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Staking claims

Small steps toward a new understanding of health condition claims

By Bill Giebler

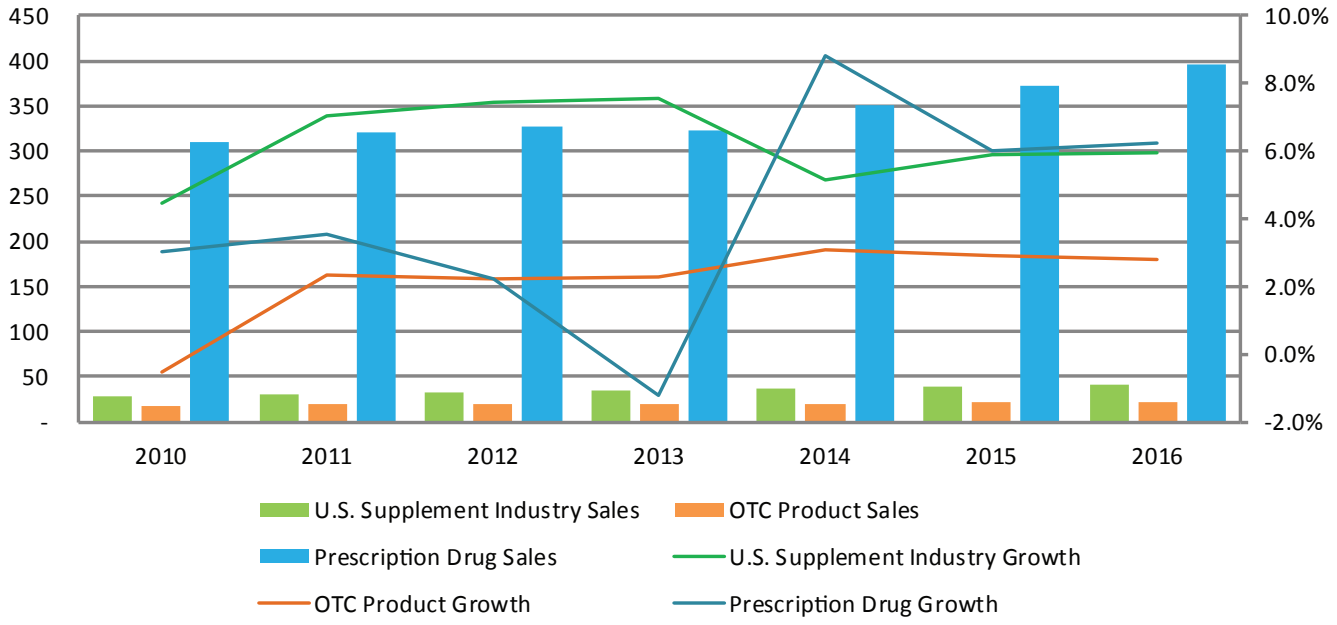
A nutrient's climb to health claim status is an arduous one. Even vitamin C, arguably the first nutrient to take up residency in the mainstream vitamin cupboard, proceeds through the marketplace without the benefits of general health claims.

In fact, very few nutrient-related health claims are approved by the FDA, and those few are notably specific, even for nutrients

NBJ Takeaways

- Nutrient health claims are few and acquiring them is cumbersome
- General health claims may lack the marketplace meaning they once held
- The FDA's all-encompassing definition of disease increasingly limits supplement claims
- Any movement around any claims may be beneficial to the industry

U.S. SUPPLEMENT, OTC, AND PRESCRIPTION DRUG SALES AND GROWTH



Source: Nutrition Business Journal estimates (consumer sales)

LETTER FROM NBJ: STRUCTURES AND FUNCTIONS

The term "healthy skepticism" is an interesting one when it comes to nutrition. It could imply that, in short, it's healthy to be a skeptic. Anybody who's read enough of the editor letters I've written for NBJ will know that I came to this job as a skeptic. But am I healthy?

It doesn't always feel that way.

Am I getting healthier as I add more supplements to my regimen? That's not clear either.

Am I more involved in my health? Certainly.

There was a time, not very long ago, that pharmaceuticals outnumbered supplements in my daily pill intake by several to zero. I've had asthma since infancy. I acquired a slight case of epilepsy along the way. Those drugs are still in my pill organizer. But the balance between supplement and pharmaceutical has changed dramatically. I take more supplements than prescribed pills now.

