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STRATEGIC INFORMATION FOR THE NUTRITION INDUSTRY

Considering a Post-DSHEA World

Are supplements regulated? Of course. Are they regulated in the right way?

This is a thought piece. This is a story that asks some basic questions about the regulatory environment facing dietary supplements. It wants to stick its neck out a bit and respectfully wonder if there's a better alternative to be had. Is DSHEA a strong or weak piece of legislation? Is it still appropriate, given the scale and impact of the supplements industry on public health? Is pre-market approval really the end of the world, or could supplement stakeholders learn something from the controlled environments of pharma? Or should those stakeholders stop pursuing research outright? These are not yes/no, either/or questions, of course, but there is mental progress to be made in asking them as such. Or so we hope.

NBJ posed these questions to some of the smartest minds around, and you will hear from them at length, in their own words, in just a moment. We approached a wide spectrum of thought leaders from within and without the industry—trade associations, lawyers (boy, did we talk to lawyers), manufacturers both large and small, activists and government officials alike. We asked them to help us figure out what's working in 2012 and what's not. We asked them to envision a post-DSHEA world and humor specific changes in the law as open windows toward a speculative future with less acrimony between industry and regulator and much more faith and goodwill between manufacturer and consumer.

These speculations matter because the future is bright for supplements. The industry grew 7% in 2011 to reach $30 billion in sales. There is much more data to follow in the charts that populate the pages of this issue, but let's pause for a moment up front on those 30 billion reasons to get this right. There is no bigger obstacle for the supplements industry, in our opinion, that the lack of clarity on the regulatory front. That lack of clarity extends well beyond the NDI guidance document. That lack of clarity extends well beyond the borders of the U.S. market to precedent set every month by **EFSA** in Europe, **NHPD** in Canada and **ANVISA** in Brazil. To put it plainly, that lack of clarity is the gray zone between food and medicine set into motion on November 12, 1994, when President Clinton signed DSHEA into law.

Is DSHEA working?

Al Powers is the CEO of **NOW Foods**, a supplement manufacturer based in Bloomingdale, Illinois. Powers won the 2010 NBJ Lifetime Achievement Award for his 40 years of service to the nutrition industry. Says Powers: "DSHEA was a work in progress over many, many years. This was the culmination of best practices and best thinking over decades. I think it's still relevant today. You wouldn't want to open it up as an industry. All that would do is end

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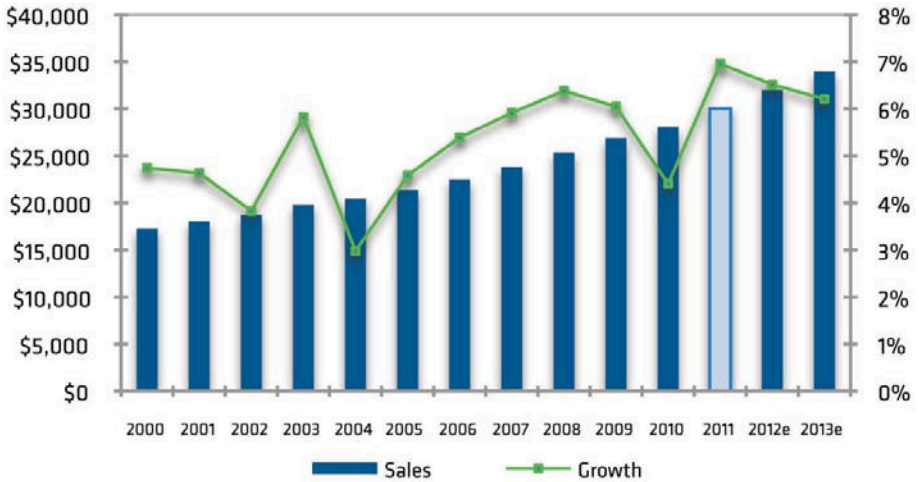
U.S. SUPPLEMENT SALES & GROWTH, 2000-2013E



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

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Letter from the editor

And I quote: "When systems promote excess, they become unsustainable. When systems become unsustainable, they break down. They then have to revert to find safer ground, a process known in nature as the 'renewal cycle.' This is how the ecological world and its species adapt and evolve. Welcome to the renewal cycle for American business, now disrupting your best laid plans with nary a concern. We are evolving as consumers into a new food world, one with much of the shape and color of a world just three generations removed, before the advent of modern food science."

