

Understanding the Financial Risks of Regulatory Non-Conformance

February 2007



Abstract

The following paper summarizes a breakfast roundtable discussion of understanding the financial risks of regulatory non-conformance that was held in November, 2006. The event featured a panel of three industry leaders, who shared their experiences and interpretation of this critical topic. An interactive question and answer session followed. A number of suggestions were provided demonstrating how regulation conformance can help protect corporate reputations and avoiding fines and costly litigation. The panel was moderated by Dr. Donald A. Deieso, President and CEO of EduNeering, and the three panelists were:

- Jill Wadland, Vice President, Life Sciences Casualty Manager, Chubb Commercial Insurance
- Cliff Saffron, Principal, Pharmaceutical Advisory Services, Corporate Governance and Enterprise-wide Risk Management, KPMG
- Martin Browning, President, EduQuest

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Background

EduNeering's President and CEO Donald A. Deieso recently moderated a breakfast roundtable program featuring three industry leaders who addressed the financial risks of regulatory non-compliance. In attendance were Chief Financial Officers and Chief Compliance Officers, from life science companies of all sizes, who heard presentations and participated in interactive question/answer sessions with these panelists:

The session demonstrated the intersection of risk management, regulatory compliance, and financial performance. The panelists explained the financial risks and necessary responses by pharmaceutical companies. The three panelists were:

- Jill Wadland, Vice President, Life Sciences Casualty Manager, Chubb Commercial Insurance, who works with life sciences companies globally to develop insurability and risk management programs;
- Cliff Saffron, Principal, Pharmaceutical Advisory Services, Corporate Governance and Enterprise-wide Risk Management, KPMG, who has created and overseen the implementation of corporate governance initiatives mandated by NASDAQ, SEC and Sarbanes-Oxley and advises life sciences companies;
- Martin Browning, President, EduQuest, who has had 22 years of experience with the Food and Drug Administration (FDA) as an expert investigator and as Special Assistant to the Associate Commissioner for Regulatory Affairs. He now advises life sciences companies on regulatory compliance and risk assessment.

The panel moderator, Dr. Donald A. Deieso, is President and CEO of EduNeering, the leading provider of compliance knowledge management solutions to assure regulatory compliance and improve business performance.

The Role of Insurance

To set the scene, Jill Wadland described a scenario and timeline of a product recall and the cascading impacts and consequences arising out of the offending organization's non-compliance.

Being in the insurance industry often means that insurance professionals be around "bad" things. In today's business environment with ever increasing scrutiny driven by a regulatory environment, companies need to put things under a microscope and dig much deeper to try and envisage potential consequences of non-conformance. The insurance industry under-

stands that bad things happen, but it's how companies respond that makes a difference.

Insurance companies do not cover ALL things that go wrong – Ms. Wadland examined some of the very significant consequences that are not covered by insurance when it comes to a product recall:

- The cost of removal of product from point of sale
- Communications expenses involved with the recall
- The loss of revenue and profit represented by the recalled product
- The reputation damage to the company and its downstream effect
- Increased scrutiny from the FDA
- Department of Justice involvement – criminal penalties are not covered
- Loss of morale and subsequent (loss of) productivity on the part of employees
- Civil litigation (class action suits) and all the time it takes
- Negative impact on the stock price for a public company
- Venture capital drying up for a start-up
- The inability to get insurance coverage moving forward

All of these imply there needs to be a greater level of scrutiny of company procedures as it is an understatement to say that it is a huge distraction when a product recall in the life sciences sector occurs.

Increasingly, most large pharmaceutical companies are going bare and do not carry insurance, stated Ms. Wadland. With self-insured retention ranging between \$250 million and \$500 million, the cost of most future law suits will have to come from the bottom line. It's clear that companies that operate with a solid risk management program will get the best rates because they get it right. You certainly can't think quarter to quarter if you are in Quality Control or risk management. The terms and conditions will vary based on the "thinking" of the company (with regard to quality and compliance).

The primary thought driver when it comes to the issue of compliance needs to be: Insurance is no substitute for proper risk management.

