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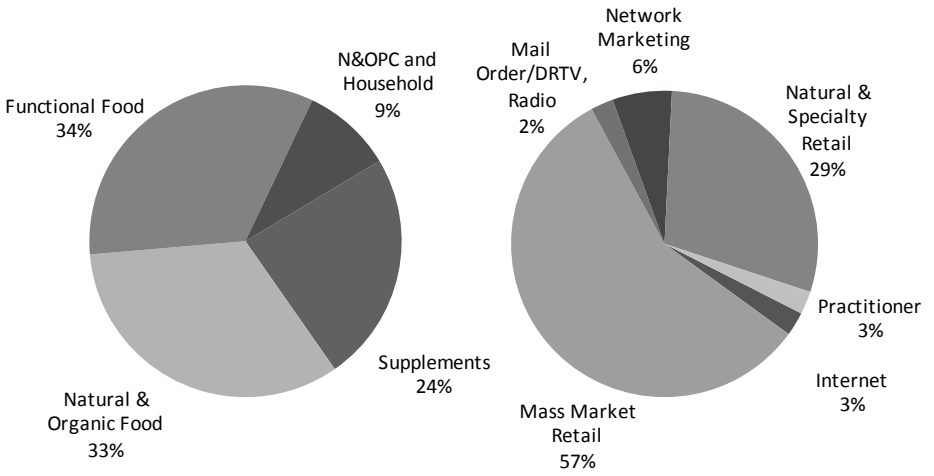
Organic Wins Big in 2010

Sales, public discourse & shifting attitudes toward science tag healthy foods as the driving force in nutrition

$117 Billion U.S. Nutrition Industry Consumer Sales in 2010



Source: Nutrition Business Journal *estimates (consumer sales)*

In January 2010 at the **World Economic Forum** in Davos, Bill Gates reiterates a longstanding support for genetic modification of the food supply in developing countries: "Our foundation is working with partners—**Dupont Pioneer** on maize and **ADM** on cocoa. Some of these are traditional breeding projects, and some of them are transgenic. In parallel, we're also funding scientific expertise in Africa so that—three or four years from now, if things go as expected—when there are advances to crops with big benefit, each country can weigh those benefits against the risks."

Gates continues: "The likelihood that the safety profile will be okay—I hope that works out, because this is a tool, particularly for disease resistance, where an RNA interference gene for a particular crop problem can be a real help. You're right on the verge of starvation all the time, so you want to look into every tool that's safe and appropriate."

Jump to December 2010, when **Dr. Oz** hosts an entire episode on genetically modified food. In an informal audience poll, 80% respond that they would not buy food they knew to be genetically modified. (And we wonder why labeling is such a daunting, contentious issue.)

Oz goes on to display a map of Europe, highlighting six countries where GMOs are "banned." He asks his panel of experts, including Jeffrey Smith of the **Institute for Responsible Technology** and the public face of the **Non-GMO Project** labeling initiative, this: "At the end of the day, I'm most interested in—and I expect the viewers are most interested in—whether this food is good for my kids. I want to cure famine in Africa too, but I'm trying to focus in on whether I give my four kids GMO foods."

Dr. Oz's bottom line for the American viewing public? "You vote with your pocket book three times a day. You can choose to buy foods with GMOs or without them. Instead of waiting for data to derive your decision, you're going to have to decide the safest foods for your family on your own. Labels do exist on some products—choose them for now."

NBJ mentions these bookends to the year that was as evidence of two trends that deserve more careful pause and reflection in the days to come. One: The debate about nutrition for American consumers shifted away from supplements toward food in 2010. Two: The debate about science's role in nutrition shifted away from the promises of innovation and functional benefit to one of villains, contaminants, disease and science generally run amok.

To the second point, GMO is fast becoming a crucible by which science, and many of the agricultural and chemical advances of the past 50 years, might soon be judged by consumers. This cover story closes with an in-depth assessment of science's precarious position in that consumer's psyche from leading voices across the industry. Not everyone agrees that a topic as nuanced as GMO even registers for the average American right now, but many see that day coming.

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Inside *NBJ*

Company & Brand Index

2010 U.S. Nutrition Industry Revenues by Channel

Category	Natural & Specialty Retail	Mass Market Retail	Mail Order/DRTV, Radio	MLM	Practitioner	Internet	Total
Supplements	$10,300	$8,200	$1,570	$4,410	$2,240	$1,310	$28,060
Natural & Organic Food	$15,470	$20,750	$800	$860	$200	$940	$39,020
Functional Food	$3,970	$34,540	$40	$260	$40	$220	$39,070
N&OPC and Household	$4,570	$3,360	$380	$1,810	$470	$370	$10,950
Total	**$34,320**	**$66,860**	**$2,790**	**$7,330**	**$2,950**	**$2,840**	**$117,110**

Source: Nutrition Business Journal *($mil., consumer sales). Primary research includes* NBJ *surveys of natural food, supplement and N&OPC manufacturers, distributors, MLM firms, mail order, Internet and raw material companies, as well as numerous interviews with major retailers, manufacturers, suppliers and industry experts. Secondary sources include SymphonyIRI Group,* The Natural Foods Merchandiser, *SPINS, The Nielsen Co., company data and others. Note: To avoid double counting,* NBJ *classifies soymilk and nutrition bars as functional rather than natural & organic foods and beverages, although both are included in natural & organic totals cited in* NBJ *elsewhere. Natural & Specialty represents natural, health food, supplement and specialty retail outlets, including Whole Foods Market, GNC, sports nutrition stores, etc. Mass Market represents FDMCC or food/grocery, drug, mass merchandise, club and convenience stores, including Walmart, Costco, etc. Mail order represents catalogs, direct mail and direct response TV and direct response radio. Practitioners represent conventional and alternative health practitioners, athletic trainers, beauticians, etc., selling to their patients/clients.*

Nutrition Up 6%, Organic Up 8%

Sales results further the argument that the real action in nutrition these days lies in food, specifically natural & organic food. With annual sales up 8.3% to $39 billion, natural & organic posted the best performance of the four nutrition categories tracked by *NBJ*. In second place? Natural & organic personal care & household products at 5.8% growth, followed by 4.6% annual growth for functional foods. Supplements brought up the rear with 4.4% growth. In 2010, the bloom fell off the rose for categories of nutrition products heavily defined and marketed along scientific claims. Categories providing "cleaner" and "safer" havens from the darker sides of science—namely, organic—performed comparatively well. It's worth noting, however, that 4% growth still trumps the anemic 0.7% growth for the larger U.S. food industry in 2010. The trend toward improved nutrition as a preventative means to improved health remains strong and unassailable.

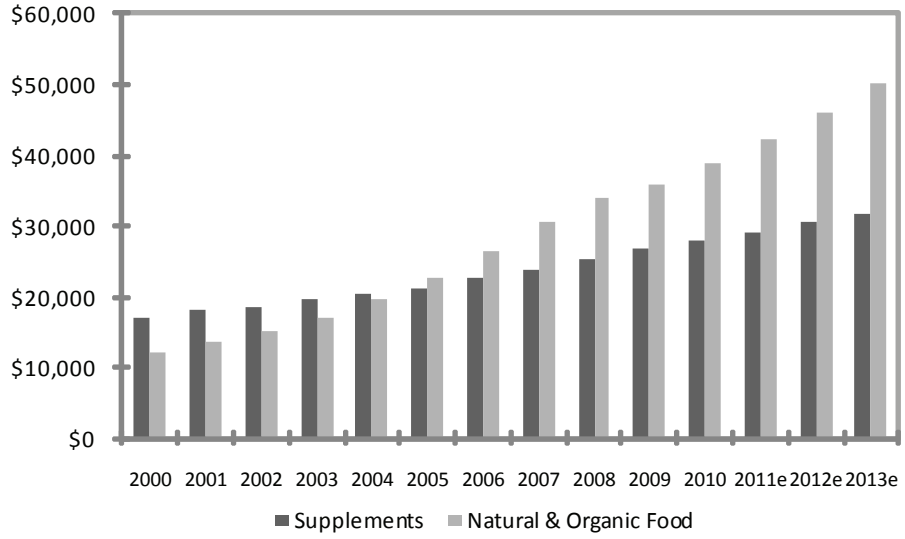
Why the slower growth for supplements? Popular suspects include a quiet year for major breakthroughs along the research front, as well as a dearth of star performers—no new vitamin Ds, no exotic new superfruits that caught the popular imagination. Speaking of superfruits, it's worth highlighting herbs & botanicals for their especially poor performance, with break-even sales of $5 billion on 0.2% growth. Again, the lack of external stimuli—no H1N1 to send consumers scurrying for elderberry—in addition to fears of pesticide contamination and product adulteration, particularly out of China, kept shoppers on the sidelines. The category suffered most egregiously from a 10% sales decline through the ever-fickle multi-level marketing (MLM) channel. *NBJ* will examine the supply chain for herbs & botanicals in greater depth this September. In October, we dive deep into 2010's shining star, natural & organic foods.

Is the prolonged soft economy a contributing factor as well? Of course, but not all categories appear to suffer softness equally. For natural & organic to nearly double the growth rate of supplements suggests to *NBJ* a trend toward market segmentation. The perceived value of science among consumers seems to be a strong determinant of the segmentation underway, but only time will tell if this is the best lens here. More on segmentation, a countertrend to the oft-discussed convergence underway in functional foods, at the end of this story.

Additional insights from our research into nutrition sales show that direct channels outside of MLM remain strong. Internet sales grew 14% in 2010, with healthcare practitioners clocking 7% growth and direct media (TV, print, radio) jumping 9%. Within the supplements category, sports nutrition stole the show with 9% annual growth on $3.2 billion in sales. Thanks to such archetypal successes as fish oil and probiotics, the specialty category also posted strong returns at 6% growth on $5.2 billion in sales.

Before we leave the sales data for trends shaping these sales, please note that,

U.S. Supplement vs. Natural & Organic Food Sales, 2000-2013e



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

What's Your Biggest Hope for NDI Guidance? Your Biggest Fear?

"I hope the guidance respects the basic goal of establishing the concept of NDIs—a mechanism to assess *safety* of dietary ingredients. What this would accomplish, if properly implemented, is a renewed commitment by industry to build into their product development and budgets a review and assessment of their ingredients' safety. This would include, in my judgment, looking at solvents and manufacturing methods, adulterants likely to be encountered, and using competent analytical tools to establish identity methods for the ingredient. My biggest fear? That FDA lacks the resources to put well-focused attention on compliance, resulting in no net improvement of the status quo. I also hope FDA would not use the NDI process as a secondary enforcement tool to go after claims or other issues not involving safety per se, particularly relating to imported ingredients."

—Loren Israelsen, United Natural Products Alliance

"I hope FDA's document provides practical guidance to assist supplement companies in better understanding when NDI notification is required, and to more successfully complete those notifications. Such guidance should have the effect of clarifying that most herbal ingredients and many herbal extracts are not NDIs, and of increasing the likelihood that submitted notifications will be filed by FDA without any substantive comments or objections. My biggest fear is that FDA will confuse its obligation to issue guidance as an opportunity to reinterpret DSHEA in a manner that narrows the intent of Congress with regard to the breadth of ingredients allowed to be sold in dietary supplements."

—Michael McGuffin, American Herbal Products Association

"I hope it provides clarity to the industry and also clears the air. FDA has taken varied approaches to submissions that have left many parties justifiably confused. The concerns remain that the agency is understaffed and may not have the adequate resources to tackle these issues without sacrificing enforcement of the cGMP requirements for the dietary supplement industry. The recent passage of FSMA increases the workload at FDA. Without better management practices and risk-based priority setting, bolstered by adequate resources, I fear the guidance document will be difficult to manage by the agency and the industry."

—Mark LeDoux, Natural Alternatives International

"My biggest hope is that it provides guidance to effectively determine whether an ingredient is actually a new dietary ingredient, as well as the level of data necessary to establish its safety. My greatest concern is that, after almost 17 years of nonenforcement, the agency will view the term 'new dietary ingredient' expansively, to the extent that at least 65% of the ingredients presently marketed would be considered NDIs subject to notification, and thus adulterated as a matter of law because that notification has never been filed."

—Todd Harrison, Venable LLP

"The NDI process to date has become frustrating and feared, as the FDA has objected far more applications than it has approved. As a result, fewer companies are electing to enter into the NDI process, instead seeking alternatives such as GRAS submission, non-compliance, or simply avoiding innovation until it becomes more clear what the guidance will be. The industry hope is that FDA will remain true to the broad intent of the NDI requirement and focus on the safety of the ingredient in an effort to better protect consumers. There exists a wide chasm of 'worst-case scenarios,' so it's possible to imagine a broad-stroke focus on the minute and specific details of the most literal interpretation of DSHEA. If this were to happen, any ingredient that has undergone even process efficiency improvement could be subject to an expensive and time-consuming NDI submission requirement. This seems unlikely, in my opinion. My biggest fear is the NDI guidance will not give the definitive answers which reopen the door for innovation."

—Scott Steinford, ZMC-USA

"Our single biggest hope is for the revised language to provide manufacturers with greater clarity in knowing whether or not they are required to submit an NDI. We also hope the guidance will provide greater transparency on FDA's requirements for a reasonable expectation of safety. With a clearer sense of what the agency requires, we hope to dramatically improve the 'no objection' response rate for NDIs. The guidance could potentially draw attention from FDA to the fringe players marketing products that are unquestionably NDIs, or not even dietary ingredients at all. Hopefully it will empower the agency to go after these products and get them off the market. Our biggest fear is that we will get an overly narrow definition of a dietary ingredient, and an overly expansive definition of what constitutes an NDI, without any instruction for the industry on how FDA plans to transition or how it would handle the backlog of NDI notices that would result."

—Steve Mister, Council for Responsible Nutrition

after detailed scrutiny, *NBJ* believes we underestimated the contribution of the mass channel to natural foods in our historical data. After revisions, our sharper model skews the data up for natural foods in the early 2000s. Detailed trending of this revised historical data is available to subscribers on our website.

The Trends

This cover story is only a passing glance at a meaningful overview of the U.S. nutrition industry in 2010. The articles that follow throughout this issue tell the full story.

Let's start with **Walmart** [*page 11*], where supplement sales declined 4% in 2010, and continue to slip in 2011. Poor strategic decisions around in-store merchandising and over-concentration on private label brands brought the giant to its knees, while the remaining major players in mass took share with better promotions and stronger alignment with wellness services. "Walmart tried to get even better buying power by limiting assortment, and that strategy clearly failed," says Greg Horn of **Specialty Nutrition Group**.

Still in the supplements world, *NBJ* takes a close look at science with our examination of toxicity as the flipside of enhanced bioavailability [*page 14*]. Leading scientists and manufacturers seem much more concerned with nanotechnology than any potential toxicity threat from more available ingredients. "With nanotechnology, you now have a synthetic version of a natural product in a sense, even though it's only particle size," says Neil Levin of **NOW Foods**. "How do you know where those particles accumulate and how they metabolize?"

This raises more questions about the kind of science the supplements industry needs to move the needle forward in the minds of regulators, the media and consumers. "When I started 10 years ago, I used to do presentations about why companies should even do research," says Jay Udani, MD of **Medicus Research**. "Now, the conversa-

tions are all about how to do it better." Those on the forefront of supplement science, including Dr. Josephine Briggs at the **National Center for Complementary and Alternative Medicine**, point toward biomarkers and studies designed more around mechanisms of action than hard, clinical endpoints, as the future model of research [*page 19*].

Omega-3s continue to garner acclaim (and sales) for the growing body of evidence proving their efficacy across nigh every physiological system in the human body. While probiotics remain a strong contender for this top-tier echelon, vitamin D may have the upper hand [page 27]. The science around D is already strong, and there's more to come. "The promising part is the breadth of the field over which vitamin D is operating," says Robert Heaney, MD of **Creighton University Medical Center**. "There are dozens of articles that show the critical role of vitamin D in many different systems and tissues."

As for the current regulatory environment, *NBJ* poses two questions later in this issue, in the hopes of drawing new lines around a widely reported topic. Can private industry, namely **Whole Foods Market**, do a better job of protecting consumers than federal regulators [*page 34*]? Also, are regulators in Europe doing a better job of protecting the food supply than their U.S. counterparts [*page 39*]? Taken together, the answers to these questions don't speak favorably of **FDA**, **FTC** or **Congress** for their effectiveness at providing safe and nutritious food to their citizenry.

Of course, new guidance on new dietary ingredients (NDIs) is the real story for supplement manufacturers, but that guidance was still pending at press time. Leading voices from industry speak to their hopes and fears for NDIs on the facing page.

What about food? If food is the real story in 2010, what's driving the growth? Two answers spring to mind: Natural & organic food companies tell a compelling story for value-driven consumers looking increasingly beyond price. Whatever values you throw on that differential—organic, local, sustainable, GMO-free—natural foods brands are slowly but successfully refashioning the consumer's mindset to veer beyond price alone. Secondly, thanks to the lack of labeling around GMOs, organic now exists as a last bastion for consumers looking for truly "natural" foods. Our profile of Justin's [*page 42*] and our Q&A with Earth Balance [*page 44*] provide insights from manufacturers succeeding in the trenches.

NBJ has sounded the alarm for increased investment by supplement companies in product development

Universe of U.S. Supplement Companies in 2010

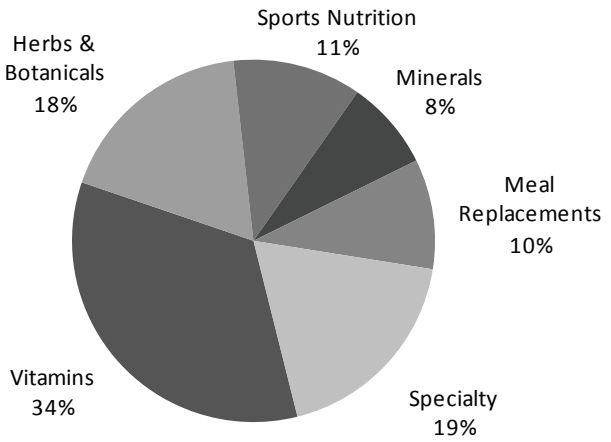
Market	No. of Cos.	Supplement Sales	% of Market
Greater than $100M	31	$6,630	40%
$20M - $100M	85	$3,240	19%
Less than $20M	657	$1,990	12%
Supplement Man./Marketers	773	$11,850	71%
Multi-Level Wholesale Value		$2,490	15%
Private/Store Label Wholesale Value		$2,430	14%
Total Wholesale Supplement Value		**$16,770**	**100%**
Consumer Sales ($mil)		**$28,060**	

**Companies with a substantial portion of revenues from contract manufacturing of supplements.*
Source: Nutrition Business Journal *[$mil., net sales (gross sales minus any returns, discounts or allowances)]. In the top company list, company revenues listed are wholesale for supplements only (including contract manufacturing) rounded to the nearest $10 million, not entire company revenue. Company brands listed are representative but not comprehensive. List does not include raw material companies or firms selling primarily through the multi-level marketing channel. Some revenues are estimates that have been compiled through information provided by company executives, industry analysts and reputable published material.* NBJ *makes every effort to be accurate, but revenue figures are not the result of audits and are not guaranteed to be accurate. Errors and omissions are unintentional. In the company universe table depicting wholesale sales, revenues for non-retailer contract manufacturing were subtracted to avoid double counting.*

NBJ's Top U.S. Supplement Companies in 2010 ($mil.)

Company ... 2010 U.S. Wholesale Supplement Sales	
NBTY (Natures Bounty, Sundown)	1,770
Pharmavite*	850
Abbott Labs/Ross Products (Ensure, EAS)	550
Perrigo*	490
Pfizer (Centrum, Caltrate)	460
GNC (contract manufacturing)*	390
Bayer (One A Day, Flintstones)	320
Schwabe NA (Nature's Way, Enzymatic)	300
Atrium Innovations (G of L, Pure Encap)	240
Iovate (Hydroxycut, MuscleTech)	230
CytoSport (Muscle Milk)	200
Glanbia (Optimum Nutrition)	200
Nestle (Boost, Carnation, Optifast)	190
Schiff Nutrition International	180
Healthy Directions (Doctor's Preferred)	180
VitaQuest Intl (Windmill)*	170
International Vitamin Corporation	170
NOW Foods	170
Basic Research/ Zoller Labs (Zantrex)	160
Nutraceutical Intl. (Solaray, Kal, Zand)	160
Alacer	150
BSN (NO-XPLODE. CellMass, Nitrix)	140
Metagenics	130
Natural Factors Nutritional Products	120
Life Extension	110
Kikkoman (Country Life)	110
Cornerstone Research and Development*	110
Standard Process	110
New Chapter	100
Unilever (SlimFast)	100
Delavau*	90
Natural Organics (Nature's Plus)	90
DSM/Martek (Amerifit)	90
Nordic Naturals	90
Jarrow Formulas	80
ISI Brands (TwinLab, Metabolife)	80
Bausch & Lomb (Ocuvite, PreserVision)	80
Arizona Nutritional Supplements*	80
Airborne Consumer Health	80
Nature's Products (Rainbow Lt, Champion)	70
Threshold Enterprises Ltd.	60
Nature's Best (Isopure)	60
S.A.N. Corp. (Bolt, V-12, Tight)	60
Atkins Nutritionals	60
Reliance Private Label Supplements*	60
Natural Alternatives*	60
Bluebonnet Nutrition Corp.	60
ReNew Life Formulas	60
Proctor & Gamble (Metamucil)	50
Matrixx Initiatives (Zicam)	50
Barlean's Organic Oils	50
Standard Homeopathic Co. (Hyland's)	50
Plethico (Natrol)	50
VPX Sports	50

$28.1 Billion U.S. Supplement Industry Sales by Product in 2010



Source: Nutrition Business Journal *estimates (consumer sales)*

for many months, and the data now clearly points to the consequences of fear and stasis on that front. When innovation dries up, perception shifts. It comes as little surprise that the conversation in 2010 moved away from supplement science—a positive message of filling micronutrient gaps and preventing disease—to food science, a darker message riddled with the legacy of villains like BPA, rBST and, perhaps, GMO.

The fact that natural & organic—burdened with the highest price premiums in nutrition—outpaced supplements and functional foods to such a degree indicates that price alone is not the single determining factor it once was. It also suggests that "clean" food is a stronger sell than ever.

As a final point, the intersection of many trends examined in this issue coalesce for supplements around the shift toward whole-food products. To whatever degree the consumer's aversion to science in the food supply ultimately develops, organic and whole-food derived supplements speak directly to this concern, and *NBJ* would expect increased sales to come. Organic supplements, a small segment with $540 million in sales, grew 7% in 2010. Think of the expansion of **Safeway**'s *O* line as a leading indicator. **NSA**, makers of *Juice Plus+*, a whole-food powder chocked with fruits and vegetables, not only cracked our top 15 company list in the MLM channel, they leaped to fifth place with $260 million in 2010 U.S. supplement sales. Sources close to *NBJ* also indicate that NOW Foods is in the process of a significant strategic migration toward whole-food based supplement lines, and selling whole foods themselves within its retail stores. It also stands to reason that traditional supplement solutions like herbs & botanicals have fair right to the whole-food game. Perhaps this trend away from synthetics will right that ship in the years to come.

"For sophisticated supplement buyers and consumers, I do see a movement away from processed and artificial supplements toward more whole-food supplements," says Thomas Aarts of **Nutrition Capital Network**. "This is driven by some big companies putting that message out there—**Garden of Life**, **New Chapter**, and **Standard Process** in the practitioner channel.

"This entire industry—the $28 billion dollar supplement industry—is based on raw materials that are processed and engineered. Ingredients get powdered, extracted, manipulated. We add excipients, magnesium stearate and binders. We stick it all in a pill, or softgels with gelatin from bovine sources. All this stuff that we do to get nutrients in our bodies is not necessarily the best way for our bodies to receive them." The trend here remains bleeding edge, according to Aarts, but leading thinkers and companies are working now to bring that edge closer to the mainstream.

The Backlash Against Science

Few of the thought leaders in nutrition would go so far as to characterize the shifting sands between consumer demand and what science supplies them in the food system as a backlash, but that very relationship is certainly getting prickly. To begin, why do food and supplements, a scientific approach to food, continue to get along so well?

"I look at food and supplements as something of a forced marriage," says Jeff Hilton of **Integrated Marketing Group**. "The two have gotten along from a distance, but it's like taking two strangers and making them sit next to each other. They've lived side by side in health food stores for a long time now, but they never really paid much attention to one another. Over the past few years, convergence in functional foods has pushed them together such that they now look across the aisle and say, 'Oh, I guess we'd better develop a relationship.' That's why you see **POM Wonderful** making supplements, and supplement companies going after GRAS status to get ingredients into food. Everybody's trying to come together now and figure out what the marriage will look like."

This promise of convergence has long held promise for the industry as a means to generate dramatic new revenue streams and, more importantly, get scientifically-backed nutrition firmly entrenched in the American diet. The problem? Science keeps changing the game, and consumers are fed up.

"Establishment keeps changing the rules, especially for moms," says Hilton. "Trans fat was the bad guy, then it was carbs. Now there are good and bad fats. Moms express real frustration in focus groups over this. There's a new villain in the food supply every day, and consumers can't keep track. Moms want you to make it simple for them. The fewer the ingredients the better."

According to Hilton, simplicity is strongly informed by the consumer's desire to avoid processed foods. But what does that really mean to a mom? "Extra ingredients and ingredients they don't understand—that's how moms gauge

it," says Hilton. "They're label readers. If moms see a bunch of chemicals, they assume a product is highly processed. Less is more." How far a jump is it in the consumer psyche from chemicals on a label to the broader value of science in their shopping carts and cupboards? When the villains crowding the consumer imagination grow bigger fangs—GMOs again come to mind—how will consumers respond to industries built around food science and products built around scientific claims? At what point does distrust of science become a precipitating factor in purchasing?

Steve Mister of the **Council for Responsible Nutrition** (CRN) also sees convergence on the rise. If we take convergence to its logical extreme, will we ever see a marketplace entirely devoid of supplements or pills? "No," says Mister. "I don't think that's where we want to go. When it comes to food—whether it's foritifed or not—everybody's eating habits are so different. Supplements control the dosage unit. You only take the product for its nutritional value. You're not taking supplements for the satiety of hunger. If we start relying on functional foods too much for nutrition, everybody's intake habits are so different—she's hungry, he's depressed, you have a sweet tooth—that some people might get the correct dose and some might get six or seven times as much."