The quotation comes from **NEXT**—a seminal report launched this summer from the minds of **NBJ** and **Sterling-Rice Group**—but there's more to finish the thought: Our food future looks a lot like our past. Listen to Michael Pollan on **Good Morning America**: "The conversation of culture—which is to say the wisdom of your mother and your grandmother and your great-grandmother—has more to teach us about how to eat well than all the scientific studies in the world so far." No matter where you look, you can see this undoing of food science to varying degrees across nutrition, even in the trend toward whole foods in dietary supplements.

NBJ began to explore the ramifications of food science under a bright consumer spotlight in last year's overview, but we can't let go of the charge. Change is everywhere now. It's, well, ramifying. The natural products industry has a front-row street in the great unraveling of the socio-economic systems fraying across the industrialized world, but it's not the only seat to be had. There are seats on Capitol Hill and Wall Street, seats in climate reform and healthcare reform, seats occupied by Occupiers and moms fearful of poisoning their children with GMOs.

This is dramatic, rapid and meaningful change. It's secular. As we selectively re-examine the advances proferred by modern food science, pillars of the established industry will come under serious and sudden attack—hello and goodbye, pink slime. At sufficient scale, this change might also prove directly competitive, if not antithetical, to mainstay categories of nutrition with decades of proven success—industries like functional foods and dietary supplements—that now need to refashion their proposition or run the risk of falling tragically off-trend. Try not to be alarmed by this, but certainly don't try to fight it. The renewing system in search of adaptive evolution is much bigger than any single trend, industry or company.

Marc Brush
Editor in Chief

up weakening the consumer protections granted under the current law."

Marc Ullman is a partner at **Ullman, Shapiro & Ullman** in New York City. He focuses his practice on compliance matters related to **FDA** and **FTC**, as well as NDI submissions and GRAS notifications. Says Ullman: "I had a client going back to 1996 who came a really long way on quality and efficacy and responsibility. They spent millions and millions of dollars on their facility and personnel and GMP compliance. Within the past six months they gave up. They couldn't make money. They were losing orders to the guys down the block who made no effort to comply, who hired people they had fired, who just didn't care."

Todd Harrison is a partner at **Venable LLP** in Washington, DC, where he leads the firm's food and drug division. Says Harrison: "From a safety perspective, DSHEA works great. From a claims perspective, it's just okay. We could improve it with a natural monograph system like Germany's **Commission E** or the **Health Canada** model where people can actually make legitimate claims for their products."

Daniel Fabricant is the director of FDA's **Division of Dietary Supplement Programs**. Neither FDA nor Fabricant chose to speculate on matters outside DSHEA and the present regulatory framework for this story. Says Fabricant: "We're seeing poor compliance with GMPs. We're seeing evidence of noncompliance with AERs. We continue to see very low numbers of NDIs, so that makes us question compliance again. We're seeing a rise in disease claims on products. We see firms that still don't register with the agency for bioterrorism. We're not even scratching the surface on safety here. These are the basic regulatory compliance obligations that all firms have to follow. Registering for bioterrorism takes you about six seconds. I can walk you through it."

Jason Sapsin is an attorney at **Polsinelli Shughart** in Denver, where he leads the firm's FDA practice. Sapsin was formerly

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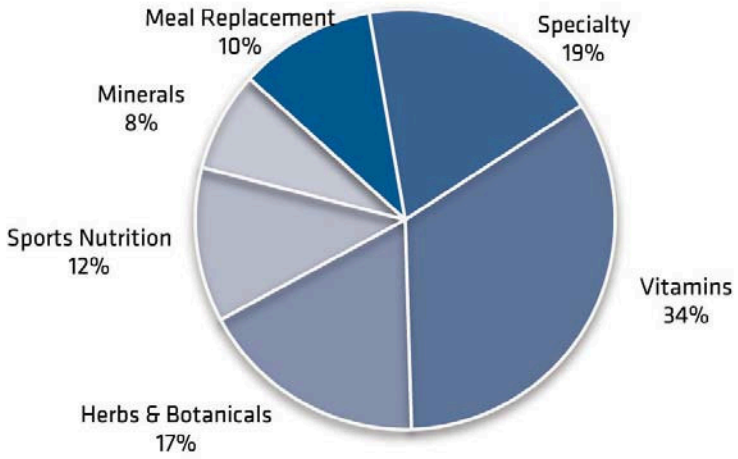
$30 BILLION U.S. SUPPLEMENT MARKET BY PRODUCT IN 2011



Source: Nutrition Business Journal estimates (consumer sales)

of counsel in FDA's Office of Chief Counsel, where he advised the agency in its pursuance of seizures, injunctions and product recalls. Says Sapsin: "DSHEA had and has a lot of potential. There are some habits and institutions that have grown up around it that are less helpful and less promising. The basic idea, it seems to me, is that you take food-type substances that are known, that people use, that are well-characterized and well-understood, and you create a system under which they can be maximally available to people as part of the diet. Many businesses have seen an opportunity to very aggressively market these products as, I won't say cure-alls, but as pharmaceutical substitutes. That's not the role of the dietary supplement."

