The Costs of Regulatory Noncompliance in the Medical Device Industry: Is it Worth the Gamble?

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The global medical device market was valued at $350 billion dollars in 2012 (Mddonline.com, 2012). The US market was valued at $127 Billion dollars in 2013 making it the largest medical device market in the world (Prweb.com, 2013). However, millions of dollars are lost every year due to regulatory noncompliance issues and related lawsuits.

In the US, the Food & Drug Administration (FDA) is responsible for ensuring that medical devices are safe and effective. This is accomplished through the regulation and oversight of science-based information, manufacture, marketing and distribution of medical device products (FDA, 2013). Companies wishing to market their medical devices are required to meet and prove they are in compliance with various regulatory requirements throughout the products' lifecycle. Any deficiency in the regulatory process is recorded and made public by the FDA. This information is provided in publication of company warnings and recalls and weekly enforcement reports on the FDA website. This level of transparency allows consumers and patients alike to become aware when a company is experiencing persistent quality problems.

In addition to quality issues posing a significant risk to patients and medical personnel alike, persistent quality issues can also adversely affect the financial profitability of the company. For example, recalls can increase the costs of the company by:

- Increasing costs for the correction of quality issues
- Increasing costs required for replacing a defective product/part
- Incurring the transaction costs of the recall process
- Incurring the cost of all the unsold inventory

Recalls can also have additional impacts which reduce company revenue including:

- Loss from product recall (above list)
- Decrease in sales of related products
- Spillover effects
- Loss of market share

Lastly, recalls and warnings can adversely affect the credibility and reputation of a company. Consumer confidence can decrease sharply in response to the assumed inability or unwillingness to produce high quality, safe and effective products.

Unfortunately, a direct assessment of these costs and the resulting lost revenue are very difficult to assign a specific dollar amount to and no public information is available. However, by looking at some of the current lawsuits that have resulted from quality issues, it's apparent that the costs are high.

The DaVinci Robotic Surgery device by Intuitive Surgery Inc had reported problems with cracks leading to accidental perforations, serious injury, and even some deaths. The FDA issued warnings to this company on this device in April of 2001, citing lack of premarket approval for expanded indications in cardiac surgery. In July of 2013, the company was cited for nonconformance of Current Good Manufacturing Process for the device's tips covers. A voluntary recall of the device was made in 2013. As a result of problems associated with the DaVinci Robotic System, numerous lawsuits have been filed and the company is still in litigation. However, shares of the company stock in March 15, 2013 were down $8.62 per share which brought it to $484.75 per share. As of the writing of this article, Intuitive Surgical share is down to $425.22 per share.

One of the largest lawsuits in recent history involved company giant Johnson & Johnson/Depuy and their metal on metal hip implants. Patients and doctors complained of injury and damage due to fretting and corroding of metal components. In 2013, the company agreed to a settlement of 2.5 billion dollars in compensation to be paid to over 8,000 patients who had to have their artificial hips removed and replaced with another device. The company also agreed to pay all of the medical costs associated with the procedures and expenses which may raise the overall costs to 3 billion dollars (Meier, 2013).

Stryker reported in 2013 that it expects costs associated with litigation from recalls for its ABGII and Rejuvenate to run between 700 million and 1.3 billion dollars. These devices were found to corrode which resulted in pain and swelling for patients (Walker, 2013).

Also in 2013, Bard was hit with a 275.1 million dollar litigation charge relating to lawsuits for the Avaulta vaginal mesh. The device was linked to erosion, pain, organ perforation, and recurrent urinary problems. This financial hit resulted in a sizeable net loss for the company (Hollmer, 2013).

Lawsuits can't be discussed without mentioning Poly Implant Prosthese (PIP). PIP was a French company that supplied silicone breast implants in Europe. Although their products were not sold in the U.S., the financial toll due to not complying with regulatory directives was catastrophic. Medical problems arose when the breast implant ruptured causing inflammation and pain. They were banned in 2010 after it was discovered that they were made from industrial grade silicone (Jones, 2012). The company is now bankrupt from the extensive lawsuits and PIP executives were charged with aggravated fraud and risk maximum prison time of five years each plus fines (Rosnoblet, Libert, & Sage, 2014).

Looking through the FDA recalls and warning letters, it is apparent that many of the issues cited by the FDA are related to manufacturing processes and quality issues. Such inadequacies have the high potential of adversely effecting company bottom lines. Medical device manufacturers can benefit greatly by tightening up their current good manufacturing processes, design controls and quality systems. Adhering to the regulatory requirements will help mitigate serious financial loss from recalls and lawsuits.

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About the Analyst

Donna Mitchell-Magaldi

Analyst Donna Mitchell-Magaldi has been with Nerac for over 12 years and partners with medical device companies, serving them in many capacities. Donna's particular expertise is within the dental field where she was involved all areas of dental hygiene, radiation, and restorative dentistry, oral surgery including implants, extractions, and periodontal treatments, prosthetics and orthodontics. As an Analyst at Nerac, Donna has been exposed to a variety of other medical device disciplines such as cardiovascular, medical imaging, endodontics, biomonitoring and medical sensors, orthopedics, gastrointestinal and more. Over the course of the last several years, Donna has been assisting our medical device clients with meeting the MedDev 2.7.1 Rev 3 "Guideline on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies" and other regulatory issues, market analysis, prior art research, research to support R&D initiatives, patient landscape, FDA clinical literature support, and much more. Ms. Mitchell-Magaldi has wide-ranging expertise, encompassing medical device regulatory; dentistry (devices, equipment, procedures, dentifrices, hygiene, impressions, prosthetics, implants, orthodontics, periodontals); medical devices (including imaging diagnostics, catheters, shunts, and syringes); radiography; environmental topics (the effects on wildlife and habitation, strategies to protect endangered ecosystems, species, and food-chain effects); ecology (population dynamics, animal behavior and organismal biology); and laboratory analysis (trace metal analysis, IACUC, lab safety, inductive couple plasma and atomic absorption).

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