

State of the Industry Review & Outlook

Experts and opinion leaders offer perspective on critical issues affecting the nutraceuticals industry.

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“There is a long list of complex challenges confronting the nutraceuticals industry—from the ABCs of GMPs (Good Manufacturing Practices) to zealous opponents in Congress, to outright criminals posing as legitimate businesses. Companies cannot afford to be reactive or complacent. Ultimately, if the U.S. healthcare system is ever going to migrate away from the dysfunctional disease treatment model and toward a truly integrative, preventive approach, then these matters will need to be addressed head on.

“According to some discouraging FDA reports, dietary supplement companies have been struggling to meet basic GMP requirements. These are the minimum standards for quality. ‘It’s like feeding your kids,’ Daniel Fabricant, PhD, Director, Division of Dietary Supplements at FDA, said recently. You just have to do it. There are no excuses.

“Meanwhile, the Food Safety Modernization Act (FSMA), which could have a significant effect on how companies do business, enhances FDA inspection and enforcement tools. The agency has already put some of these tools to work, recently seizing \$2 million worth of products containing DMAA, which the agency said is an unapproved food additive under the Federal Food, Drug, and Cosmetic Act. ‘FSMA is a game changer in a lot of ways,’ said Dr. Fabricant. It’s important to understand the final and proposed rules, and offer substantive comments to the agency where applicable.

“With the impending retirement of some of the supplement industry’s staunchest advocates in Congress (Tom Harkin in 2014 and Orrin Hatch in 2018), others like Richard Durbin may revisit attempts to undermine DSHEA with a pre-registration system.

“Lastly, despite the failure of Initiative 522 in Washington State in November, which would have mandated labeling of Genetically Modified Organisms (GMO), the Non-GMO Project Verified seal has become the fastest growing label in the natural products industry’s history. Demand for increased transparency in the food supply is too strong to be denied indefinitely.”
—**Sean Moloughney, Editor**



“As we move into 2014 and an anticipated landscape dominated by availability of the Affordable Care Act, the sheer volume of noise on health and the cost of insuring it will create an enlarged space for marketing nutraceutical products which protect health and moderate chronic disease. High deductible premiums on health insurance plans will continue to gain share in the available private insurance market. Well positioned functional products with solid claims and trusted brands will resonate with consumers increasingly motivated to protect their, and their family’s, health into the future.”

—**Nancy M. Childs, PhD, Professor of Food Marketing and Gerald E. Peck Fellow, Saint Joseph’s University, Erivan K Haub School of Business**



“The state of the natural products industry is more unsettled and challenging than at any time since the passage of DSHEA in 1994. Why? Let us count a few of the ways: An impending changing of the guard on Capitol Hill with the retirement of champions Sen. Tom Harkin (2014) and the final term of Sen. Orrin Hatch (2018); lack of clarity (and agreement) on DSHEA implementation; increasingly aggressive and shifting FDA enforcement; poor dietary supplement GMP compliance as presently noted by FDA; the brazen spiking of supplements with drug ingredients; media and consumer confusion about the difference between responsible industry and criminal outliers; the GMO-labeling issue and the prospect of national legislation—as well as ongoing litigation against companies with natural product labels and a lack of federal clarity on exactly what this means. What’s most challenging, however, is a fractured industry where the key common values and goals of the food and supplement sectors have been lost along with the will to support proactive measures to ensure a continued place of trust with our most valued asset—our consumers. A viable future is dependent upon industry engagement, self-policing and rebuilding of that trust.”

—**Loren Israelsen, President, United Natural Products Alliance**



“It is exciting that hundreds of research papers from the recent Human Microbiome Project are linking microbes in the intestines to reduced risk of obesity, type 2 diabetes, and many other consequences of aging, and that prebiotic fibers are regarded as a natural route to shift the microbiota toward health. The supplement and food industries are starting to capitalize with selected prebiotics, which deliver consumer-driven benefits substantiated by credible evidence. I expect to see more differentiation in the near future between different fiber sources, as they can deliver significantly different benefits.”