Marion Nestle is the Paulette Goddard Professor of Nutrition, Food Studies and Public Health at **New York University**. Nestle has written several award-winning books on the politics of the food industry and how it affects consumer nutrition. Says Nestle: "The industry made an enormous mistake in working so hard to pass DSHEA. For awhile, it worked really well to stimulate sales, but there were some unfortunate provisions in DSHEA that I think the industry has lived to regret. The structure-function claim reduces credibility. It's just not a credible way to market things, although lots of people fall for it. The idea that the industry wanted research done—I thought that was a big mistake. The people who run the offices of dietary supplements and alternative research are very good scientists, so they sponsored the research and it's consistently shown no benefit from supplements."

Steve Mister is president & CEO of the **Council for Responsible Nutrition** (CRN) based in Washington, DC. CRN's member companies include such names as **Abbott**, **BASF**, **Bayer**, **DSM**, **GNC**, **Herbalife**, **NBTY**, **Pfizer** and **Vitamin Shoppe**. Says Mister: "DSHEA is still the appropriate model for this industry. Many of our consumers don't really care about FDA blessing the efficacy of our products or not. In fact, they're distrustful of FDA assessing the efficacy of a product. The consumer wants to know this—'If I take Echinacea, is it being made in a safe way, in a consistent way? Am I getting what the label says I'm getting?' GMPs, if they're robustly enforced, will give consumers reassurances on the safety side."

Fabricant: "I think GMP noncompliance sends a message. Roughly 35% of inspections come in from the districts classified as 'official action indicated,' which means that we're going to move toward a warning letter or a stronger action, maybe pursue something with the **Department of Justice** that has an injunction or seizure attached to it. Another 35% is roughly classified as 'voluntary action indicated,' which means that the firm could self-correct or the investigator didn't gather all the evidence needed to proffer a warning letter. That's 70%, the majority of firms we've visited. If you were going to get into a boat and you knew that 70% of the time something was going to be wrong with the boat—maybe the engine doesn't work, maybe it's something as severe as that, or maybe the windshield's just out—are you going to continue to get on the boat?"

In search of enforcement

Ivan Wasserman is a partner at **Manatt, Phelps & Phillips** in Washington, DC. He focuses his practice on matters involving the marketing of foods, dietary supplements, cosmetics, drugs and medical devices. Says Wasserman: "Like FSMA, DSHEA, and even the FTC Act, you have well-crafted laws out there and then you have the issue of the government funding available to police and enforce the law. When DSHEA was passed in 1994, the dietary supplement market was much smaller, not only in terms of the number of products and customers, but remember back to 1994. The internet was a baby. In 2012, the internet has become part of our life—it often is our life, for better or worse—so you now have the ability for companies to easily market and advertise dietary supplements and other products to a national, nay international, market. Without, and even with, adequate funding, it's become a difficult task to police that enormous market."

Ullman: "The problem is on the industry. There's no place else to point the finger. The industry's sensitivity to quality and efficacy is woefully inadequate to its sensitivity to price. I'm painting with a terribly broad brush here, but as long as the industry's prevailing motivation is economic, quality will be a challenge. There's self-regulation on any number of levels—turning people in to the **Better Business Bureau**, working through the **Natural Products Foundation**—we can make all the right noise about doing that, but what we don't see is the big retailers and big economic powers in the industry, saying, 'I'm not going to buy that crap. I will not allow that into my store. I will not allow it to be sold in association with my name.'

Scott Steil is the president of **Nutra Bridge**, an outsourced sales & marketing firm in Minnesota representing branded, patented, scientifically proven ingredients. Nutra Bridge won the 2010 NBJ Award for small-company growth. Says Steil: "With 7-Keto, we've done two filings with the FDA at

different doses and that continues to be a really nice feather in our cap. If someone says, 'I only use clinically validated, FDA-compliant products in our line,' then great. That's music to our ears. I'm competing with a ton of guys who should be required to file an NDI. You've got to all play by the same rules."