Mister does have consumer distrust of science on CRN's radar screen, but the threats to industry don't keep him up at night. "I do think we are going to see more emphasis on local, on organic, on small farms to get as many of the available nutrients as we can from food. People are concerned about genetic modification, to a degree. In supplements, there will be more organic product lines, more consumers looking for Echinacea—for example—that was never sprayed with pesticides."

The core consumer of natural products and the average American consumer are two entirely different beasts, as we all know, but the two camps seem to becoming closer and closer friends. "Look at the numbers of people finally discovering their gluten intolerance," says Bob Burke of **Natural Products Consult-**

Interesting Collisions: Monsanto & GOED

Monsanto is a first-tier member of the **Global Organization for EPA and DHA Omega-3s** (GOED). Is that surprising to you?

If not, then you fully understand the supply & demand dynamics of fish oil, as well as the interesting collisions taking hold in natural products. GOED exhibits at major trade shows. GOED quite effectively advocates for what some would argue is the shining star of the supplements industry, the best that industry has produced in collective terms of science, impact and sales. GOED could be a leading light in the natural products world, but then there's Monsanto. For core consumers in natural products, Monsanto comes straight out of a James Bond movie—even Hollywood could not produce a better villain. How exactly did these two come together?

The story begins in September 2009, when Monsanto petitioned **FDA** for GRAS status over stearidonic acid (SDA) soybean oil. By inserting genes for two enzymes—one from flowers, one from bread mold—Monsanto created a soybean that converts its own alpha-linolenic acid (ALA) into SDA. These acids are all omega-3s, by the way, but not every omega-3 was created equal. The human body is significantly more efficient at converting SDA into EPA and DHA—those coveted long-chain fatty acids (LCFA) linked to heart health, mental health and a host of physiological benefits—than it is converting ALA. The thinking goes that, with 375mg of SDA fortified into commerical food products, a raft of problems plaguing fish oil, from sustainability to contamination to cost, go by the wayside. In its petition, Monsanto expressed plans to introduce SDA soybean oil into cereals, puddings, grains, gravies—you name it.

"Monsanto is indeed a member," says Adam Ismail, GOED's executive director, "along with most of the other plant biotech people working on omega-3s, like **Nuseed** and **BASF Plant Sciences**. We work on EPA and DHA issues beyond just the natural products space, including pharma, infant formulas, medical devices and clinical nutrition. If you do the numbers, we will ultimately need every source of EPA and DHA to nourish the human population, including genetically modified plants." In June of this year, research sponsored by GOED, Monsanto and others, appeared in the *British Journal of Nutrition* pegging minimum daily intake of LCFAs at 250mg.

To the numbers, Ismail offers the following argument: "To meet the minimum intake recommendation for 7 billion people would take 2.5 million tons of anchovy oils, but there are only about 350,000 tons that can be produced sustainably. We can turn to the other fish oils, but there are only 1 million tons of total fish oil produced in the world, and most species have much lower levels of EPA and DHA. So the burden could increase to 5 million tons. Regardless of how you look at it, we are talking about multiples of what is needed just for basic nutrition. Also, keep in mind that this is a minimum. Many scientists believe you need 500mg per day, so that would double the burden again to 10 million tons.

"There have to be new sources to supply what we need as a species. While many in the natural products space are against GMO plants, there are markets for these products beyond natural products, and the supply & demand dynamics basically mean all sources are going to have to be developed."

While Monsanto and GOED working together presents an interesting collision of industries and further clouds the picture of just what "natural products" might come to mean, Ismail's math suggests a subtler threat to the widespread adoption of fish oil in the American diet—pharma. On the heels of **GlaxoSmithKline**'s *Lovaza*, several additional companies are now entering the space for non-nutrition applications, according to Ismail. Pharma is less price sensitive on supply, and this means pharma has better leverage to source the majority of available fish oil in the marketplace. For everyone else ... how about a fancy soybean?

ing. "Or 50-year-olds suddenly becoming allergic to shellfish. Consumers like these start to beg the questions—What is it about the inputs in our food supply? What is it about how food was raised, processed, collected? People are making more declarations—maybe totally unfounded—that the food we eat today is nothing like what our grandparents ate, due to GMOs or endless hybridization or the cumulative effect of all the questionable inputs that might link back to their health conditions. That's when you reach the blue-collar worker. It finally dawns on them that there's something to this."

For evidence of the push down, Burke sees traction in several clean-food categories clearly defined at arm's length from science: vegan, raw foods, gluten-free, especially among people who may not have a gluten intolerance but still view the diet as a means to lose weight, gain energy and sleep better. Perhaps science is the filter here, and perhaps not. Perhaps science is the undercurrent that collects many of these early signs pointing toward market segmentation within the broader nutrition industry. If so, this would indicate a certain maturity to the industry, that nutrition now has the mainstream strength to stand on its own two legs and decamp into viable factions defined by the varying degrees to which they want science tinkering with their food.

Sure, convergence as a macro-trend is alive and well, but perhaps segmentation is too. "Eating yogurt is one thing," says Burke, "but microencapsulated probiotics in bars or shelf-stable cereal is something entirely different." The number of people who might respond to this statement, much less understand it, is only growing.

The Dawn of Segmentation

Donald Wilkes of **Blue Pacific Flavors** speaks of "wholegrarians," a consumer movement built around traditional, fresh, whole foods and the rejection of processed and functional foods. This is the best example *NBJ* has found to date that begins to understand the segmentation developing within nutrition in reaction to science. "I do see segmentation," says Wilkes. "Look at the history of convenience foods in the United States. Nutrition was not a part of that discussion. Nutrition was not generally available to consumers. For years, the marketers had a great opportunity to promote products that did not necessarily meet higher standards of fresh, nutritious food.

"I think that opportunity has passed. The future consumer is evolving so rapidly that our traditional business models and how we approach consumer need has to evolve to stay relevant. I think supplements, for example, will always be relevant to consumers, but finding ways to position products as whole foods is very important as a marketing strategy going forward. As the consumer becomes more forensic about what they consume—because of fears and uncertainties surrounding food saftety, or fears and uncertainities about questionable supplement claims—companies have to build more credibility going forward."

There is a trend here, if not a movement, that in some way defines itself in opposition to the scientific advances embedded in the food system over the past 50 years. As the public debate focuses more on organic foods and sales follow, companies in the supplement and functional foods space need to better understand this new segment of consumer and better fashion their response.

"Science should really be communicated as safety in food," says Wilkes. "If you start talking about science in terms of health claims, I think that can easily become a barrier to consumption."

U.S. Nutrition and Supplement Sales by Retail Channel in 2010

Independents/ Small Chains	# of Stores	Total Retail Sales($mil)	Nutrition Sales($mil)	Supplement Sales($mil)
Natural Food Store <2000 sq ft	1,230	$580	$580	$140
NFS: 2001-6000 sq ft	1,900	$4,530	$4,530	$480
NFS: >6000 sq ft	1,020	$9,340	$9,340	$910
Health Food Store: <1000 sq ft	1,350	$350	$350	$260
HFS: 1001-2000 sq ft	1,730	$870	$870	$570
HFS: >2000 sq ft	1,610	$3,900	$3,900	$1,900
VMS Store: <=1000 sq ft	1,680	$760	$760	$710
VMS Store: >1000 sq ft	1,400	$1,160	$1,160	$1,060
Subtotal	**11,930**	**$21,490**	**$21,490**	**$6,030**
Large Chains				
Whole Foods	290	$9,080	$9,080	$1,350
GNC	5,650	$1,250	$1,250	$990
Vitamin World	450	$180	$180	$170
Vitamin Shoppe	480	$660	$660	$630
Other*	17,240	$1,650	$1,650	$1,140
Total Natural & Specialty	**36,050**	**$34,320**	**$34,320**	**$10,300**
Mass Market				
Food	97,770	$550,060	$43,250	$1,230
Drug	37,410	$222,270	$5,330	$1,950
Mass Merchandiser	6,860	$284,210	$11,820	$2,950
Club	1,220	$121,620	$5,170	$1,640
Convenience/Other	146,340	$146,500	$1,280	$430
Total Mass Market Retail	**289,600**	**$1,324,660**	**$66,850**	**$8,200**
Total Retail Nutrition	**325,650**	**$1,358,970**	**$101,170**	**$18,500**
Non-Retail Nutrition	n/a	n/a	$15,940	$9,560
Total Nutrition Industry			**$117,110**	**$28,060**

Source: Nutrition Business Journal *and* The Natural Foods Merchandiser *market overview survey, SPINS, The Nielsen Co., SymphonyIRI Group, U.S. Department of Commerce, FMI, NACDS, public company filings and others. *Other includes specialty/gourmet, personal care, cosmetic, gyms, herb shops, mall stands, delis, bakeries, salons, gift/boutique stores, etc. Nutrition sales include natural & organic and functional foods, supplements and other (N&OPC, books, household goods, etc.).*

Ten Years From Now, What Should the Nutrition Industry Look Like?

Assessing progress since 2002, envisioning more progress for 2020

An editorial by Thomas Aarts

This article is the third in a series addressing the state of the dietary supplement industry in a post-DSHEA world. The first article, written with Loren Israelsen of the **United Natural Products Alliance** and published in December 2002 inside the pages of *Nutrition Business Journal*, urged companies to resist their reactive stance in defending DSHEA, and instead focus greater energies on self-regulation. We encouraged the supplement industry to take responsibility for its own future, proving by our own proverbial hand that this industry is well-regulated. Thanks to self-policing initiatives and more effective communication between the industry and **FDA**, **FTC** and **Congress**, I believe this has happened.

In December 2003, Mr. Israelsen and I surfaced again with another editorial in *NBJ* that addressed the signature issues of the day: the lingering myth that our industry is unregulated, the scourge of drugs posing as dietary supplements, and our lack of quality and safety standards. Since that article appeared, the ephedra ban and the steroid precursor ban went some signifcant measure toward debunking this myth. The ephedra ban, in particular, robbed industry foes of their tallest lightning rod, while the ban on steroid precursors began to seriously address concerns over drug spiking.

We are still dealing with adulteration issues today, driven largely by economic opportunity and vague testing and analysis protocols. To address this issue more pointedly, the **American Botanical Council** is working with several groups, including the **American Herbal Pharmacopoeia**, to provide a series of reports on adulterants in botanical materials. The reports from this project will publish over the next few years, with the first white paper on solvents to come out this year.

On the question of protecting the most important provisions of DSHEA outlined in our second article—a definition of dietary supplements, distinguishing between supplements and food additives, and the burden-of-proof problem—I believe that the industry has been even more successful. There are now more executives and leaders who understand the importance of DSHEA's core provisions. Our leading trade associations have grown larger and more effective at communicating with each other and the government.

In 2001, the **Dietary Supplement Education Association** (DSEA) was formed with a stated mission to educate the public about the positive aspects of dietary supplements. This group eventually merged with the **Natural Products Foundation**, but before that it did help to fund and broadcast the results of the **Lewin Group Study**, which documented concrete savings in healthcare costs associated with five supplements. The first two—calcium & folic acid—demonstrated combined savings of over $14 billion over five years, while omega-3 supplements, glucosamine and saw palmetto showed substantial promise for improving health and quality of life.

> *"I have long believed that an industry that supports as many trade associations and segments as ours would benefit from a 'federation' of associations and leaders that convenes on a regular basis."*
>
> —Thomas Aarts

Since Congress heard the results of this study in September 2004, growing numbers of consumers have taken to calcium and folic acid, so the actual savings could be even higher. Moreover, the consumption of omega-3s has increased dramatically, with consumers now spending over $1 billion annually on omega-3 supplements in hopes of preventing cardiovascular disease. In 2005, the **Centers for Disease Control** estimated that at least 84,000 heart-disease-related deaths each year could be prevented with omega-3s.

As healthcare costs and related personal bankruptcies approach staggering numbers, some industry leaders have proposed that we update the Lewin Study, adding several additional supplements such as vitamin D3, vitamin K and magnesium, among others. I concur. I believe that certain nutritional ingredients, whether delivered in supplement or food form, can help mitigate healthcare costs from diseases associated with the Western diet. These supplements can counterbalance the perverse incentives in the current healthcare system for quick fixes and sickcare solutions.

On the question of restoring public confidence, the **Council for Responsible Nutrition** (CRN) has implemented and funded a successful industry self-policing initiative in partnership with the **Better Business Bureau**'s National Advertising Division. With enforcement teeth provided by FTC, the program allows industry to self-regulate its peers over erroneous and illegal claims. This single intitative has unquestionably raised the bar and helped to weed out many bad apples.

Finally, the industry has made a concerted effort to communicate to the media and the general public that we are, in fact, a regulated industry. Last year, at the annual **NBJ Summit**, several industry leaders charged CRN with creating a summary document entitled, "Does DSHEA Give FDA Adequate Authority over Dietary Supplements?" The report cites FDA commissioners verbatim, on the record, that DSHEA does provide the adequate authority to regulate dietary supplements. [NBJ *will provide this document, as well as a full history of the interactions between regulation and dietary supplements from 1994 to 2010, on its website at nutritionbusiness.com.*]

These two documents were used extensively by trade associations and industry leaders to help explode the myth of an unregulated industry in the minds of regulators, government officials and consumers. Changing existing mindsets is a challenging endeavor, and much more is left to do on this front.

The Future

In this third article, I want to front-engineer our path to progress by creating an "idealized redesign" of the entire supplement industry. The goal is not to plan away from a current or forecast state, but to plan toward a desired state.
It has been well documented that, when an industry has a clearly articulated vision, it will move towards that vision in better concert. There is perhaps no better example of this strategy than when John F. Kennedy articulated in 1962 his vision of putting a man on the moon by the end of the decade. Followers of systems theory will recognize this approach as the work of Dr. Russell Ackoff. In his approach to interactive planning—starting in the future and working back to the present—Ackoff seeks to stimulate imaginative and creative solutions.

One of the key challenges for the supplement industry over the past two decades has been the disambiguation of its stakeholders across many product segments, business sectors, links in the value chain, and shifting overlaps with the pharmaceutical, food, beauty and fitness industries. Many believe that without a more coordinated and constructive dialogue between these stakeholders, progress will be slow.

At the NBJ Summit, industry leaders gather to discuss key issues and challenges. I am fortunate enough to co-chair this event, where we host executives from the four leading trade associations, as well as CEOs from leading nutrition industry companies. This is the perfect venue to shape and promote the coordination that leads to real growth.

The organic industry demonstrated what is possible when leaders get together and agree on a common vision—a federal standard for organic foods, which propelled organics to double-digit growth rates. In a commercial context, a similar dynamic led to the creation of **Whole Foods Market**. A handful of entrepreneurs got together to create a vision for the marketing and retail of natural & organic foods, supplements and personal care products to the public in a large-format store. This vision led to dramatic category growth in super natural foods stores, and brought dramatic numbers of new consumers into the space.

An idealized vision can inspire people to move in the same direction. Shared visions often materialize at a time of crisis, as in the early 90's when the industry fell under siege, but this is hardly a requirement. Rather than wait passively for the next crisis to occur, it would behoove us to pick points of commonality now, and get behind them in a meaningful way. Lester Crawford, former FDA commissioner, once said that he had never dealt with so many factions within one industry, and that nutrition was shooting itself in the foot by not creating one strong, centralized voice.

I have long believed that an industry that supports as many trade associations and segments as ours would benefit from a "federation" of associations and leaders that convenes on a regular basis.

I would like to put forward the beginnings of an idealized vision that articulates this voice. This vision should address how companies will act, as well as define our relationship with consumers, healthcare providers, regulators, retailers and investors.

The Vision

Ten years from now, I believe the following attributes will be used to describe our industry:

• The nutrition industry will be self-policing, so that any company that makes non-defensible claims or sells tainted products will be drummed out by the industry itself.

• The term "unregulated industry" will no longer be front of mind for consumers, doctors, regulators and the media. Perception will improve so that dietary supplements are viewed as safe, effective and contributory to the health of the population.

• The medical establishment will move towards an integrative approach [*See* NBJ*'s June 2009 Q&A with Andrew Weil*]. Doctors will accept key nutraceutical products as alternatives to drugs, or in concert with drugs, to prevent disease and reduce healthcare costs. For example, doctors will prescribe products like probiotics after courses of antibiotics, red yeast rice and diet changes in lieu of statin drugs, and fish oil for heart health and arthritis.

• Healthcare reform will move from access to prevention, and more government resources will be applied to nutrient research so that Alzheimer's disease, cancer, heart disease, and a wide host of conditions can be postponed or even prevented outright.

• Intellectual property laws will change so that qualified nutraceutical products receive legal protection, providing incentives for companies to invest in proprietary nutrient solutions.

• Consumers will take ownership of their own health, make conscious connections between diet and disease, and thus make healthier choices that lead to prevention.

• Schools will no longer sell sugary sodas, milks or juices, but will offer healthy, nutritious food choices that significantly decrease childhood obesity.

This is just the beginning. It's my personal vision of how we can define this industry for a future full of promise and progress. In the coming months, I plan to reach out to industry stakeholders, including politicians, regulators and consumers, to ask for their feedback and their own idealized visions.

Thomas Aarts is co-founder of Nutrition Business Journal and co-chair of the NBJ Summit. He is also a founding principal at Nutrition Capital Network and managing director of Nutrition Business Advisors. You can reach him at tom@nutritionadvisors.com.

Supplement Sales at Walmart Down 4%, Drug and Club Stores Big Winners in Mass

Strategic missteps plague the retailer as 'suicide bidding' in private label reverberates throughout the channel

Fifteen years after **Walmart** plunged headfirst into the wellness business with its in-store nutrition centers and cut-rate vitamins, the nation's largest purveyor of dietary supplements appears to have hit a serious rough spot.

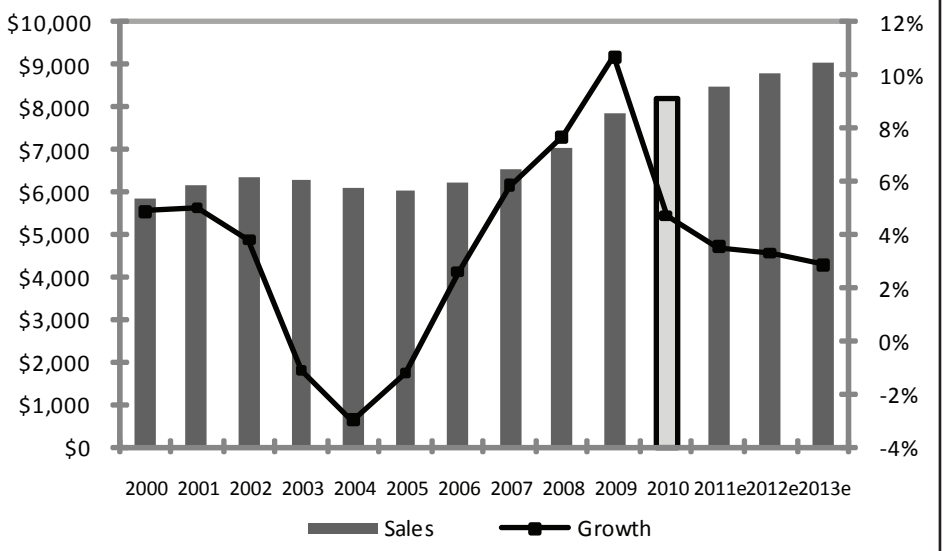
According to numerous *NBJ* sources who asked to speak off the record, the retail goliath saw sales of supplements slip approximately 4% in 2010, a stark contrast to the modest 4.7% gains made across the mass channel as a whole. Walmart's missteps in the supplement aisle helped drag the mass channel down considerably from its heady 10.7% growth in 2009. Sources close to Walmart confirm that the 4% decline at the retailer continues into 2011 sales.

Meanwhile, club stores **Sam's Club** and **Costco**, mass market retailers **Target** and **Kmart**, and drugstores **Walgreens**, **CVS** and **Rite Aid** appear to be stealing the show in mass with frequent couponing, broader selections of branded products, and—in some cases—better customer service, sources say.

According to *NBJ* research, the 2010 story in mass looks like this, : Drugstores posted the strongest annual growth for supplement sales at 6.8%, followed by club with 6.5% growth. Food retailers grew 5.8%, convenience stores grew 4.7%, and mass merchandisers, including Walmart, eked out a 2.0% gain.

"Walmart has been doing some things that are very anti-consumer lately, and it is costing them," says Kurt Jetta of **TABS Group**, a research and consulting firm that reported a 1.4% annual decrease in Walmart's share of the vitamin, minerals and supplements market nationally.

U.S. Supplement Sales in the Mass Market Channel, 2000-2013e



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

Democratizing Supplements

Flashback to the '90s and, in many ways, Walmart broke open the supplement category for the masses. The **Dietary Supplement Health and Education Act** (DSHEA) of 1994 cleared the way for many mass retailers previously concerned by the product category's fuzzy regulatory climate. As the powers that be at Walmart eyed double-digit gains and plenty of room for growth in nutrition products, they boldly jumped in.

On May 3, 1997, the 35-year-old retailer launched its inaugural *OneSource Nutrition* store in Bedford, Texas, a 1,000-square-foot store-within-a-store concept featuring faux-wood flooring, mood lighting, and an ambiance that was decidedly more calming than the fluorescent-lit main store. The thoughtfully designed shelves were stocked with Walmart's new *OneSource* private label vitamins, amino acids, protein powders, and weight loss products, as well as value brand supplements from **Weider Nutrition** and supersized bottles of herbs from **Rexall Sundown,** both key vendor partners who advised Walmart on the OneSource concept, according to press reports.

NBJ also spoke to veterans of **Leiner Health Products** who remember vividly their visits to Walmart in these early days to encourage and prompt the company to stretch the inventory beyond its comfort zone.

The concept stores provided trained pharmacy staff to answer questions, and vowed to offer supplements at 20% to 30% price discount. Walmart also pulled out the stops to raise awareness, hosting media events, handing out free samples, and creating elaborate displays to educate consumers about the then largely-unknown benefits of herbs. "They almost single-handedly created the herbal supplement category in the mass market," recalls Jetta.

By 2000, Walmart's other private label supplement line, *Spring Valley*, supplied mostly by Leiner and somewhat by **Pharmavite** at the time, controlled 8% of all supplement sales at retail, according to *Drug Store News*. The company had become the darling of the supplement industry, much lauded for taking chances with new products and treating vendors with respect.

"A lot of chains ask for as much as they can get and give nothing back, but at Walmart, the whole premise is, 'How can we do more business together more efficiently? What can I do to help you?' " said Frank Cirone, vice president at **SlimFast Foods**, speaking to *Drug Store News* in a glowing 2000 profile of Walmart.

By 2009, Walmart controlled up to 40% of consumer sales, according to several sources, but a perfect storm of market changes coalesced in 2010 to knock the Bentonville behemoth off its pedestal.

BOGO Madness, Too Few SKUs

U.S. same-store sales have been falling for eight straight quarters at Walmart, with the company posting another 0.9% loss in the 13-week period ending April, 30, 2011. While the health and wellness category overall (which includes over-the-counter medication, pharmacy, and eye care) has remained fairly strong, according to statements made by Walmart officials, dietary supplements have been another story.

Many sources interviewed for this story blame Walmart's fall on the company's store-wide initiative to clean up aisles—taking away displays, end caps, and point-of-sale promotional displays. Other key missteps include scaling back on the number of SKUs offered, and boosting emphasis on private-label brands.

The result? A confusing and somewhat soulless supplement offering with little-incentive to try new things on impulse. "Walmart tried to get even better buying power by limiting assortment, and that strategy clearly failed," says Greg Horn, a sustainable business consultant with 20 years experience in the industry. Horn is the former CEO of both **GNC** and **Garden of Life**.

Another source spoke of Walmart's revised supplement set as "a morass of products," begging the question, "How would a consumer even make a buying decision in there?"

Still another source: "Walmart's mixing with their set failed. When you take away secondary promotional product placements, that hurts your impulse business. You're not putting product in front of the foot traffic."

Jetta, whose company does data analytics for nutrition companies to help them better understand consumers, says that the vitamin category is among the "most responsive to more choice. If you increase your assortment by 10%, you are likely to increase sales by 10%. Of all the categories, you don't want to cut back selection on this one."

Again off the record, one source told *NBJ* that several years ago, Walmart set its sights on Target, performing a store-wide rationalization that hit the supplement aisle with dramatic reductions in off-the-shelf promotional displays. "The vitmain business is better than 50% impulse buying," says this source. "Walmart's overall merchandising strategy just didn't work for them, so they're trying to turn things around. Of course, that's like trying to move a huge aircraft carrier."

> *"Walmart tried to get even better buying power by limiting assortment, and that strategy clearly failed."*
>
> —Greg Horn
> Specialty Nutrition Group

As Jetta and others note, an overemphasis on private label can also turn off consumers. "There are a lot of consumers out there who don't buy private label and will never consider it," says Jetta. "You can't turn your back on them."

Tom Zimmerman, vice president and general manager of nutrition at **Perrigo**, one of the nation's largest contract manufacturers of store-brand products, declined to speak specifically about market dynamics at Walmart or other mass retailers. However, he did say that one factor that could be driving supplement shoppers away from mass merchandisers is the recent flurry of Buy-One-Get-One-Free (BOGO) offerings at drug stores, for such broadline brands as *Nature Made* and *Nature's Bounty*.

"Over the last year, the number of these weekly BOGO promotions featured on the front page of national circulars has increased dramatically in the chain drug channel," says Zimmerman. According to overview data from **Efficient Collaborative Retail Marketing**, CVS ran 57 BOGOs for these two brands between May 2010 and May 2011, and Walgreens ran 77. "Price competition from chain drug is increasing and putting pressure on the 'everyday low price' strategy of mass retailers," says Zimmerman.

He also cited another factor, a small but important one: negative press accounts about joint health products (glucosamine and chondroitin were together down 3.6% in 2010, according to *NBJ*) and calcium (forecast down 1% in 2011) have impacted sales of those supplements across all channels.

