VITAMINS AND supplements are in their own fields of risk in the pharmaceuticals space.

THE RISK OF REMEDY

Makers of vitamins, supplements, herbal remedies and nutraceuticals believe their products are safe and effective, but insurers are not so quick to agree.

● **BY JARED SHELLY**

It's no secret that people want to be thinner, stronger, live longer and feel better. And these days, everybody seems to be looking for a magic pill or remedy to achieve those results. So companies of all shapes and sizes are rolling out vitamins, supplements, herbal remedies and nutraceuticals to meet the public demand. Some promise weight loss, while others promise increased muscle mass or more capacity to concentrate.

While the supplement makers would argue that they test rigorously and deliver safe products — and the public might see them as heaven-sent alternatives to traditional medicines — insurance companies are wary and aren't in any hurry to offer these manufacturers comprehensive coverage.

That's because these products are not tested by the Food and Drug Administration before they hit the market, so who's to know if they have harmful side effects?

"That means products can hit the market, be ineffective, and the FDA would never get a call to investigate," said Phil Walls, chief clinical and compliance officer of myMatrixx, a pharmacy benefit manager in Tampa, Fla.

A supplement company only has to ensure that their labeling is correct and that any serious adverse events are reported to the FDA, in accordance with the Dietary Supplement Health and Education Act of 1994.

But the public may not be familiar with the intricacies of the law, and they may think that these products are regulated by the government, warned Mark Wood, president of LifeScienceRisk, a managing general underwriter of Ryan Specialty Group in Chicago.

"People think, 'they are just supplements. If they were the least bit dangerous surely the government would step in and regulate them,' " said Wood. "But few products are totally safe."

The word "natural" can also be a misnomer.

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Products may be sourced naturally but companies tend to accumulate them in potentially harmful quantities, said Wood. For example, to get the benefit they want in a capsule or tablet, the makers will often concentrate a large quantity of a certain plant, herb or vitamin into a capsule. Consuming such high doses could cause side effects.

But while there are some bad actors, which is natural in the absence of regulation, there are plenty of companies producing their supplements safely. It's up to the insurance industry to figure out who's who.

"There are many high quality manufacturers of supplements today but not every manufacturer holds themselves to the same standards," said Wood.

Dirk Van Heyst, a broker specializing in the supplement market, said that controls and laboratory testing of these products is often "extremely impressive."

"They don't have losses. There are some great companies who are in this business. I've been to manufacturing plants where you can eat off the floor," said Van Heyst, New York-based senior vice president of Lockton Cos. in Kansas City, Mo.

THE CLOUD OF EPHEDRA

Casting a cloud over the supplements business is the ephedra scandal of the early 2000s. Ephedra was a supplement designed to help people lose weight and gain muscle, but users started having adverse reactions after it came on the market.

In 2002, MetaboLife Corp. — under pressure from the government — revealed 15,000 consumer complaints of side effects from its weight-loss product, MetaboLife 365. People complained of insomnia. In some cases the product was even linked to deaths. A federal judge in 2002 ordered the company to pay $4.1 million to four people who suffered strokes or heart attacks after taking MetaboLife 365, which contained ephedra.

In perhaps the most public ephedra tragedy, Baltimore Orioles pitcher Steve Belcher died of a heart attack during spring training in February, 2003. A medical examiner said ephedra played a significant role in Belcher's death. If that weren't enough reason to prohibit the substance, a government study found that it did not produce long-term weight loss and another study found that it led to significant side effects. The FDA finally banned ephedra in 2004.

"You're looking at essentially a very potent stimulant that impacts heart rate and blood

Summary

- **Insurers argue that without a long history of low claims, vitamin and supplement manufacturers are risky to insure.**
- **Vitamin and supplement manufacturers argue that their products are tested rigorously and are safe for the public.**
- **The ephedra scandal of the early 2000s still casts a black cloud over the business.**

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pressure," said Wood. "But because it was derived from a plant material it was 'a natural source.' "

Insurers have been wary ever since, and that has made life for supplement manufacturers and the brokers that represent them more difficult.

"We're still fighting ephedra scare," said Edwin Albers, director of the Aon Risk Solutions Life Sciences Group. "It's always in back of underwriters' minds."

While he said that claims activity in the space has been "fairly minimal" since then, it doesn't matter all that much because "insurance companies have long memories."

But it's not just the harmful products that scare insurers — it's also the harm of these products mixing with other medications. A vitamin K supplement, which offers many of the same health benefits as spinach and broccoli, can interfere with blood-thinning medications.

St. John's Wort, a plant species taken for depression, can interfere with certain anti-depressants or birth-control pills, said Wood. Anti-oxidants are another class that needs to be watched. While they are believed to protect cells and lower the risk of cancer and other diseases, they may have a negative impact on cancer therapies, he said.

"You've got to be careful," said Wood. "Supplements can make prescriptions less effective or may cause more serious problems."

A FAIR ASSESSMENT?

