

LIFE SCIENCES POVSM

Product Liability: Managing a Large and Growing Risk

Product liability claims pose a major threat to all life sciences companies. To minimize their exposure, organizations should exercise as much care when addressing their insurance needs in this area as they do when evaluating their basic property and casualty risks and coverage.

The following scenario illustrates the extent of loss that may occur if a business partner's insurance policy does not adequately cover potential liabilities:

XYZ Inc. is a drug and surgical product distributor serving hospitals and pharmacies. The firm is named as an additional insured on the insurance policies of the companies that manufacture the goods handled by XYZ. Appropriate risk transfer appeared to be in place until ABC Ltd., a manufacturer of alcohol wipes sold by XYZ, initiated a recall due to alleged product defects. Following the recall, ABC's plant was seized by federal marshals and placed under a consent decree by the U.S. Food and Drug Administration. Both XYZ and ABC were named as defendants in multiple lawsuits claiming serious injury, including death. Notwithstanding the indemnification agreement in place between XYZ and ABC, XYZ bore most of the costs associated with these claims. XYZ Company was unable to obtain indemnification (including defense costs) from the manufacturer, because ABC's policy had too low a liability limit – something that XYZ's leadership had failed to examine sooner.

This issue of *Life Sciences POVSM* presents a series of strategies designed to help companies reduce exposure to third-party liability claims through insurance coverage, as well as contractual indemnification and other risk management measures.

Assess potential liabilities and coverage requirements. When evaluating degree of loss exposure and insurance needs, consider both defense expenses and indemnity costs – i.e., potential verdict or settlement amounts. Other factors to be weighed include projected levels of revenue and contractual requirements with vendors and partners. A knowledgeable, experienced insurance broker is the best source of information regarding insurance coverages and limits needed to address specific risks.

Review current company insurance arrangements and those of partners. With the assistance of a broker or other insurance expert, examine coverage limits and sub-limits, as well as policy terms and conditions. Focus especially on such key provisions as automatic indemnification clauses (see below), as well as coverage for additional insureds, company sales representatives, independent contractors and punitive damages. In addition, scrutinize claim reporting requirements and other procedural matters.

Pay close attention to contractual indemnification provisions. Life sciences companies will almost certainly be required to indemnify – i.e., secure against future liability – others in the course of doing business. Therefore, when selecting an insurance program, it is essential to understand how contractual obligations affect coverage, and to ensure that the policy adequately covers all parties.

Conversely, always inquire as to the limits of liability being carried by organizations that indemnify one's own company, and confirm that indemnifying entities maintain appropriate coverage. It is good business practice to check – and if necessary, increase – the insurance limit requirement in both master service and supply and distribution agreements.

If current indemnification agreements do not effectively transfer risk to the negligent party, one's own company may be held responsible for managing and paying most costs resulting from a claim, as in the above scenario. By carefully managing the indemnification process, organizations can significantly reduce their level of risk.

Be aware of the limitations of contractual indemnification. Some company leaders believe that indemnification clauses provide sufficient security, obviating the need for individual insurance coverage. However, this strategy can backfire. While contractual indemnification should play a key role in an organization's enterprise risk management program, it does not replace a liability insurance policy designed to cover the organization's exposures.

For example, indemnification will not protect against the indemnifying party's insufficient coverage or insolvency. If an organization lacks the resources to pay for its own claims and expenses, it obviously cannot cover those of indemnified parties. Other circumstances that may nullify the contractual right to indemnification include breach of contract and punitive damage awards.

In the life sciences industry, the potentially catastrophic nature of tort liability requires a rigorous enterprise risk management program and a broad range of coverage. Purchasing a company insurance policy enhances financial security, while providing greater control over legal costs and the defense process.

Take additional precautions when contracting with foreign business partners. The international operations of life sciences companies continue to grow exponentially. Most leading organizations today have a global footprint, sourcing, developing and marketing products on a worldwide scale.

From an indemnification perspective, contracts executed with foreign partners may present an additional level of risk. Collecting monies owed through indemnification from foreign entities can be a challenge, rendering contractual provisions less than reliable if a claim arises.

Furthermore, insurance regulations vary significantly from country to country. Some international partners may require coverage through locally admitted insurance carriers, while others may stipulate that policies be written in the native language and include terms and provisions addressing relevant laws. In these circumstances, indemnification will not substitute for locally admitted coverage and other country-specific regulations. To ensure compliance with local laws and avoid fines and penalties, consult with a broker regarding foreign admitted policy requirements. (See *Life Sciences POV*SM 2013-Issue 1, "Working with International Suppliers: Sound Contracts Minimize Risk," available at www.cna.com.)

Do not rely solely on risk transfer to manage product liability. To reduce the danger of potentially catastrophic losses, life sciences organizations must institute enterprise-wide risk management strategies. These include

- establishing and consistently implementing robust quality systems and processes
- maintaining regulatory compliance and responding proactively to an evolving legal and regulatory environment
- enhancing vendor and partner relationships by utilizing scrupulous due diligence procedures, quality and master service agreements, contract management programs and effective crisis-response protocols

Life science companies confront a wide array of legal and regulatory challenges. Sound risk management strategies, including insurance coverage assessment and thorough contract review, are essential to minimize exposure to third-party liability claims and strengthen financial stability.

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