Customer Service Always Wins

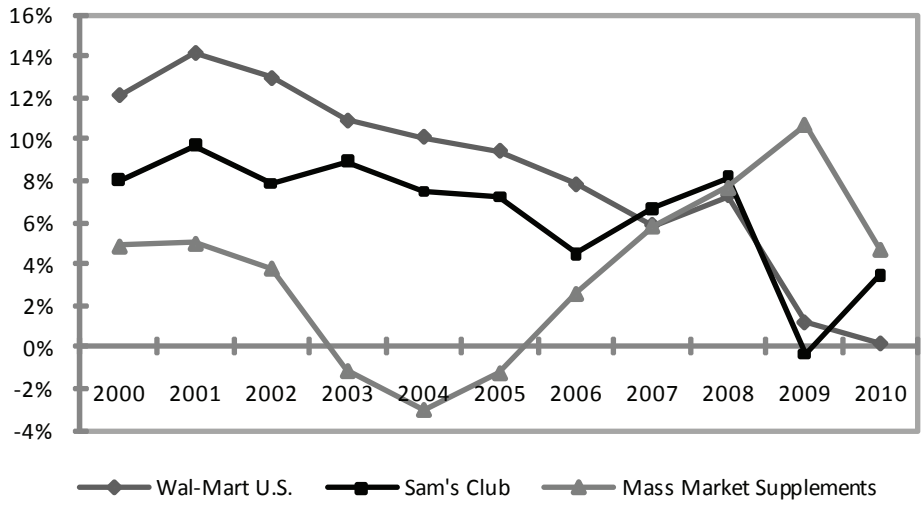
As Walmart has scaled back offerings and refused to play the BOGO game, club stores—including Walmart's sister Sam's Club—appear to be ramping up customer service and selection in the supplement realm, and reaping the benefits. Overall, Sam's saw same-store sales rise 3.9% in the past year. According to *NBJ* sources, supplements are believed to be up around 5% in 2010.

"It's a friendly competition that Sam's is winning big," says one source. "Sam's is succeeding by cultivating consumer relationships around health and wellness. They have pharmacists in management who make smart buying decisions."

In March, Sam's began carrying select GNC products in bulk sizes. Examples include a two-pound container of *GNC Pro Performance Whey Protein* and a 1.7-pound bottle of *GNC Total Lean Lean Shake*. Over the next few months, Sam's intends to roll out a new line of products as part of its successful *Member's Mark* private-label line, a company spokeswoman says. Sam's also recently launched the Prevention Plan, a $99 program billed as '**Turbotax** for health,' which promotes personalized wellness.

Along these lines, one source spoke to *NBJ* of a triple-strength fish oil now carried by Sam's as evidence of the company's ability to make good decisions about attractive new products and then execute quickly to the shelf.

Walmart vs. Mass Market Supplement Industry Growth



Source: Nutrition Business Journal *estimates for mass market supplement sales (consumer sales). Wal-Mart Stores growth based on public filings for fiscal year ending January 31 of the following year.*

CVS, Rite Aid and Walgreens are also upping their customer service emphasis on health and wellness. More than 2,000 Rite Aid stores around the country feature *GNC Live Well* store-within-a-store supplement sections. Walgreens CEO Greg Wasson recently told shareholders that he wants nothing less than to own "well."

Vendor Discontent

Representatives of Walmart declined to be interviewed for this story, and contract manufacturers for the retailer's private-label lines were equally tight lipped. But it appears that the once fuzzy relationships fostered between the two camps a decade ago may be souring.

Several sources confirmed that manufacturing for the *Spring Valley* line is currently up for bid. These same sources describe cutthroat competition in which companies are being pressured into "suicidally low" bids for private-label business.

In June, when **NBTY** issued its disappointing second-quarter financials (down 0.2% for the three months ending March 31, 2011), company executives went so far as to blame the numbers on "lower net sales of private-label products—including contract manufacturing—as a result of the highly competitive environment in the private-label business as well as lower sales from certain contract manufacturing agreements."

During a conference call, NBTY President Harvey Kamil elaborated, suggesting that the company may "walk away" from such business if it appears unprofitable. "These bidders that are bidding below cost sooner or later will go out of business."

We've seen this behavior before in the supplements industry, with ingredient suppliers in China driving prices to unsustainable and dangerous levels. Speaking to *NBJ* last October, Mark Ledoux, CEO of **Natural Alternatives International**, said, "We've reached a point where many of the commoditized ingredients are sold at or below replacement cost of the primary chemistry involved."

Insiders now believe China controls supply for more than 60% of the letter vitamin market, but, as price increases in recent months across several commoditized ingredients might suggest, the bias has to be on the upside. "China wants prices going up to avoid a diminishing-returns scenario," said Ledoux, again from last October. Have we reached the point of diminishing-returns in private-label manufacturing for supplements?

As a quick aside, **International Vitamin Corporation** (IVC) appears to be one manufacturer bucking this trend. Sources suggest to *NBJ* that IVC has picked up significant business amidst the turmoil.

Moving Forward

Walmart is already switching gears. Recent changes in store include more selection, and building displays of such hot sellers as kids' vitamins and fish oil at check-out or near the pharmacy. As the aircraft carrier slowly moves back on course, expect to see a return of those all-important, impulse-friendly power-wing displays. Sources indicate that Walmart plans to entirely remap its planogram in early 2012, with minor cut- ins beginning this fall. The company has also added new personnel to the category staff in recent months, including a new buyer.

According to Zimmerman, "The buyers in mass, food, club and chain drug are really smart people. They experiment, and if it doesn't work, they course-correct. That is what we are seeing happen right now." While a slump in supplement sales is bad news for everyone in the industry, Horn sees a silver lining. Will other contract manufacturers follow NBTY's lead and stand up to buying practices by major retailers that squeeze margins to ridiculous levels?

"If this is an end to the era of race-to-the-bottom pricing on bids for big contract manufacturing jobs like *Spring Valley,* that would be very relevant to the supplement world," says Horn, noting that higher bids could mean slightly higher private-label prices. "It could close the gap between specialty and mass a little."

Another important question: If supplement shoppers are turning away from Walmart, does that mean they are finding something worth paying a little bit more for in its competitors' aisles?

"Does this mean that, at long last, the extra knowledge, service, education, quality formulations, and specialty environment that is provided in the specialty channel is finally being validated?" asks Horn. "That remains to be seen, but it sure would be nice."

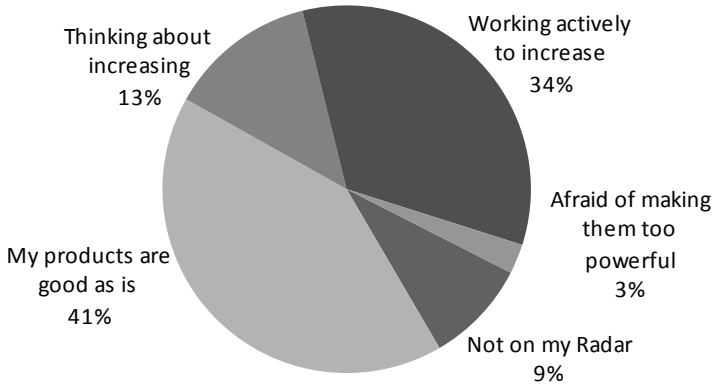
NBJ Spotlight on Science
The rise of toxicity | Nawgan | Big thinking on better science

Nutrition Business Journal®
Strategic Information for the Nutrition Industry

Is Toxicity the Flipside of Enhanced Bioavailability?

Industry concern focuses more on nanotechnology for its potential to toxify natural products

NBJ Survey: Bioavailability Concerns



Source: Nutrition Business Journal *survey of 77 supplement manufacturers, marketers and distributors conducted 5/20/11 - 6/20/11. Question: "How concerned are you about the bioavailability of your supplement or functional food products?"*

A promising phytochemical is one thing. Proven efficacy in the human body is an entirely different matter. "Some of the more popular botanicals have poor bioavailability," says Bill Gurley, PhD, professor of pharmaceutical sciences at the **University of Arkansas for Medical Sciences**. "Researchers are thinking, 'If we can improve bioavailability, we should be able to improve efficacy.' I think that's a logical step to take."

"Bioavailability is something we've been concentrating on at **NOW Foods** for some time," says the company's nutrition education manager and product formulator, Neil Levin, CCN, DANLA. "What are the kinetics of it? How does it absorb? How is it excreted? These are the things we try to pay attention to when we're formulating."

Across the industry, the bioavailability spotlight shines brightly right now on epigallocatechin gallate (EGCG), curcumin, and many of the polyphenolic compounds with poor water solubility and inadequate dissolution in gastric and intestinal fluids. Other common targets for enhanced bioavailability include resveratrol, CoQ10, quercetin, silymarin (the active compound in milk thistle) and grape seed proanthocyanidins. But as manufacturers work to amp up the bioavailability of these supplements, some in the industry have begun to ask, could they also be increasing the risk of toxicity?

Kalyanam Nagabhushanam, PhD, **Sabinsa**'s U.S. president of research and development, thinks so. "When you do this indiscriminately, you precipitate toxicity," says Nagabhushanam. "In many nutraceuticals, the active constituents are enzyme inhibitors or enhancers. If you increase the bioavailability a thousand times, it inhibits or activates an enzyme very strongly. You see negative effects that were not studied using the simple herbal extract." Take COX-2 inhibitors, for example. "When you have such exceptionally strong enzyme inhibitors, you can have cardiac liabilities. You do not want nutraceuticals to tread in that region."

A Toxicological Pandora's Box

Even with an ingredient as safe as curcumin, all bets are off. "Increasing the bioavailability is a laudable effort," says Nagabhushanam, considering its natural bioavailability is practically nil. "But when you increase the concentration dramatically in the blood, you do not know the consequences."

Not everyone is quite so alarmed. "Raising the issue of toxicity is throwing questions on herbs as if we didn't know what they were," says Steven Dentali, PhD, chief science officer at the **American Herbal Products Association**. "We have been eating herbs as part of our traditional use of diet and medicine since before there was science. We're manufacturing concern."

But the very fact that we've been eating plants for so long is the reason they are not bioavailable to begin with, says Gurley. Plants produce phytochemicals as a means of warfare—to fend off predators such as herbivores and microbes. As a result, our bodies have evolved to metabolize these substances without absorbing them. In a recent article in *Clinical Pharmacology & Therapeutics*, Gurley writes: "Some caution must be exercised in this quest to circumvent Mother Nature's well-honed mechanism for disposing of phytochemicals in humans. For some botanicals, this approach may well open a toxicological Pandora's box that millions of years of evolution have managed to effectively keep shut."

Not that Gurley thinks we shouldn't pursue better bioavailability. Most botanicals, he says, will probably prove to be perfectly safe. "I don't think there are any that are overly toxic if we increase bioavailability, but there may be greater chances of herb-drug interactions or even herb-herb interactions," says Gurley. "The ephedrine-caffeine com-

binations are a classic example. Multi-component botanicals, with 10 or 12 different extracts—if you improve the bioavailability of many of those—that could potentially be problematic. Now you're dealing with an animal you've never dealt with before."

Dentali asserts that every meal involves an episode of mixing botanicals. "Nobody chews on turmeric. Nobody eats a meal of one thing. One reason for mint jelly with lamb is to enhance iron absorption. If someone puts extra pepper on their Italian food, or starts putting on hot sauce, do we say, 'Wait, you might be getting too much lycopene there?' "

NOW's Levin says that for most botanical formulations, Dentali's point is well taken. Consider peppermint, for example. "If you make a tea out of it, if you take a capsule of it," Levin asks, "is there really much difference? No. If you start doing unusual extracts and potions of it—taking a minor component, isolating it and making that the item you're supplementing—you've left the natural matrix. Even with the long history and medicinal use of peppermint in the past, it's different if you change it," he says. "Who knows what it will do? It's reasonable to study it."

Overdosing on Water

And that's what many researchers are doing. Scientists routinely consider all of the factors that might contribute to unwanted side effects. "When food technologists use the various tools at hand to increase solubility or suspendability of ingredients, we might wonder, are they also making contaminants or toxicants more available?" asks Dave Bechtel, PhD, DABT, vice president at **Cantox**. "That generally is not the case. The ingredients are generally insoluble in the first place, so they couldn't follow the food chain."

"This is all about the dose," says Ikhlas Khan, PhD, professor of pharmacognosy at the **University of Mississippi School of Pharmacy**. "If you make something more bioavailable, it's going to have some effect somewhere. The general rule is: If something is regarded as effective, the higher dose is going to have side effects."

"Everything is a matter of dosing," agrees Frank Jaksch, CEO at **ChromaDex**. "Almost everything is toxic. Water is toxic. If you drink too much, you'll die. Any time you affect the bioavailability of anything, somebody should take a step back and look at toxicity. Understanding the compound before you get to that point is critical. If you know the molecule doesn't show any toxicity at, say, 1,000 times the dose that's typically sold into the marketplace, you know you'd have to make it crazy to get up to a toxic dose."

Researchers do typically incorporate at least a hundred-fold safety factor in their risk assessments, according to Bechtel. "We know that CoQ10 is not toxic at levels of hundreds of milligrams, so we're not concerned, safety-wise," says Levin. Manufacturers can further assure safety by adjusting recommended doses to account for greater efficacy.

> *"With nanotechnology, you now have a synthetic version of a natural product in a sense, even though it's only particle size. How do you know where those particles accumulate and how they metabolize?"*
>
> —Neil Levin
> NOW Foods

Good thing, because Americans have a tendency to be excessive, says Gurley. "If we can increase bioavailability by twofold and get good results, then it's really got to be good at 300-fold. But it's the law of diminishing returns. 'The poison is in the dose,'" he says, quoting the ancient botanist Paracelsus.

It's not just manufacturers who tend to think more is better. Sabinsa's Nagabhushanam recalls a product containing EGCG marketed for weight loss. "This was probably a good product, but people started consuming it in large quantities," he says. "When you consume EGCG in large quantities, it starts affecting liver toxicity. The product was eventually taken away because of indiscriminate use."

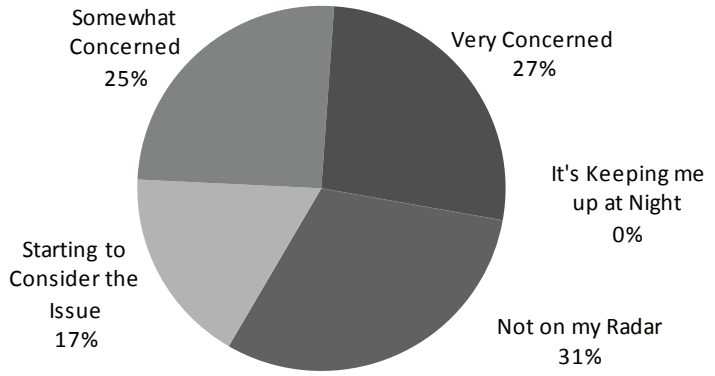
Most consumers prefer to take fewer capsules each day, however. For example, NOW sells the *Meriva* brand of turmeric, which Levin says is several times better absorbed than plain curcumin or even a curcumin, pepper extract and lecithin combo. "We're not concerned about toxicity on that because it allows you to take a lower dose to get the same effect," he says. "We've also got *T-Lean*, which is an enhanced form of EGCG. You only take two capsules a day, and you get the amount shown effective in clinical trials."

The higher per-pill price is also likely to limit overdosing. "These are more expensive products because they're more effective," Levin says. Most consumers prefer to shell out for only two per day rather than six or 12. Manufacturers, too, have to limit just how much they up the efficacy in each dose. "It's an expensive technology where you tend to get lower yields," says Levin.

The greater risk for complication arises when substances have a narrow window between therapeutic effect and toxicity, according to Jaksch. Zinc is a well known example. Vitamins and minerals, on the whole, are more prone to toxicity than herbal supplements. But, as Bechtel points out, the **Institute of Medicine** (IOM) establishes upper limits for safe intake and does consider the likely percentage absorbed. "To the extent that some new technology results in higher rates of bioavailability than was accounted for in setting the upper limit, then from time to time the IOM may re-evaluate what an appropriate upper limit is," he says.

Levin notes that the side effects of overdosing on natural products, including vitamins, are widely documented and, for the most part, are more likely to be uncomfortable or inconvenient than life-threatening. For example, when NOW

NBJ Survey: Toxicity Concerns



Source: Nutrition Business Journal *survey of 75 supplement manufacturers, marketers and distributors conducted 5/20/11 - 6/20/11. Question: "How concerned are you about the toxicity of your supplement or functional food products?"*

Foods issued a recent recall of a calcium and magnesium product containing remarkably high levels of vitamin D, the side effects consumers were warned about included irritability, fatigue, nausea, dry mouth and ringing in the ears.

The Greater Threat

With all the safety mechanisms in place, Levin's not overly concerned about toxicity from most of the usual methods of enhancing bioavailiability: manipulating polarity or binding sites, using novel delivery methods such as phytosomes and liposomes, or combining them with other substances, such as a curcumin and piperine blend. "What we are concerned about," Levin says, "is nanotechnology."

As Gurley points out in his paper, nanotechnology uses minute particle sizes to provide both greater efficacy and stability. "The brag is they're so small," says Levin. "They just come into the body and are available. The questions is, available for what? It's a novel particle size that has different properties. The burden of proof falls on the developer to show it's safe and effective, because it's likely to enter pathways in the body where it's never gone before, and it's not found that way in nature. You now have a synthetic version of a natural product in a sense, even though it's only particle size. How do you know where nanoparticles accumulate and how they metabolize?"

Khan has similar apprehensions. "People are trying to push nanotechnology without knowing what it does to efficacy and drug interaction." This is an important question, according to Gurley, because most of the research on nanotech has been done in test tubes or, at best, in mouse models. "Even though it might be safe in a mouse, that doesn't necessarily mean it's going to be safe in a human," he says. "If you can improve the bioavailability by a factor of 10, there's a good likelihood this may also be the case in humans, but until you actually give it to humans, you're not going to know. It may be more bioavailable by a factor of 200, or of two."

Other questions surround what even qualifies as nanotechnology. Are we simply describing the naturally tiny molecular weight of a substance, or are we somehow, with nanotechnology, making a smaller particle size than exists in nature? On June 9, **FDA** issued draft guidance in an attempt to help clarify the issue. In its outline of elements that it will consider in determining whether a product uses nanotechnology, the agency stated: "FDA is particularly interested in the deliberate manipulation and control of particle size to produce specific properties, because the emergence of these new properties or phenomena may warrant further evaluation. This is distinct from the more familiar use of biological or chemical substances that may naturally exist at small scales, including at the nanoscale, such as microorganisms or proteins." FDA is urging manufacturers to consult with the agency early in the development cycle if there's a possibility nanotechnology will be involved.

Show Me the Data

Despite the flailing of arms over the potential risks, Dentali maintains that little has changed. "If you're creating something new, you've got a responsibility to submit something to FDA to prove it's safe," he says, whether this is a new technology or a new dietary ingredient. "In the meantime, let's not dream up the worst possible situation we can and then paint the whole bioavailability issue with that. Let's see the pharmacokinetic data first and see if we have a real problem to solve."

The lack of research on bioavailability of nutriceuticals is overwhelming. Even for curcumin—arguably the most well-studied of the bunch—Khan sees little in the way of rigorous, science-based research. "The supplements are coming in so many different formulations and shapes," says Khan. "What formulation of curcumin you have is where the bioavailability is going to be affected."

That lack of standardization contributes to the whole toxicity puzzle, according to Nagabhushanam, and informs his recommendation that safety studies be done on a product-by-product basis.

The responsible players in the industry are doing exactly that. Levin says proving enhanced bioavailability is simply a matter of showing you're getting the desired effect from a smaller dose.

"You also want to show that any known effects of overdose or toxicity are not demonstrated by the dose you're using with your product," he says. NOW and Sabinsa both have clinical panels looking at these factors, and they publish research on their websites. "There are products we have looked at for years," says Levin, "and have not come out with because we're not satisfied with the data. Other companies sell them. Maybe they are safe, but we don't have the evidence to convince us."

Does Nawgan Have the Science and Brand to Lead in Brain Health Beverages?

A functional beverage with proven, finished-product efficacy, Nawgan lends credibility to a growing space

Functional beverages are no small market. Heavy hitters like *Gatorade*, *Vitamin Water* and *Red Bull* all play in the $15 billion functional soft drinks, sports drinks & waters space in the United States. The category has enjoyed a double-digit trajectory for most of the last decade, save for 2009, when the category sunk to 4% growth. Sales growth clambered back up to 10% in 2010, predicated on the strength of energy shots and drinks, from such stellar performers as *5 Hour Energy*.

Buried in all those billions is an area of note: the small, high-growth subcategory of soft drinks targeted at cognitive health. B-vitamins, ginkgo, ginseng, caffeine, citicoline, resveratrol, amino acids and scores of other ingredients make it into these products. Few companies play in the space, though, and you can count the relevant brands on your left hand. *NeuroSonic*, *THiNQ* and *Brain Toniq* have all built substantial equity and distribution in the space.

But the real story here is **Nawgan Products, LLC**, a St. Louis-based company founded by neuropsychologist Rob Paul, PhD. The company offers the *Nawgan* brand brain health drink, which carries the pedigree of finished-product testing for clinical efficacy.

Science First ...

"Science, unfortunately, does not do a very good job of communicating itself outside of the scientific community," says Paul. "My interest was to take a functional product and really approach it from a scientific perspective as a truly functional product."

Paul, one of the world's youngest and most acclaimed experts on dementia and cognitive health, developed the formula for *Nawgan* in his own kitchen in 2006, having scoured the industry for ingredients that, used in tandem, could naturally increase alertness in the brain.

He settled on a four-tiered combination of citicoline, alpha-glyceryl phosphoryl choline, lycopene and vitamin E. Together the ingredients activate certain brain mechanisms that tie into alertness, focus and concentration.

The ingredients themselves are already individually supported by a wealth of scientific studies. Citicoline alone boasts over 500 peer-reviewed research articles touting its health benefits. But Paul took the equation a step further.

"We have gone far enough to conduct a study on the full blend," he says, "so as not to rest on just the great science of the individual ingredients. We took it to the next level, initiating a rigorous, placebo-controlled trial that got at the same biomarker outcomes that one would expect from the individual ingredient studies." The independent study, conducted by the **University of Missouri-St. Louis**, confirmed that, versus placebo, *Nawgan* upped cognitive focus.

Such dedication to finished-product efficacy puts *Nawgan* a step above others in the brain health beverage space, which is, of course, ripe for over-marketed claims. The product naturally attracted early investors.

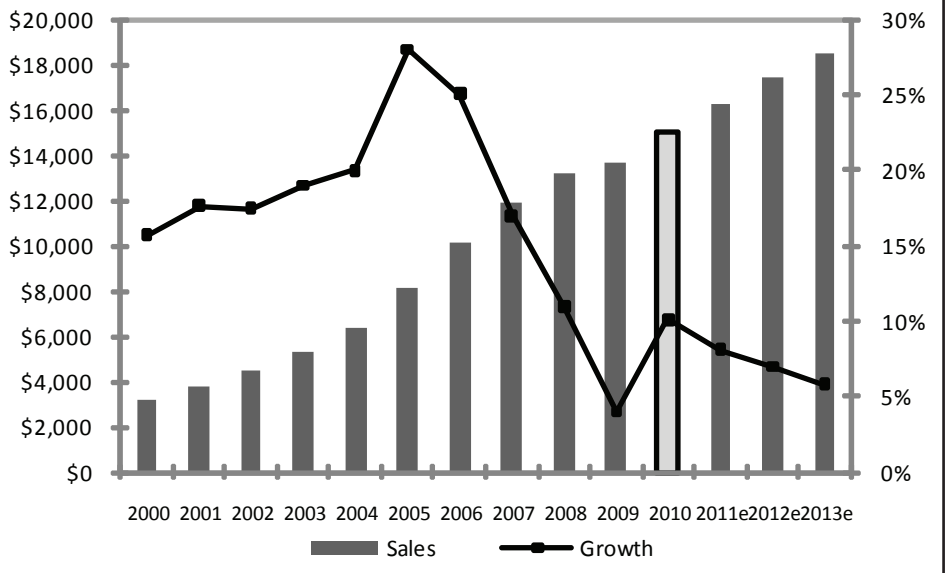
"We feel that this product, compared to all other products in the brain health space today, is the most science-based and most efficacious," says Jim Tonkin, president of beverage consultancy **Healthy Brand Builders**, and founding investor and board member at Nawgan Products.

The brand's science basis also scored them an exclusive deal with ingredient supplier **Kyowa Hakko USA** for use of their *Cognizin* brand citicoline in food and beverage applications. *Cognizin*—winner of the 2004 *Nutracon NutrAward* for best new ingredient—is a well-researched and efficacious proprietary ingredient present in numerous cognitive health supplements.

"Nawgan LLC and Kyowa Hakko share a similar commitment to create products that are proven safe and effective by the best science," says Leo Cullen, vice president at Kyowa Hakko. "This was extremely important to use when evaluating an exclusivity agreement with *Cognizin*."

Right on cue, the **University of Utah**'s **Brain Institute** recently released a study demonstrating *Cognizin*'s effica-

U.S. Functional Soft Drinks, Sports Drinks & Water Sales & Growth, 2000-2013e



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

cy in promoting cognifive focus and mitigating cognitive decline. And consumers can rest assured that *Nawgan* employs research level doses of *Cognizin*.

ROI for Finished-Product Testing?

Nawgan's scientific clout is certainly laudable and exemplary for industry. Says Jeff Hilton of **Integrated Marketing Group**: "I see *Nawgan* as a prime example of a food product that has science to bear, and can deliver proven benefits."

But many marketers in the functional food and beverage, and even supplement spaces, are apt to neglect finished-product testing because of regulatory limits on marketing the health claims that can be drawn out of clinical trials.

"The key is to stay within the boundaries of the science," says Paul. "The outcomes of the studies behind *Nawgan* tie into alertness, focus and concentration. That's the marketing we're specifically driving. If the science is right, you don't need to overpromise. You just need to educate consumers about the quality of the product and the science. You don't even need to sell them, you just need to educate them."

These are certainly idealistic assertions coming from what is essentially still a startup company. *Nawgan* still has only regional distribution in drug and convenience stores in Missouri and Illinois, with sales approaching $1 million in 2010, according to *NBJ* estimates.

But beyond the science, *Nawgan* has other strengths that suggest it stands to grow quickly and lead the brain beverage space—namely, solid leadership and growing brand strength.

... Beverage Second

Not a businessman by trade, Paul brought on a CEO to head up the company. Jim von der Heydt, CPG veteran and former VP of research and development at **Purina**, came on in 2010. "I was a bit skeptical of *Nawgan* at first, because, having been in the nutrition industry for some time, I've tasted and seen an awful lot of products that claim to have performance."

