Miscellaneous Healthcare Spotlight

Nutraceuticals: Navigating Risks With No Fine Print

by John Livatino

While the name "nutraceuticals" implies nutritious, even natural medicines, the reality is that these products can be fraught with risk. Nutraceutical products can take numerous forms, and target a vast array of wellness and lifestyle issues. Lack of product regulation makes for an underwriting challenge – but with a deep understanding of the market nuances, these risks can be successfully underwritten.

Nutraceuticals are a $30 billion industry in the U.S., and even bigger elsewhere. Nearly two-thirds of Americans take some type of nutraceutical healthcare product[1]. The most commonly reported reasons for using supplements were to "improve" (45%) or "maintain" (33%) overall health but only 23% of products were used based on recommendations of a healthcare provider[2]. With baby boomers aging, the number of Americans heavily focused on health and wellness will increase; growth of this segment will surely accelerate.

Nutraceuticals come as drinks, pills, capsules, bars, powders, lotions and potions, promising therapeutic and medicinal benefits ranging from enhanced sports performance and fewer wrinkles, to increase immunity and energy, lessen anxiety, clearer vision, and renewed sexual vigor. Many are nutritional supplements, taken to support general good health. These include vitamin supplements, fish oils, and protein bars.

Dangerous medicine?

Dietary supplements are not required to be tested or registered with the U.S. Food and Drug Administration (FDA). The Dietary Supplement Health and Education Act of 1994 (DSHEA) sought to bring some regulation to the industry, but its effect was very limited. The FDA's role in oversight is mainly registering facilities, confirming they are operating within current good manufacturing practices and investigating products after they are on the market shelves. Both the FDA and Federal Trade Commission (FTC) share responsibility for regulating the labelling of the dietary supplements, with the FTC also focusing on advertising. Although some nutraceutical companies may claim their product has been clinically tested, no testing is mandated by the FDA. As a result, some companies have been known to "clinically test" their product by giving their employees samples for a few weeks and monitoring their health. Essentially, it is up to the importers, manufacturers and distributors to ensure that a product is safe before it is marketed. This allows unscrupulous companies to enter the market with potentially dangerous ingredients.

Many of the raw materials used in nutraceuticals are obtainable only outside the U.S. – and many of the ingredients commonly used in nutraceuticals are inherently risky. For example, yohimbe, which contains the chemical yohimbine, acts as a stimulant and is used in multiple applications, including products for sexual performance, sports training and weight loss.

[1] Young, Alison (Dec. 20, 2013). "Unmasking the People Behind Risky Pills", USA Today
[2] JAMA Intern Med. 2013 Mar 11; 173(5):355-61. doi:10.1001/jamainternmed.2013.2299

In recent years, yohimbe's safety has been questioned and the product linked to severe side effects, including irregular or rapid heartbeat, kidney failure, seizure and heart attack. Yet it remains widely available.

There have also been issues with the ingredient 1,3-dimethlyamylamine (DMAA), a stimulant touted to help burn fat and build muscle. Several deaths have been allegedly linked to its use, including high profile cases involving military personnel who died of heart failure. The FDA found the substance to be illegal and has banned its use as a dietary supplement. However the damage has been done with products still in circulation and being consumed by unaware customers. Now, there are concerns about yet another stimulant, BMPEA (beta-methylphenylethylamine), and its chemical relationship to amphetamines, but the FDA has remained silent on the issue.

As always insurers, manufacturers, retailers and consumers should proceed with caution. Taking a bunch of unproven ingredients, and combining them in untested ways as often happens in the nutraceutical world, amplifies exposure. The unknown effects of caffeine, taurine and ginseng blended into popular sports drinks is an example. Recent stories of minors collapsing after energy drink consumption have made headlines and even spurred U.S. Senate inquiries.

Then there is the issue of ingredients that were never intended to be part of the product. Contamination is a substantial risk. It may be unintentional, deriving from slipshod manufacturing processes, with ingredients coming from unknown distributors around the world, but there have been cases of purposeful contamination as well: for instance, a seemingly benign sports nutrition powder being revved up with illegal amphetamines and anabolic steroids to help its maker improve results and "break out" of the crowded sports nutrition pack.

While risking serious bodily injury, athletes taking these "innocuous" supplements have also been disqualified from competitions after testing positive for banned substances they have unknowingly ingested. Even when there is no bodily injury, the mental anguish and pain and suffering in cases like these (not to mention lost revenue or endorsements for an elite athlete) can be substantial. Lawsuits against nutraceutical providers have arisen from this issue.

