Turning up the Heat: Product Liability in Biotech, MedTech, and Nutritional Supplements

No matter what area of the life sciences industry you pay attention to, product liability has become the driving force behind claims and behind underwriting decisions. From nutritional supplements and personal care products to medical devices and development, product liability is putting pressure on the industry through claims, and through litigation.

As organizations approach a hard market, such pressures can be difficult to traverse. Depending on the industry segment, those difficulties could be the toughest that have been seen in decades.

NUTRITIONAL SUPPLEMENTS AND PERSONAL CARE

Within the consumer goods space, the industry has seen increasing litigation surrounding nutritional supplements, homeopathic and personal care products. Attorneys are building cases against these products based on false advertising claims, harmful ingredient claims or labeling that does not match the ingredients. Many of these suits are class action events that, if successful, could be devastating for the defendant companies.

MEDICAL DEVICES AND PHARMACEUTICALS

Another type of litigation is impacting the pharmaceutical and medical device arena: medical malpractice cases. Physicians, surgeons, and other medical professionals are seeing increased medical malpractice litigation, however, most medical malpractice coverage limits are quickly reached by lawsuits. As a result, plaintiffs’ attorneys are looking first to the companies whose products and devices were part of the treatment or procedure that was used by the medical professional in question. Since these companies often have more policy limits, they are having cases filed against them whereas, in the past, those suits might have been filed against the medical professional.

REACTION FROM INSURANCE MARKET

Thanks to the increased action around product liability and around organizations supplying the medical profession, both the insurance and reinsurance markets are feeling the pressure. Carriers have reservations around taking on the business of insuring nutritional supplements or homeopathic products.

As more claims are brought against organizations providing medical devices, pharmaceuticals or research, the insurance marketplace is responding. Underwriters are tightening terms and conditions, reducing limits, increasing premiums and, in some cases, refusing new business or renewals. The more plaintiffs’ attorneys decide against medical malpractice cases in lieu of the seemingly more lucrative product liability cases, the more ratcheting down on underwriting terms there will be.
Such market trends make it difficult for brokers to place coverage. As new underwriting restriction and requirements surface, policyholders and those seeking coverage will be required to provide more documentation on products, on manufacturing processes, on risk management strategies or on how they validate ingredients and dosing.

Fortunately, there are insurance carriers entering the life sciences market from both a product liability and care perspective. These new participants are limiting coverage for the moment but, as participation grows among insurers, there is hope that the appetite for these risks will grow as well.

**LOWERING THE RISKS**

Until then, organizations are tasked with finding ways to improve their exposures. Fortunately, they can reduce their loss exposures enough to satisfy insurance underwriting requirements.

The first step is to establish appropriate protocols and responses based on a more litigious environment. Also, organizations should start the insurance buying process at least six months in advance. That allows the broker to work with carrier partners to understand requirements, communicate the organization’s amended risk mitigation processes and develop customized programs that help mitigate the most critical risk exposures.

Working with a broker that specializes in the industry can help organizations identify more quickly the coverage requirements and the loss control strategies they need in order to obtain coverage and lower losses. NFP’s Life Sciences Group regularly monitors the marketplace, legal activity and coverage changes.

Life sciences organizations face unique challenges from a product liability perspective. Thanks to increasing claims and litigation, extra caution must be used whenever developing, manufacturing, or introducing new treatments or products into the market. Working with a specialty broker gives organizations a competitive edge by equipping them with the resources and advisory services that can help them improve their risk management measures and compete with confidence.

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