Von der Heydt was adequately impressed by both Rob Paul's scientific diligence and the efficacy of the product. Paul functions as the company's chief science officer, but keeps his hand on the business end as much as possible. "I think Rob Paul is one of the most compelling and dynamic players in the market, specifically from the science side, and he has a real understanding and a temperance for building a business," says Tonkin. Paul himself argues that his greatest strength, both from his research background and now in the nutrition industry, is his ability to assemble a strong team.

> *"If the science is right, you don't need to overpromise. You just need to educate consumers about the quality of the product and the science. You don't even need to sell them, you just need to educate them."*
>
> —Rob Paul
> Nawgan

Nawgan has also developed brand equity from a taste, design and market perspective.

"We solved the science issue first and worried about the flavor second," says Paul. "That's something that we're just now hitting." *Nawgan* just entered its third evolution from a taste perspective, notes Tonkin, and stands on its own as a refreshing beverage regardless of its functional benefit. As such, the company is considering moving from an eight-ounce can to an 11.5-ounce can.

The product started originally as a dietary supplement, but since all its ingredients passed GRAS approval in 2010, *Nawgan* can now label itself as a beverage. "Some consumers are hesitant to try a dietary supplement because of the labeling requirements and the disclaimers," notes von der Heydt. "I think, when faced with a choice, consumers are going to tend toward products that carry food or beverage labeling."

As for labeling, the can's design is subdued, simple and communicative, featuring a maze logo in the shape of a brain, and a tagline—"What to drink when you want to think"—which easily highlights *Nawgan*'s benefits without overstepping any boundaries.

From a market perspective, *Nawgan* is able to draft behind the recent success of energy drinks and shots, but is able to target an underpenetrated demographic. "The demographic of 35- to 55-year-olds is not well-served by conventional energy products," argues von der Heydt.

The company initially targeted this demographic, but found that their customers skewed all over the age spectrum, from college students to Baby Boomers to active adults. Though an ageless demographic may be ideal from a distribution and growth perspective, the challenge becomes making product viable and attractive to a wide array of people.

"If you take this product once or twice, it's not going to have a very efficacious effect," Tonkin points out. "This should be a behavioral concoction consumed daily for several weeks before you really feel an effect." While an older consumer is a creature of habit, six weeks of daily drink can be a tough sell to a younger crowd. As such, two of the three *Nawgan* flavors come caffeinated, offering less patient consumers an initial feeling of alertness.

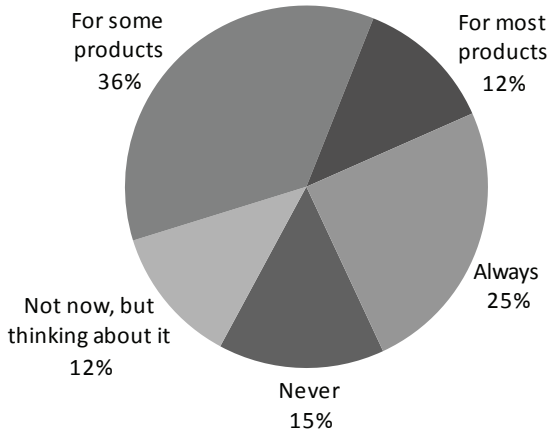
The company is currently working out distribution partnerships to sell in natural food stores in its current market, with plans forthcoming to move into a new target market. In addition, the company is seeking out investment capital.

Says Tonkin: "We did our homework at the beginning, rather than downstream, so it's taken us two years to get here. We feel we're now prepared to go attack the market with a very predetermined market and geographic strategy."

The Supplement Industry's Search for Better Science

Attention shifts away from hard clinical endpoints to mechanisms of action and surrogate biomarkers

NBJ Survey: Scientific Support of Finished Products



Source: Nutrition Business Journal *survey of 81 supplement manufacturers, marketers and distributors conducted 5/20/11 - 6/20/11. Question: " Do you invest in science to support the efficacy of finished products (NOT raw materials)?"*

Walking into a Washington, D.C. courtroom on May 24 for the latest battle in their war with the **Federal Trade Commission** (FTC), the undisputed champions of pomegranate, **POM Wonderful**, appeared well-armed. The company had spent $35 million on research, according to legal briefs, and supported "more than 90 scientific investigations with over 65 studies on POM products, including 17 clinical trials."

But those numbers did not impress FTC attorney Heather Hippsley. After the hearing, she told the swarming press that POM's studies lacked adequate control-group comparisons, were too small, measured the wrong biomarkers, and that the company "repeatedly ignored warning signs that the marketing didn't match the science."

Just how this latest embarrassment in deceptive advertising will play out remains to be seen, but the moral of the story is already loud and clear: In an age when regulatory agencies crack down ever harder on claims, and policymakers cast sharper eyes on dietary supplement research as they update critical health recommendations, quality matters as much—if not more—than quantity.

"When I started 10 years ago, I used to do presentations about why companies should even do research," says Jay Udani, MD, founder of **Medicus Research**, a contract research organization for the natural products industry. "Now, the conversations are all about how to do it better."

In Search of Better Research

While many policymakers insist that the randomized controlled trial (RCT) should be held as the gold standard, some supplement industry leaders say such trials (originally designed for testing drugs) are ill fit for evaluating nutrients. Many in the industry are now calling for a new "evidence-based nutrition" paradigm. Meanwhile, the cash-strapped **National Center for Complementary and Alternative Medicine** (NCCAM) and the **Office of Dietary Supplements** (ODS) recently released five-year strategic plans which promise to pull back on splashy clinical trials (which to date have been largely disappointing) and instead prioritize studies exploring mechanisms of action and biological markers.

Udani believes it's also time for companies to get smarter about designing their own trials on both ingredients and finished products, assuring at the onset that populations are appropriate, anticipated results are realistic, and that—if the outcome is positive—they can legally boast about it without treading into the dangerous waters of drug claims.

"A lot of the studies coming out now were designed years ago," says Udani, a time when claims enforcement was less stringent and there was less understanding about the **Dietary Supplement Health and Education Act** (DSHEA). "In a lot of ways, they were set up to fail."

The Tired, Old Paradigm

Ask Douglas "Duffy" MacKay, ND, what needs to be done to improve the quality of dietary supplement research and his answer is simple: Remember that supplements are not drugs.

"One of the greatest lessons we have learned in the past 10 years of research is that nutrients and botanicals cannot be studied in the same fashion as drugs," says MacKay, vice president of scientific and regulatory affairs for the **Council for Responsible Nutrition** (CRN).

While drugs tend to have singular effects on targeted organs, nutrients often work in concert and impact multiple organs. While drugs tend to work fast to eliminate symptoms, nutrients often work gradually to prevent or reduce them. While it's easy to find a control group who has had no exposure to, say, a statin drug, it's impossible to find a placebo group with no omega-3 fatty acids or calcium in their body. All of these nuances can make it costly and messy to design a clinical trial.

In a lengthy treatise in the December 2010 issue of *Natural Medicine Journal*, MacKay and former CRN executive Andrew Shao, PhD (now of **Herbalife**) argue that "evidence-based medicine" and its cornerstone, the RCT, have been

tragically misapplied to nutrients and bioactives, leading to skewed research results, a misinformed public, and poor public health policies.

For instance, during the famous *Women's Health Initiative* (an RCT which found, among other things, that calcium and vitamin D supplementation did not benefit bone health), the so-called "placebo group" actually had a median calcium intake of about 1,100 mg per day. The trial has been recycled repeatedly in meta-analyses nonetheless.

In the *Physician's Health Study II*, which concluded that vitamins E and C had no impact on cardiovascular disease, the antioxidants were studied independently, rather than in concert.

Shao and MacKay note that an over-reliance on such trials can paralyze or taint those making public health recommendations. When the **National Institutes of Health** held a state-of-the-science conference on multivitamins in 2006, they relied only on 63 RCTs, omitting thousands of other studies. Their conclusion? Not enough evidence to recommend multivitamins. In November, when the **Institute of Medicine** (IOM) unveiled new calcium and vitamin D recommendations lower than many in the industry had hoped for, "the near total reliance of the committee on clinical trials essentially excluded all observational data," says CRN's John Hathcock, PhD, noting a glaring double standard. "How many RCTs were needed to establish that cigarette smoking causes lung cancer? Or that fruits and vegetables help to lower cancer risk?"

As part of its five-year strategic plan, the Office of Dietary Supplements expressly vows to use updated research to revisit Daily Recommended Intakes for other nutrients. (Up next: omega-3 fatty acids and folate).

The New Paradigm

But if the lens of evidence-based medicine is flawed, what should we use instead? MacKay envisions a new "evidence-based nutrition" paradigm in which policymakers value epidemiological studies and practitioner surveys alongside RCTs, and aren't afraid to make recommendations when RCTs are not feasible.

CRN also advises researchers to measure baseline nutrient status before the onset of a trial to determine if, for instance, some participants in an omega-3 trial are already eating a lot of fish. CRN would like to see more studies of how nutrients and other practices act in concert. For instance, a trial could look at a natural cholesterol-lowering or allergy-relief protocol (including supplements, lifestyle and dietary changes) compared to the standard drug therapies. "It's imperative that we place supplements back in the context of a healthy lifestyle and study that lifestyle," says MacKay.

> *"We have partnered with pharmaceutical companies and are certainly looking at drug applications of probiotics."*
>
> —Greg Leyer
> Danisco

While CRN calls for a bigger-picture approach to evaluating supplements, NCCAM and ODS are zeroing in on details. "These very large studies that look at hard clinical endpoints need to be built upon a body of translational evidence," says NCCAM Director Josephine Briggs, MD. That translational evidence includes a better understanding of a nutrient's active compounds, their mechanism of action, and the biological markers they influence. "We are now building that database," says Briggs.

In the case of an NCCAM-funded 2010 study on Echinacea (which found its impact on shortening colds miniscule at best), Briggs would have preferred to know how it impacted specific immune markers, like white blood cell counts.

She points to a May 6, 2010 study in the *New England Journal of Medicine* as the way she sees biomarker research going in the future. Rather than vaguely asking whether vitamin E can ameliorate fatty liver disease, the study looked at whether the antioxidant impacted inflammation and the presence of certain liver enzymes. It did. "That's something we can build another study around," Briggs says.

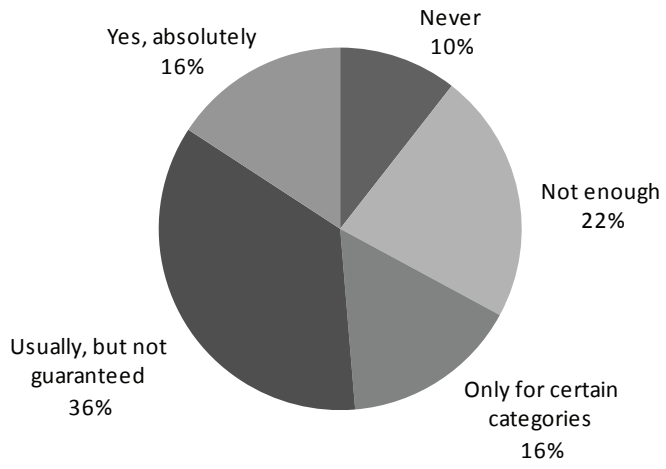
CRN's MacKay agrees that looking at "surrogate biomarkers" (short-term indicators that a nutrient may have a long-term impact) is worthwhile, and he adds that it "dramatically improves the feasibility of human trials both in terms of duration and cost." But he'd like to see policymakers broaden their "disappointingly brief" definition of what constitutes a valid biomarker. For instance, the carotenoids lutein and zeaxanthin have been shown repeatedly to improve macular pigment density in the eye, a lack of which is believed to be a precursor to macular degeneration. But when it comes to claims, these biomarkers mean very little. "If you went to the FDA wanting to get a health claim for macular degeneration based on this, they wouldn't consider it," MacKay says.

The New Uncle Sam

The government's giant step back from large human clinical trials is already evident in NCCAM's funding choices: In 2003, when the organization spent $48 million on dietary supplement research, 50% was spent on clinical trials. In 2008, with a $58 million budget, it spent only 33%. And this year, as NCCAM doles out its $61.9 million (down from $63.1 million in 2010), it's five-year plan prioritizes initiatives like defining the anti-inflammatory actions of omega-3 fatty acids, studying the effects of probiotics on the human microbiome, and identifying the biological effects of "small molecules that are constituents of natural products … like quercetin and curcumin."

At ODS, which doled out $21.7 million in research projects in 2010, Director Paul Coates envisions a sharper focus on shorter-term biomarkers on the one hand and—when it comes to longer-term studies—a greater emphasis on nutrients already believed to reduce chronic

NBJ Survey: Market Return on Scientific Investment



Source: Nutrition Business Journal *survey of 76 supplement manufacturers, marketers and distributors conducted 5/20/11 - 6/20/11. Question: " Do you see a market return on your investments in science for finished goods?"*

diseases such as cancer, heart disease, diabetes, mental health and cognitive decline. ODS is already contributing to the multi-center, multi-year *VITAL* trial, which will test the impact of vitamin D and omega-3s on cancer, heart disease and stroke in 20,000 subjects.

"We don't know for sure," says Coates, "but we are certainly getting messages that there is going to be a sharp cut in spending. We are having to rein things in and be very thoughtful about our spending."

Pharma Beckons

With the federal government tightening its spending belts and clamping down on claims, supplement companies are under more pressure than ever to invest in research on their own ingredients and finished products. But Udani says they too need to be careful who and what they study.

"**The U.S. Food and Drug Administration** has issued guidance that if you use a diseased population in a study, then what you are testing is a drug, and the same goes for endpoints," he says. That means a supplement trial might test "glucose-intolerant people" rather than "diabetics" and look for "improved blood sugar" instead of "diabetes relief."

So, what about POM Wonderful's $35 million in research, which concluded that its products slow prostate cancer and treat heart disease and erectile dysfunction? "It is great to see a company doing so much research," Udani says politely. "But I don't believe they followed the spirit of DSHEA when choosing their endpoints and populations."

Greg Leyer, global business development director for probiotics ingredient firm **Danisco**, says the company has already bolstered its attention to quality research significantly in recent years, honing in on how certain strains impact specific demographic populations with particular ailments. (For the record: Leyer believes the RCT is a good fit for probiotics, since their biological impact is often easy to measure). One successful study, recently published in *Pediatrics*, found that children age three to five who took Lactobacillus acidophilus NCFM and Bifidobacterium animalis for six months experienced fewer cold and influenza-like symptoms.

"The number of subjects we use is increasing, and we're taking care to study a more relevant population," says Leyer. "We don't want there to be any confusion that we might be doing a drug trial."

At least not yet. In some rare cases, industry observers say, when the foundational science is strong enough, RCTs prove positive, and the company has the willingness and staying power to invest in large, long-term studies, the grand payoff for doing good science may ultimately be drug status—and many companies are peering down that road.

In 2004, a then-obscure Norway-based company called **Pronova Biopharma** earned FDA approval for the world's first prescription omega-3 fatty acid, now known as the blockbuster *Lovaza*.

In 2006, the FDA approved the topical green-tea extract *Veregen* (a wart treatment) as the first botanical extract ever to be approved for prescription.

Today, a half-dozen companies, including omega-3 therapy maker **Amarin Pharmaceuticals**, are lined up to unveil the next dietary supplement turned prescription drug. "We have partnered with pharmaceutical companies and are certainly looking at drug applications of probiotics," says Leyer.

But for those who wisely plan their research for the supplement realm, there's also a payoff: staying power.

Bob Rountree, a long-time naturopathic doctor and the chief medical officer for 25-year-old supplement company **Thorne Research**, says Thorne has built its reputation around solid research. It formulates products with the specific doses and compounds used in safety and efficacy trials and then tests the finished products for things like bioavailability.

In May, Thorne announced it is receiving a minority investment from the **Helsinn Group**, a pharmaceutical company based in Lugano, Switzerland. But Rountree says it has no intention of becoming a drug company.

"If a pharmaceutical company is willing to buy into Thorne without telling us we have to change anything," says Rountree, "that says a whole lot about the quality of products we are putting out. No, we are not going to make drugs in our facility. Our core competency is making natural products. But what about making super-high-quality natural products comparable to *Lovaza*? Reliable, consistent, and pure. That, we can do."

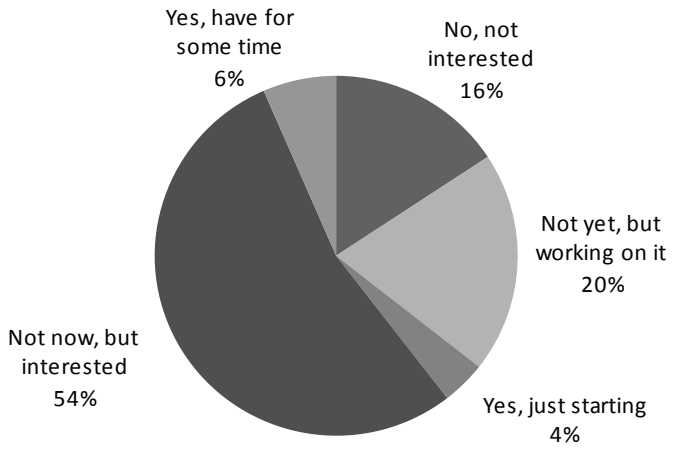
NBJ Supplement Insights
The military outlook | VMI Nutrition | Vitamin D

Nutrition Business Journal®
Strategic Information for the Nutrition Industry

Military Eyes Supplements for Targeted Use, Slow to Develop an Official Policy

Fish oil studies underway to include supplementation as part of mental health discussion for combat veterans

NBJ Survey: Nutrition Products in the U.S. Military



Source: Nutrition Business Journal *survey of 76 supplement manufacturers, marketers and distributors conducted 5/20/11 - 6/20/11. Question: "Do you currently have relationships with any branches of the U.S. military*

With 10 million potential customers to reach, the U.S. military is a respectable market for food and supplement manufacturers. The trouble? It's also one of the most difficult to enter. As a matter of policy, the military does not provide, nor does it pay for, supplements for soldiers. To even be sold on a military base, all products must first go through a rigorous approval and selection process that can take three years or longer.

Several sources chose to not go on the record for the reporting of the story. One such source put the selection process this way: "Several vendors have had product pulled from the shelves in commissary and exchanges because they failed to have their facilities inspected and approved by the Vets." The Vets, or the **Army Veterinary Command** (VETCOM), are responsible for food safety on military bases. You read that correctly: VETCOM's power extends well beyond veterinary service to food oversight and quality assurance at more than 300 bases worldwide with resident populations of the **Army**, **Air Force**, **Navy**, **Marine Corps** and **Coast Guard**.

Commissaries & Exchanges

For the manufacturers that succeed in getting approval and can then maintain a foothold in the market, military bases, as you might expect, are a rather regimented retail environment. There are essentially two channels for members of the military to purchase goods.

Commissaries, run by the **Defense Commissary Agency** (DeCA), sell products at roughly 30% less than what soldiers might find "outside the gate." And although these stores tend to be small in size, they do 10 times the volume of a regular grocery store. One source pegs the vitamin business in DeCA commissaries at about $50 million, made up essentially of the same brands sold outside the military.

"That assortment pretty much mirrors what you see in a typical grocery store," he says. "It's a smaller set, but it's your national brands—your *Centrums*, your *One A Days*, and so forth."

Then come the exchanges, of which there are about 100 in the United States. Sources compare these stores to **Walmart** or **Target**, and say they move about $12 million a year in sports nutrition products. As for specific products demonstrating the strongest performance, there's little difference between sales within the military and without.

Bars and shakes are sold in this market, but like outside the gate, they haven't done very well, according to sources. (*NBJ* did note a resurgence in bar sales, broadly defined, in 2010. After six years of underperformance, bars grew 12% in 2010 to reach $2.5 billion in U.S. consumer sales. Perhaps military sales are set for their own, lagging rebound.) The biggest sellers remain fat burners and pre-workout products.

Monster Milk deserves a special call out here. On both sides of the gate, *Monster Milk* is one of the hottest items on store shelves right now. "I can't keep enough on the shelf," says one source. "I'm selling hundreds a week. Those are crazy numbers for us. It's the only cold protein drink available just about anywhere in the military."

Meanwhile, the one bar that's doing well is **Clif**, he says. "Clif is the one whose numbers continue to go through the roof. Others are just barely hanging on."

Supply & Demand

Buyers are based at military headquarters and tasked with buying for overall categories, rather than making customized decisions for individual stores. How products are chosen is driven largely by demand, not by policy. "A buyer

doesn't really care what your product is or what it's branded as, they just care how much sells in a given time period," says Stan Riegel, founder and director of operations for **Riegel & Associates**, a consulting firm that helps companies navigate the government testing and procurement process.

So creating demand is particularly crucial for success in the military, but stimulating it is a challenge unto itself due to the unique nature of advertising in the market. "In this world, marketing happens through weekly flyers, like you'd see at Target or Walmart," says one source. "To participate in that, it runs about $4,000 per week. So to get your one shot, you're having to pay whatever the cost is to be in that ad, plus the cost of the price reduction. For a lot of people, that's too steep."

But considering that the sports nutrition category in total is worth about $95 million at retail, according to *NBJ* estimates, and vitamins and diet about $65 million, the military market remains appealing enough for companies skilled at navigating all of the rigorous and bureaucratic requirements.

Compliance Challenges

"One aspect that most manufacturers fail to understand is they have to be compliant to even begin the process," says Riegel. To be compliant, a company must be 51% American-owned, and products must have a shelf stability of three years, a qualification Riegel says is easily obtained for most products by forcing oxygen-starved conditions and using mylar packaging.

A rule created by the Berry Amendment also requires the **Department of Defense** to give preference to items produced or grown domestically. According to Riegel, excluding seafood and coffee, 99% of products purchased for the military food program are grown or procured domestically.

This "local sourcing" is one of the single biggest challenges, at least in Riegel's experience. "I cannot find a local source for probably 65% of the items that I've been asked to source for the government," he says. "It's become next to impossible for small businesses to compete in the open market because most manufacturers that are even branded in America do not manufacture in America. It's a mess now."

The number of registrations a company has to go through before it can do any federal contracting doesn't make things easier, and if done improperly, can result in serious and unpredictable complications.

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>
> —Stan Riegel
> Riegel & Associates

Riegel says he had a client once "fail miserably on the initial registration." An ointment ended up registered as a pesticide. Says Riegel: "The military wanted to know why I was rubbing pesticides on soldiers. This is why people shouldn't do it on their own. They should seek out companies that do compliance work."

Lobbying and big business interests have also affected how procurement contracts are formed. "Policy is written for the interest of big business, not small business," says Riegel, adding that companies like **Halliburton**, **DynCorp**, and **Raytheon** run the show.

Official Supplement Policy?

While there is no official supplement program and active soldiers can only purchase supplements as individuals, that does not mean there is no discussion of how the military should officially promote or police supplement use. Recent newsflow suggests talk within the military about both restricting and promoting supplements, but, according to our source, such discussion is largely unsubstantiated.

"There have been rumors about Air Force or somebody saying that they can't take this or that," says one source. "None of it is ever true."

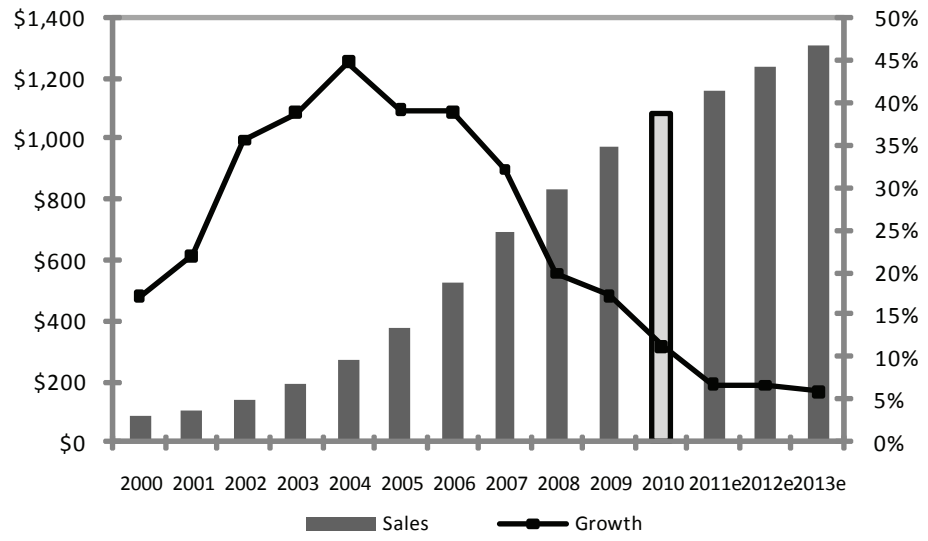
Riegel has not seen any official talk of restricting supplement use, and the only shift he sees right now is one away from any policy that would encourage supplements. He attributes the shift to a pendulum swing in attitude following the military's decision to push caffeine among soldiers a few years ago that resulted in soldiers overcaffeinating. After that, "they really started to move away from any and all supplements in the program," says Riegel. "They're still rejecting the attitude of promoting supplements."

"The military is not the supplement police, or the police on anything consumable," says another source. "Whatever's sold outside the gate, they will sell as long as there's a reason to sell it."

The one effort this source does see underway is an emphasis on fitness. "The military's always been strict on weight and fitness, and they've really pushed that up," says this source. "But this has been internally driven rather than externally, meaning unless you're in the service, you wouldn't see it. It's not something you'd see by shopping in the stores. This is more for command, when your first sergeant is jumping down on you to do better on your tests. The weight restrictions have been tightened as they try to get people more fit."

The **Institute of Medicine** (IOM) Committee on Dietary Supplement Use by Military Personnel has recommended that a military entity or committee be designated to oversee and advise on the use of dietary supplements by military personnel. Though no such committee has been formed, the argument

U.S. Fish Oil Supplement Sales & Growth, 2000-2013e



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

put forth by IOM raises a few significant issues that could motivate official guidance regarding use of supplements in the military.

In making its case for an adverse events reporting system and improved policy on supplements in the military generally, IOM highlights examples of supplements that can have different effects within the military than they might outside. For example, ginkgo biloba and garlic have anticoagulant effects that pose potential risk if they cause extended bleeding for soldiers in combat, and the legacy of ephedra lingers.

Ephedrine, before and after the ban, remains one of the few substances to generate widespread discussion of the potential need for official restrictions on supplements. The cardiac risks associated with increases in heart rate and blood pressure take on special significance for soldiers. IOM also raises a concern about the lack of knowledge about the effects of ingredient interactions when taking blended formulations.

