In 2015, a total of 1,144 medical device recalls were initiated and another 239 pharmaceutical recalls were posted on the FDA website. While more than half of these cases were due to quality issues, product recall perils are rising on the priority list of risk managers and continue to have a major impact on the life sciences industry.

Sensitivity around the value of brand has never been greater, and with social media, information has never moved so quickly across the globe. Increased regulatory authority and oversight has also impacted the recall environment with greater frequency and severity, affecting all parts of an ever more complex supply chain. These are unfortunate events on many levels but insurance options are available.

Recall expenses
Companies who are required or who voluntarily recall products face a myriad of expenses related to the recall. First, there are expenses directly incurred by the company (referred to as first party costs). These direct expenses include:
- Media announcements and public relation expenses
- Shipping costs
- Additional storage and warehousing
- Hiring outside personnel
- Employee costs and overtime
- Product disposal
- Retail slotting fees
- Loss of gross profits
- Costs to acquire replacement product and refunds to purchasers
- Costs to reestablish market share

Next, companies could face claims for financial damages suffered by its distributors (known as third party costs). These third party liability demands can include:
- Customers’ loss of gross profits
- Customers’ loss mitigation expenses
- Customers’ costs to comply with the recall notice requirements

Is insurance available?
The insurance market has responded with several products that address some, if not all, of these expenses. However, you may find that insurers have a limited appetite for offering options to life science companies. Some will offer coverage for OTC and generic products but not branded pharmaceuticals. Some like medical devices while others shy away. Some will write topical and ingestible treatments but not injectable. Others reject nutraceuticals and food supplements. Each markets appetite varies and each policy form differs from one another. The WTW Recall Team is staffed with some of the best technicians in the marketplace, so they’re well-equipped to navigate the most innovative life science placements.
Everywhere you plan to be

Are all recalls covered?
The intent of a Product Recall & Contamination insurance policy is to respond to events where products pose injurious threats to consumers’ health, which results from a manufacturing defect or contamination. Some policies do require the physical recall or withdrawal prior to responding, and other policies will respond to the actual contamination. Examine the policy and its definition of “covered incident” or “insured event” to determine the scope of coverage.

Governmental recall coverage is also available to potentially respond to events where a government agency determines a product to be unfit for its intended use, regardless of whether the product is actually defective or contaminated. This is another critical area where policyholders must pay very close attention to their policy language, as each markets’ wording differs.

Bodily injury or property damages that may have been the cause of the recall are excluded but may be covered by a Product Liability policy. Bodily injury liability claims often arise after a company announces a recall. Be prepared and have a plan for potential future litigation resulting from a recall action.

Conducting a recall to protect consumers from injury is a proper response when a company becomes aware of an issue with its product. But recalls are expensive and only some of these costs may be mitigated by insurance. A skilled insurance broker can lead you through the maze of policy options and help you find the best solution for your risk profile.

Life science expertise

- 350 industry colleagues in more than 100 countries including 200 in USA
- More than 500 clients in North America and 700 Globally
- The most advanced loss modeling in the industry
- A globally integrated practice that operates as a key part of your team, providing industry specialist insight and complete insurance solutions

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