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The Financial Impacts of Risk

In addressing the financial impacts of risk, Cliff Saffron cited his past experiences serving as general counsel, where he drove the turnaround in reestablishing risk management following the legal and regulatory woes his employer faced a few years earlier. He also cited examples of the results of non-compliance at several high profile companies. One company is now just recovering from prior missteps in manufacturing, but it took outstanding leadership to steer that ship. Another company had a huge manufacturing issue in vaccines a couple of years ago, is now run by Novartis. Another company is now under scrutiny by the FDA for channel stuffing issues.

However, for many companies, the good news is that senior management is starting to get it – often driven by their boards of directors and audit committees, according to Mr. Saffron.

In the sales and marketing arena there are two primary risks to companies in the industry:

1. The promotion of unapproved indications;
2. Payments to healthcare professionals. Both the federal government and individual states are becoming increasingly involved in this contentious issue. This presents a challenge to companies who now (will) have to report on a state by state basis.

Mr. Saffron described a worst case non-conformance scenario for a public company:

- If they do not file their quarterly reports because of regulatory issues, they could be delisted
- Stock option backdating is becoming a bigger issue
- Negative effect on stock price impacting their ability to raise capital

As examples, Mr. Saffron cited Merck and GSK, who have been fined billions of dollars for tax non-compliance. This threat of non-compliance opens up an opportunity for other companies. There is a great deal that can be done to avoid the above examples of non-compliance, such as:

1. Introduce proactive risk management;
2. Identify the areas of non-conformance, mitigate against them and prioritize them as one cannot possibly deal with them all at the same time.

However, having said that, this principle is not something that a lot of companies embrace, hence the ongoing high profile incidents of non-confor-

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mance that find their way to the front pages of newspapers and business magazines.

What the FDA Expects

Martin Browning conveyed to the executives present that creating a culture of compliance and quality would enable them to avoid problems.

While the FDA gives companies many chances, since 1992 more than 4,000 people have been arrested and more than 3,000 have been convicted.

- The FDA is concerned with risk to patients and products
- The FDA is slow to change the rules so many US companies wanting to operate globally have to live by a combination of US and European regulations
- But, the FDA can prosecute you and send you to prison
- It is difficult to regain the trust of the FDA if you have done wrong.
- While the FDA gives companies many chances, since 1992 more than 4,000 people have been arrested and more than 3,000 have been convicted.
- Companies have been fined billions of dollars, assets have been forfeited and laboratories have been disqualified from performing R&D
- Although products are approved overseas, the FDA can refuse entry of your product to the US market causing one company to recently lose \$5.5 billion in estimated sales.

The state of the industry in terms of its own measurement is not healthy. As Mr Browning noted, the industry numbers tell the story:

- Billions are lost because products are not shipped.
- The numbers of recalls have increased at huge cost to the companies involved.
- Recalls are because of a violation of the law and means companies are compelled to take corrective action.
- The FDA wants companies to follow a preventative approach to non-conformance.
- The FDA wants to mitigate both patient and product risk.
- Very importantly, the FDA wants companies to manage their process risk. Unfortunately, however, the industry does not understand its processes very well.

Recent enforcement actions involving the Anti-Kickback Statute and False Claims Act put life sciences companies under the microscope regarding the selection and payment of “key opinion leaders” working on behalf of the Company.

The FDA is slow to make changes but it will tighten the screws over the next few years, according to Mr. Browning. This will result in the life sciences industry getting an increased focus of attention from Congress, the public and many other stakeholders.

Mr. Browning closed by stating that life science companies need to learn how to evaluate risk and move to risk avoidance in preference to operating in a reactive mode. They need to establish good, coherent and workable solutions that incorporate technology with knowledge and expertise. The culture and attitudes about compliance must change—that is the key.

Question and Answer Session

The highly interactive Question and Answer session saw the following points made:

