

Biggest Loser or Ultimate Winner? Six Ways to Win the Product Liability Game

By Kevin Quinley CPCU

“The Biggest Loser” is a reality TV show where contestants vie with each other to drop weight. The biggest loser of weight wins the contest. Less may be more in the dieting game, but in product liability, no life sciences technology company wants to be known as “the biggest loser.” To be a winner at the product liability claims game, it helps to have a sound game plan.

The need for such a game plan may seem muted these days, given some pricing trends in the insurance market. Insurance costs for commercial general liability, including product liability, have recently leveled off for many manufacturers and distributors of healthcare technology products. While this helps the bottom line, it does not mean that life science technology executives should forego risk management in protecting their company’s assets. What can these executives do -- in addition to buying insurance -- to protect company assets? Here are six tips:

#1. Pick the right insurance broker to procure proposals from the handful of insurers willing to sell to the life science niche. A broker who specializes in the medical device, biotechnology and pharmaceutical arena is a sound choice. You deserve a broker who is on top of industry issues and knows the specifics needed to assemble an information package about your company that underwriters will find useful. This may result in more reasonable premiums. A broker should be able

to identify insurers that specialize in product liability for life science companies. The right broker will belong to or know of industry trade associations, attend trade shows or networking events, and understand the source and meaning of GMP’s (good manufacturing practices), informed consent, protocols and other certification processes.

#2. Invest in a “legaleagle.” Find a good attorney who is familiar with the life science industry and, preferably, has actually defended medical device firms in front of a jury. Such an attorney will know plaintiff lawyers “end games” and can craft strategies to deter plaintiffs’ lawyers from attacking your company. The lawyer should be versed in FDA regulations, labeling issues, etc. Retaining a seasoned attorney before lawsuits arrive is an investment that can prevent major disruptions and business costs.

#3. Get insurance evidence from business partners: A way to shift risk is to have business partners provide evidence of their product liability insurance; have them add you as an “additional

insured” on their policies. For product manufacturers, these business partners might include vendors, dealers, distributors, component suppliers and contract manufacturers. This request may give you coverage under their policies if both of you are sued. It may keep you and your insurer from having to defend the claim. This keeps your loss record clean, lowering future insurance costs. Beware of any business partners who tell you that they do not carry insurance. Going bare is fine for a nudist colony, but bad risk management!

#4. Assess product representations: Check and double check product labels for proper warnings and (improper) advertising claims. Even if there is no design defect in the product itself, “*failure to warn*” claims about product features can spawn expensive lawsuits. In fact, “*failure to warn*” claims are often the easiest allegation to make and the most frequent liability that Medmarc sees in claims. If you are a product manufacturer choose your contract manufacturers with care. Verify the existence of quality controls,

good manufacturing processes, etc. Do not rely on “the honor system.” Recall the old adage, “Trust but verify.”

If you are a contract manufacturer and a client supplies its labels, check the labels to make sure they match the specifications the customer provided. Also, design a written document that customers sign, stating they understand the product you are making is their design and they will be responsible for liability arising from their design. Moral: Supply chain management involves not only assessing inventory and distribution, but also bulletproofing against product liability risks.

#5. Document! The devil is in the details – and so are the liabilities! Have good record-keeping procedures throughout every phase of the company, including personnel, marketing, and distribution. Keep records of product samples and complaint files. An absence of records allows plaintiff attorneys to invite jurors to draw their own – usually negative – inferences. Lack of documentation implies slovenliness, not a quality that a responsible healthcare technology manufacturer or distributor wants to project. Have a record retention policy. Carefully word email content! You may think that the “Delete” key means it’s gone, but email will be recovered by sharp technicians working for plaintiff

lawyers.

#6. Embrace certifications and GMP’s: Earn certifications from the organizations that offer them. They leapfrog you ahead of the competition and boost your risk management processes. **“Be Prepared”** is a sound attitude to take to protect you and your company’s assets.

No quick fix insulates life sciences technology firms from the sting of product liability. Given the litigious legal climate, legal minefields trip the unwary. Build your firm’s corporate immune system by pursuing these six risk management steps and become “The Ultimate Winner” of the product liability game!

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Created in 1979 by the healthcare technology industry, Medmarc’s purpose is to be the superior provider of liability insurance protection and related risk management services at consistently fair prices and to support the development, testing and delivery of products that save lives and improve the quality of life. Further, through a strategic alliance with The Hartford, Medmarc policyholders benefit from all-lines property and liability insurance protection, loss prevention services and claims management tailored to the needs of life sciences technology companies.

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We Can Meet the Changing Needs of Life Science Technology Companies

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