The military is not, at least officially or publicly, close to developing policy regarding these or other concerns related to dietary supplements. These concerns only bolster the notion that if a policy is issued, it is more likely to be restrictive in nature, or at least bring greater surveillance and monitoring to supplements used by the military. Odds remain against the creation of any programs officially promoting supplement use.

Fish Oil Opens the Door

Except for fish oil. The one exception on record with any real traction in the military right now is omega-3s, with potential applications in alleviating soldier depression and post-traumatic stress disorder.

"When we talk about omega-3s in the military, what we're trying to do is solve these issues, trying to help with traumatic injuries and deal with the issues of depression in the soldier population," says Adam Ismail, executive director of the **Global Organization for EPA and DHA Omega-3s**.

"We're trying to get the military to look at this more closely, and they are," says Ismail. "There's a trial that ran in Iraq on omega-3 prevention of depression in soldiers in a specific area of Iraq. There's another group of people looking at the traumatic brain injury aspect."

The depression study, led by Lt. Colonel Daniel Johnston, MD, ran for two months, ending in February 2011, and focused on 250 Army personnel at three bases in northern Iraq. Results are set to publish this summer. The study is meant as a launching pad for a larger, placebo-controlled trial, which would focus on a special ops unit spending a third of the year in combat.

Even if the research pans out, it's a complex undertaking to establish a system that provides omega-3s supplements, not least because the military is currently prevented by law from directly handing out supplements to soldiers. "It's not as simple as sticking a fish oil pill in a ready-to-eat meal," Ismail says, adding that there are legislative as well as scientific hurdles to be overcome before any official policy on omega-3s can even be considered.

Some of those hurdles include concerns about the misuse and abuse of omega-3s. In addition to mental health, omega-3s have a reputation for reducing inflammation and boosting post-workout recovery. Says Ismail: "We've heard anecdotal examples of soldiers who are using steroids to gain an advantage and then are trying to find omega-3s as well because they think it might be beneficial. That is obviously very dangerous." Speaking of fish oil's potential to redefine the role of dietary supplements in the military, Ismail puts it this way: "We're still a fair ways away, but we're moving in the right direction."

NBJ Bottom Line

As a retail channel, military commissaries and exchanges are far from the most attractive option. Selection is often limited, margins are squeezed by up to 30% discounting, and product compliance hurdles are significant. Furthermore, annual sales don't measure well against retail channels "outside the gate." Sources familiar with the channel peg the military market for sports nutrition supplements at $95 million, compared to $3.2 billion in 2010 non-military retail sales, according to *NBJ* research.

A bigger coup for industry lies with potential supplementation inside the combat soldier's diet. If omega-3s could gain purchase within MREs and field rations, not only would this add some modicum of incremental sales, but the boost to credibility and awareness would be far reaching. Official policy on this front is not pending, though interest is clearly on the rise.

VMI Nutrition: A New Breed of Contract Manufacturer

Success attributed to dogged focus on quality and strategic partnerships that promote value-based IP

Sometimes one plus one equals a lot more than two. Take **VMI Nutrition**, a contract manufacturer in Salt Lake City that specializes in custom nutrition formulation, cGMP testing, blending and packaging. Since taking over the business formerly known as **Vance's Manufacturing Inc.** in 2006, co-owners Jeff Reynolds and Bruce Remund have established a strong strategic vision for the company and begun the hard work of systematically implementing that vision throughout the organization. The company now sits at the cutting edge of contract manufacturing, with state-of-the-art capabilities, a product development team and science-based initiatives that are way ahead of the industry curve.

And the proof is in the pudding: VMI's strategy is paying off, with impressive sales growth from $13 million in 2006, the first year under new management, to an estimated $40 million this year. Sights are set on $90-100 million in 2012, if not sooner.

So what sets VMI apart from other companies? Reynolds and Remund are two guys that live their business, and you don't see that much anymore, according to Don Thorpe, president and owner of **Premium Ingredients** in Carol Stream, Illinois. "These are guys who love their work, believe in what they do, and work hard at it," says Thorpe. "I have been in the business for 25 years, and these guys run their business like a family."

Right Place, Right Time

Trust and quality are especially important in the high-stakes atmosphere of product quality control in today's industry. It is becoming more and more important to have the highest quality ingredients and to comply with all regulations and good manufacturing practices (GMPs), notes Ryan Petrosky, CEO of **Wellements**, a nutrition company in Scottsdale, Arizona.

This is the real differentiating factor in what VMI does, as opposed to other contract manufacturers, according to Petrosky. "VMI is the most competent and well versed in cGMP compliance in my experience—especially in powders and blending." VMI is so far ahead of the curve, Petrosky added, that he often uses them as a model for how things should be done when working with other manufacturing companies.

Reynolds admits that their capabilities and expertise in regulatory compliance is peaking at an opportune time. Brand marketers are finally realizing that they must step up their efforts to comply with GMPs and additional regulations, such as Prop 65, to uphold the integrity of their brands.

> "We believe that this is an untapped market—intellectual property that companies can afford to use."
>
> —Jeff Reynolds
> VMI Nutrition

As a result, the industry is seeing marketers transition their business to contract manufacturers who offer this expertise. "They know their product could be at risk if they use a company without this capability," says Reynolds. "So marketers are switching, rather than end up with an **FDA** audit. We have definitely been rewarded by this, and it is driving some of our growth."

In addition to an 80,000-square-foot NSF-certified facility, VMI differentiates its quality position through a strategic alliance with **Genysis Nutritional Labs**, which handles full-scale analytical and microbiological testing of ingredients and finished goods.

The vision, Reynolds says, was to build support for VMI so we could meet the GMP and Prop 65 requirements. "We seized an opportunity to define ourselves and distinguish ourselves from the competition," he says.

Their three-year partnership has also allowed VMI to develop a huge database of raw materials, to identify the best suppliers with the cleanest ingredients, Reynolds explains. "And by clean, I don't mean unadulterated ingredients, but suppliers with raw materials that have a good assay, low heavy metals and low micros."

The ISO-certified lab is a successful business enterprise in its own right with a current run rate of $1 million. It also brought the expertise of 15 full-time chemists, a food scientist and a microbiologist to the team as well as supporting VMI's efforts in product development and intellectual property.

Sticking to the Plan

Remund and Reynolds possess a special synergy that works well for their partnership. It is kind of uncanny, Reynolds notes, that both of them have always gravitated to their particular expertise and interests, which have always been complementary.

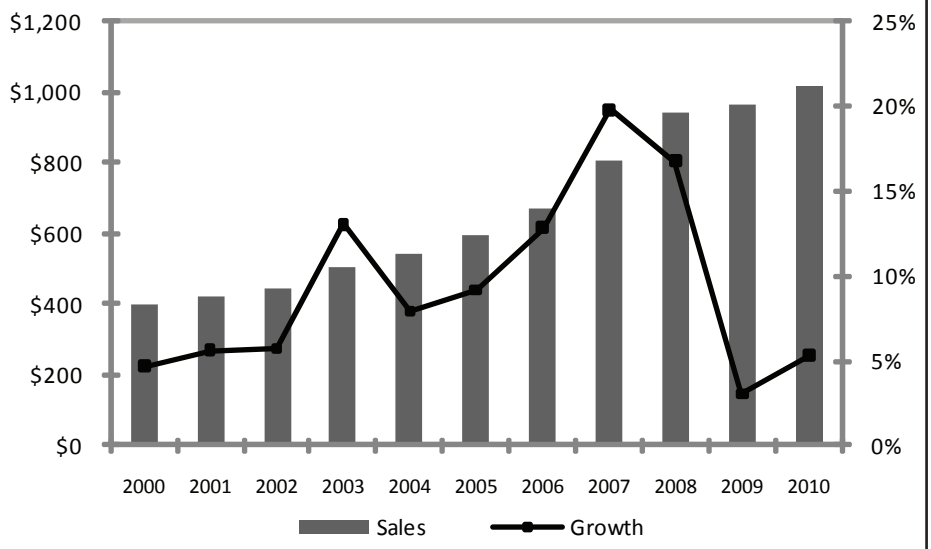
For example, Remund, who was vice president of operations for **Nutraceutical Corp.**, is mechanically minded, which has made him more operationally focused. Reynolds, though he grew up around the nutrition business (his father worked for **Weider Nutrition** and his brother Jeremy for **Leiner**), cut his teeth in banking. This financial background played a key role in shaping the company's development.

When the partners took over the company, originally partnering with Reynolds' brother Jeremy, who was an initial owner of Vance's, they saw that the existing strengths were more sales oriented than operational. "We had a run rate of $10 million in 2006, but things were not running at top efficiency," Reynolds recalls. Systems were cobbled together, he says. The culture was more of a "trust me—I'll hit the deadline" kind of attitude.

Remund and Reynolds quickly realized they would need to make significant investments in infrastructure to see the kind of growth they wanted without having to be there themselves driving a forklift at midnight. "In order to grow, we had to have the infrastructure in place, improve our understanding of efficiencies and vendor partnerships, so we charted a path for that," Reynolds says.

That path included a critical investment in a customized enterprise resource planning system (ERP) modeled after tools Reynolds used in banking. The system helped them define ways to remain nimble and growth-oriented, while staying focused on strategic partnerships and science-based services.

U.S. Diabetic Condition Specific Supplement Sales & Growth, 2000-2010



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

The system also helped Remund and Reynolds develop a plan to build out staff while funding the growth internally. "We hit a point where we were doing customer relations, driving product development and initiating sales," says Reynolds. "We knew we had to build this out to achieve the goals we set, but we had also made a decision to fund our growth internally rather than using outside investors. By sticking to the plan, we have been able to hold to that. We had to take it step by step in order to be successful, and we had to pay our dues. I would have liked to get to the IP earlier, but we had to have the staff and the capacity to do it right."

Value-based IP

The pieces are now in place. The company has 12 staff members (out of a total of 70 full-time employees) dedicated to product development. The ERP helped them design a 100-step product development process that takes a product from concept to shelf very quickly—another signature of their service.

"We had a vision to develop an intellectual property focus to work with some of the best brands in sports nutrition and natural food," Reynolds says. To that end, VMI hired a full-time staff physician and is working to develop unique raw materials and blends to create innovative products, and do it without a huge price premium.

As a result, VMI developed an IP relationship with the **University of Utah** sports nutrition department. "We recently performed our first trial on a raw material that we believe will be as much as 300% more effective than arginine for increasing nitric oxide in the blood, which helps blood flow to muscles." The ingredient, *Triflow*, will be licensed to sports nutrition brands. Based on the results of the first study, VMI is working with the university to fund a second trial that will apply the same technology to diabetic health.

This is a good example of the company's longer-term vision. VMI certainly understands the need for industry marketers to create value for branded products and the role of good intellectual property. But, as Reynolds explains, VMI is also working to create a middle ground in unique raw materials, or what they call value-based IP.

At the high-end, a raw material added to a product might increase the cost to a finished product by $3, which can become prohibitive in the market. Reynolds and Remund want to create raw materials that increase costs by as little as $1. "We believe that this is an untapped market—intellectual property that companies can afford to use."

Next on the agenda is to complete a strategic partnership with a flavoring company, similar to their alliance with Genysis, which they hope to close in the next six months.

Part of Something Bigger

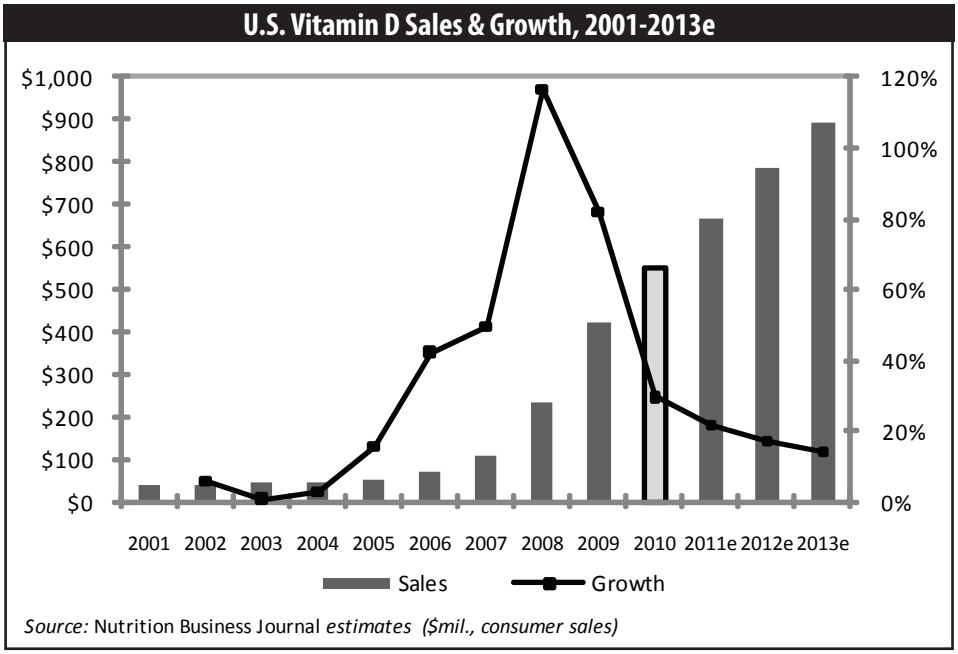
Not surprisingly, the pace of work at VMI is about 100 miles per hour for both Reynolds and Remund. Sometimes they go days without seeing each other. Still, the partners go to great lengths to communicate their vision, energy and passion regularly and clearly to staff.

In the last six months, VMI has developed a leadership team to further define strategic aspirations and goals for the business. The team came up with the following four objectives: Drive profitable growth through science-based services. Become an indispensible strategic partner. Optimize performance through technology and design. Lead highly engaged people.

"We have tried to instill our passion and interest for the industry into our employees so the business doesn't wear off for people," says Reynolds. "That's the culture of the company now. It is not just driven by our growth or success. It's a feeling that everyone is an instrumental part of something bigger, something they want to be a part of."

Vitamin D Sales Strong in 2010, Supply Costs Rising

Balls in motion to up fortification levels in dairy and link D to chronic health conditions far beyond bone density



The year 2010 was another banner one for vitamin D, with supplement sales up another 30% to $550 million. D basked in the glow of promising research with more than 1,000 studies looking at the vitamin's effect on health conditions veering far beyond bone health to immunity, inflammation and even protection against some forms of cancer. Consumer awareness of D's importance was also on the rise, especially after TV's **Dr. Oz** began touting its benefits and the importance of supplementation for adequate daily intake.

But the vitamin's unfettered momentum from 2009 did hit a few snags in recent months. First came the **Institute of Medicine** (IOM) report in November 2010 stating that most Americans are, in fact, getting enough D, and setting new recommended intake levels far below what most experts felt necessary. Then, in April of 2011, **Consumerlab.com** found eight vitamin D supplements with inaccurate dosing information on the label. The potential fallout from these incidents has some industry experts asking if the D boom might stall before it even really begins?

A Fortified Future

There is little worry on the research front, however. Experts in that community think the buzz about D is just getting started. Product development may have dampened a bit since the negative reports, but there is no doubt that D has a bright future, according to Robert Heaney, MD, of the Osteoporosis Research Center at **Creighton University Medical Center** in Omaha. "The promising part is the breadth of the field over which vitamin D is operating," says Heaney. "There are dozens of articles that show the critical role of vitamin D in many different systems and tissues."

Overall signs in the market are also good. While D does express some seasonality with sales declines in the summer months, Scott Steinford, president of **ZMC-USA**, does not see signs of consumption falling off. In fact, Steinford sees a growing number of products with high daily dosage levels, as much as 5,000 IU and 10,000 IU. "These are products that weren't around a year ago," says Steinford. "They seem to be selling well, even though they run contradictory to established recommendations. What may be most important here is that consumers are buying in."

Consumer awareness of D is also continuing to rise, particularly for the vitamin's benefit to bone health, notes David Mark, PhD, a nutritional biochemist who provides product development and regulatory consulting to supplement and functional food companies. "Many people are anecdotally asking their doctor for their vitamin D level," says Mark. "That wasn't happening a couple of years ago."

This kind of testing and awareness is a positive thing, Mark adds, because on the whole, Americans are still generally D deficient, especially people with darker skin, who don't synthesize D from the sun as well as those with fairer complexions, and the obese (body fat sequesters D and keeps it from entering the bloodstream.

One point is clear, says Mark: Most people cannot get enough vitamin D from food alone, particularly if they are attempting to reach the new recommended daily allowance from the IOM report of 600 IU. "People will absolutely need to take a supplement or get more vitamin D from fortified foods," says Mark. "I wouldn't be surprised if the dairy industry is not looking at increasing the allowable fortification levels."

Turns out the **Dairy Research Institute** (DRI) has taken the first steps to show that vitamin D fortification could increase by 2.5 times to 250 IU per serving in dairy products, such as milk, yogurt and processed cheeses, without effecting taste, texture, functionality or bioavailability.

Gregory Miller, DRI's president and executive vice president of the **National Dairy Council** in Rosemont, Illinois, acknowledges both the long history of fortifying dairy to prevent health issues and the compelling research on D, but he notes that the data may not yet be sufficient to warrant higher intakes. "The field of nutrition is burdened by the problem of proof, which is held to a medical model in terms of evidence-

based outcomes in research," says Miller. In nutrition, he added, there are multiple issues, pathways and organs to consider, so it is much more complicated to do the necessary human trials.

Even with enough research, the process for approving higher fortification levels is a complicated and lengthy one, according to Cary Frye, vice president of regulatory and scientific affairs for the **International Dairy Foods Association**. Frye notes that the industry is not seeking any immediate changes for D fortification, but is currently analyzing whether to pursue it. Once that decision is made by either the collective industry or a specific company, there are two regulatory levels that must be addressed: A food additive must first be proven safe and permitted for use, and then the food's standard of identification determines maximum levels for an additive. "An effort to modify the standard of ID for yogurt and cheese has been pending for about 11 years," says Frye, "so this is not an easy process."

Price Increases & RDA Drama

With additional fortification on hold for now, the most pressing issue in the vitamin D market may be the cost and availability of supply. For the last six months, raw pricing has remained fairly stable, at somewhere between $41 and $47 per kilogram for a purity of 100,000 IU. **DSM** is still the biggest player here with the lion's share of the raw D market.

The price of vitamins is on an upward trend, though, particularly those raw materials coming from China, according to Steinford. Part of this is due to currency issues in the United States and Asia; but there is also a looming energy crisis in China, due to pricing issues between the government and state-owned utilities, that will likely affect the supply chain for some time to come.

"Manufacturers in China are getting electricity for one out of every three days," says Steinford, "and businesses can't get water for two or three days because their pumps are not working. These things will certainly impact production." With a large supply of D coming from China and demand on the rise, Steinford does not expect a short-term fix. Prices, he says, have gone up by as much as 10%, and that trend will likely continue.

Steinford predicts a more modest 2% to 4% jump in raw prices over the next year or two. Put into perspective, these price increases at the supply level are unlikely to have a significant bottom-line impact. "Compared to the entire supplement industry, ingredient pricing for D still represents only a small fraction of the total consumer spend," says Steinford. "Because of this inexpensiveness, these increases in raw pricing will never be a predominant force."

> *"People will absolutely need to take a supplement or get more vitamin D from fortified foods. I wouldn't be surprised if the dairy industry is not looking at increasing the allowable fortification levels."*
>
> —David Mark
> Dmark Consulting

Slight price increases, though, could compound after the IOM's November 2010 vitamin D report. The recommended daily allowance (RDA) of D remains at the center of debate in the scientific community. While this is nothing new in the arena of nutrition science, the level of disagreement elevated significantly following last year's IOM report on calcium and vitamin D needs for optimum health. IOM did recommend an increase in vitamin D for all age groups—600 IU for ages 70 and under, and 800 IU for those over age 70. The previous recommendations ranged from 200 IU to 600 IU.

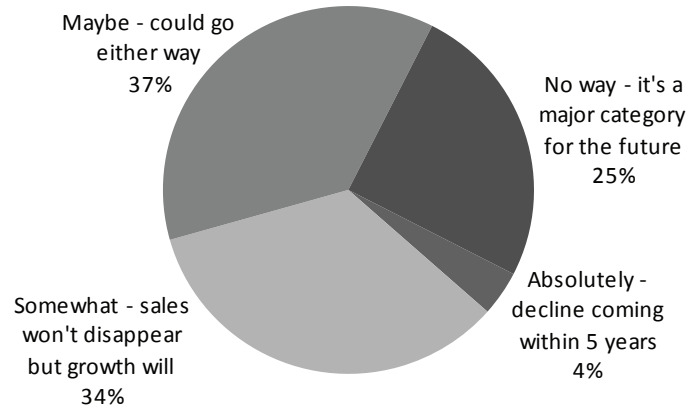
The report drew sharp criticism from experts who say that is far from enough. "That is what they said, and we can't really ignore it—but this is really the 800-pound gorilla," says Heaney. Most D scientists dismiss the findings from the report because things just don't add up. For example, Heaney explains, in addition to the 600 IU RDA, the report recommended a D blood level of 20 nanograms. The intake is inconsistent with the recommended blood level, says Heaney. "Whoever wrote the study must not have had experience measuring vitamin D units in the blood," he says. "It's a silly mistake. I understand that they didn't want to make a recommendation on intake of vitamin D for the prevention of cancer, but 600 IU to sustain a level of 20 nanograms in the blood is flat out wrong."

Also at issue is IOM's stance that most people are consuming adequate amounts of vitamin D, which puts the institute in direct conflict with both researchers and the 2010 **Dietary Guidelines Advisory Committee**, which found that a majority of U.S. adults don't get enough D. This has created confusion for both consumers and industry.

At best, the IOM report has muddied the waters, says Bruce Hollis, MD, of the **Medical University of South Carolina** (MUSC). Hollis is the lead researcher for **NIH**-funded studies on vitamin D needs in pregnancy and lactation. The IOM's basic mission, he explains, is to guide food manufacturers regarding how much D they can put in milk or yogurt. "I understand their caution," he says. "To take milk from 400 IU to 2,000 IU per unit is a big change. I don't dispute their recommendations for food supplies, but this shouldn't relate to patient care. They never should have mentioned appropriate blood levels, because they missed the mark."

The general feeling in the research community is that the report will create some short-term confusion among consumers and potentially longer debate among practitioner groups, but over the long term, vitamin D is here to stay. "Everyday there are new papers showing this and that about vitamin D," says Heaney. "That's still going strong, but the IOM report caused quite a stir and raised a number of questions in the general public about how to interpret it."

NBJ Survey: Is D a Fad?



Source: Nutrition Business Journal *survey of 76 supplement manufacturers, marketers and distributors conducted 5/20/11 - 6/20/11. Question: "Do you believe the phenomenol growth of Vitamin D supplement sales is a fad?"*

Remarkable Research Standards

Hollis believes there will be continued discourse among groups like the **American Academy of Pediatrics** and gynecology professionals, who have largely ignored D and still only recommend 400 IU in prenatal vitamins. The other problem, he says, is that potential grant reviewers, unfamiliar with the vitamin D story, will be reluctant to fund further investigation if they deduce that there really is no deficiency problem.

That, most agree, would be a shame, because there are still many questions about D to be answered. Good research is already difficult enough. Hollis's two NIH studies have taken 10 years and $10 million to establish safe amounts of D in pregnant and lactating women. The research is remarkable on several levels. First of all, **FDA**, citing potential safety issues on upper safe intake levels, required the team to do an investigative drug application. This is the first time FDA has required an IND for a vitamin, but having it in place established even greater credibility for the groundbreaking study. "We never believed there were any safety issues, and we did not have one single adverse event attributed to vitamin D at any level," says Hollis. He adds that the study incorporated a safety monitoring board to check for signs of toxicity.

While the lactation research is still ongoing, preliminary results are showing women may need as much as 6,000 IU per day to pull enough D for themselves and a nursing infant. "We feel like we have some of the most exciting and credible data," says Carol Wagner, MD, also from the MUSC team. "Of course, this is not an end-all be-all. Every study has to continue building on the next, but the results have furthered the field. We will have accomplished a lot if we can improve the lives of pregnant women and babies."

It takes a lot of effort to make a study like this successful, adds Wagner. In contrast to pharmaceutical studies with ample funding and resources, a lot of people have to volunteer their time for a study like MUSC's to proceed.

Moving Beyond Intake

Heaney points out that the MUSC study signals a change in perspective on D, as it looks at the vitamin's impact on new-life, rather than end-of-life, outcomes. He suggests that we need to move beyond the question of intake. "We know that a light-skinned person can go outside in mid-summer in a bathing suit long enough to get some pinkness, not a burn, and take in 15,000 IU of vitamin D in about 15 minutes. When you talk about needing 2,000 IU, that's really not so much."

There are many important questions to answer. Heaney cites a recent Danish study that identified a strong association between vitamin D deficiency at birth or in the first year of life and schizophrenia. "That's astounding," he says. "If we could reduce incidence of that disorder by even 10%, that alone would be worthy of a **Nobel Prize**." Hollis cites additional research that suggests a link between low D levels and multiple sclerosis later in life. "It's not just me," says Hollis. "There is a growing belief that vitamin D presents significant options in improving the autoimmune system and preventing such issues."

Vitamin D is hot and will remain so, agrees DRI's Miller. Most people now believe that D plays a significant role in reducing the risk of chronic disease. "We might not be ready to make educated guesses just yet," says Miller, "but the studies are ongoing. I believe we will see things progress over a three- to five-year process."

NBJ Bottom Line

Vitamin D played its cards well. A raft of well-designed research begun years ago finally began to make waves in 2009, leading to dramatic sales growth, media coverage and fervid debate about adequate intake levels. **IOM**'s 2010 report may have disappointed many in the industry, but it did up the ante for D in the marketplace and kept the vitamin squarely in the public discourse about health. Another year of outsized growth—30% in 2010 to $550 million in supplement sales—is strong evidence that D is much more than just another supplement fad.

D's future is shaping up to look very different from its past, however, and that future looks a lot like food. Any escalation in fortification levels for dairy and juice products means big volume increases for D suppliers, as will meaningful developments in the functional arena. Just this year, news of **Lallemand** working on bread fortified with D2 yeast hit the wires, and **LycoRed** introduced a water-soluble, microencapsulated D3 for beverage.

