describing component selection, device design, device specifications and device construction.

- Testing the device and assuring conformity to the standard.
- Classification III—In addition to the above, demonstration and approval of safety and efficacy of the device.

The fundamental underlying message in these regulations is to protect the consumer and society from harmful products. In keeping with this theme, significant consulting opportunities exist ranging from dynamic hazard validation analyses to assessing the financial impact of the various litigious risks involved. These opportunities would ultimately benefit both the consumer with a safer and more reliable product, and the developer/manufacturer with a sound business model.

The Designer/Manufacturer Perspective

Developers of new technologies need to balance several events simultaneously. These include:

- Protecting their intellectual property and rights via patents, copyrights and trademarks.
- Determining market potential, physician/patient demand and critical market capture.
- Designing an affordable and marketable product within the constraints of current market practices and demands.
- Assuring safety and efficacy of their product.
- Testing their product.
- Actual marketing of their product.
- Maintaining records of misuse and potential liabilities of their product.

In protecting intellectual property, designers generally go through a step-by-step process to determine the novelty of the product, and to ascertain as to whether the product is worthy of future investment in time and research. These steps generally include describing the product in terms of its use, its purpose, its novelties and its significant advantages.

While the use and purpose of the device tends to be the idea itself, determining novelty and advantage requires research and development. The novelty of an idea is justified by an extensive review of preceding and tangential technologies. This requires a historical background review that presents an overview of the evolution of the significant incorporated technologies. In addition, reviewing current technologies in the market, which may be considered competitive or as the basis of substitution, is a fundamental task as well. The advantages of the product can be based on the patient's perspective or from the physician's perspective. For example, from a patient's perspective, how will this device improve well-being, recovery, monetary cost...etc. From a physician's perspective, how can this device also reduce liability while improving diagnostic or curative capabilities?

In developing a preliminary market analysis model, several key questions are usually addressed. These include:

- How should the product be tied to the market? Is the product diagnosis-oriented or procedure-oriented? Is it specific to a particular disease or condition, or can it be applied across a broad spectrum? For example, an IV system can be used for various diagnoses; however, glucose monitors are predominantly used by diabetics.
- How accessible is useful data and at what cost?
- Do any medical associations provide useful data?
- Is it appropriate to obtain data by classifications of severity?
- Given the current market, where do potential competitors and substitutes fit in? Where are their geographic strengths and weaknesses?
- What is the market size?
- What percentage of the market must be captured to achieve profitability assuming product cost of $X.00?

The cost analysis model generally consists of six separate categories. These are general and administrative costs, research and development costs, production costs, marketing and promotion costs, distribution costs, and equity costs. Upon creating such a cost model, various competitive comparisons can be made that present economic advantages of using new technologies.

Product Failure and Litigation Risk

So far, four areas of new device technology have been briefly discussed, these being government regulation, novelty of an idea, the market, and production costs. An additional area to consider is the potential of product failure and the risk brought upon by the device design, the production process, the use of the device and the outcomes of the device. Such product failures can lead to patient harm and should be reviewed for the potential adverse outcomes of product liability.

These failures need to be identified during the design phase. Generally, failures are identified by theoretically allowing an aspect of the design to

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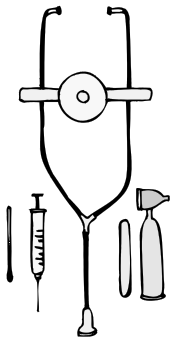
fail, misusing the device and/or considering the biocompatibility of an individual. For example, imagine the product is a portable electro-muscular stimulator. Several potential failures may include:



- Voltage indicator reads too low, (design failure).
- Voltage indicator reads too high, (design failure).
- Electrodes are placed incorrectly, (misuse of device).
- Electrodes are used without conductive gel, (misuse of device).
- Frequency used causes seizures similar to epilepsy, (biocompatibility).
- Over sensitivity to electrode material, (biocompatibility).

For each of these failures, risk and its associated cost must be defined, quantified and reduced sufficiently to make the product economically feasible. Risk and the cost outcomes can be better assigned by answering the following questions:

- What are the causes of these failures?
- What is the likelihood that such a cause will happen?
- What adverse patient reactions can occur?
- What is the severity of the reaction?
- What actions must be taken to reduce this risk?

Looking at two of the above, adverse outcomes can be developed to better estimate the potential of product liability and any litigious concerns that should be addressed.

Failure Study Example #1, Voltage indicator reads too low.

- What are the causes of these failures? Possible internal circuit component failure in analog/digital control component. Possible error in calibration of device.
- What is the likelihood that such a cause will happen? 1 in 100,000? 1 in 1,000,000?
- What adverse patient conditions can occur? If input of voltage is greater than believed to be input, second or third-degree burns, possible skeletal fractures from excessive contractions, potential for heart defibrillation and potential for seizures may occur.
- What is the severity of the reaction? Moderate litigation damage for burns and fractures. Catastrophic litigation for heart conditions and seizures. $100,000? $10,000,000?
- What actions must be taken to reduce this risk? Allow for preventative design measures to calibrate device and to limit voltage potential to a maximum safety level.

Failure Study #2, Electrodes are placed incorrectly, (misuse of device)

- What are the causes of these failures? User doesn't follow indications and directions.
- What is the likelihood that such a cause will happen? 1 in 20? 1 in 100?
- What adverse patient reactions can occur? Little or no muscle stimulation enacted. Potential for burns if voltage is increased to create a stimulus response.
- What is the severity of the reaction? Nuisance litigation. Return of product.
- What actions must be taken to reduce this risk? Proper training demonstration of device through distribution system.

Role of the Actuary

Actuaries persistently take on an integral role in the decision-making process, the development and maintenance of a financial system. This is evident in many arenas including but not limited to medical insurance, managed care, provider networks, long-term care and continuing care retirement communities. In taking on this role, actuaries draw upon several areas of formal training including economics, statistics, financial modeling and risk management, which is a broader span of knowledge than an economist, a statistician, or an MBA can provide. This fundamental knowledge base is essentially transferable in addressing potential consulting needs of a medical device company.

In addition, the actuary's knowledge and experience can be significant in designing and maintaining a financial model for a medical device company. Such a model will not only assist in determining and understanding the cost benefits for all parties involved (medical device company, consumer, provider network, insurance carrier, managed care organization, society as a whole), but also provide a tool to continually and dynamically reassess any risk implications borne upon a medical device and the consequences of addressing or ignoring the risk. In this manner, the actuary provides a sound demonstration, often the best marketing tool to potential buyers, addressing a win-win scenario for all affected parties.

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