Ullman: "There are companies that regularly submit NDI notifications, who do things the way they are supposed to do it, who take the time and spend the money, only to watch a wave of competitors magically appear on the market six months after the NDI goes public. A lot of these come in from China. How about a carrot from FDA in addition to the stick that they're wielding? How about they ensure that the me-too companies who don't file the NDI don't make it into the U.S market?"

Mister: "FDA does not have to prosecute every violator of the law in order to make DSHEA work. If they do a good job of showing that they will flex their muscle, most of the industry will fall into line. There will still be outliers, but if the industry believes that there's a sound and rational enforcement from somebody watching, they'll fall into line."

Fabricant: "This agency has always been challenged with competing priorities and limited resources. One out of every four dollars spent in this country is spent on an FDA-regulated good."

Nestle: "What the industry confronts now is a lack of credibility. It's divided between very responsible companies that put into the product exactly what they say on the label, that use high levels of quality control, and that don't oversell their products. And then there are companies that do whatever they feel like doing, and don't pay attention to whatever rules do exist. Because there's nobody chasing them down, they push the envelope as far as it can be pushed. The FDA isn't going to do it because they'll lose in court. People at the FDA have told me that they're not pushing against supplement health claims because the courts will go against them and they're tired of fighting those battles."

Fabricant: "In the past 18 months, we've taken a much more active role in enforcement. You've seen the first injunction tied to supplement GMPs. You've seen the first seizure tied to supplement GMPs. You've seen an awful lot of warning letters. You've seen us use the NDI provision on failing to file DMAA. We know our toolbox, and we're going to use every tool in there to our fullest ability to build what we need to build."

Sapsin: "When I was at the agency, it was shocking to see what some businesses considered to be acceptable manufacturing practices in their facilities. Maybe this is part of the regulator's dilemma—you're exposed to so many horror stories that everyone becomes suspect. It's everything from pests, to failure to clean equipment, to failure to provide adequate sanitation facilities, to cross contamination between lines, peeling paint, dripping ceilings, you name it. Industry will tell you—and not incorrectly, I say this to my clients as well—that the agency can and will find something wrong. The issue is whether or not the industry and the public are prepared to trust that, by and large, the agency is trying to make fair calls and do the right thing."

Ullman: "I think that when FDA shuts the doors on a couple of these companies for GMP violations, and brings strict criminal liability cases against executives for ignoring repeated warnings about GMP deficiencies or not taking appropriate steps to avoid adulteration with APIs, then you might see an attitude change."

Learning from pharma

Wasserman: "There are benefits and drawbacks to a pharma model. If it's a resource

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Data Corner

Recovery was the name of the game for the nutrition industry in 2011 with total sales growing 8.5%. That's the highest growth the industry has posted since 2007.

Carla Ooyen, Director of Market Intelligence

U.S. NUTRITION INDUSTRY REVENUES BY CHANNEL IN 2011

Category	Natural & Specialty Retail	Mass Market Retail	Mail Order/DRTV, Radio	MLM	Practitioner	Internet	Total
Supplements	$10,970	$8,640	$1,630	$4,810	$2,450	$1,530	$30,030
Natural & Organic Food	$16,600	$23,420	$920	$900	$220	$1,080	$43,130
Functional food	$4,130	$35,970	$80	$370	$220	$310	$41,070
N&OPC and Household	$4,860	$3,770	$420	$1,840	$520	$410	$11,820
Total	**$36,560**	**$71,790**	**$3,050**	**$7,920**	**$3,400**	**$3,320**	**$126,050**

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, OTC Update, 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.

burden, as the drug approval process certainly is, there will be far fewer companies with the ability to bring supplements to the market, which would decrease the availability of important, safe supplements to consumers. On the other hand, I was at a dinner party the other night and one of the guests was complaining about her post-menopausal hot flashes. I suggested a particular herbal ingredient, and she looked at me like I was crazy. All of her family are doctors, she told me, and she would never try an herbal product because it hasn't been approved by the FDA. So, from a marketing perspective, some form of pre-market system could attract new customers. Look at the medical device market. Over-the-counter devices like anti-acne lights and muscle-toning belts, that have gone through FDA's premarket notification process boldly proclaim: 'FDA Cleared!' in all of their marketing materials."

Michael Jeffers is president and CEO of **Helios**, an ingredient developer in Santa Fe, New Mexico, with human clinical studies underway on several products. Helios won the 2011 IFT Innovation Award for NC-518, its novel calcium ingredient targeting improvements to bone density. Says Jeffers: "Our investment in NC-518 and in EstroG-100 is extensive. Extensive. We hope to recoup that investment based on what we think is superior science."