But am I treating my asthma and epilepsy with nutrition? This is where that healthy skepticism should come in. I'd like to say that I'm merely helping my body to achieve a better baseline of health that gives me a better chance of controlling my conditions with pharmaceuticals, but let's face it, skepticism wilts in the face of hope, even for an ex-newspaperman like myself.

I'm not limited by DSHEA language, and some of the supplements I take I am banking on to treat, or at least mitigate, one or more of my conditions. But I don't know that they are. That's why I still fill my prescriptions every month. I accept that both pharmaceuticals and supplements entail a mix of faith and science. I have a better faith in the science for pharmaceuticals than nutrition in the case of epilepsy and asthma, but I'm not ruling out nutrition, either.

That balance, at least for now, has come to define "healthy skepticism" for me.

Everybody gets to find their own balance, their own definition, but I wonder sometimes if too many voices in the supplement industry are too rigidly outspoken against pharmaceuticals. "Complimentary medicine" too often becomes "contrarian medicine." I think about this every time we publish a Condition Specific Issue, and I wonder if the balance is too far off for too many people.

In the end, I think a balance of skepticism that moves away from an all-or-nothing mindset is the wiser philosophy, and I think the better science we are seeing will help create that synergistic symmetry.

I also think it's a better business proposition. One of my coworkers still calls me "the house cynic," but I haven't shown him my pill organizers lately. If the house cynic can be won over by "healthy skepticism," there are millions of consumers who might be similarly swayed.

Rick Polito
NBJ Editor in Chief

COVER STORY CONTINUED

with wide ranging benefits. Take C's neighbor D, a vitamin recognized for a spectrum of health benefits from colds to cancer. Only one condition (osteoporosis) is currently approved, and then only when the nutrient is served up in combination with calcium.

Most of the approved health claims focus on broad dietary categories like fruit, fiber and fat for their roles in a surprisingly limited number of conditions: notably, and repeatedly, cancer and coronary heart disease.

With so little of this holding marketing relevance for dietary supplements, the value proposition of supplementation comes into question and is answered very differently by different stakeholders. The regulatory viewpoint provides a backdrop that is at philosophical odds with much of the industry it regulates and much of the population it serves.

This is not surprising to industry experts. "FDAs mission is not about health; it's about safety," says **Organic & Natural Health Association** (O&N) Executive Director Karen Howard. "And if you look at where they spend their money, their budget lines, their initiatives, that is very clear." She lists HACCP, FSMA and their relationship with FTC. "There isn't really an organization in the federal government whose job is to promote health, per se, other than really looking at treating disease."

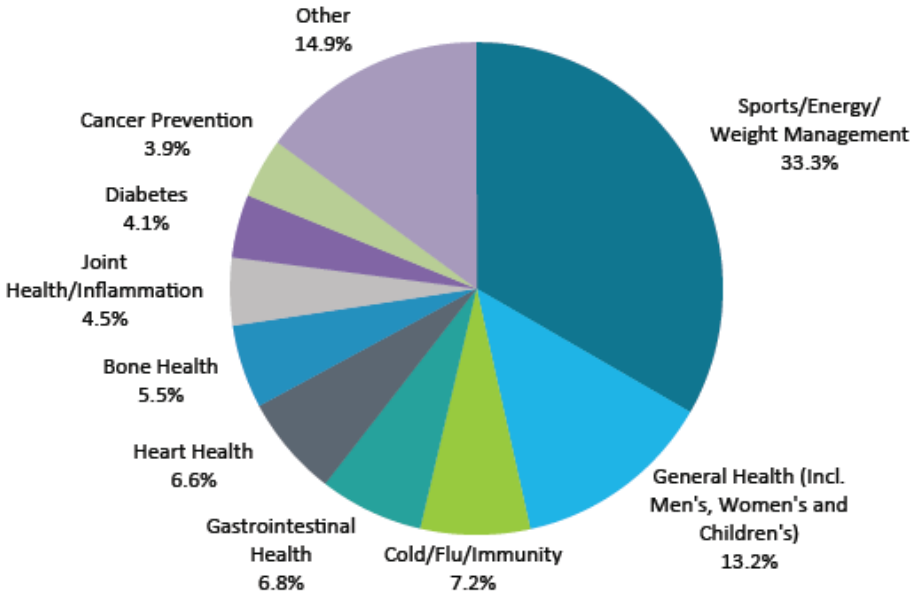
The FDA positions supplements, then, to keep the well well, with drugs waiting to heal the sick. But it's in the massive space between these black and white poles of wellness and disease that we find the vast majority of supplements—those approved for neither health claims nor nutrient deficiency disease claims (this is where vitamin C steps forward for its ability to ward off scurvy). This is the vague grey world of structure/function claims, and *that* is the home of condition-specific supplements.

