MARSH

Life Sciences Risk Study

TREATING THE SYMPTOMS OF A DRUG RECALL

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On July 13, 2018 the US Food and Drug Administration[i] (FDA) issued a voluntary recall of several drug products containing the active pharmaceutical ingredient "valsartan", used to treat high blood pressure and heart failure. This recall was due to an impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled products. NDMA, an organic chemical, is classified as a probable human carcinogen (a substance that could cause cancer). Amongst other products, the chemical has been used to make liquid rocket fuel, softeners, and lubricants[ii].

The FDA's recall came after 22 other countries issued recalls involving 2,300 valsartan batches sent to Germany, Norway, Finland, Sweden, Hungary, the Netherlands, Austria, Ireland, Bulgaria, Italy, Spain, Portugal, Belgium, France, Poland, Croatia, Lithuania, Greece, Canada, Bosnia and Herzegovina, Bahrain, and Malta.

FDA scientists estimated that if 8,000 people took the highest valsartan dose (320 mg) from the recalled batches, daily for the full four years, there may be one additional case of cancer over the lifetimes of those 8,000 people.

This problem was confirmed during tests by the European Medicines Agency, [iii] of batches of valsartan from a Chinese supplier, who we'll call Company XYZ, containing the impurity. The Chinese supplier had raised the alarm and voluntarily suspended its supplies in the international market, after detecting the impurity. The agency said the impurity was a result of a change in the manufacturing process [iv].

Recalling drugs is a very common practice in the Life Sciences industry. It's a good strategy to avoid future litigation, especially if the tainted products are out in the market for a long period.

To offer context, failed specifications account for 40.7% of pharmaceutical recalls. In 2018 to date the FDA has ordered a total of 38 drug recalls. 2017 saw the FDA recall 58 drugs[v].

Despite such staggering numbers, there continues to be little awareness in Asia about the risks a recall incident can pose to a company's balance sheet. Further, while there are agencies to evaluate medicinal products in Asia, they are country, rather than regionally based, and criteria and standards vary across countries.

LET'S LOOK AT THE CASE STUDY CLOSELY

Company XYZ is Chinese pharmaceutical company. It had supplied the active pharmaceutical ingredient for this drug to most major pharmaceutical companies across the globe. It sold CNY328 million (US$50 million) worth of the ingredient in 2017. A small error, which could be human, impacted 2,300 batches and led to recalls in 23 countries, and a stock price drop of 20% on the Shanghai Stock Exchange (SSE).

Recalling the drug in 23 countries will entail direct costs and indirect costs:

- Direct costs involve the cost of the product such as: packaging, freight, transportation, distributor margins, retailer slotting fees, advertising costs, and reverse logistics (most contaminated drugs are required to be destroyed. This entails destruction costs of the goods which can be expensive and include the cost of licenses.)
- Indirect costs include: lawsuits, stock value declines, fines and penalties especially if it's a lifesaving drug, loss of licenses (in the case of a contamination this includes licenses for an FDA approved plant), lost sales, etc.
- On top of this are the reputation-based, business impact costs – also indirect costs. According to a consumer poll conducted in 2014 by Harris Interactive, a market research firm in Rochester, NY, after a product recall, 55% of consumers polled would temporarily use a different brand, almost 15% wouldn't buy that particular recalled product again, and 21% wouldn't buy any brand associated with the manufacturer[viii]. These costs can be crippling, and have led many businesses to downsize or even close as they are hit hard by both direct and indirect costs.

As noted above, Company XYZ was also listed on the SSE, and the market was quick to respond with more than a 20% stock slip reported widely.

ESTIMATING THE COSTS OF A RECALL

DIRECT COSTS

Price of recalled product × **Quantity of recalled product** + **Notification costs (4%)** + **Transportation cost (10%)** = **Direct cost of recall**

INDIRECT COSTS

Litigation | **Stock value decline** | **Fines** | **Loss in sales** | **industry impact**

Source: https://foodsafetytech.com/news_article/trends-real-cost-product-recalls/

A FOCUS ON INDIRECT COSTS

Most direct costs can be addressed by comprehensive recall insurance or a contaminated products insurance policy, both of which are widely available.

In contrast to direct costs, indirect costs are not quantifiable, and they are not predictable. A company doesn't know whether they will occur or not, and, if they do occur, which of them will occur and in what order of magnitude. Indirect costs can arise over a long period of time, which is an additional complexity and interruption when a business wants to mop up and move on.