Nestle: "Research will do damage to the industry. If I remember correctly, there have been articles in NBJ that documented the fall in sales of certain supplements after negative research came out, and the negative research is astonishing. It's so comprehensive—single nutrients, one a days. My interpretation is that none of this is going to make healthy people healthier, and since it's healthy people who take supplements, the probability of doing any good is very small. I don't think the probability of doing harm is very great either. I'm not very impressed by the evidence for harm. We're talking about very expensive placebos."

Steil: "This is a $30 billion industry, but the milestone in pharmaceuticals for one blockbuster globally is roughly $2 billion. For one product. Pharmaceutical companies will see something they like, and they'll commit $800 million. They might then get to a pivotal point in development where they say it's not working, pull the plug and walk away from $800 million. Then they'll sell it to a supplement company who markets it anyway."

Jeffers: "A few years ago, I thought FDA would modify the regulatory environment and make it more pharma-like. It seems like that's happening, and our company is staged to take advantage of this changing landscape. We have the clinicals and the safety and toxicity studies to back what we think will become stronger structure-function claims within the category. The language for us with our bone-density product is this—NC-518 provides next-generation bone health. We can't make a disease claim, but if we did, it would then be up to pharma to embrace our technology and take it to the next level. That gets you into a Phase 3 clinical that could run you three-plus years. Keep in mind that Pfizer's research budget peaked at more than $10 billion a few years back. We're slowly seeing the spending translate to Nutra. We're following an arc—science met pharma in the 40s, and now nutra will meet both science and pharma in the next decade."

Steil: "I've been personally challenged by the resistance to perform more science in this industry. It's really hard for CEOs of companies to sell the idea to investors of dropping $1 million into an R&D portfolio. For an ingredient supplier, if you can do $5 million in business on that, you've got a pretty good product. You're not talking about a billion dollars in supplements. Every $150-200K study that you look at, it's like pulling somebody's fingernails out. There are plenty of companies who could invest in gold-standard, clinical data that gets published in a decent journal. If it's a conscious decision to invest in products and put resources into clinical studies, we're just not doing it as an industry."

Harrison: "Would pre-market approval be the death of the industry? Yes, because FDA doesn't have the time or the ability to do the safety reviews."

Mister: "Pre-market approval of supplements? If it's not the death of the industry, it's the life support. If you look at the current view of what FDA requires for approval, those levels of safety and efficacy would cripple the industry. Look at what happened with NDIs. FDA is supposed to simply tell you they don't object to marketing something, and what they came back with was a food-additive requirement with millions of dollars of rat studies through second and third generation. They try to force us into two RCT trials whenever they can. Boy … that would be disastrous."

Nestle: "The supplements industry doesn't want a pharma model because they won't be able to prove efficacy. Look at what **POM Wonderful** is doing. It's not a supplement company, but they're acting like one. They spent $35 million to prove that pomegranates have antioxidant activity. If you feed them to animals, their antioxidant activity goes up. I'm not kidding. That's what they've shown. If you read the court transcripts, it's hilarious. All you can do is laugh."

Improving the law

Mister: "If we were doing this all over again, we might ask ourselves, could we stomach a little more regulation in certain areas as a tradeoff to prevent unreasonable action in

> "The industry made an enormous mistake in working so hard to pass DSHEA. For awhile, it worked really well to stimulate sales, but there were some unfortunate provisions in DSHEA that I think the industry has lived to regret." —Marion Nestle, New York University

UNIVERSE OF U.S. SUPPLEMENT COMPANIES IN 2011

Market	No. of Cos.	Supplement Sales	% of Market
Greater than $100M	34	$7,270	40%
$20M - $100M	94	$3,430	19%
Less than $20M	727	$2,060	11%
Supplement Man./Marketers	855	$12,750	71%
Multi-Level Wholesale Value		$2,720	15%
Private/Store Label Wholesale Value		$2,480	14%
Total Wholesale Supplement Value		**$17,950**	**100%**
Consumer Sales ($mil)		**$30,030**	