A Business Primer on Vertical Integration

How to think strategically as value moves upstream and 'clustering' replaces acquisition as the path to innovation and collaboration

By Mona Pearl & Marco Galante

The continually evolving economy of the last couple of years has prompted companies around the world to seek a competitive edge, while lowering operational costs and focusing on efficiency and effectiveness. The search for feasible growth models that provide the right strategic moves opens the dialogue for companies to more closely examine the strategy of vertical integration.

The objective of vertical integration is the creation or enhancement—either upstream or downstream—of market positioning, targeting particular markets for the development and extension of a supply chain. This strategy ideally creates or enhances both cost effectiveness and market positioning within the vertical chain, at one or multiple levels within that chain. Such a business organization would substantially put all stages of goods production—from the acquisition of raw materials to the retailing of the final product—under the control of one company or a group of companies.

As major manufacturing sectors experience commoditization, increased competition from emerging markets, and the resulting need to improve profit margins, companies should explore vertical integration and examine its compatibility with their operations.

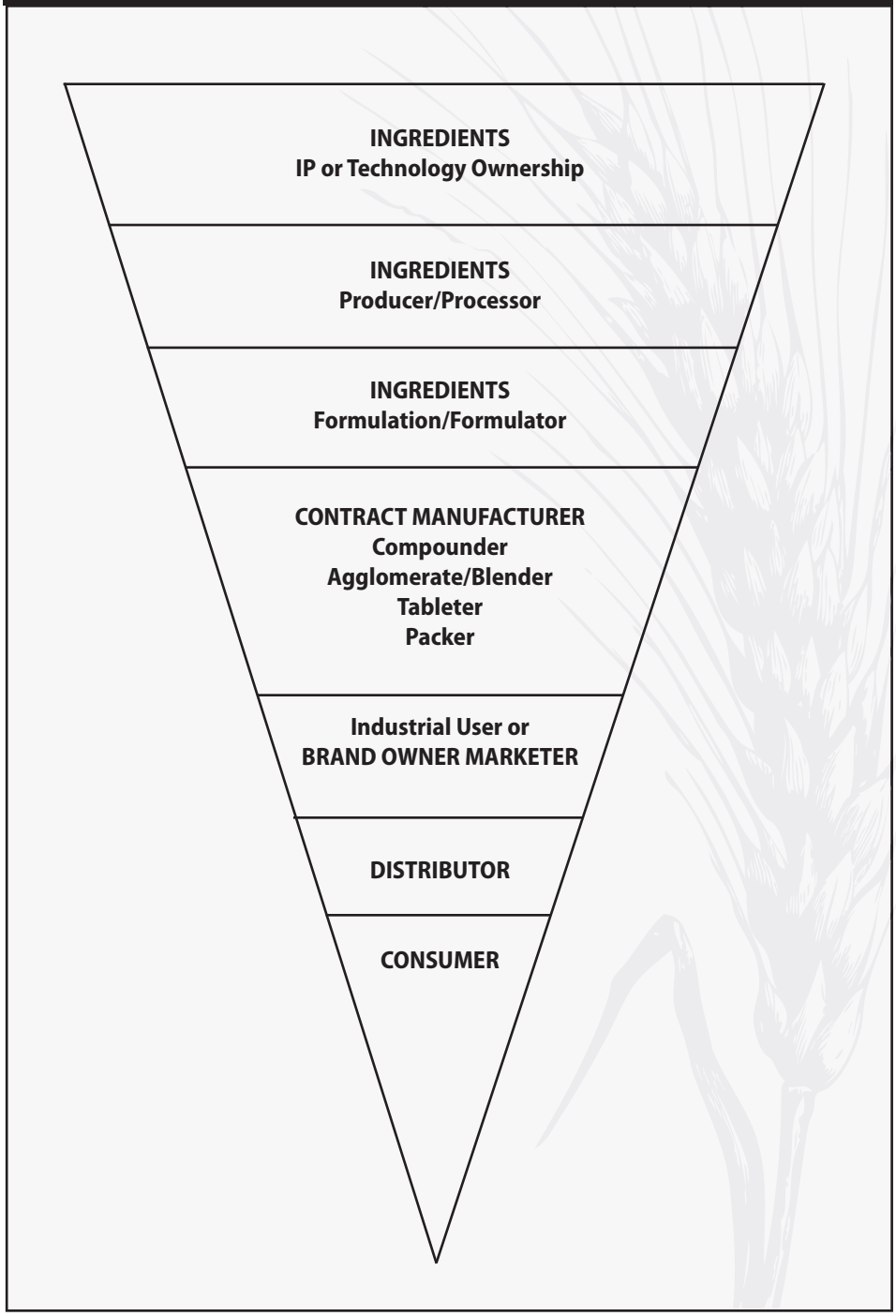
Opportunities in Nutrition

Within the functional food, beverage and supplement sectors, the final "use cost" of effective, health-specific ingredients is increased by the multiple margins required at each point of the vertical chain, as illustrated by the steps in the accompanying diagram. Selective vertical integration eliminates some or the majority of these "intervening" steps and, via the reduction of multiple margins, can ultimately create savings. This strategy should allow for more cost-effective ingredients, particularly regarding their end use within the functional food, beverage or supplement categories.

Vertical integration is an opportunity for the potential elimination or reduction of incremental margins endemic to a fragmented supply chain, as seen in particular within the healthy food and dietary supplement sectors.

Motivation for vertical integration comes from a desire to exercise greater supply chain control, as well as create value in order to decrease costs or increase rev-

Multiple Margins along Vertical Chain Increase Use Costs for Nutrition Companies



enues, or both. In addition, a vertical integration strategy can augment operational flexibility, leverage the company's capabilities, provide a more defensible market position, reduce the potential threat of opportunism, and ultimately enhance selling advantages.

A large number of empirical studies indicate that cost is the most statistically and economically important factor in the decision to vertically integrate. Consequently, a company makes this decision by comparing the benefits of the strategy with the cost and the capital investments required, of both human and hard assets. The decision to vertically integrate should be based on whether the benefits of control and profits exceed the risks and the investments.

Integration makes strategic sense when all or a large part of the company's chain captures more value than any market "exchange" is providing.

Types of Vertical Integration

There are three basic types:

• **Backward or "upstream" vertical integration** occurs when a company controls subsidiaries that produce some of the inputs used in the production of its products.

• **Forward or "downstream" vertical integration** occurs when a company controls distribution centers and retailers in the sale of its products.

• **Balanced vertical integration** is used when a firm controls all or most components, from raw materials to final delivery.

The three types noted are only general concepts, as firms use a wide variety of subtle variations. For example, suppliers are often contractors, not legally owned subsidiaries. Still, a client may effectively control a supplier if their contract assures the supplier's revenue stream and profitability. Distribution and retail partnerships exhibit similarly wide ranges of complexity and interdependence.

Examples from the Food Sector

Poultry Processor (B2B and B2C)

While breeding and growing operations are not necessarily owned by the processor, stringent, contractual control is exercised over the breed and feeding in collaboration with the farmer. Slaughter, portioning, further processing, cooking, marketing and sales, and distribution are functions owned and all undertaken by the processor.

Fast Food Service (B2B)

While fast food companies may license or franchise their restaurants, very large chains exercise substantial control over exclusive suppliers of various food and non-food items, as well as over exclusive distributors. In this form of vertical integration, the chains may not have actual ownership of the assets of their downstream supply chain.

Value Moves Upstream

A company should vertically integrate into those business activities in which it possesses valuable, unique, and costly-to-imitate resources and capabilities.

Likewise, a company interested in vertical integration would likely be looking to enhance market positioning and better control costs, as well as to harvest a portion of the multiple margins. One's capacity for cost improvement depends on the cost of the outsourced side supply versus the investment in and the cost of administering the same activities internally.

Vertical integration may intensify competition upstream and/or downstream, which, in turn, affects the distribution of margins and profits along the chain and, ultimately, end-user prices.

When a company vertically integrates and self-supplies some input, potential suppliers are often precluded from providing those inputs and thus operate at a competitive disadvantage. However, suppliers may choose to be acquired or partially controlled by that company.

In many industries, particularly on the manufacturing side, products have become commoditized (e.g., meat: beef, pork and poultry). As a result, a considerable portion of added value has moved upstream, and companies have put an emphasis on customizing products that meet consumer requirements. Evolving market trends reinforce this shift, including trends in economics, consumer demographics, tastes, and lifestyle changes.

The portion of value-added services from traditional production activities that include core product design and manufacturing has declined substantially with the rise of new global economies, as have margins. In many mature industries, products have reached levels of performance that already satisfy the requirements of the majority of customers.

Further refinements of the technical/functional performance of mature products tend to confront severely diminishing returns. Companies are looking for ways to differentiate their products and justify the pricing to the customer or end-user.

A company should not vertically integrate into activities where it does not have the resources or knowhow to achieve competitive, cost-effective advantages. It must have sufficient financial resources, organizational structure and management controls to successfully implement a vertical integration strategy.

Vertical integration strategies typically require that one business be integrated with an existing business (in the case of acquisition), thus resulting in challenges in and around management integration.

Vertical Integration SWOT Analysis

Strengths

- Lower transaction costs, which can lead to increased margins/profitability
- Improved supply chain coordination: ability to synchronize supply and demand along the chain of products in a more effective and efficient manner, while customizing the process and adapting it to changing needs
- Less uncertainty and more sustainability through higher investment
- Important strategic similarity among the vertically-related activities
- Economies of scale with sufficiently large production
- Increased barriers to entry for potential competitors

Weaknesses

- Core competencies between activities may be different
- Diminished ability to increase product variety if significant in-house development is required and costs of materials are higher
- Higher investment, monetary and organizational costs

Opportunities

- Capture and own upstream suppliers and/or downstream buyers as well as resulting profit margins
- Create access to distribution channels
- Expand and develop core competencies either within the company, by driving change and innovation, or through acquisitions
- Differentiate and create a competitive edge and improved market positioning

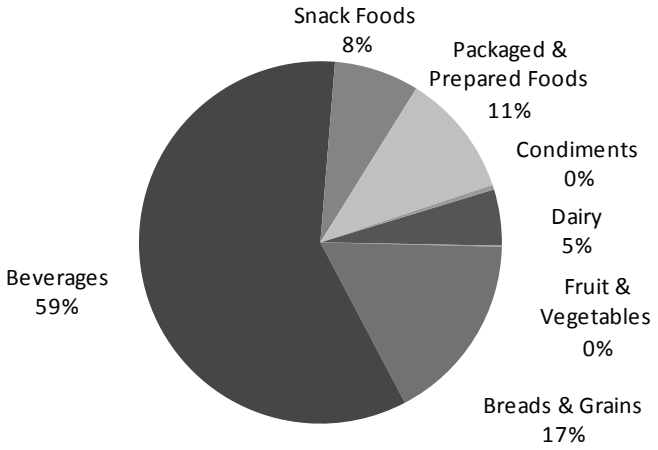
Threats

- Developing new core competencies may jeopardize existing competencies
- The perception/possibility of a company monopolizing the market/sector may lead to collaboration among competitors if the vertical integration is viewed as too serious a threat
- Potential for increased administrative and marketing expenses

Vertical integration could potentially diminish a company's flexibility, as the integrated organization expands its oversight to include multiple activities, changes to structure and control systems, and compensation practices reflecting its larger organization.

It is important to be flexible when facing an uncertain future, but alternatives to vertical integration—particularly strategic alliances—should also be considered. Also of note, the advent of strategic partnerships has led to advances in collaboration and business clusters.

$39.1 Billion U.S. Functional Food Sales by Product in 2010



Source: Nutrition Business Journal *estimates (consumer sales)*

Organic Expansion

Corporate organic growth—through the development of specific processes, strategic alliances, or strategic clusters—also requires an investment in the company and the initiation of changes in its operations. This process may be similar to a start-up process, which may require less initial capital, but is much slower and less certain.

Vertical expansion through the acquisition of companies that either produce intermediate goods needed by a business, or market and distribute its product, is strategically desirable when planning for growth because it more quickly secures the supplies needed to produce and sell the product. Appropriate due diligence and actionable execution should result in a more efficient business, with lower costs and more profits.

Vertical expansion through acquisition increases company size, which can help to reduce cost and gain market share

with more market dominance. Acquisitions can help meet a number of objectives if approached and executed as part of a long-term strategy:

- Enter an adjacent market space
- Expand into a new geography or obtain a physical footprint in a new location
- Access new customers
- Complete or add a product or service line
- Capture market share
- Prevent a competitor from gaining these advantages
- Accelerate revenue growth
- Reduce costs
- Access technology
- Strengthen pool of talent and capabilities

Clusters Are the Future

Winemakers know that the best wine starts with grapevines planted just close enough together to compete for nutrients, causing the plants to put more energy into reproduction, thus improving both quality and quantity. Businesses located together in clusters also demonstrate the best results.

Clusters have been shown to increase productivity, innovation and the entrepreneurial spirit, leading to new business creation. They may provide greater access to human capital, informational resources, cross-industry relationships, and financial incentives.

Clusters also provide greater collaboration in sharing infrastructure and transportation hubs, a more economical supply chain, access to information about competition, and a reduced corporate footprint on the environment. Opportunities to reduce operating costs may come as a result.

It's Time to Integrate

In response to a rapidly changing global marketplace, companies must craft flexible business models that are capable of responding to those changing dynamics, suitable, of course, to their unique capabilities. Vertical integration by strategic acquisition, appropriately assessed, planned, carefully executed and subsequently nurtured, is the road to success. Through this paradigm shift in mindset and strategy, businesses will create and foster a sustainable competitive edge.

Being established is never equivalent to being relevant. There is danger in losing market relevance by delivering less value and neglecting the competitive edge.

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Bios

Marco Galante, principal of investment banking firm **J. H. Chapman Group**, is a global food industry veteran with a 25-year pedigree, having held senior management positions at such companies as **Prima Foods**, **Viskase**, **Freddy Hirsch Group** and **Debs Vogue**.

Mona Pearl, founder and COO of consultancy firm **BeyondAStrategy**, specializes in international strategic development consulting. She has founded and operated three successful companies, and authors columns on global strategies for *Manufacturing Today* and *Management Today* magazines.

NBJ Bottom Line

In a vacuum, vertical integration certainly sounds like a bed of roses, but does the strategy have a proven track record in the nutrition industry? In truth, the pendulum swings both ways, but many companies have made successful forays up and down the chain in recent years.

On the sour end, much of the industry's vertical flops come from suppliers drifting downstream into brand ownership. Feature **Kemin** and **Cognis** both developing branded finished products for sale on the consumer market—Kemin with *FloraGlo* and Cognis with *Tonalin*—but pulling back after the required marketing spend loomed too large. And because of a lack of marketer interest, **DSM** recently assembled a small, retail-focused team to bring its *i-flex* and *i-cool* ingredients all the way downstream, though the jury is still out on the level of consumer interest.

To Galante and Pearle's point, organic expansion in a vertical direction can be a slow and uncertain undertaking, especially for raw material and ingredient suppliers, as they often lack the experience, expertise and extra cash required to successfully market products at the consumer level.

Acquisition strategies, however, have proven successful for several suppliers, with finished product companies acting as exclusive funnels for their ingredients. **Glanbia**, a world leader in whey protein, recently glommed two of the biggest U.S. sports nutrition companies, **Optimum Nutrition** and **BSN**, both of which are heavyweights in the protein powder market. DSM has also taken the acquisition route downstream, having purchased **Martek** earlier this year, which itself acquired **Amerifit Brands** in early 2010. **GLG LifeTech** is another supplier that has found a modicum of success in vertical integration, controlling all the means of its stevia production while, through a joint venture, simultaneously selling RTD stevia-sweetened teas in the Chinese market.

On the brand-owner side of the spectrum, heavy hitters like **NBTY** and **Atrium Innovations** continue to integrate by swallowing up contract manufacturers and assuming control of individual proprietary ingredients. A few MLMs have also made headway with vertical strategies. **Herbalife** owns a substantial amount of its manufacturing, and **Univera**, under its parent company **ECONET**, is the last link in a full chain from supply to consumer.

The list is fairly short thus far, but—especially considering the acquisitions from Glanbia and DSM, as well as increased interest from pharma and traditional CPGs—nutrition industry interest in vertical integration appears to be a growing trend.

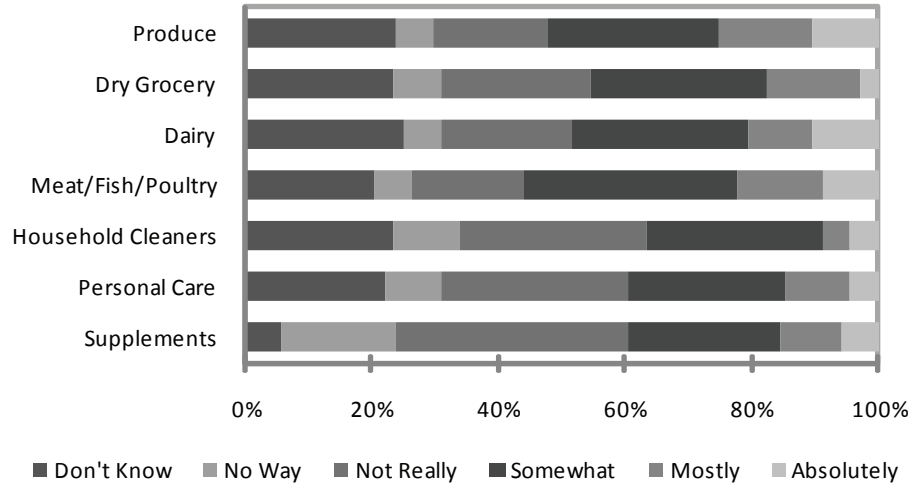
NBJ Spotlight on Regulation
Whole Foods | Congressman Stupak | EU Trendspotting

Nutrition Business Journal®
Strategic Information for the Nutrition Industry

Is Whole Foods Market Now the De Facto Quality Standard for Nutrition?

Private industry displays leadership and caution for consumer safety that federal regulators can only dream of

NBJ Survey: Whole Foods as Quality Standard



Source: Nutrition Business Journal *survey of 68 supplement manufacturers, marketers and distributors conducted 5/20/11-6/20/11. Question: "Does Whole Foods set the de facto quality standard for these sectors of the natural products industry?"*

In December, the **U.S. Food andDrug Administration** (FDA) launched a crackdown on the supplements industry to rid the market of products spiked with steroids and prescription drugs. The agency enlisted the support of five trade associations for the initiative, a move viewed by many insiders as tacit admission by the government that bad acting in the supplements industry has become too big a problem for the agency alone to handle. The thinking goes that Uncle Sam needs help policing adulterated supplements, and who better to proffer that help than leading voices from within the industry.

It's hard to know how effective these voluntary disclosure programs will prove, and, come to think of it, who knows how effective FDA can ultimately be as a regulator of the nutrition industry as it grows beyond traditional boundaries. Many of the ingredients already approved for use by FDA are coming under increasing scrutiny for their longer-term, negative impacts on human health. The scrutiny, oddly enough, often comes directly from consumers demanding better oversight.

Two Views of Parabens

Take methylparaben. Methylparaben is now thought to be an endocrine disruptor, and is treated as such by the **Environmental Protection Agency**. FDA takes no such stance. On its website, the agency recognizes concerns that have been raised about the safety of parabens in food and cosmetic products, but concludes thusly: "FDA believes that at the present time there is no reason for consumers to be concerned about the use of cosmetics containing parabens. However, the agency will continue to evaluate new data in this area. If FDA determines that a health hazard exists, the agency will advise the industry and the public, and will consider its legal options under the authority of the **Food, Drug and Cosmetic Act** in protecting the health and welfare of consumers."

Part of the problem with FDA's regulation of substances like methylparaben lies in the fact that the science guiding their decision making often comes from the manufacturers themselves, not an independent source. "When you have industry providing the data and doing its best to say that these things are safe at minimum levels, we just don't know the truth about safety at higher levels," says Steve Taormina, standards director of **New Hope Natural Media**.

The aggregate effect of multiple ingredients—how different ingredients interact with each other in the body—is even less known. Furthermore, it's not information that manufacturers are able or required to supply.

The Third View

Whole Foods Market, on the other hand, clearly has methylparaben on its list of 83 unacceptable ingredients for food, ingredients that are not allowed in any products sold in Whole Foods stores. This list, according to many of the thought leaders *NBJ* spoke to in reporting this story, is single-handedly changing the face of natural products.

"Whole Foods is driving consumer demand for a better type of product, which raises everybody up to a higher level of standards across their products," says Taormina. "I think that's the real goal of this industry. Rather than dropping down to 'their level,' so to speak, we should be trying to raise the level of commitment to cleaner products and cleaner agriculture." In recent years, Whole Foods has made major commitments to overhauling its inventory, aisle by aisle, with improvements to standards for categories ranging from supplements to cleaning products.

Methylparaben is just one example, but it symbolizes well the larger question of whether Whole Foods is looking out for the safety of its consumers more than

the U.S. government is for its citizenry. As a private company, Whole Foods has the freedom and ability to act quickly and independently, whereas the FDA is everything you'd expect from a government agency, forced to operate under all of the bureaucracy brought to bear by the full force and weight of the federal government.

Whole Foods can decide to ban an ingredient and implement the change in a week if it wants to, and for any reason, whether that reason is related to safety concerns or not, and whether the scientific evidence meets the standards of federal regulators or is based on composite knowledge linking a substance with, say, cancer.

"The FDA's going to say, 'Well, you know what, the science really isn't there to call this ingredient totally unhealthy, so we're going to allow people to sell it,' " says Taormina. " 'If you present us with really good science that this is contributing to cancer, then there's a chance that we could try to outlaw it.' "

The Precautionary Principle

Whole Foods might be seen as adopting something that resembles the concept known as the precautionary principle, while FDA abides by more of an innocent-until-proven-guilty approach.

Even when the science is there, Taormina refers to the process of enacting policy change as "cumbersome." "The FDA's not going to move quickly on this kind of stuff," he says.

It can't move quickly. The process is clearly muddied with political agendas, as one quick look at FDA's ongoing evaluation of bisphenol A illustrates. It took nationwide momentum and concern about the health risks of the plastics chemical to spark the agency into action, which then goes on for years before any final decision is reached.

Whole Foods, meanwhile, has moved from one category to the next, announcing new standards that all products must meet if they are to be sold in its stores. The company has rules for both food and supplements—no starch, extra gelatin, artificial colors, sweeteners and preservatives, lactose, or unnecessary fillers and hydrogenated fats. Perhaps the most extensive banned-ingredient list is reserved for body care products.

Whole Foods also recently launched a new initiative specifically for cleaning products. *Eco-Scale* is a tiered rating system that evaluates products based on environmental and sourcing standards, and as Whole Foods pointed out in its announcement of the program, the U.S. government does not mandate full disclosure of ingredients in cleaning products. *Eco-Scale* establishes exactly that requirement: to list all ingredients on product packaging. To ensure compliance, an independent third-party verification system will be used to audit all products before they are rated.

> *"Once Whole Foods allows or disallows an ingredient, that reverberates throughout the industry. They've got enough power in the marketplace that, if you're serious about doing business in the channel, you're probably going to adhere to the standards."*
>
> —Bob Burke
> Natural Products Consulting

"Whole Foods is getting an unbiased assessment of products against their standard," says Cara Bondi, a research chemist at **Seventh Generation**. "I don't believe any other retailer is doing that. They're really going above and beyond to make sure the products they carry in their store are what they're telling consumers they are."

More Independent Third Parties

Eco-Scale is not the first independent certification system to be used for items sold in a grocery store, and organic certification is probably the most well-known and most successful. But it could be a sign that the third-party certification system has legs, that it's a system worth replicating more broadly across our grocery stores and adapting to new product categories. There are certainly adaptations to be made—as Bondi points out, organic standards use pure percentages, whereas *Eco-Scale* is a more comprehensive evaluation—but the use of the independent third-party verification system could potentially become a more common template for all categories.

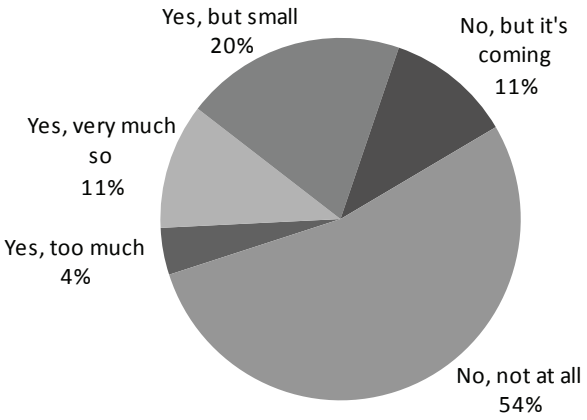
Jason Sapsin, of counsel at **Polsinelli Shughart** and formerly of counsel at FDA, points to the **Food Safety Modernization Act** as another realm where a third-party system is being adopted for enforcing regulations of imported products. "This idea is not a new one," he says. "It's an idea that has been discussed now at FDA for years in terms of food safety. In part, it reflects the reality that it would be tremendously expensive and difficult for the agency, if not impossible, to go around and inspect all of the food suppliers sending food into the U.S."

Sapsin believes that third-party certifying organizations can be helpful for smaller companies because they offer an "aggregated opportunity," meaning individual companies can invest simultaneously in verification work, and all benefit from their collective investment.

Dietary supplements in particular could benefit from such a certification, says Sapsin. "That's a category of product that can pose tremendous hazards to companies buying from manufacturers and distributors, and also to retailers and consumers."

The challenge, as Sapsin notes, is to ensure that the third party is a trusted intermediary. "From a practical perspective," he says, "the real questions is this: Is it possible to get to a point where third parties are certifying and their certification activities are distinct from their sources of revenue such that there's no conflict of interest?"

NBJ Survey: Impacts of Whole Foods' Standards



Source: Nutrition Business Journal *survey of 71 supplement manufacturers, marketers and distributors conducted 5/20/11 - 6/20/11. Question: " Do Whole Foods' standards have a measurable impact on your product line?"*

The Standards Business

As for why Whole Foods undertakes these efforts, some speculate that robust standards give the company a competitive advantage. As commodity natural and organic products are sold in more mainstream stores, standards could become the point of differentiation that ensures Whole Foods goes a little farther for its customer than its competitors.

"The consumer who wants to avoid exposure to certain ingredients," says Taormina, "that consumer knows they can go into the store and, with a fair amount of certainty, not buy any of those ingredients in products."