But first, a look at some shifts taking place in dietary health claims. Shifts that may signal the stirrings of philosophical change.

Ups and downs

On March 27th, 2018, O&N submitted a petition to the FDA for an authorized health claim connecting vitamin D with

U.S. SUPPLEMENT MARKET SHARE BY CONDITION



Source: Nutrition Business Journal estimates (consumer sales)

preterm births. Two days later, and presumably unrelated, FDA commissioner Scott Gottlieb, M.D., put out a call for additional health claim petitions. In his remarks, he expounded on the role of nutrition in avoiding disease and enumerated the incidents and costs of heart disease and obesity. Marketing health benefits on label, Gottlieb believes, could go a long way toward changing the way Americans eat—directly and indirectly by way of the incentives new claims would represent for product formulators.

"Consumers have long been interested in finding easier ways to identify healthful foods by looking at the label when shopping for groceries," the commissioner said in his remarks. "Science-based claims can help people do that."

It's too early to tell if the climate for claims will change, and it's not all rosy in the claims department. Recent months have seen the FDA propose revocation of a long-standing soy protein/heart disease claim (which, they say, is called into question with the "totality of currently available scientific evidence") and reject a different vitamin D claim: Bayer's petition to link the nutrient with multiple sclerosis.

The soy case is out for comment presently. If pushed through, the protein will be relegated to the less rigorous *qualified* health claim—which can be labeled as being "supported by scientific evidence" (a downgrade from the "significant scientific agreement" allowable, and required, for an authorized health claim). Bayer's D claim, was the behemoth corporation's second try and was a voluntary downgrade to the qualified status after denial of an authorized health claim in 2016.

It's the more rigorous claim that O&N seeks.

"There are three questions that you have to justify in a petition," says Howard. "The first is to document that the supplement or food retains this attribute of nutrient value when consumed at the proposed level." So, basically, effectiveness. The second is to prove that the nutrient is safe and lawful. "And the third one is that it's actually associated with a specific health-related condition that can be identified by a sub group of the population. So, in our case it's preterm birth, pregnant women."

To get there, O&N compiled all related science, most promisingly recent research conducted at the Medical University of South Carolina, and then petitioned based on the above questions and focused on the reduction of risk associated with preterm birth and poor health outcomes for infants. In later Hill visits, organization representatives further tallied potentially averted healthcare costs.

Proving safety and efficacy for D, Howard says, was not a problem. But it was still a big effort. "When you look at the definition of 'significant scientific agreement standard,' it's pretty tough. You've got to be very thorough, very organized and give them nothing that has a hole in it."

Even in light of the Bayer rejection, Howard is confident. "Can they say no? Of course," she says. "And yet, every day more healthy babies are born in more facilities that see the data for what it is: a highly effective, tangible solution that results in changing the standard of care for obstetrics."

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- Loren Israelsen, UNPA

Understanding nutrition

"Before there were health claims for foods and nutrients, there was nothing," says Loren Israelsen, president of **United Natural Products Alliance** (UNPA). In the 1980s, Kellogg's sought to promote All-Bran cereal as effectively reducing the risk of colon cancer. This, says Israelsen, was "the big bang moment."

Both the National Cancer Institute and the FTC saw the claim as valid, but the FDA protested.

The general response at the time, Israelsen says, was "something is wrong with a system that doesn't allow us to tell the truth about what could be life-saving simple changes to your diet." This led to the passage of the Nutrition Labeling and Education Act (NLEA) of 1990 and the basis of health claims.

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- Darrin Peterson, LifeSeasons

Nearly three decades later, the health claims, while few, are commonplace. "They have become very important as a background message," Israelsen says. Consumers across demographics have learned a lot about the relationship between foods and ingredients and chronic conditions. Yet, they may be too commonplace. "People ask, quite rightly: so how much do people pay attention to these types of claims. Is it paint on the wall or is this really a billboard?" he asks.