**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 2011 ($MIL.)

Company	Wholesale Supplement Sales
Carlyle Group - NBTY	1,820
Pharmavite*	1,230
Abbott Labs/Ross Products (Ensure, EAS)	560
Perrigo*	540
GNC (contract manufacturing)*	440
Pfizer (Centrum, Caltrate)	440
Glanbia (Optimum Nutrition, BSN)	380
Bayer (One A Day, Flintstones)	350
Schwabe NA(Nature's Way, Enzymatic)	320
Iovate (Hydroxycut, MuscleTech)	270
Atrium Innovations (G of L, Pure Encap)	250
CytoSport (Muscle Milk, Cytomax)	210
Nestle (Boost, Carnation, Optifast)	190
Schiff Nutrition International	190
NOW Foods	190
Healthy Directions (Doctor's Preferred)	180
International Vitamin Corporation	180
Alacer	170
VitaQuest Intl (Windmill)*	160
Nutraceutical Intl. (Solaray, Cal, Zand)	160
Basic Research/ Zoller Labs	150
ProCaps Laboratories (Andrew Lessman)	150
Metagenics	140
Natural Factors Nutritional Products	130
Life Extension	120
New Chapter	120
Standard Process	120
Unilever (SlimFast)	110
Cornerstone Research and Development*	110
Kikkoman (Country Life, Allergy Research)	110
DSM/Martek (Amerifit)	100
Delavau*	100
Jarrow Formulas	90
Nordic Naturals	90
Natural Organics (Nature's Plus)	90
Arizona Nutritional Supplements*	90
USP Labs	90
Bausch & Lomb (Ocuvite, PreserVision)	80
Factor Nutrition	80
ISI Brands (TwinLab, Metabolife)	80
Airborne Consumer Health	80
Gaspari Nutrition	80
Nature's Products, Inc. (Rainbow Light)	70
Nature's Best (Isopure)	70
ReNew Life Formulas	70
S.A.N. Corp. (Bolt, V-12, Tight)	70
Bluebonnet Nutrition Corp.	70
Natural Alternatives*	70
P&G (Metamucil, Align Minerals)	60
Atkins Nutritionals	60
Threshold Enterprises Ltd.	60
Reliance Private Label Supplements*	60
The FRS Company	60
Barlean's Organic Oils	50

others? Maybe having a product registration in the statue would be a good thing. CRN does not have a position on that, but there are people in the industry who raise the point. Every time we hear FDA talk, they say—35,000 products in the market, 50,000 products in the market, 60,000 products in the market. It's pretty clear to us that FDA has no idea how many products are in the market. Registration is very different than saying we would give them any kind of premarket approval. It would have to be the kind of thing where you register and they can't say no. It's the difference between a driver's license and a birth certificate."

Harrison: "What would make a difference is a rational system in place for making disease claims. We need over-the-counter disease claims for non-life threatening, supplement-appropriate conditions. You can be a dietary supplement or you can be an herbal medicinal product. Your choice. If you want to make structure-function claims, be a supplement. If you want to make those disease claims, submit your dossier to FDA and that's it, you're done."

Sapsin: "Some work could be done to clarify provisions of the law, but fundamentally, companies are seeing these market opportunities and they want to respond. Consumers want alternatives. They're pill exhausted, but you know what, I'm exhausted by going to the dentist. I'll bet other people are too, and I could invite them over to my house and pull their teeth out on the kitchen table. There are lots of market opportunities, but that doesn't mean we don't first engage in a reasoned consideration of whether there are limitations on how we ought to pursue them. We could require dietary supplement manufacturers to prove safety. Not to prove efficacy, but to prove safety premarket. We could also have a clearer and stricter rule around claims. The agency spends a lot of time regulating substances as drugs, not because of what they are but because of what they say they can do."

Harrison: "If you're willing to do a well-done, clinical study on your Echinacea product and you show that it limits the duration of your cold, maybe you get exclusivity on that claim for two-to-three years. If you do the clinical trial and it shows positive results, you get to make the claim and nobody else does. Let's call a spade a spade. If we could make the disease claim, I know people would pay for the studies. The study would have market value. This is how the law gets in the way right now."

