

TITLE

The Financial Risks of Non-Compliant Medical Devices

AUTHOR

Jasmine Birlew

Degree candidate for Master of Science in Regulatory Affairs at Johns Hopkins University

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INTRODUCTION

Many professionals that have worked on the regulatory/quality side of medical devices have experienced the financial gains and losses a company goes through during its natural life cycle. Coupled with these gains and losses generally includes environmental changes to the company's practices and resources. Of note, is when a company experiences a restructuring or budget cuts that create a shift in resources. It is during these times that companies tend to target departments that do not generate income or profit¹. Specifically, support departments are targeted and consequentially experience a loss of resources due to budget cuts or to maximize the efficiency and decrease operational costs². Legal departments such as regulatory departments are generally considered to be a support department³. The hypothesis of this study is that the quality of the product declines because the company puts itself at regulatory risk which costs the company more in the long term.

This study will review the financial risks of non-compliant medical devices by assessing current reported reasons why and how a medical device manufacture places itself at risk of non-compliance, what the legal ramifications may be for being non-compliant, the costs of the legal ramifications for being non-compliant, and assessing if it is worth being at risk for non-compliance.

Why do companies fall into non-compliance?

When we speak of compliance, we are referring to the existential laws that exists and are enforced to help facilitate quality medical devices. Food and Drug Administration (FDA) defines a quality medical device as products that are safe and effective⁴. With this logic, regulatory compliance can be considered synonymous with quality. When performing the research in this paper, multiple industries were researched to find associations between resources and

employee motivation (otherwise known as employee morale); this is to help facilitate the psychological impacts of budget cuts on employees as there is limited research on this topic in the medical device industry alone.

The first correlation of consideration for the relationship between non-compliance and downsizing exist in the corporation publicly announcing a downsizing event and then in the timespan of 1-3 years, FDA cites the company in a non-compliant event. The following companies provide an appropriate example of this phenomenon:

- On January 4, 2013 Accuray announced a global restructuring and a strategic effort to cut 13% of its employees as a result of the “strategic transformation”⁵. On January 27, 2014, Accuray, Inc. posted a product recall for their CyberKnife Robotic Radiosurgery System⁶.
- On January 9, 2018 Medtronic announced a global restructuring initiative to cut costs by \$3 billion; they dubbed this the “enterprise excellence program”⁷. On July 30, 2018 and August 23, 2018 Medtronic received two warning letters stating that the company’s products were adulterated^{8,9}.
- On August 20, 2014 Invacare Corporation announced a restructuring initiative to help save up to \$14-15 million¹⁰. On December 12, 2014 Invacare Corporation posted a recall for their Invacare Perfecto 2 V Oxygen Concentrator due to process control issues¹¹.
- On October 09, 2014 Philips announced a restructuring that would result in job losses but save up to \$342 million USD¹². On August 18, 2017 Philips was issued a 483 due to several non-compliant quality citations¹³.
- On August 30, 2012 St. Jude Medical Announced that 300 employees were going to be let go in a restructuring initiative that would help save \$50-60 million per year¹⁴. On September 30, 2015 a warning letter was issued to St. Jude Medical by FDA for having adulterated medical devices¹⁵.

Why does a company downsize lead towards non-compliant events? It is postulated that the companies face non-compliance after downsizing due to a substantial decrease in employee resources. Surviving employees become burdened with additional tasks and work¹⁶. Additional burdens decrease the ability to focus on quality tasks and a decrease focus on quality tasks leads towards a lower quality product. Additionally, greater work burdens affect employee morale. One study by Ko et al. showed that downsizing a company had a significant negative impact with the employee job satisfaction¹⁷. A study by Huang et al. found that downsizing companies leads towards an increased probability of employee deviance which ultimately costs more money in the long run¹⁸. Employee deviance in this study refers to employee behavior which harms the organization. A study by Hopkins et al. found that the perceptions created by employers initiating the downsizing to employees is negative in the eyes of the employees experiencing the downsizing or hold sentiment to employees that are being laid off¹⁹. This perception can lead towards a decline in moral, productivity and competitive problems as well as professional problems for the company.

Further research has found that low morale affects the quality of the employees' work. A study by Mefford found a link to employee morale and product quality in that an employee is more likely to have a stronger work ethic if their moral and job satisfaction is high²⁰. Another study found that the consequences of low employee moral results in a low cognitive performance, low focus, inadequate performance, skill set decline, fatigue, anxiety, stress, and an overall decline of quality²¹.

Legal ramifications of non-compliance:

As quality begins to diminish the company is now at risk of non-compliance; low resources and low moral leads to legal ramifications of non-compliance. There are various legal consequences to non-compliance. Some of them are minor, others are severe. A minor citation may be given

by FDA as a 483 form²². This form is provided after an inspection by an FDA investigator and lists issues of concern. The company is expected to address these observations and find appropriate resolutions. Such observations may lead towards reputational risks, but can usually be addressed with no penalties or fines by FDA.