Supplement makers and the insurance brokers who represent them are left to plead their case with skeptical insurance companies. Van Heyst works with plenty of unregulated supplement companies and realizes just how different his job is from trying to get FDA-regulated pharmaceuticals insured.

"When an underwriter looks at a pharmaceutical, they have a comfort level of knowing this has been carefully scrutinized and the product has been tested before it hits the market and can be bought by third parties," said Van Heyst.

While pharmaceutical companies elicit visions of scientists in white lab coats, carriers' perception of the unregulated supplement industry is that they are "operating out of someone's garage" even though they are often manufactured in state-of-the-art facilities, he said.

"There are companies doing great things and their products are really helping people. Our job is to differentiate our clients," said Van Heyst.

Many insurers offer coverage to supplement manufacturers on a nonadmitted or surplus lines basis with mandated deductibles or retentions. Carriers also make sure to write in exclusions for known harmful substances like all forms of ephedra or things that mimic epinephrine, like Ma-huang, a Chinese root.

When it comes to the thorniest products to gain coverage for, weight-loss supplements seem to top the list every year, said Albers.

Being a broker in the supplement space means having a unique understanding of the companies you represent — or it will probably be tough to be successful.

"We need to understand controls and process, and understand the companies because not having that the same level of oversight [as pharmaceuticals] is something more challenging for insurers to get their heads around," said Van Heyst.

Aon's Albers puts it another way: "knowledge is power."

"What are the raw source materials? Where are they coming from? What are specific ingredients?" said Albers. "These are all underwriting questions. The more certainty they have on these variables, the better."

Insurers assess the risks involved in insuring vitamin or supplement manufacturers through their claims history. Those numbers don't lie. A small or nonexistent claims history should yield a low premium rate with high coverage limits, especially after the product has been on the market for a number of years.

But that leaves newer manufacturers in a lurch. How do they get their businesses off the ground with high insurance premiums or limited coverage? In fact, Van Heyst said he normally doesn't even deal with companies that aren't well established in the businesses.

"It's a little more difficult because they typically do not have history of products, or the infrastructure of risk management or risk mitigation," said Albers. "They also may not have crisis plans."

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Walls from myMatrixx said that reputation and history are "huge" parts of gaining coverage.

"If the company has not had lawsuits, has not had problems, it's a stable company that's been around for a long time — that all adds to credibility," he said. "But it's still not any assurance that a product is safe."

After a product has been on the market for a while, however, insurers get a new concern: will its widespread usage lead to people experiencing side effects?

"As more people get exposed to [these products], side effects begin to show," said Wood, from LifeScienceRisk.

So brokers try to quell the concerns of insurers by telling them exactly what's in the products, how they are made and any potential side effects.

"Better underwriters are looking at the products themselves. They understand if people are selling nutritional supplements with ingredients, they have a tougher safety profile. They also spend more time making sure those ingredients are in lower concentrations in the products," said Wood.

"At the end of the day it's a consumer product. Our concern is if someone ignores a label and still sues."

WHEN BIG PHARMA GETS IN THE GAME

TV commercials for pharmaceuticals seem to be all over the airwaves these days — and after talking about how beneficial a new product is, the commercials describe the medicine's side effects in painful detail. Different from vitamins or supplements, traditional pharmaceuticals make bolder claims (curing or preventing disease) than supplements (enhancing or improving well being.) While such bold claims and possible side effects may make insuring a new pharmaceutical medicine sound incredibly risky, pharmaceutical manufacturers tend to have an easier time gaining insurance coverage than vitamin or supplement manufacturers. That's because pharmaceuticals go through stringent testing and are subject to FDA regulation, leading underwriters to typically see them as less risky. Another reason is because doctors prescribe pharmaceuticals, while regular consumers, many of whom are often uneducated in basic pharmacology, prescribe themselves supplements, which could lead to abuse or mistreatment.

"I'm not sure consumers are the right decision makers," said Phillip Walls, chief clinical and compliance officer of myMatrixx in Tampa, Fla. "Even if I have a patient that has done their own research about alternative therapies, I'd still want them to check with nurse case managers or their treating physicians."

But what happens when a pharmaceutical giant is also manufacturing vitamins and supplements? Those companies have well-established risk profiles and well-established relationships with brokers and carriers. Certainly, since insurers have less of an appetite for supplement risks vs. traditional pharmaceutical risks, the broker-client relationship could get strained when a large pharmaceutical company gets into the supplement world. That means the onus is on the broker to understand testing procedures and all potential side effects so they can be communicated to the insurer.

Underwriters seem more amenable to writing policies for supplements made by large pharmaceutical companies than smaller manufacturers because they can assume that they have rigorous testing standards for all types of products made at their facilities.

Even though supplements are unregulated, companies "don't have two sets of standards" meaning they'll manufacture "everything to full FDA manufacturing practices," said Mark Wood, president of LifeScienceRisk, a managing general underwriter of Ryan Specialty Group in Chicago.

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