Sapsin: "I would require a pre-market inspection of dietary supplement

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U.S. NUTRITION AND SUPPLEMENT SALES BY RETAIL CHANNEL IN 2011

Independents/ Small Chains	# of Stores	Total Retail Sales($mil)	Nutrition Sales($mil)	Supplement Sales($mil)
Natural Food Store <2000 sq ft	1,220	$600	$600	$150
NFS: 2001-6000 sq. ft.	1,900	$4,690	$4,690	$520
NFS: >6000 sq. ft.	1,000	$9,720	$9,720	$1,000
Health Food Store: <1000 sf	1,340	$350	$350	$260
HFS: 1001-2000 sq. ft.	1,730	$890	$890	$580
HFS: >2000 sq. ft.	1,620	$4,060	$4,060	$1,980
VMS Store: <=1000 sq. ft.	1,640	$790	$790	$740
VMS Store: >1000 sq ft	1,340	$1,200	$1,200	$1,090
Subtotal	**11,780**	**$22,300**	**$22,300**	**$6,310**
Large Chains				
Whole Foods	300	$10,180	$10,180	$1,500
GNC	5,930	$1,400	$1,400	$1,110
Vitamin World	440	$220	$220	$200
Vitamin Shoppe	530	$770	$770	$710
Other*	16,550	$1,680	$1,680	$1,130
Total Natural & Specialty	**35,530**	**$36,560**	**$36,560**	**$10,970**
Mass Market				
Food	98,910	$571,200	$45,850	$1,310
Drug	38,530	$229,330	$5,760	$2,010
Mass Merchandiser	6,940	$294,520	$12,870	$3,050
Club	1,220	$133,690	$5,900	$1,800
Convenience/Other	148,130	$158,790	$1,430	$460
Total Mass Market Retail	**293,720**	**$1,387,530**	**$71,790**	**$8,640**
Total Retail Nutrition	**329,250**	**$1,424,090**	**$108,350**	**$19,600**
Non-Retail Nutrition	n/a	n/a	$17,700	$10,420
Total Nutrition Industry			**$126,050**	**$30,030**

*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.).*

facilities. It's GMP pre-market, and you don't go on the market unless you can pass that safety inspection."

In the long, long term

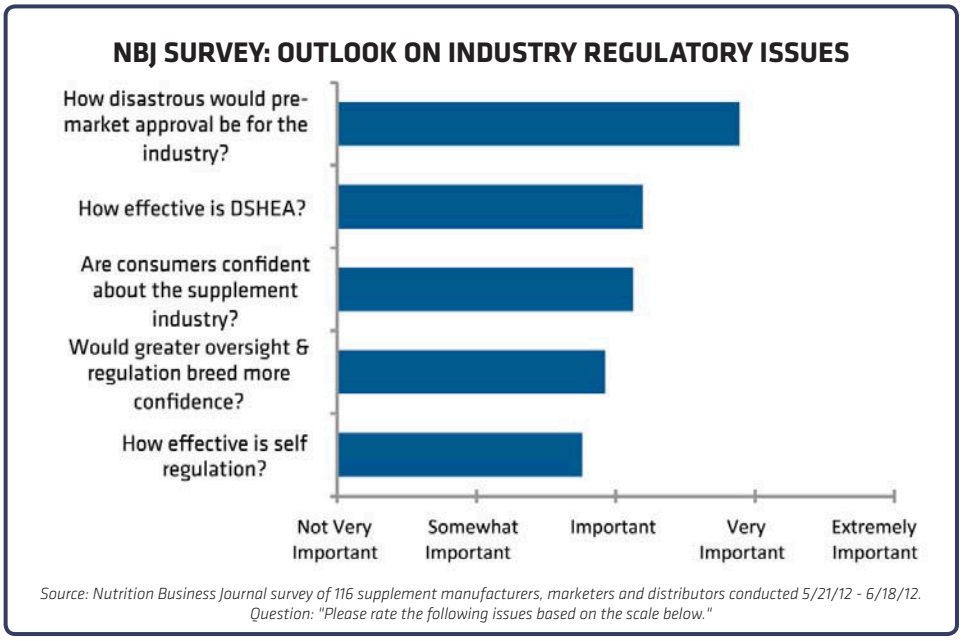
Wasserman: "The big paradigm shift in enforcement has been the incredible rise in consumer class actions against supplement and food companies over claims. It's just been an explosion, in California especially. So consider this: If FDA approves a drug and someone tries to sue the drug company over the truthfulness of their claims or the inadequacy of their warnings against potential side effects, the drug company points to the FDA approval process as a preemptive defense. Supplement companies, without any kind of FDA stamp, are much more vulnerable to class actions."

Sapsin: "Patent protections in natural products are weaker, yes. But you're not stuck if you're on the side of dietary supplements as an important component of a healthy and balanced lifestyle, of dietary supplements using ingredients well-studied in the food supply over a long period of time. If that's your view, then why do you need to do a safety or efficacy study? Don't recreate the wheel. Where you get into trouble and where you begin to need the science is when you decide to make specific statements about what the product is going to do for you—and I'm going to exaggerate now—tomorrow. Or you get into trouble with the hot new dried beetle extract from Peru, something people haven't seen before. The things that I would call the circumstantial guarantees of trustworthiness—the history of use, the understanding of the substance—those aren't there anymore. If that's where you are, in my mind you're not really talking about a food anymore. Peruvian beetle extract is not food in the United States, and the burden of proof and the responsibility that should be incumbent upon the manufacturer of that extract increases proportionally."