The next tier of FDA non-compliance is issued in the form of a warning letter. A warning letter may include a more serious observation by FDA and require the company to outline an appropriate response to said observations. Beyond 483 forms and warning letters, the FDA's penalties become significantly more detrimental to the company. These penalties include seizure, injunction, and even criminal prosecution²³. Penalties that may incur per law and legal cases on major citations can range from \$100,000-\$500,000 per offence and possible imprisonment.²⁴

A severe example of potential fines that a company can receive from FDA is the case of Terumo Cardiovascular Systems Corp. In 2011, FDA fined Terumo \$35 million and also placed manufacturing restrictions on the company²⁵. Manufacturing restrictions are often issued in the form of legal injunctions. It's also possible to have product recalls and/or seizures in these instances. A seizure from FDA is when the company's FDA approved product is removed from the market to minimize potential public harm²⁶. An injunction is when the court prohibits the medical device manufacturer from performing a specific act²⁷. This act is generally one that was in or leading towards a violation of the law. Criminal prosecution includes possible fines and imprisonment for 1-3 years²⁸.

These fines and penalties can be incurred by either an individual or a corporation depending upon the circumstances. For example, in 2015 Maquet Holding B.V. & Co. had a permanent injunction filed against them to halt all manufacturing of specific medical devices²⁹. This injunction also included two of the company's officers: Heinz Jacque and Gail Christie. In 2015 Medtronic received a legal injunction to stop the manufacturing and distribution of an

implantable pump³⁰. In 2017 Philips received a permanent injunction to halt production of their defibrillators³¹.

Costs of Non-compliance:

The potential costs of legal injunctions can be detrimental to a company's profits. For example, when Philips received its injunction to halt production of their defibrillators, the company projected that they would lose gross earnings of around \$23.1 million³². Additionally, their shares dropped by 1.57% (which was around \$40.22 per share), which is an expected consequence of a company losing its reputation³³. When a company faces non-compliant scenarios and legal fines and penalties it affects their reputation. When a company's reputation is at risk it affects customer and investor loyalty and thus stock potentials³⁴. For example, in 2016 the company Syncardia filed bankruptcy following a medical device class I recall³⁵. This announcement came shortly after the company pulled out of a \$27.5 million public offering deal. As demonstrated, there are cases where downsizing or restructuring a company leads towards financial and non-compliant risks. These non-compliant risks can be a side-effect of the aftermath (e.g. loss of resources, funding, etc.). Additionally, common practices for corporations are to target either non-productive and non-profit generating departments and/or employees. Alternatively, companies may target senior employees depending upon the premises for their layoffs. A company can save millions and potentially billions from downsizing. As mentioned with the following companies:

- Medtronic planned to cut costs by \$3 billion.
- Philips planned to save up to \$342 million.
- Invacare Corporation hoped to save up to \$15 million.

Risks and Benefits of Non-Compliance:

Historically, the minimum risk of non-compliance can be something as simple as an observation from FDA. The maximum risks can range from millions of dollars to imprisonment with a loss of reputation and a chance of the corporation dissolving. Because of this, it is best to ascertain whether any risk a company takes is worth it. Every company experiences risk, it's an intricate part of running any business. However, one must weigh the costs of the risks before executing them. When seniors are let go, extensive regulatory knowledge is lost. When regulatory and quality resources are cut back, proper regulatory checks and balances are at risk. Restructuring within a company may be a result of financial issues or an attempt to maximize efficiency, but whatever the case it is a risk that the company is taking.

Risks are taken when new senior management is hired, risks are taken when mergers happen. These are things that may be worth risking. Risks that affect the company's quality, reputation, and legal compliance are not risks worth taking.

This research would suggest that the risks outweigh the benefits. The benefits of compliance extend beyond financial risks. Proper compliance provides a legal map to high quality products and loyal customers. Utilized properly, regulatory and quality personnel can be used for more than just regulatory principles. These individuals generally work in cross functional groups across the company and as such maintain company oversight that most employees don't see. This oversight can be utilized to identify strengths and weakness within a company which may ultimately lead towards process improvements and cost savings.

Conclusion:

In summation, the value in maintaining compliance extends beyond the costs, it extends to the reputation, the moral, the legal protection, and the longevity of the company. Companies fall into non-compliance for various reasons, notably however, is cost cuts to departments that directly affect product quality as a result. The legal ramifications of non-compliance can be severe and not worth the risks. Additionally, compliance helps protect companies beyond a regulatory standpoint, it helps

protect the company's legal integrity. The financial risks of non-compliance outweigh the savings, in that there are also reputational costs that incur, and as a result, company longevity risks.

Some minor risks may be worth taking for a company as long as it doesn't affect the overall compliance of the product; a company needs to weigh the risks carefully. The benefits of full compliance far outweigh the risks of non-compliance. Beyond legalities, reputation and other risks, full compliance creates a strong integrity and network within the manufacturer's quality system. This network allows for the identification of manufacturing risks, inefficiencies, and other unforeseeable resources that are not often utilized from a regulatory standpoint.

Non-compliance is not a risk worth taking due to potential legal risks and the costs of the legal ramifications; despite the reasons why a company falls into these positions. Instead, a company should consider what additional resources can be gained from a regulatory standpoint as regulations create an oversight into the company's strengths and weaknesses and as a result may help increase efficiency and ultimately save money through other means.

Finally, while this evidence is on a broad level, it does help provide points that can be used for further research. There is a strong correlation between product quality and available resources to the employees. While companies need to take financial risks, further research in this matter can help them maintain their product integrity when making such decisions.

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