The remainder of this article examines indirect losses and costs, and what insurance protections could be put in place to minimize these types of losses.

DIRECTORS & OFFICERS INSURANCE

Most well designed Directors & Officer's insurance policies offer cover for derivative lawsuits, actioned by investors.

A derivative lawsuit is a type of lawsuit brought by one or more stockholders, on behalf of a corporation, alleging financial loss to the organization. For shareholders to pursue a derivative action, the alleged harm must be to the corporation as a whole, such as the corporation's diminishing assets.

How does a derivative lawsuit work?

In 2004 US drugmaker Merck paid US$830 million to settle a federal class-action lawsuit involving allegations the company had failed to adequately inform investors about the heart risks associated with its now-recalled, Vioxx pain medication. This class-action derivative lawsuit arose or "derived" from issues of the drug's safety. In contrast, by 2008 Merck settled most remaining product-liability lawsuits for an additional US$4.85 billion[xi].

Let's assume Company XYZ has robust and well-designed D&O insurance. If there is derivative shareholder litigation for loss to the investors, the Directors & Officers insurance will cover:

- Defense costs.
- Risk exposure with respect to regulatory actions, investigation costs, and civil fines and penalties (where insurable by law). These coverages can be worthwhile when regulators of 23 countries are looking at you under a microscope.

It will continue to protect directors and officers and the company, regarding derivative claims (due to the final adjudication feature of the policy).

BUSINESS INTERRUPTION INSURANCE

In Company XYZ's case, there were several other companies affected by the recall – from major international pharmaceutical companies to five local Chinese companies, all of whom had to recall the drugs manufactured by Company XYZ.

This demonstrates that, in a recall situation, there are companies who suffer the loss of products which were not manufactured by them, but by their supplier. Further, it shows that one supplier's product can lead to a global crisis across different countries and companies.

In 2004, **Merck** (one of the largest pharmaceutical companies in the world) took a loss of US$725 million in sales after recalling one of its arthritis drugs due to risk of heart attacks/strokes, and paid out **US$4.85 billion** in lawsuits[vii].

Let's set aside the possible lawsuits that result from the product defect, and failure to warn allegations. These would be considered direct costs.

Instead, let's focus on the interruption to a business in a recall situation - one of the most ignored but crippling risks that organizations face in such scenarios. In insurance parlance these risks are known as "non-damage business interruption" because they arise from damage that is not physical. They include:

- Loss of profits.
- Loss of market share.
- Increased cost of working (not just now to source the products from elsewhere but also the work of searching for another vendor and reviewing their quality to supply these products back to their customers now and in the future).
- Loss of reputation.
- Loss sustained from regulatory actions that companies face because their supplier's product was tainted.
- Loss associated with suspension of manufacture as result of significant manufacturing defects/deficiencies.
- Product recall costs as result of manufacturing deficiencies.
- Costs associated with labelling errors and malicious tamper.
- Loss, damage, theft, or destruction of digital assets.
- Crisis management costs.

Cases like XYZ's would trigger a number of these loss scenarios. The important thing is that all these potential losses can be considered before they occur and minimized through risk management measures and risk transfer mechanisms, such as insurance. Where these haven't been considered, minimized or transferred, companies often find it difficult to respond appropriately. Panic can set in. Compounding this alarm is the fact that quantification of the loss is one of the biggest challenges, as the loss events can develop over a number of years and the resulting management of the loss and reputation damage can be a drawn out process.

Organizations with aware risk managers, who are able to create an understanding of these potential losses within their organizations and guide the board's planning and responses, will be in the best position to handle such crises.

Please note, this article deliberately does not discuss the potential product liability issues and corresponding insurance coverages. It's worth noting that Company XYZ did not have product liability coverage for this product, and the loss and impacts of that loss will play out in subsequent months and years.

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iii. The European Medicines Agency is a European Union agency for the evaluation of medicinal products.

iv. http://www.google.com.sg/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=2ahUKEwiB1b_9-83cAhXEzbwKHYLpDksQFjABegQICRAC&url=http%3A%2F%2Fwww.ema.europa.eu%2Fdocs%2Fen_GB%2Fdocument_library%2FPress_release%2F2018%2F07%2FWC500252167.pdf&usg=AOvVaw2gIV9Aq1rvxehQe_xHNUUY

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