Fabricant: "Just a few weeks ago, we found a product from Mexico with two pretty potent NSAIDs—diclofenac sodium and methocarbamol. They both have a really difficult safety profile. They're used for pain but can be really tough on the liver. We're seeing this shift. If you look at weight loss and bodybuilding, those are lifestyle products. We expect to see more and more problems with drug adulteration in lifestyle products, including the pain area."

Jeffers: "Worst-case scenario, if the industry evolves to strictly pharmaceutical

> "I would require a pre-market inspection of dietary supplement facilities. It's GMP pre-market, and you don't go on the market unless you can pass that safety inspection." —Jason Sapsin, Polsinelli Shughart



Source: Nutrition Business Journal survey of 116 supplement manufacturers, marketers and distributors conducted 5/21/12 - 6/18/12. Question: "Please rate the following issues based on the scale below."

standards, we're stepping up by providing pharma-like clinical studies. They're not specifically pharmaceutical standards, but they're pharma-like. That's our niche. We want to bring ingredients to market that demonstrate Phase 1 and Phase 2 human clinical studies conducted in a certified, registered research facility. As we move farther through this maze of FDA and FTC's evolution of their market view, we believe that not only are Phase 1 and Phase 2 clinicals going to be important, but the researchers who did the studies (in an unbiased environment) will also be important."

Powers: "Look at Canada. I've seen Canadians come to the U.S. with an extra suitcase and they fill it with supplements. They've bought them in our stores. So now we have people smuggling vitamins. Before the shifts toward pre-market approval, I'd only heard of drug smuggling, not vitamin smuggling."

nbj: At the end of the day, the law is the law. Baked into the very DNA of DSHEA is this tension between supplements positioned as food and supplements positioned as medicine. The very nature of the law attempts to create a third category and legitimize a gray space between these two camps, and this nature expresses itself in constant, competing tensions to pull supplements into one or the other. Some voices see little cause to champion dietary supplements as much more than placebo, and that the industry's future would be best served by a retreat from primary research and health claims to adopt a benign stature as a small thing you can do to improve nutrition. Market forces, however, seem downright determined to pull supplements toward drugs by targeting more and more specific functions, by making stronger and stronger claims, and by digging in with industry's sharpest heels at nigh every turn when threats to these freedoms surface from Washington, DC.

It's fair to ask the question: If the free market wants supplements to be drugs and to serve as medicine—to, in essence, offer a less expensive, less risky alternative to pharmaceuticals—then what is the regulatory framework that will allow the science to blossom and begin to really prove efficacy for consumers? DSHEA was designed to concern itself much more with safety than efficacy. Is it the right law for a maturing industry looking to capitalize on the very real trends toward natural alternatives to drugs? Are the free-market forces so adamantly defending DSHEA doing themselves a disservice by protecting the grayness, which leads ineluctably to consumer misperceptions and distrust? Is DSHEA truly serving the long-term health of the industry?

Maybe not. Maybe the industry would be better served to stay put inside the gray area much more closely aligned to the food camp than the drug camp. Either that, or open up Pandora's box and amend the law to truly promote efficacy through better science.

News from engredea

NEW DIRECTIONS IN FOOD PRODUCT INNOVATION

Interesting tensions are afoot in the consumer packaged goods world, especially for those looking to hop on the health and wellness bandwagon. I see three main directions in the food world today:

- **Fortified so as to be functional.** This is the M.O. of the "nutrition by addition" crowd.
- **Naturally functional:** nutrient-dense, clean-label foods that do not induce inflammation. Among the naturally functional superfoods that consumers seem to be gravitating towards are these: orange juice, cranberry juice, pomegranate juice, green tea, Greek yogurt, coconut water and chia.
- **Food/supp/pharma convergence.** This is stuff like extending shelf life for years. Or extracting stem cells from tissue taken from a cow's muscle, growing muscle cells under tension to bulk them up in a petri dish, and the new muscle fibers are minced and turned into burgers. I'm still waiting for truly progressive food product designers to develop foods and affect life—how about modulating brain chemistry for optimum office performance? What about sleep? How about libido? You know, the stuff we really care about!

Todd Runestad
Editor-in-Chief,
Functional Ingredients