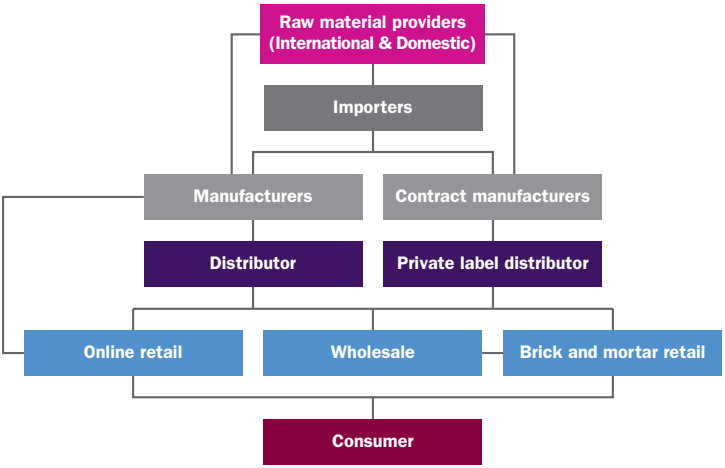
Athletic disqualification has been somewhat alleviated through the work of NSF International, which provides public health standards and certification programs that help protect food, water, consumer products and the environment. Its recently created "NSF Certified for Sport" program uses a unique mark to indicate products that have been tested for substances banned by governing athletic bodies. The NSF also tests and certifies dietary supplements. All NSF testing and certification is purely voluntary.

There is inherent difficulty proving causation in bodily injury claims involving nutraceuticals. A bodybuilder overloads on protein and amino acids in a quest for greater strength and experiences kidney failure, requiring ongoing medical treatment. A high school basketball star suffers cardiac arrest after ingesting a popular energy drink before a game. A woman taking a weight loss supplement with synephrine faints, hitting her head and suffering serious injury. Was the nutraceutical to blame or some other condition? Proving the cause was the nutraceutical may be difficult or impossible, but this challenge is no shield. Rather, it typically means protracted litigation and

[4] Lattman, Peter and Singer, Natasha (Feb. 13, 2013). "A Workout Booster, and a Lawsuit", The New York Times

heavy defense costs for nutraceutical makers and/or distributors in claims, even absent any settlement or judgment. Moreover, defendants in this class are typically reluctant to settle cases; doing so could give rise to more claims.

The nutraceutical insured distribution channel



Managing the risk

Finding a seasoned underwriter who understands the intricacies of this class of business is key to helping companies mitigate risk and build coverage that works.

Some best practices we recommend to nutraceutical insureds to mitigate risks include:

- Have a proven third party importing ingredients, lessening the exposure to potentially contaminated and untested materials.
- Perform robust testing of both raw materials and finished products. This can be done both in-house and through third party laboratories.
- Keep accurate records of goods and shipments, complete with lot and batch numbers, so the product and the raw materials from which the product was made are recorded. This enables the nutraceuticals maker to track product and contain an incident if there is a problem, such as contamination of a certain batch.
- Require that an insured's supplier or contract manufacturer carry product liability coverage with adequate limits, limited exclusions and include the insured as an additional insured.

Key points for securing effective coverage in this class include:

- **Know what's in the product.** Many insurers automatically exclude substances such as bitter orange, kava and yohimbe. These exposures can be underwritten by the insurer through detailed product label review in an effort to responsibly grantcover to fit the exposure where appropriate.

- **Test the limits.** Standard products liability limits have long been $1 million each claim, $2 million in the aggregate. Meanwhile, larger retailers have pushed the contractual requirements for this class to minimum limits of $5 million and even $20 million. Many insurers will only offer a maximum of $5 million limit, so this may require purchasing both primary and excess policies. Brokers will need to intelligently and effectively build these limits.

- **Go global.** If an insured has operations or sales outside of the US, an insurance carrier that provides true global coverage is needed – including coverage for a policyholder's foreign subsidiaries and vendors worldwide.

- **Protect finances and reputations.** It is important professionals handling these claims have a deep understanding of the issues involved in defending claims in this class – and of the reputational damage at stake for insureds. Consent to settle is typically required. Experienced claims handlers and attorneys, working in collaboration with insureds on claims defense, are pivotal to minimize all adverse impacts.

- **Total recall.** Policies will typically exclude coverage for voluntarily or involuntarily recalling the insured's products but may be amended to include sublimited coverage for the expense associated in such recalls. For broader coverage and full limits of liability, brokers will need to find stand-alone policies.

While the dangers of this class are many, there are also many ways to make coverage work. Drawing on extensive experience, Beazley is proactive in doing just that – and in helping our nutraceutical insureds to ensure the healthiest possible future for their operations worldwide.

To learn more about Beazley's solutions for miscellaneous healthcare professional liability risks, contact John Livatino at john.livatino@beazley.com

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