

How Media and Government Affect Dietary Supplement Insurance (Overcoming Whisper Campaigns)

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"Five years ago, the dietary supplement industry claimed they had no reports of health problems—zero—related to their products. Thanks, in part, to our legislation, today we know that there are hundreds of serious problems each year, many involving hospitalization and death." – U.S. Sen. Dick Durbin (D-IL)

Sen. Durbin made the above statement about FDA's recent news release that detailed 604 adverse event reports (AERs) for the first four months of 2008. While the factual content of this controversial declaration is under scrutiny, it grabbed the headline for Sen. Durbin, and any corrective or contradictory news that follows will probably not get the attention it deserves.

FDA's press release and a subsequent article in *USA Today* were equally as disturbing. The newspaper opened its story by saying, "Serious side effects from the use of food supplements resulted in 604 'adverse-event' reports—a list that includes at least five deaths—through the first six months that such accounts have been required by law."

Only later in the article did FDA spokesman Michael Herndon point out, "Some of these deaths were likely due to underlying medical conditions." Also, FDA refused to disclose exactly which supplements precipitated the AERs, thus painting all supplements as potentially harmful.

Can this type of negative and questionable publicity affect the rates for product liability for supplement companies? The answer is a resounding "yes." There are two reasons why.

The first reason is insurance underwriters get their information from television shows like *60 Minutes*, publications like *Consumer Reports*, and newspapers like *USA Today*. And, like most of us, they tend to believe what they read, especially when it comes from government authorities or agencies. In the absence of incontrovertible information, fiction often becomes fact.

Add to this the unfortunate lack of knowledge insurance underwriters have about the supplement industry. It is apparent even when completing an application for product liability insurance. The questions asked of the applicant have little or no bearing on evaluating insurable risks generated by a raw materials supplier, contract manufacturer or retailer of supplements. Unfortunately, based upon the responses to these and other, often irrelevant questions, they establish a premium for a company's policy!

Second, bad press affects both the coverage and pricing of liability insurance. Have you ever wondered why certain ingredients, such as tryptophan and bitter orange, are excluded from coverage? Two words: bad press, followed by a knee jerk reaction by underwriters unwilling to

listen to the facts.

Tryptophan is excluded to this day by most insurance carriers offering liability insurance to the supplement industry. How did this happen? Almost 20 years ago, a contaminated batch of imported tryptophan caused many injuries and deaths, and resulted in much-publicized congressional hearings. Insurance underwriters were reading their newspapers, too; despite the fact that the contaminated tryptophan was made by a Japanese company, tryptophan immediately went on exclusion lists.

Bitter orange suffered a similar fate. I spoke about a year ago with an underwriter who specialized in over-the-counter (OTC) and supplement liability insurance underwriting. I asked him why he had added bitter orange to his exclusion list. His reply was this: "After ephedra was banned, we did an internet search that indicated the industry was going to substitute bitter orange for ephedra, so we thought we had better exclude it."

In fairness to the insurance industry, tryptophan and bitter orange exclusions can now be removed from policies. However, many companies don't even know there is an exclusion list on their policies. Many insurance brokers selling liability insurance to supplement companies aren't familiar with the exclusions either, and even if they are, they don't know they are negotiable.

So, how can dietary supplement companies and the industry combat misinformation that can raise premiums and restrict coverage? Companies should consider joining and supporting trade associations such as the United Natural Products Association (UNPA), American Herbal Products Association (AHPA), Natural Products Association (NPA), Council for Responsible Nutrition (CRN) and the Drug, Chemical and Associated Technologies Association (DCAT). Generally, these associations carry the industry torch to both FDA and the consumer.

Supplement companies also need to carefully select an insurance broker. A capable and knowledgeable broker is a valuable asset who greatly improves the chances of obtaining the right coverage, limits of insurance and competitive premiums. Look for a broker who specializes in the supplement industry. They are compelled and motivated to be on top of industry issues. In addition, brokers who have active accounts in the industry should be able and willing to share references to underscore their performance claims.

It is critical that brokers understand the industry's particular issues. Active brokers within the industry appreciate the importance of staying abreast of hot topics and taking steps to stay educated, including attending trade shows and networking events. Companies can gauge a broker's industry familiarity by the questions the broker poses about the company's business operations. A good broker should be well-versed in the ingredient exclusions of all carriers and should engage you about the ingredients in your products.

A competent retail broker should also be able to readily name all of the current insurers for product liability and identify specific traits of each one (minimum premium, minimum and

maximum deductibles, etc). The broker should also have a network of other consultants to recommend if need be, such as attorneys, GMP consultants, venture capital firms, etc.

In conclusion, support of trade associations and the selection of a knowledgeable insurance broker will help buttress your company against bad press about supplements and help ensure your message is carried to insurance underwriters in an organized process that will guarantee the best coverage and price.

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