Justin Gold of **Justin's Nut Butter** thinks that a marketing strategy could be playing a role. Because Whole Foods' prices tend to be higher, Gold sees the value proposition as a viable way to communicate with consumers and convince them to pay the difference in cost. Whatever the motivation, there's no question that by establishing these standards, Whole Foods is asserting its leadership. Nor is there doubt about the significant impact that the changes will have on the industry.

"Once Whole Foods allows or disallows an ingredient, that reverberates throughout the industry," says Bob Burke of **Natural Products Consulting**. "Essentially, they've got enough power in the marketplace that, if you're serious about doing business in the channel, you're probably going to adhere to the standards."

Whether the FDA would be able to implement a comparable set of standards is a question in which few have much confidence. "It's the job of the FDA to provide a safe and high-quality food supply," says Sapsin. "I think the agency is sometimes reluctant to take positions that will compromise it with affected industry, because in order for it to function well, FDA requires, on a lot of different levels, the cooperation of regulated industry. FDA also recognizes that industry should have an important role in defining and policing its own standards as well."

What Whole Foods is doing with standards, says Sapsin, "might be one example of a powerful part of the industry sort of testing the waters in how far it can go."

The ANDI Angle

Whole Foods has also rolled out a nutrition education initiative called ANDI, or the **Aggregate Nutrient Density Index**. ANDI evaluates foods for their total content of select macronutrients and gives them a score from zero to 1,000. Kale ranks 1,000, for example, while cola gets a zero.

Is FDA effective at stepping over the great divide from regulator to educator? Not if you measure success by the agency's development of front-of-package (FOP) labeling. Commissioner Margaret Hamburg at FDA has publicly expressed the agency's longstanding desire to create FOP labeling that helps consumers make healthy, quick decisions at the point of purchase, but bureaucracy still seems to hold the upper hand.

FDA issued a call for public comment on the matter in May, on the heels of 17 warning letters to food manufacturers—including **Nestle**, for its *Gerber* baby food line, and **POM Wonderful** for egregious health claims. This comes just a few months after the conventional food industry, as represented by the **Grocery Manufacturers Association** (GMA), produced its own plan for FOP nutrition labeling and immediately began to implement it in the marketplace. According to media reports, GMA plans to spend $50 million on public relations and advertising to promote the new label.

This undercutting is not necessarily a sign of weakness within the agency, since some, including Taormina, argue that FDA is not responsible for educating the public about nutrition. But an FDA spokesman confirms that nutrition is still ostensibly part of its mission, and the agency's nutrition-focused efforts seem to validate that notion. So why is FDA not doing more?

There's more than a little skepticism as to why. A metric like ANDI, for example, would be tough for the FDA to try to tackle. "From a regulatory agency's perspective, FDA can end up dealing with food producers—whether they're natural food producers or organic food producers or highly-processed food producers—that feel like the simplified metric unfairly characterizes their product," says Sapsin. "That creates difficulties for regulating industry. This might be one example where Whole Foods is able to push the boundaries a little bit more and try this as an experiment. It's something that, at least philosophically, works well with the agency's regulatory mission."

Stupak: Congress Not Overly Concerned with Supplements

Industry has a great story to tell, and should lobby more to tell it

Congressman Bart Stupak represented Michigan's first district from 1993 until January 2011, during which time he served as chairman of the Oversight and Investigations Subcommittee of the Energy and Commerce Committee. Stupak began his career in public service as a state trooper, and he now serves as a partner in **Venable LLP**'s legislative and government affairs group.

***NBJ*: What are some specific ways you were connected with the supplement industry when you were working in Congress?**

Bart Stupak: I chaired Oversight and Investigations for 16 years. When we started to get into active ingredients, pharmaceutical ingredients, food, supplements and health claims, we were always looking at them, first and foremost, from a safety point of view. We saw that there had to be more regulation of the nutrition industry, but there just haven't been many safety concerns to date. There are always wildcards, but not to the point where people get E. coli, die, or have their kidneys taken out. You supplement, you help build strong bones or muscle, which is a good thing. Now, if there was an adverse impact upon the human body with dietary supplements, you'd have **Congress** breathing down your neck. That's where steroids came in, and that's why we addressed them in the **Food Safety Modernization Act**.

The other issue is false advertising. If someone claims a dietary supplement can cure colon cancer, you're going to have a problem, but if you say it helps the digestive system, which certainly helps you fight off colon cancer, you're okay. So, phraseology. Whenever I looked at food and drug safety, I always asked 'What's on the bottle? What's in there? What are the ingredients, what is the dosage and what are the claims being made?'

***NBJ*: Behind closed doors, how do policymakers view this industry?**

BS: It does come up, specifically about claims. What has hurt the industry, from a legislative point of view, are all the claims made on the internet. I'm sure all your readers rightfully sell themselves on the internet. But then you get these other rogue sites that are willing to take your supplement, counterfeit it, and label it as the pill that can cure colon cancer. These sites are usually four or five portals over, four or five different companies removed from the claim, and they're coming up out of Micronesia or Tibet, and they're not a bunch of monks, either.

That reflects back on the entire industry. I'm willing to bet you that those rogue sites, at least half of the tablets in the bottle are counterfeit—they're placebo. The **FDA** does not have the resources to keep up on industry with the explosion of the internet.

While rogue stuff is out there floating about, it usually does not cause anyone harm. But if I take a bad *Lipitor*, I'm never really getting my cholesterol treated. That's the difference. With one of our last drug safety bills, I was working on trying to shine the spotlight on this, and I found that at least 20% of all prescription drugs sold on the internet, or even through pharmacies, are probably counterfeit. In the supplement industry, it's even easier to counterfeit because there's no prescribed or restricted flow of an ingredient.

With serious adverse events, the product is usually laced with something else, and you can usually make a criminal case. Plus it's not that widespread, like an E. coli or salmonella outbreak. But it's coming. You may not want to be regulated, but a smarter approach is to work with Congress to protect yourself before the problem occurs. Work with Washington before Washington has to work you.

***NBJ*: What is your perception of DSHEA? Is it effective?**

BS: I haven't seen much trouble with it. No one is saying, 'Let's go after it.' From your typical Congress member's point of view, this industry is not very well understood. When the FDA regulates everything—and they really do—when this issue comes up, members just say, 'Well, that falls underneath the **Food, Drug and Cosmetic Act**.' Well, not really. As you know, there's a separate act for dietary supplements. Members just think the FDA is handling it and there hasn't been a problem, so that's that. When supplements come up, they come up mostly for labeling and claims issues. Members aren't really focused on the industry.

It's the fringe guys who are going to kill this industry. And that's why, in the Food Safety Modernization Act, the only thing we really went after with FDA is to make sure that products are clean on steroids.

***NBJ*: You were instrumental in healthcare reform—how does this industry intersect with the Affordable Care Act? Is that legislation a success?**

BS: Yes, and I still believe it will continue to be a success. How do you intersect? Easily, because the healthcare bill really puts emphasis on insurance premium reductions, healthy lifestyle and prevention. So, if I walk to keep my diabetes in check, is there a supplement that I can take that will help me out?

When seniors turn 65 and go on **Medicare**, they're encouraged to get a free physical. If we can catch disease early, there's where your nutrition and your dietary supplements certainly would help us out. Up in Connecticut, [Congressman] Joe Courtney has talked about the preventive part of the healthcare bill and the Medicare physical you are required to do. He has this doctor he's trying to get to come before the committee to testify. Through these free physicals, she's already found three patients with life-threatening illnesses, and she's treating them right now. Just doing a normal physical, which Medicare pays for, doesn't cost the patient anything. When your doctor says, 'Look, you're re-

ally low on your calcium, you need some supplements,' that's your industry.

***NBJ*: Is there any movement toward more insurance coverage of supplements?**

BS: If it's part of your prescribed regimen. I have been working with some clients that play sports and are focused on health, from major-league baseball to football to beachbody types. If you go and say, 'My standard is to lose 20 pounds, bring down my blood pressure and get off some of this medication,' and you achieve those standards, then the most you could get before was a 20% deduction under **IRS** for your gym costs.

But now, under the discretion of **Health and Human Services**, provided that you achieve what they call 'measurable standards,' you can reduce a person's healthcare premium up to 50%.

That's the tough part. It's why these sports groups are saying, 'What is the measurable standard here?' It's not like everyone is going to be 6 foot, 180 pounds with low blood pressure, so what's a realistic goal? And that's the part where there's going to be some fighting. The nutrition industry clearly has a role to play here. Not only would you get a deduction in your premium, but your employers would get a huge deduction, and think of the money you would save them.

The critical theme with the healthcare bill is this move away from a payment system based upon transactions, where the more a doctor sees you, the more money they make. We're trying to move to a situation where it's not the number of times you see the doctor, but how healthy are you when you finish seeing the doctor. It's going to be quality-based as opposed to quantity-based. If you're going to have quality-based healthcare, a big part of any illness and injury recovery is diet and mental health. If I'm eating junk food all the time, I'm going to feel like junk food. I'm going to feel like a *Big Mac* and I'm going to look like one too.

***NBJ*: Should the supplement industry be lobbying more?**

BS: In this case, I think you should be doing more. Lobby in light of where this industry can go. It's a positive industry. You have a story to tell, your product is not dangerous, and you live within the guidelines set by the government. Get the government to help prevent the black eye certain to come when something gets adulterated and people get sick. Right now, the country is ready for healthy living, they are striving for it. You can play a critical role in it—you have a good story to tell. That's why Congress hasn't been all over you.

***NBJ*: What are your goals now? What kind of role do you see yourself playing in nutrition?**

> *"Lobby in light of where this industry can go. It's a positive industry. You have a story to tell, your product is not dangerous, and you live within the guidelines set by the government. Get the government to help prevent the black eye certain to come when something gets adulterated and people get sick."*
>
> —Congressman Bart Stupak

BS: I'm doing a lot of work on the healthcare bill, in the implementation stage. There are benefits in the legislation that we can all take advantage of right now, and people are just not aware of it, states are not aware of it. I'm doing a lot on healthcare implementation. I'm doing work with FDA, the **Federal Trade Commission** and **Federal Communication Commission**, because I know those areas so well and I've investigated them for so many years. The areas I'm concentrating on besides healthcare are telecommunications, energy, and oversight investigations.

***NBJ*: Is the FDA equipped to monitor the nutrition industry?**

BS: No, they don't have the resources and personnel to do it. And why would Congress give it priority? I mean, think about child pornography. I know something about that world from my subcommittee work, and you wouldn't believe it. It's a $6 billion industry, most of it coming from the United States.

***NBJ*: So, among other things, FDA needs more resources.**

BS: Correct. But in the Food Safety Modernization Act, just by putting in a registration fee, that makes FDA more than enough money to add resources. A lot of this will come back to the personality of the President or whoever is head of the FDA. [Former FDA Commissioner Andrew] von Eschenbach had no interest in supplements—he had a lot of interest in cracking down on drugs that were making claims, especially in the area of cancer, because his specialty was cancer research.

If you were putting up a drug that was going to fight bone cancer, then I'm sure von Eschenbach would want to know more about that, but it all depends. Now, [current Commissioner Margaret] Hamburg, she comes from a public health point of view, so she sees this as a bigger picture, and I would dare say she is not that keen on drug safety, drug review and public trials—that's not her area.

***NBJ*: Who is really moving the needle in terms of healthcare and nutrition? Is it the President, is it Congress, is it supplement companies, doctors, consumers—have they all got their hands in there?**

BS: Congress gave the power to move the needle to the Secretary of Health and Human Services. There will be a number of commissions, which people don't like, but there's actually going to be a commission on setting acceptable medical practices, with quality-based outcomes as opposed to traditional forms of quantity-based medicine.

***NBJ*: Do you take supplements?**

BS: I do periodically, yes. Am I regular at it? No. Why? Because of my crazy schedule, the only thing I'm regular on is being late.

Does Europe Do a Better Job of Policing Its Food Supply Than the United States?

As 'villains' mount in the food supply, America looks across the Atlantic for another model of regulation

After years of trailing in its wake, the United States' organic food and beverage market is set to overtake its European counterpart for the first time.

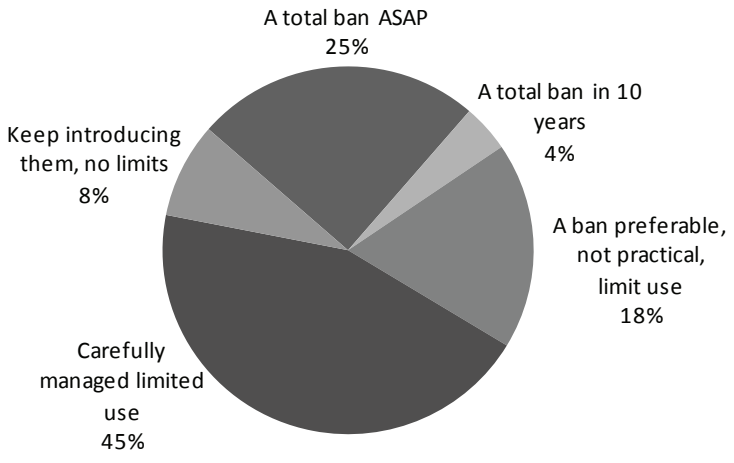
Analysis from specialist consultancy **Organic Monitor** shows that in 2009 (the latest date for which data is available) the North American and European Union organic sectors were each valued at $26 billion. [*NBJ* plans to publish its own updated global sales data at the end of 2011.]

When figures are published for 2010, North America is expected to have edged ahead, bringing an end to an era when Europeans could rightfully claim superiority over their trans-Atlantic cousins when it comes to putting your money where your mouth is in the name of organics.

Amarjit Sahota, managing director of the London-based Organic Monitor, says this state of affairs has now been consigned to history for good. "The European and North American markets for organic food and drink were about the same size in 2009," he says. "However, we expect North America to overtake Europe because it is growing at a slightly higher rate, and we expect the North American market to remain the largest from 2011 onwards."

Why has this happened? On one level, experts believe it is a simple question of economics. "The European organic food & drink market was adversely affected by the financial crisis, more so than the North American market," explains Sahota. "In comparison, healthy growth has continued in the U.S. and Canadian markets."

***NBJ* Survey: Future of Genetically Modified Organisms**



Source: Nutrition Business Journal *survey of 72 supplement manufacturers, marketers and distributors conducted 5/20/11 - 6/20/11. Question: "What do you think should be the future of GMOs (Genetically Modified Organisms) in the U.S. ?"*

Laura Batcha, chief of policy and external relations at the Vermont-based **Organic Trade Association** (OTA), concurs. "Part of it is just the dynamics of the global economy, with the U.S. economy rebounding faster than the European economy," she says.

But to really understand the reasons behind the accelerated march of organics in the United States, it's important to look at some fundamental differences in how the U.S. and EU governments regulate their respective food and beverage markets.

Specifically in the United States, organic has become a clear refuge for a growing number of consumers who want to be sure that the products they consume remain free of genetically modified organisms (GMOs) and bovine growth hormone, substances completely banned under organic regulations, but permitted—and endemic— in more conventional foods.

GMOs & rBST

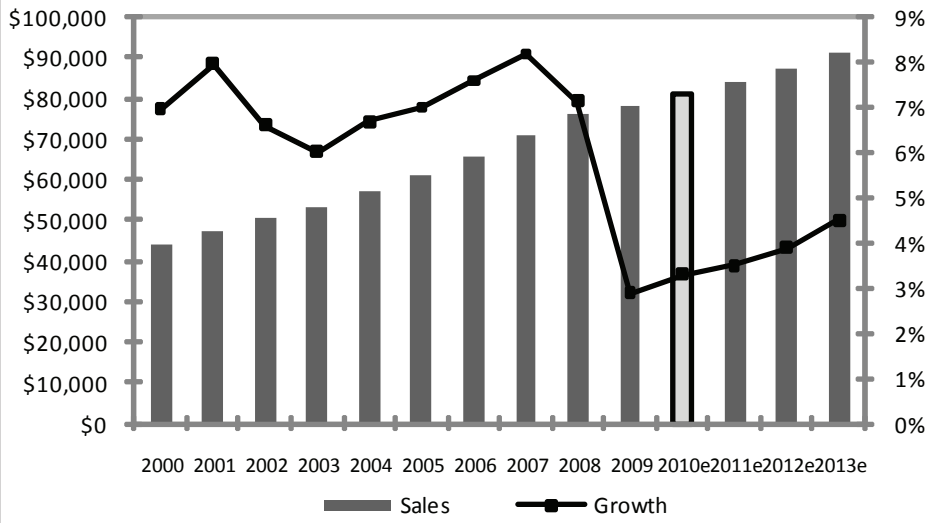
The use of GMOs is easily one of the most contentious issues in the global food sector right now. GMOs are legal in both the United States and the EU, subject to regulatory clearance. But there is one major difference in how the authorities handle these contentious ingredients. In the EU, the supplier of any product containing levels of a genetically modified substance above a certain threshold must inform the consumer of this via the label. In the United States, there is no such requirement.

In Europe, amid public concern about the safety of GMOs fueled by scare stories in the media, this has amounted to a de facto ban. Patrick Coppens, senior advisor of food law at **European Advisory Services** (EAS), says: "In the European Union, although GM-derived ingredients are allowed in foods, you will find virtually no use of GM material within food." OTA's Batcha agrees. "The labeling and threshold really act as a suppressor to adoption," she says.

Officially, the U.S. government rejects the idea of labeling products containing GMOs because its scientists do not recognize them as being materially different from non-GM equivalents. But many opponents of GMOs claim the real reason is that the authorities are too close to major biotech companies, which subsequently have an undue influence on how GM crops are evaluated, approved and regulated.

Jeffrey Smith, executive director of the Iowa-based **Institute for Responsible Technology**, says concern exists even within the **U.S Food and Drug Administration** (FDA)—the government

European Nutrition Sales & Growth, 2000-2013e



Source: Nutrition Business Journal *estimates ($mil., consumer sales). 2010 global estimates will be finalized in December 2011.*

body responsible for food and beverage labeling—and the **U.S. Department of Agriculture** (USDA)—which evaluates the environmental impact of GMOs—that this is the case.

Smith points to a survey conducted in 2010 by the **Union of Concerned Scientists** among food safety staff working at these two organizations. About 1,700 employees responded, with 25% admitting that at some point they had personally experienced, either frequently or occasionally, "situations where corporate interests have forced the withdrawal or significant modification of [an agency] policy or action designed to protect consumers or public health."

"In general," says Smith, "in the United States we see that corporations have a significant impact on policy, but the influence of biotech companies and big ag has been legendary."

Smith adds that Europe is not entirely free of such influence, claiming that scientists within the **European Food Safety Authority** (EFSA), which issues opinions on approving GM crops in the EU, have their own links with the biotech industry. But the fact remains that, thanks to the labeling requirement, GMOs in the EU are effectively outlawed, and no amount of undue pressure from any biotech company appears capable of changing that any time soon.

There is even clearer water between the United States and the EU on the use of the synthetic bovine growth hormone rBST (also known as rBGH) to increase milk yields. The hormone, which is injected into dairy cattle, is controversial for its link to various cancers in humans and an increase in the likelihood of pregnant women giving birth to twins.

In Europe, rBST is banned altogether because of those health fears. In the United States, it is considered safe. Not only is it permitted but, as with GMOs, companies are not required to declare on the label that milk in their product was produced from cows injected with a growth hormone. Again, the FDA does not recognize milk produced from a cow injected with the hormone to be any different from milk from a cow not injected with the hormone.

Things are changing, however—though not through any political will. In fact, industry is leading the way, with several major names, including **Walmart**, **Starbucks**, **Yoplait** and **Dannon**, having declared in recent years that they will no longer produce dairy products under their brands with milk from cows treated with rBST. "It will be the food companies wanting to maintain market share that will drive it out," says Smith.

Coppens thinks the GMO and rBST issues illustrate a fundamental difference between how regulators in the U.S. and Europe view the world. He explains: "In the U.S., the principle is: 'If something has been shown to be safe there is no possibility for us as an authority to restrict its use.' In the EU, other legitimate factors, like ethical ones, play a far more important role. This discrepancy between the attitude in the EU and United States is really at the basis of many of the differences in the regulations."

Smith sees the issue from a slightly different angle. In America, he says, "we've seen time and time again, both in terms of GMOs and also certain drugs, a willingness to overlook certain risks to benefit the companies that are supposed to be regulated."

Ironically, all of this has unquestionably served to benefit the organic market in America. Organic Monitor's Sahota says that U.S. and European consumers essentially buy into organics for the same reasons: "Concern for the environment, fears over food safety, and growing ethical consumerism." In addition, the rules and regulations covering organic production are broadly the same in America and Europe. But, thanks to the different ways in which GMOs and bovine growth hormone are regulated, consumers on each continent face starkly different challenges and choices when making purchasing decisions in the grocery store.

The upshot of the U.S. government's reluctance to require labeling of products made using GMOs and rBST is that consumers in the United States who wish to be sure that they are avoiding both completely have only one option. "U.S. consumers cannot make a distinction," says Coppens. "They cannot source GM-free products unless they go organic."

EFSA & FDA

It's hard not to conclude that, on the whole, the food and beverage industry seems to get a somewhat easier ride from U.S. regulators than it does from authorities in the EU. Rightly or wrongly, this perception is only encouraged by the ways in which health claims for di-

etary supplements and food and beverage products are regulated.

The EU's Nutrition & Health Claims Regulation has grown infamous globally for the severity with which it controls the use of all types of health claims, whether they pertain to structure-function or disease risk reduction.

Henceforth, any company wishing to use a health claim to market a product in the EU will be able to do so only after the evidence for that claim has been assessed and validated by EFSA. It sounds simple—but as keen followers of European affairs will already know, EFSA is evaluating claims using criteria and a level of scrutiny not unlike those usually applied to pharmaceuticals. Unsurprisingly, in this regime most claims already put through the process have been rejected.

The situation is markedly different in the U.S., where, although disease risk reduction claims require pre-market approval from the FDA, companies are free to use structure-function claims without seeking prior permission. Why this disparity in approaches? Coppens says the reasons can be traced back more than 200 years to December 15, 1791, when the First Amendment was adopted into the U.S. Constitution.

"The U.S. system is more favorable than the EU system, and I think in general this is because the U.S. is far more bound to principles of legal right," he says. "The principles of freedom of speech and proportionality are very important in the U.S. Companies take the authorities to court if they think they are surpassing their power and infringing the legal rights that have been imposed by the constitution.

"This means that, in general, the FDA, or any other government authority body, initiates regulations in a way that is necessary for their objective but is the least restrictive to the rights of the individual."

In Europe, this state of affairs would be "unthinkable," says Coppens. "There is nobody who would dare take the authorities to court." This gives European legislators far more power than the FDA, he says, adding: "The FDA actually envies the EU system. They are very supportive of the way in which the European Union does things—at least on claims—but they are not allowed by their constitution to do the same."

Hope for Private Label

In the space occupied by controversial issues such as GMOs, growth hormones and health claims, there appears to be a regulatory and cultural gulf developing between the EU and United States. In terms of consumer behavior, however, there is evidence of greater convergence between the two countries.

> *"The FDA actually envies the EU system. They are very supportive of the way in which the European Union does things—at least on claims—but they are not allowed by their constitution to do the same."*
>
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> European Advisory Services

We have already seen how organic won consumers over in the United States, to the extent that sales are now surpassing those in Europe. A similar trend is now evident in the area of private label. There remains a long-standing belief among global observers of the food supply that America's taste for advertising and branded products far exceeds that of its European peers, but does the data prove it so?

Statistics produced for the **Private Label Manufacturers Association** show that in 2009 (again the most recent data available at press time), private-label products accounted for 25% of sales in value terms across the 20 European countries monitored by PLMA.

In the United States, meanwhile, private label sales through supermarkets (excluding drug stores) hit what PLMA calls a "record high" of 18.7%. *NBJ* research also indicates 9% growth in U.S. private label supplement sales in 2010. As such, it is not such a leap to posit that the U.S. private label market could soon achieve what organic has already managed—to overtake its EU equivalent.

Yes, while the United States lags behind Europe in terms of private label penetration overall, **Euromonitor** data shows that 12.4% of U.S. vitamin and supplement sales by value in 2010 were private label, compared with 7.9% in Western Europe. Could this be a sign of things to come in the private label market as a whole?

The trends in organics and private label we have seen here suggest that, in general, U.S. and European consumers harbor many shared desires and concerns, and that placed in common environments, they will behave and shop in a similar fashion. The key differences between them, therefore, appear to be largely the result of outside influence—predominantly regulation, or lack thereof. Markets, it seems, are only as free as governments allow them to be.

NBJ Bottom Line

When it comes to regulation and the American food supply, insiders have pointed to Europe increasingly over the past year or two as a model to study. Few would go so far as to call it a *better* model, but evidence appears to be mounting for just such a conclusion. GMOs, rBST, levels of organic penetration and private-label adoption ... trendspotting in Europe could pay real dividends for companies looking to navigate and predict the regulatory environments to come in America.

Perception matters here. As our story about **Whole Foods** (page 34) posits, forces beyond the **FDA** and **FTC** are gaining serious traction in our debate about food & health. Whether you believe the U.S. regulatory system is compromised by industry interests or not, the fact remains that comparable agencies in Europe, and corporations themselves here in the United States, are safeguarding consumers to a degree that the regulators, sadly, cannot.

NBJ Healthy Food Insights
Justin's Nut Butter | Earth Balance | Dr. Michael Roizen

Nutrition Business Journal
Strategic Information for the Nutrition Industry

Justin's Looks Beyond Peanuts, Pushes $20 Million in Sales

With a squeeze pack in every Starbucks and organic peanut butter cups at every checkout counter, Justin's has the brand equity to go big

A decade ago, Justin Gold, a Pennsylvania native and recent college graduate, settled in Boulder, Colorado, splitting up his time waiting tables and selling tents, along with partaking in a steady diet of hiking, biking, skiing and climbing. A vegetarian, Gold found himself eating oodles of peanut and almond butter to bridge the protein gap and support his active lifestyle.

