

Risk and Litigation Avoidance in Addition to Liability

Insurance

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5/29/06

Natural Products Insider

Insurance costs for commercial general liability, including product liability, have finally leveled off for companies in the dietary supplement business. In fact, currently all sectors of the industry are seeing their renewal rates decrease, in some cases dramatically.

While this is good news for the bottom line, it does not mean that due diligence should be discarded when purchasing the insurance. There is still the constantly changing landscape of the **ingredient exclusions** to deal with. These exclusions vary greatly from insurer to insurer, and the lists of exclusions are getting longer, not shorter. (There is, however, an increasing willingness by most insurers to negotiate some of the ingredient exclusions off the policy, thus granting coverage). Your insurance broker may offer you several quotes at a lower premium, but be sure to carefully review the ingredient exclusions before making a final decision.

Having Insurance—Simply a Good Idea

Having a product liability policy in place is a good idea for several reasons. A major, often unappreciated feature of the policy is the payment of attorney fees and related costs of litigation. Most often in the dietary supplement industry, the allegations will involve bodily injury or death, and the cost to defend these lawsuits can be substantial, even if the lawsuit is groundless. Generally, plaintiff's lawyers will be somewhat intimidated at the prospect of having to battle the "big bad insurance company" with deep pockets to fund a vigorous defense. Being uninsured when the lawsuit comes, and having to fend for yourself, will be expensive and make the plaintiffs lawyers more aggressive about extracting money from you to settle.

Many people bristle at the large deductible that comes with a product liability policy. Typically, deductibles start at \$10,000 but often go much higher. However, what most people do not realize is that the deductible only is applied to final judgments or settlements for damages. It does *not* apply to the defense costs. One large West Coast contract manufacturer was sued by a big pharmaceutical company. The contract manufacturer should never have been a party to the lawsuit, and finally was dismissed from the litigation on summary judgment. Their insurance company paid over \$150,000 in the successful defense of the claim. Even though the company had a large deductible, they paid nothing in connection with the lawsuit.

The key to getting the best insurance is to select the right broker to procure proposals from the handful of insurers willing to sell it to the dietary supplement industry. An insurance broker who specializes in the dietary supplement industry is the best choice. A broker with just one or two clients in the industry probably won't be on top of industry issues and specifics needed to assemble an underwriting package about your company that underwriters will find informative, thereby resulting in a lower premium for you. A

competent broker should be able to readily identify all of the insurers for product liability, belong to or have knowledge of industry trade associations, attend trade shows or other networking events, and understand the source and meaning of GMP and other certification processes.

What Product Liability Insurance Does Not Cover

Many people are under the impression that a product liability policy will cover any litigation that involves the company's products. This is not the case, in fact, far from it. In addition to the ingredient exclusions, there are numerous other exclusions, most of which fall in to one of two categories: Risks that are meant to be insured by another type of insurance policy (automobile, workers compensation, etc.) or risks that are generally uninsurable (nuclear attack, asbestos, etc.). Basically, a liability policy only covers allegations of bodily injury or property damage to others. People are often upset when they are involved in a simple business dispute involving their product (for example, an allegation of stolen trade secrets), are sued, and find out their product liability policy does not defend the litigation or pay any resulting damages.

Risk Management Tools to Avoid or Reduce Risk

So what can a company in the dietary supplement industry do, in addition to buying the insurance, to protect itself from lawsuits *in general*, whether or not that lawsuit may be covered by insurance?

Get a Good Attorney: Finding a good attorney who is familiar with the industry and, preferably, has actually defended dietary supplement industry companies in front of a jury will be worth its weight in gold. Such an attorney will come to you knowing the plaintiffs lawyers "end game" and will be able to advise you on numerous strategies to implement which will substantially deter the plaintiffs' lawyers strategy to attack your company. The lawyer should be versed on FDA/FTC issues, DSHEA, labeling issues, and the like. Retaining a competent attorney *before* the lawsuit comes in is an investment that might someday prevent a major disruption and cost to your business.

Get Insurance Evidence from Suppliers: One way to shift risk away from you and on to others is to have your suppliers give you evidence of their product liability insurance and adds your company as "additional insured" on their policy (so-called vendors coverage). This will provide you with coverage under their policy in the event they and you are sued for a covered claim. It will insulate you *and* your insurance company from having to defend the claim, thus keeping your loss record spotless, reducing future insurance costs for you. For these reasons, you should be wary of suppliers that do not carry insurance (and there are many that still do not).

Representations on your products: Implement a system to check and double check your product labels for proper warnings and (improper) advertising claims. Even if there is no design defect in the product itself, a "failure to warn" about certain characteristics of the product can lead to a costly lawsuit. If you are a contract manufacturer and the

customer supplies his labels, check the label to make sure it matches the formulation the customer gave you. If you are a contract manufacturer, design a written document that the customer signs, stating that he understands that the product you are making are *his formulation* and he will be solely responsible for any liability arising out of his formulation.

Keep Good Records: Have good record keeping procedures throughout every phase of your company, including personnel, grounds (physical plant), equipment, production and distribution. Keep records of product samples, complaint files and have a records retention policy.

E-mail: Be careful what you say in electronic mail! You may think it's gone, but it probably can be recovered by a sharp technician working for the plaintiffs lawyer.

Certifications and GMPs: Strive to earn certifications from the organizations that offer them. They will put you ahead of your competition and improve your risk management processes. The coming FDA cGMPs will address some of the above items, so like a good Boy Scout, "Be Prepared" is an appropriate and timely attitude to take to protect you and your company's assets.