PRODUCT RECALL

Medical device and pharmaceutical product recalls happen with some regularity. In 2011, 48 medical device recalls and 61 pharmaceutical recalls were posted on the FDA website. These are primarily Class 1 recalls; i.e., a reasonable probability exists that the use of or exposure to the product will cause serious adverse health consequences or death. These are unfortunate events on many levels but in this article we will address the financial exposures and consequences for the manufacturers and how they might best be mitigated or dealt with.

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 (sometimes called first party costs). These direct expenses include:

- Media announcements
- Shipping costs
- Additional storage and warehousing
- Hiring outside personnel
- Overtime for staff
- Staff travel and lodging
- Product disposal
- Retail slotting fees
- Loss of gross profits
- Costs to acquire replacement product and refunds to purchasers
- Costs to re-establish the product in the marketplace

Next, the company could face liability claims for financial damages suffered by its distributors (sometimes called third-party costs). These third-party liability demands could include:

- Distributor/retail loss of gross profits
- Distributor/retail loss mitigation expenses
- Distributor/retail cost 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. But in the case of Product Recall/Contamination insurance, it’s caveat emptor...buyer beware.
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. A competent insurance professional should be able to direct a life science company to the most appropriate insurer. Don’t expect to get many quotes to compare…this is a limited market and virtually no “apples to apples” comparisons are available. Every insurer has its own unique form.

ARE ALL RECALLS COVERED?

A recall can occur when a product causes harm after it is sold and distributed in the market. For example, it may be discovered upon wide use by consumers that a drug causes an unexpected and dangerous side effect that was not seen during clinical trials. The FDA and the company may agree to recall this drug. This type of loss will not be covered by an insurance policy. Insurance covers only accidental contamination or product manufacturing defects. Examine the policy and its definition of “covered incident” or “insured event” to determine the scope of coverage.

Most people don’t enjoy reading insurance policies; nevertheless, if you are going to purchase product recall/contamination insurance, get a sample policy and read it carefully. You may find the very risk you are concerned about is excluded (e.g., gradual deterioration, decomposition or transformation of the chemical structure of a drug).

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.

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