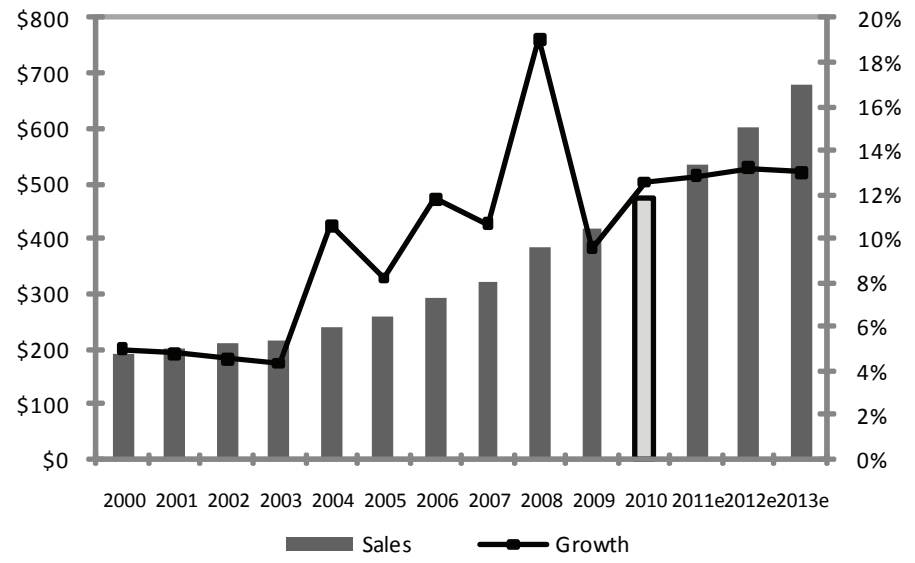
"I was really shocked that organic nut butters came only in creamy and crunchy, and that was it. I really wanted flavors and varieties," says Gold. For fun, he began making his own flavors of nut butter at home in his food processor, mixing nuts with other ingredients like chocolate, coconut, honey and agave. "My roommates kept stealing jars of it out of my cupboard, so I had to write *Justin's* on it," he says.

Friends and family helped him sell his nut butters at local farmers' markets. Ten years later and Gold operates one of the fastest growing snack brands in the natural foods space. Having minted nearly $10 million in 2010 sales, **Justin's** now stands to reel in between $15 million and $20 million by the close of 2011, all without launching any new products.

Knead & Squeeze

Gold's debut at local farmers' markets developed into a spot on shelves at local **Whole Foods** outlets. From there it was steady growth and expansion of distribution until a new idea began percolating a few years later.

U.S. Natural & Organic Nut Butter Sales & Growth: 2000-2010e



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

"I was on a mountain bike ride, back in 2006, and I had the idea of doing a squeeze pack," says Gold. "I was eating *GU* or a *Clif Shot*, and I really wanted portable protein. That was a big idea." Gold drafted a business plan and approached existing squeeze pack manufacturers, but none wanted to share their line co-packing an allergen. He instead raised the money himself, garnering $100,000 from friends, family and angels, and funded his own filling operation.

"In my mind, it was an energy product," says Gold, "I sold them in the energy set, with bars and gels, and presented them to **REI**, selling them for $1.19. And it failed. Nobody knew what it was, and it was too expensive."

Not to be discouraged, Gold reformulated and repackaged the squeeze packs and sold them for 69 cents in supermarkets in the peanut butter set. "The consumer already knew what it was, so I didn't have to explain," says Gold. "And it was a trial size, instead of the $10 jar size, and if the consumer likes it, they'll buy the bigger size. This is what really catapulted the business."

Most importantly, the squeeze packs offered consumers a touch point with the *Justin's* brand that was more mobile than a jar of peanut butter. A one-ounce pack of nut butter can grab more visibility, set up at supermarket checkout counters and in cafes. In fact, one of the biggest coups for the company came when **Starbucks** picked up the packs for nationwide distribution in 2008.

The Power of Clusters

Up to that point, Gold had simply been a young entrepreneur with a good product. But since then, he's evolved into a veritable brand owner. Gold was lucky in that Boulder is both a naturally receptive market for a local brand of organic peanut butter and a geographic cluster of numerous natural brands. He befriended local business leaders, and assembled an advisory board comprised of Peter Burns, general manager of **Celestial Seasonings**; Hass Hassan, managing director at **Greenmont Capital** and former president of **Wild Oats**; and John Maggio, founder of **Boulder Chips**. Maggio, who had pitched to Starbucks before, came on in an advisory role to help with the transition.

"I knew that he wasn't set up to deal with Starbucks in any way, except that he had a great product," says Maggio. The distribution deal was sealed, and the squeeze packs shipped.

The visibility that the Starbucks distribution created not only attracted new customers, but attracted more human capital, including its new president, Lance Gentry, former marketing executive for natural beverage company **IZZE**. "When IZZE moved into Starbucks, our whole world changed," says Gentry, who worked for the beverage brand up to its purchase by **PepsiCo** in 2006.

"The changing moment for my company came in 2008, when I brought on Lance Gentry," says Gold. "The man understood exactly what I wanted to do. We were about $1 million at that time, we had just gotten into Starbucks and Whole Foods, and I wanted to grow to $25 million to have the opportunity to exit. Not that I want to or will, but I want to build something that's going to be valuable."

Brand Equity & New Products

In order to jump from one to 25, *Justin's* has delivered on two distinct fronts. For one, a rebranding effort, with a new focus on building brand equity. And two, diversifying the product line.

"People have to be attracted to the brand, to the look of the product," says Gentry. "That's something that Justin didn't have when I came on." To that end, *Justin's* hired **TDA Boulder**—a design firm with past clients including IZZE, Celestial Seasonings and **Chipotle**—to redesign their packaging. The resulting design is simple and attractive. It uses a fair amount of white space, which differentiates it from the busy, earthy branding of most natural products.

With that came the evolution of the company from *Justin's Nut Butter* to simply *Justin's*, and the development of products beyond nut butters. "You can't charge $20 for a jar of peanut butter," says Gold. "And if you're a family of four, you're going to eat a jar of peanut butter once a month. So that's slow turns and low margins. But if you look at a *LaraBar* or a *Clif Bar*, you can sell one of those every day, and charge a higher premium. We're looking at foods with good brand visibility, decent margins and good returns. It has to be something you can consume every day. And those products seem to be healthy snack foods."

Beside Justin's eight flavors of almond, peanut and hazelnut butter, the first snack food launch was a peanut butter cup. "What we've done is given people a *Reese's* experience that's fair trade Belgian chocolate, organic, and better-for-you," says Gentry. The cups sell at checkout counters in natural retail and some mass. "We can't make them fast enough," says Gold.

> *"Kettle Foods started as a nut butter company. Now it's a $300 million potato chip company, though there's still nut butter on the shelves that says Kettle Foods. I think you never know where the business is going to lead you."*
>
> —John Maggio
> Justin's Advisory Board

Forthcoming products include small sacks of natural nuts, as well as some as-of-yet undisclosed projects. And with the brand equity developed through the Starbucks distribution and the new design, the sky's the limit.

"I use an example from the snack foods industry," says Maggio, "about how **Kettle Foods** started as a nut butter company. Now it's a $300 million potato chip company, though there's still nut butter on the shelves that says Kettle Foods. I think you never know where the business is going to lead you."

Though the company's stated mission is "global nut butter domination," *Justin's* has to diversify to stay viable. "We don't own any intellectual property on this product," says Gold. "It's a food processor plus peanuts. Anybody can do it. So we have to grow as fast as we can before somebody beats us on shelf. A lot of that has to do with the brand."

Organic Forever?

Justin's has developed into a fast growing company with widespread brand visibility, though struggles still percolate under the surface. "Operations are the hardest part of a hyper-growth brand," says Gentry. "We've just gotten a loan from a local bank, and we're spending between $400,000 and $500,000 on the infrastructure to be able to grow to $50 million in revenue."

Beyond operations, sourcing nuts can be an expensive headache. Organic peanut prices take wild swings, while almond harvests are subject to brief blooming periods and the capriciousness of bees. *Justin's* almond and hazelnut SKUs have to carry an all-natural designation because organic almonds and hazelnuts would require an unjustifiably expensive finished product.

Organic is a bigger priority for peanuts, though. In the Southeast, legumes are rotated with cotton, one of the most pesticide-heavy of all U.S. crops. But steadily rising commodity prices for organic peanuts may provoke a potential trade-down to natural for *Justin's* in the future, especially as their distribution expands. *Silk* comes to mind. "Organic for peanuts is a given, until tomorrow, and maybe my story will change," says Gentry. "I don't know where peanut prices will go, and whether people will tolerate the price hike. We'll do whatever our consumers want."

And while national distribution in Whole Foods is certainly valuable for brand integrity, *Justin's* is gaining more and more purchase in mass, where the words natural and organic have less impact. "Our short term goal is $20 million to $25 million," says Gentry, "because when you get to that spot, you get a lot of offers. It means you've gotten into 80% of the stores in the country, and you just need a little bit of help to close that distribution gap. Then you can get up to $100 million really quick."

Non-GMO Tipping Point Still Far Off for Consumers, But It's Coming

General manager of Earth Balance discusses the role of natural products in shaping mainstream consumption

T. J. McIntyre manages the operations of *Earth Balance*, a natural foods brand from holding company **GFA Brands**, also owners of the popular buttery spread *Smart Balance*. Earth Balance is a strong player in natural spreads and organic soymilk, as well as an early adopter of the **Non-GMO Project**'s new product labeling. McIntyre spoke to *NBJ* about his company's foray into mass, **Whole Foods Market**'s status as a kingmaker for health trends, and the progress of the non-GMO movement.

***NBJ*: Is the mass market meaningful to you?**

TJM: It is, but we maintain a very concerted natural foods focus. We see an enormous amount of growth from the natural foods industry, and we're able to take some risks in the natural foods industry with early ideas—things like our new coconut spread—that we would not be willing to take if we were launching into more mainstream distribution out of the gate. Heavy users of the *Earth Balance* brand have traditionally continued to be natural foods consumers. So our marketing efforts, all of our messaging, all of our social media components are really focused on the natural foods consumer.

Mass represents an opportunity to take an idea that has blossomed in the natural foods industry and offer a very high-quality, all-natural product to upgrade a category. In the case of our soymilk launch, we have a team at *Earth Balance* that worked closely on soymilk in the past. Many of us worked together at legacy **White Wave**. We knew how to make soymilk, how to manufacture it and achieve efficiencies from a usage perspective. We understand the value of organic in the soymilk category—more than 90% of soybeans are now genetically-modified, and the organic attribute is something that, prior to the Non-GMO Project, was validation that you were not going to be using GMO.

***NBJ*: What are the challenges that you face in more mass grocery? We've heard it over and over again—that you lose the core when you get big. How do you prevent that from happening?**

TJM: Well, we don't have to have a $200 million expectation on soymilk for the project to be a success for the *Earth Balance* brand. In the United States, refrigerated soymilk is now battling almond milk and coconut milk. The overall category is becoming increasingly price competitive, and soymilk is a dairy-category staple where retailers are going to look for a very competitive price point, whether they be mass, grocery, or even Whole Foods. It is difficult for us to compete with non-GMO or 100% **USDA** organic soymilk on a mass and grocery scale.

> *"There are not a lot of examples of failed initiatives where a retailer like Whole Foods has asked for a certain type of upgrade from their manufacturers and that didn't turn into a pure consumer trend in the years to come."*
>
> —T.J. McIntyre
> Earth Balance

***NBJ*: What are the differences between working with a mass retailer like Walmart versus a Whole Foods?**

TJM: Well, let me speak exclusively to Whole Foods, because that is a customer that we have aligned ourselves with from a selling and marketing perspective. I think the challenge that we face with the way that Whole Foods makes decisions is that they are not centralized, but very regionalized. The natural foods strategy of any manufacturer really has to be focused regionally, because you have so many key independents. Even with the **Independent Natural Food Retailers Association** (INFRA) and the **California Grocers Association** (CGA), it takes time to turn the process into a more collective one where, with a handful of calls and regional shows, you can address a lot of retailers. You still have to be as focused in Sacramento as you are in San Francisco, and as focused in Santa Cruz as you are in Los Angeles.

One of the things we take pride in is our ability to touch, literally, all of the independent A's and a lot of the B's in the country on a relationship basis, and that leads to distribution and programming with all of those independents. We're not simply skimming the top for the most efficient sell-in process. That's a mistake that a lot of companies make as they get bigger, and they have to drive the sell-in efficiencies through their organization. They have models that push them exclusively toward very high-volume calls, and they're not as willing or not as adept at all of these one-off type of relationships. They're not as adept at developing one-on-one relationships with all of the smaller one-to-three-store chains. That makes it tough to greenhouse really new, cutting-edge, innovative ideas.

***NBJ*: What do you think of Whole Foods' standards? Do they have an impact on your business?**

TJM: Well, some of the terms like the ANDI system and sustainability for seafood don't really affect us. I think the key push that Whole Foods has been behind is the much larger Non-GMO Project, and that is a trend that they are trying to turn into something like what happened with organic 10 years ago. It aligns very well with what we're trying to accomplish at *Earth Balance* because we use a lot of ingredients that are on the short list of products that are genetically modified.

We've been committed to non-GMO as a company for over 10 years ourselves,

and learning more about the Non-GMO Project about a year and a half ago, we decided that it's an effort worth investing in.

With Whole Foods, you see a lot of leadership, and I think they are looking for a continuous and pertinent process, a pure ingredient perspective to include sustainable agriculture and overall environmental footprint. The bar is just going to continue to be raised as consumers become more aware of what happens with their voting dollars by way of what they purchase in the store. If a retailer like Whole Foods, which has amassed a lot of power in the natural foods industry, continues to press the trade to upgrade their products from an environmental, sustainable perspective, everybody can win. That's how they compete with a lot of the more mainstream retailers that are simply not thinking that way.

***NBJ*: Are those standards a good way to differentiate between your products and products that might cost less?**

TJM: Yes, and it also speaks to the type of relationships that Whole Foods is looking to develop with manufacturers. As an example, I heard a couple of weeks ago about a manufacturer that was going to try and push new products into the store, and what Whole Foods requested was that the products be non-GMO verified. The conclusion that the manufacturer reached was, "Well, we'll launch non-GMO verified products with you and we'll be conventional everywhere else." That's not what Whole Foods is really asking. They are trying to get the type of companies that they partner with to act in a responsible manner across the board. That's the type of company that they're going to get behind.

There are not a lot of examples of failed initiatives where a retailer like Whole Foods has asked for a certain type of upgrade from their manufacturers and that didn't turn into a pure consumer trend in the years to come.

***NBJ*: What do you think about GMO standards as they exist today?**

TJM: On the one hand, you have a very overwhelming situation where, like with soy, you have some 94% to 96% of the world's product being genetically modified. If you ask consumers if they're in favor of or opposed to consuming GMOs, the majority are going to say that they are opposed. But it's never easy for them to do anything about it because they are so ubiquitous in our food supply chain. What is happening inside the industry and outside the industry is a two-pronged approach that is becoming increasingly refined and gathering momentum.

One side is Jeffrey Smith and the **Institute for Responsible Technology** (IRT) pushing to educate and energize consumers, and collectively drive awareness around the GMO issue to a tipping point. Then either legislation or pressure on manufactures will enact some kind of a change. Simultaneously, the Non-GMO Project is producing a solution to the issue with a label. GMO labeling is not mandatory today, so you've got to get labeling in place for the natural food industry to take a leadership position.

***NBJ*: Are GMOs on the radar of consumers in Middle America? Say an auto-worker in Detroit? What does he think of GMOs?**

TJM: He may not be thinking about GMOs, but he probably is thinking about high-fructose corn syrup, or maybe hydrolyzed protein or hydrogenated oil. It can be argued that the trends of moving away from those ingredients started in the natural foods industry. The avergae consumer might now be thinking about not only looking for the absence of those ingredients, but he may be attracted to a product that has a "natural" claim.

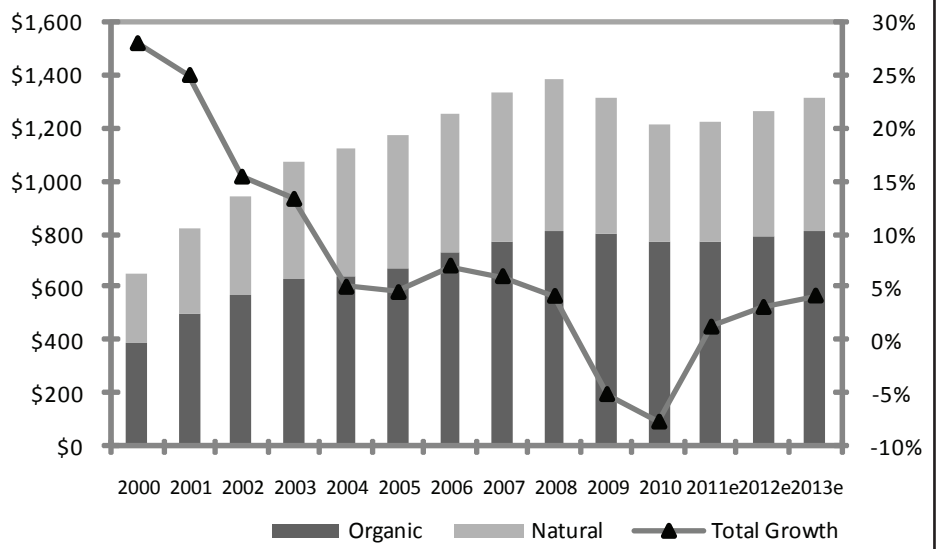
Overall, consumer acceptance of trends like super fruits, antioxidants, organic, local, these ideas accelerate towards consumer acceptance at a far faster rate than they would have 10 years ago. All of that is very attributable to the efforts of the natural foods industry. And non-GMO happens to be at the top of the current agenda.

***NBJ*: How does non-GMO certification compare to USDA-certified organic in terms of cost and effort?**

TJM: We found it to be about as costly and a lot more time intensive. That has to do with the fact that it's the early stages, and the supply chain is not really aware of all the necessary steps, including the complexity of the DNA testing that you need to subject high-risk ingredients to.

We absolutely went through a painful learning process, but now our soy supply chain is up to speed and, going forward, it won't be as difficult.

U.S. Natural & Organic Soymilk Sales & Growth, 2000-2013e



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

Healthcare Costs Threaten Society as We Know It

Dr. Michael Roizen directly links corporate wellness with the stability of the U.S. economy and our global competitiveness as a workforce

Dr. Michael Roizen is a frequent contributor to the public debate about health in America, with appearances on the *Oprah Winfrey Show*, the *Today Show* and *20/20*. Roizen is the co-author, with Dr. Mehmet Oz, of several volumes in the popular *YOU* series of health manuals. Roizen is a practicing anesthesiologist and internist in Cleveland, Ohio, where he now serves as chief wellness officer of the **Cleveland Clinic**.

***NBJ*: How are you spending your time right now?**

Michael Roizen: My main job is working for the Cleveland Clinic as chief wellness officer and as chairman of the **Wellness Institute**. The majority of my time is spent on our own corporate wellness and promoting corporate wellness to other companies. I help Cleveland Clinic employees to get healthy, using these results as our reference account to teach other corporations how to foster a healthier workforce. This allows them to be more competitive by bending their cost curve for medical care substantially downward.

***NBJ*: How are supplements advancing the cause of healthy aging?**

MR: There are a series of supplements with low risk and lots of gain that everyone should take. The active component in fish oil is DHA—there is no reason not to get DHA. One of the companies you follow, **Martek**, makes DHA from algae, which is where the fish get it. The only two fish in America left with DHA are salmon and trout. All the other fish get fed corn and soymeal, so you'd have to have just a salmon-trout diet to get enough DHA without supplements.

Lutein protects the macula in your eye. Vitamin B5 lowers LDL cholesterol, raises HDL cholesterol, and has no known side effects. Vitamin D3's another one—we don't get enough from our multivitamins. If you're concerned about arterial aging, there's no reason not to have arginine and citrulline. So yes, these are supplements that are not commonly taken in America with no downside and plenty of benefit in slowing either specific degenerative diseases or the overall aging process.

One lady was asking me, for example, why, when she went to Germany, her bowel disease got better. She was drinking German beer, which has much more of the B vitamins in it than American beer. We switched her to a multivitamin and that alone cured her bowel disease.

***NBJ*: What health factors do you address to promote wellness?**

MR: There are four factors that affect 75% of disease—tobacco, physical activity, food choices and portion size, and stress. Many people would say stress is the most important, and others would say food is the most important. I don't know that I can answer the question because we don't have good enough data to say one overwhelms all the others.

But, if you look at it from a longevity standpoint, stress has the greatest impact, as it affects all three of the major systems relating to aging—arterial, immune and mental. If you look at it from an 'If I change one thing, what changes most in health?' standpoint, it's probably nutrition. If you change nutrition, you change chronic disease.

***NBJ*: Is the government doing a good job here?**

MR: No. The government is the biggest insurer of all, spending roughly $1.5 trillion, if you include **Medicare**, **Medicaid**, the campus programs and the deductions that corporations take in medical care. If you remember that 75% of what we spend on healthcare doesn't have to be spent, then you could wipe out 95% of the budget deficit and save roughly $12 trillion over the next 10 years. Republicans are focusing on rationing, and the Democrats are focusing on keeping the system the way it is and just pumping more money into it.

Healthcare costs are our leading cause of job discompetitiveness. We lost manufacturing when our differential with Mexico went to 9% in 1990. We will lose education and service industries when our differential goes to 21% with Mexico, India, China and Japan in the year 2020. We have a major problem that the country can either solve or not solve.

If you mean the government in terms of Medicare, or the government in terms of **NIH** funding innovations in this area, or the government in terms of **Congress** being able to put in performance standards or promote individual responsibility for health, they all get an F—none of them have done a decent job.

The question is, 'Will we in America continue to exist?' We need to maintain our job competitiveness by substantially bending down the curve, as the administration has talked about, by putting in individual responsibility to get people healthy.

***NBJ*: What's one thing we need to change right away?**

MR: First, you've got to give people 'aha moments.' And secondly, you've got to change the environment so it's easy to make healthy choices and hard to make unhealthy choices. Then you have to incentivize people to continue.

***NBJ*: What should the media be doing differently?**

MR: The media hasn't presented a solution to bending the cost curve reasonably and safely to wipe out the budget deficit. It hasn't been in the *New York Times*, the *Wall Street Journal*, *USA Today*, or the *Washington Post*. At the Cleveland Clinic, we're working with corporations, like **Eaton** and **General Electric**, to implement change.

But it's the federal government, with its $1.5 trillion allotment, where you could actually save jobs for the whole country. You'd wipe out our budget deficit, or at least two-thirds of it easily, and the side effect would be a healthier, more vigorous population.

***NBJ*: Where's the momentum for wellness right now?**

MR: I don't think you can make change in one area without doing it in others. You have to wipe out all four of the big four to radically change health and thought. There's a time-lag. It takes five years to get your payback, but once you start to get that payback, it's substantial and continuous.

***NBJ*: How do you view the food supply and wellness?**

MR: Be selective. Avoid what I call the five food felons: saturated fat, trans fats, simple sugars, added syrups, and any grain that isn't 100% whole grain. If someone were to develop a fast-food restaurant that did just those things and made it economical, you would be able to out-swamp **McDonald's** in 20 years. For example, **Subway** has a poor-quality bun. If someone made a more nutritious bun, it would force Subway to compete or wipe them out.

***NBJ*: How much do you worry about toxins in the food supply?**

MR: There is nothing bigger that I worry about than toxins in the food supply, other than Greece, Ireland, Portugal, Italy and Spain going belly-up. One of my current worries is this mating of salmon with a bottom-dwelling fish. I wonder: Does that mean the new salmon, if they approve its use or if it gets wild, will it end up with more mercury in it? Will we lose that great, pure source of omega-3s and healthy protein?

I worry a great deal about food from China. We have to be very careful about eating anything from the drought-stricken areas of China next year because of the pesticide wash-off. When you look at the frequency of ADHD and autism spectrum disorders, the data from **UC Davis** and a number of other universities indicates higher rates in children of farmers who use pesticides and drink their own well water than those who drink from city supplies.

So, am I worried about it? Yes. Do I know what to do about it, other than try and speak out about it? No. The real problem is that when certain levels of toxins and pesticides get into the ground or the water, even if you farm organically, even if all you do is insist on organic food, you're going to get that contaminated food. That's probably one of our greatest risks going forward as the planet gets more populated. Do I worry about it? You betcha.

> *"If we don't implement systemic change in healthcare, we will be at such a disadvantage with Japan, China, India and Mexico that we will no longer have a service industry or manufacturing jobs. We will lose society as we know it. We either have to solve these problems or we will have a very different standard of living.*
>
> —Michael Roizen, MD
> Cleveland Clinic

***NBJ*: Do consumers read labels? Do they care about what's in the products they eat?**

MR: Consumers are not reading labels, and that suggests the labels are confusing. Even the front labels on food are very tough. How do you make it so that they are easy and doable? I don't have the answer for that yet.

Although there is some interest in things like labeling, we don't really have a choice. In eight years, we won't have education and service jobs, like banking and insurance, if we do not change this. That's how serious it is. We will either change, or we as a country will not exist in the same form. And so, just like we lost the manufacturing jobs, we will end up losing the education and service industry jobs in a short period of time if we don't change. It's that clear.

***NBJ*: How do I make that link between jobs and an inadequate food label?**

MR: The government sure doesn't make the link. The biggest partisan issue we have is the budget deficit and Medicare. If we don't address these challenges now, we never will. We need to radically change the nature of the United States for many years to come, because the amount we spend on healthcare is too large. It's now roughly 18% of GDP—it will go to 28% by the year 2020 with the same criteria used for care. If we don't implement systemic change in healthcare, we will be at such a disadvantage with Japan, China, India and Mexico that we will no longer have a service industry or manufacturing jobs. We will lose society as we know it. We either have to solve these problems or we will have a very different standard of living.

At the Cleveland Clinic, we know we have to be the leader in illness care, that's what we do. But we also have to lead in wellness care, especially if we are going to change the job competitiveness of America. I think we have a process now that, at least for the last seven quarters, has flattened the cost curve, and it looks like it's starting to turn it down. Once again, it's this three-step process of giving people ah-ha moments, changing environments to make it easy to make healthy choices and hard to make unhealthy choices, and then incentivizing them to continue. It's easy to get change for two weeks—everyone goes on a diet for two weeks, right? But it's tough to change the environment and incentivize people to stay changed.

You need performance standards for the incentive, meaning you've got to have normal blood pressure, normal height and weight, normal hemoglobin, normal lipids, no ketones in your urine. If you follow this plan, you can radically change the cost curve and make America more competitive again.

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