Israelsen isn't complaining. The benefits to our nation's collective health are undeniable. "What we're seeing, however, is a slowdown of the number of approvals or recognitions for official health claims," he says.

For the supplement industry, it's the structure/function claim, birthed out of DSHEA four years behind NLEA, that holds the most opportunity. And the most frustration.

The condition our conditions are in

"Because we view everything as being either disease or optimum health," says Todd Harrison, FDA expert and partner at **Venable**, "there's very little room to promote nutrition for overall health and to address concerns that we all have as we age."

For instance, osteoarthritis which, Harrison says is not a disease unless it becomes debilitating. "For people who are active in general, osteoarthritis is a common part of aging. It is aging in and of itself. So, if you were to ask an orthopedic surgeon, they'd tell you that almost everyone over the age of 50 has some sort of osteoarthritis because it is a condition of wear and tear on the body." But because the FDA chooses to view it as a disease, he says, a drug is the only thing that can be used to treat it.

We've created a paradigm that doesn't understand that health evolves as we age,

says Harrison. "What is considered normal health for a 50-year-old is not normal health for a 20-year-old. There are certain facts of life that are just facts of life."

"It's probably the number one frustration that I have," says Darrin Peterson, founder and CEO of supplement brand **LifeSeasons**. "The FDA and the AMA keep broadening what they define as a disease state," he says. "Diabetes is a disease state. Now they're saying prediabetes is a disease state. And *now* they're saying metabolic syndrome is a disease state. So, what they're basically telling the nutraceutical companies of the world is, you can do clinical studies on healthy people that have no issues and tell us that they're healthy when you get done with it."

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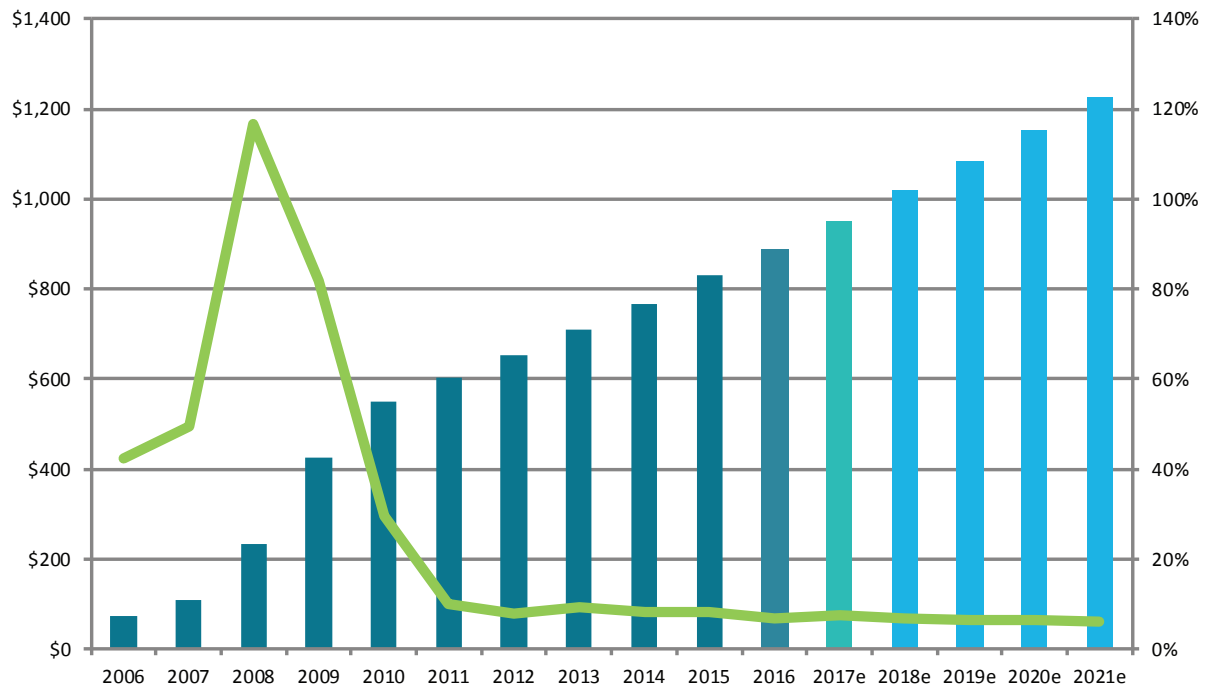
Peterson still finds clinical trials critical. LifeSeasons formulates only with ingredients that have clinical studies behind them, he says, and moving forward, the company is seeking clinical trials on each of their finished formulas as well.