- Sarbanes-Oxley, which was introduced primarily as a financial regulatory measure whereby CEOs and CFOs had to sign off a company’s financials as being totally accurate, is now being used to measure other areas of a company’s performance, including clinical and sales & marketing. Bausch & Lomb is a case in point – they were recently served notice by the SEC because supply chain (agreements) had not been audited for years. The FDA is refocusing on data integrity – from planning to the supply chain i.e. all the processes. If companies don’t have control of these processes, there will be repercussions all the way up to the C suite of companies.
- There is a significant issue today on the Sales & Marketing compliance front, related to the use of contracts for consultants. Recent enforcement actions involving the Anti-Kickback Statute and False Claims Act put life sciences companies under the microscope regarding the selection and payment of “key opinion leaders” working on behalf of the Company.
- In order not to fall foul of the FDA and the SEC, companies have to make a commitment to risk management with an in-depth assessment of all processes; they have to prioritize this list and, most importantly, they have to be committed implementing and maintaining it. Part of the problem is that assessments are not granular enough. Companies need to understand the environment they are in – compliance with the FDA is not going to protect companies falling foul of regulations. It cannot be taken for granted that all is well. Companies need a more rigorous risk management effort and take this assessment to the next level of scrutiny e.g. “do you audit what your salespersons say to doctors by asking the doctors what’s been communicated – without the salesperson being present?”

Companies must not take a silo approach to risk management - it has to be enterprise wide.

- Companies need to prioritize their risk management actions. For a start up company it could be concentrating on their R&D operation and in the case of a mature company, it could be a focus on sales and marketing and manufacturing divisions.
- Communications with the C-suite could be a problem and mid-management translation of the issues to upper management must be improved. However, if risks can be translated into hard financial implications that will affect a quarter or a year's results, issues become to ignore.
- Companies must not take a silo approach to risk management – it has to be enterprise-wide. Very often one gets a more objective view of risks from someone in another area of a company who is able to see/perceive something people directly involved with the issue on a daily basis are not able to.
- Corporate compliance and a progressive ethics program can mitigate the penalty if a company falls foul of regulations. Recently one company that had no compliance policy was fined \$1.5 billion dollars while another, which had a robust compliance plan, was fined \$35 million. While the latter made a mistake, they were doing what they were supposed to be doing in terms of risk management. Another mitigating factor is a company's speed and integrity of its response to issues that arise.
- Finally, plaintiff attorneys are getting smarter. They took \$250 billion from the tobacco industry and they are gearing up to take \$750 billion from the life sciences industry. Companies need to understand they are going to have to pay for things even if they have done no wrong. They will have to pay because they have the money.

Conclusion

The conference concluded with the panelists disclosing several “golden rules” that, if followed, would greatly enhance the potential for conformance to regulations, thereby protecting corporate reputations and avoiding fines and costly litigation. They include:

- Having insurance is no substitute for a rigorous risk management program – even if a company can get and is prepared to pay the substantial premiums.
- The downside to non-conformance is life threatening to companies, their employees, their customers/patients, and their shareholders.
- While recognizing that changing behavior is never easy, a culture of compliance needs to become part of an organization’s fabric.
- All indications are that plaintiff attorneys are gearing up for a massive onslaught on the life sciences sector.
- Companies should seek knowledge management technologies to resolve issues of risk, knowledge and performance; this technologies could include interactive computer-based training, document control system that assures receipt and comprehension of Standard Operating Procedures (SOPs) and corporate policies to Codes of Conduct, regulatory updates, safety procedures, and human resource communications

About EduNeering

EduNeering (www.eduneering.com), a Deloitte Technology Fast 500 Company, develops technology-enabled knowledge solutions for improving business performance and assuring regulatory compliance.

For more than 25 years, the company has served corporate and government clients in the life sciences, healthcare, energy and industrial sectors using proprietary platforms that integrate business, learning and technology. Additionally, EduNeering maintains several unique partnerships with its clients, including a Cooperative Research and Development Agreement with US Food and Drug Administration.

Headquartered in Princeton, NJ, EduNeering Holdings, Inc. has offices in Houston, TX; Bloomsburg, PA; and the UK.

EduNeering's Headquarters
202 Carnegie Center
Suite 301
Princeton, NJ 08540
Tel: 627-5300
Fax: 609-627-5330

EduNeering's UK Office
19 Cotswold Way
Ashby de la Zouch
Leicestershire, UK LE65 1ET
011-44-7813-677728
011-44-1530-450585 (Fax)

EduNeering's Houston, TX (US) Office:
EduNeering
3700 Bay Area Blvd.
Suite 550
Houston, TX 77058
Tel: 281 709 0900
Fax: 281 709 0907

EduNeering's Bloomsburg Office
30 East 6th Street
Bloomsburg, PA 17815
(570) 387-9121
(570) 387-9122 (Fax)



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