With products like Mobili-T Healthy Joints and Pros-T Glandular Support, LifeSeasons, like many companies, walks a fine line around disease claims. "There's this ethical dilemma and you never ever purposely want to break the law," Peterson says. A fan of DSHEA, something he supported at passage and continues to support, he acknowledges that "in some ways it causes more confusion because of

U.S. VITAMIN D SALES AND GROWTH, 2006-2021E



Source: Nutrition Business Journal estimates ($mil, consumer sales)

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- Todd Harrison, Venable

the limitations of how we are to communicate." If DSHEA exists to protect the consumers, he says, it's often off target. "Because of what we're forced to do and to dance around the regulation," he says, "we actually promote more confusion."

Recently, as the company submitted clinical trials to the FDA for its formula, Diabet-X, they changed the product name to Glucose Stabili-T. The concern was that the name was too suggestive of a disease, and the clinical studies which indeed support such a claim, Peterson believed, would hasten that clash with the FDA. So, as the company bolstered the science to support a diabetic claim on its formula, it watered down its marketing.

"Drugs target disease states; our supplements really target conditions and make structure/function claims," Peterson says. "That's kind of a fine line and it gets really grey in between there. It becomes extremely difficult, it becomes extremely burdensome, and it becomes extremely expensive when you're dealing with FDA lawyers. And the other frustrating part is you can talk to 10 different lawyers and get 10 different opinions." The law may be clear, but the interpretation isn't.

Harrison agrees that structure/function claims—in place to ensure only truthful claims are made—often encourage the opposite. "Does glucosamine really help support healthy joints and muscle?" he asks. "I'm not sure if a 20-year-old kid started taking glucosamine now you wouldn't still have arthritis at the age of 50." Perhaps a claim that the nutrient reverses the effects of arthritis would be more truthful.

Harrison's frustration continually circles back to what he sees as the fundamental misunderstanding of health. "You can repeal the Affordable Care Act; you can keep the Affordable Care Act. The bottom line? Healthcare is not going to be affordable unless we address the underlying issue, and the underlying issue is: we do not do anything to promote health in this country. We promote fixes rather than health."

Baby steps

"DSHEA was a small victory," Harrison believes, "but in the end, because you have an agency that thinks everything is a disease and very few things are normal functioning, you never get to the real issue, you never get to the purpose of what DSHEA was."

The situation will remain frustrating, Harrison believes, "until we can get our federal government to understand that life is not a disease, that life is various different stages of health."

With structure/function claims currently immovable, and the FDA calling for additional petitions for health claims, will health claims be the best route for supplement companies?

"I honestly don't see it," Israelsen says, contemplating the current state of government affairs and the big health initiatives on the horizon. "If we've really moved into personalized and genetic medicine and have lost a government resource to try and figure these things out for the collective, what is the future of new health claims? What is the future of *old* health claims that are now so generally understood that they don't really make a difference?" For Israelsen, it comes down to the question of who will pay for these efforts. They're expensive for private entities to push through, and the results become public domain.

Furthermore, the specificity of aligning individual nutrients with individual conditions makes the effort seem Sisyphean. Israelsen calls that specificity a good news, bad news story. "To the extent that we can get more specific and help people that have specific health needs, we should do so," he says.

About preterm births Israelsen asks, "Is it a big market? No. Is it an important one for those folks? Very important. Is it worth doing? I certainly think so. If you were in that risk group, you would certainly think so, too."

Harrison, too, believes the effort worthwhile. "Because it's the only way you push it. It's the only way you change it. If you don't follow these things to show the agency that their concepts are wrong, you never ever make any headway. It takes baby steps. It's always worth it."

These baby steps may eventually add up to big philosophical shifts. Peterson is hopeful: "The American people are disenfranchised, they are frustrated with the current healthcare system, they are demanding changes to the current approach.

"I understand it's kind of a David and Goliath story," he says. "But there's plenty of those in history when the David has won."