—**Rhonda Witwer, Head of Nutrition Communication (NAFTA) BENEIO Inc.**

“It is great to see the nutraceuticals industry is alive and thriving. Today we continue to see the convergence of mainstream food and beverages with dietary supplements, and even pharmaceuticals. Beverages are leading this trend, with the healthy beverage category showing double-digit growth, including energy drinks (caffeine and protein based), sports beverages, meal replacements and fortified ready-to-drink coffee beverages. The health and wellness megatrend offers both opportunities and mega-challenges to formulators to ensure new fortified products meet the indulgent and gourmet palates of today’s consumers, without objectionable aftertaste or vitamin off-notes.”

—**Sharrann Simmons, CFS, Director of Marketing, Edlong Dairy Technologies**

Megatrends to Watch

New market opportunities will include Hispanic consumers, blood sugar control and choline supplements.



“Three new mega trends will have a dramatic effect on the nutraceutical marketplace in 2014 and beyond: 1) Specialty nutritionals have moved up right behind vitamins and above minerals in terms of consumers’ nutritional priorities; 2) Two-thirds of the best-selling new supplements last year carried a new or unique ingredients/formula claim. Expect effectiveness, bioavailability and absorption to be critical product differentiators; 3) High potential markets are fast-emerging for licensed health practitioner sales and for nighttime supplementation. Sales of Ayurvedic and Chinese herbal supplements rose 26% and 15%, respectively, in 2012.

“Curcumin/turmeric, magnesium, probiotics, melatonin, iron, vitamin D, vitamin K, vitamin B complex, digestive enzymes and milk thistle are projected to be the fastest growing ingredients through 2017. We believe that choline, potassium, hydroxytyrosol, cocoa flavanols, astaxanthin and probiotics will be among the next superstars.



“Beyond weight management and satiety, protein associated with muscle, mobility, sarcopenia prevention, joint support, energy and immunity will be among the ‘must address’ markets, along with circulation, lower GI and eye health. Atherosclerosis and blood plaque control are among the new heart markets; half of men and one-third of women have undesirable plaque levels.

“At Sloan Trends, we believe that the Hispanic marketplace, leg cramps, liver health, blood sugar control and choline supplementation are among the next generation of new market opportunities. Additionally, children’s health remains a high potential market since preventing chronic diseases later in life is second only to growth and development for moms’ worries about the health of their children.”

—**Dr. A. Elizabeth Sloan & Dr. Catherine Adams Hutt, RD, Sloan Trends, Inc.**



“The year 2013 saw continued growth—6% to 8%, I expect. That’s because the major consumer base truly believes natural products make them feel better. Our customers showed an intense interest in natural ingredients and demand for more and better science to substantiate claims. To answer these market trends, Capsugel has recently introduced two new hard vegetarian capsules. Delayed-release DRcaps capsules demonstrated with an independent human gamma scintigraphic study to deliver almost the entire dose of probiotics to the small intestine where the live cultures work best. Pullulan Plantcaps capsules allow marketers to use front-label organic wording to describe contents and can use the word ‘natural’ to describe the capsule.

“The industry underwent greater scrutiny in 2013. A 100% increase in FDA inspections revealed a third of manufacturers were not adhering to GMPs. The ingredient DMAA was removed from the market. U.S. Senator Richard Durbin of Illinois re-introduced the Dietary Supplement Labeling Act (S. 1425) calling for mandatory pre-registration of supplements. The industry is also anxiously awaiting a final rule from the FDA related to New Dietary Ingredient guidelines.”

—**Peter Zambetti, Director, Global Business Development, Capsugel LLC**



“The nutrition industry in 2013 enjoyed another successful year with most existing categories growing and others continuing to emerge. While we may not consider 2013 a ‘banner’ year, we can certainly remark on 2013 as a ‘banter’ year as talk of healthcare reached an

unprecedented level. In the overall dialogue of the Affordable Care Act, healthcare in total has been discussed more than any other time in U.S. history. One cannot look at healthcare and logically only think in reactive terms. Preventive healthcare continues to come to the forefront and the dialogue is not only serving an older demographic. 2014 offers our industry the opportunity to continue the ‘banter’ and continue to engage and expand upon successful education, proving the importance and value of nutritional supplements.”

—**Scott Steinfeld, CEO/President, Doctor’s Best, Inc.**



“This past year has seen the implementation of a number of new or changed regulations in the European Union, with the newly published appendix to the Health Claims (HC) Regulation and the first steps toward a unifying food labeling regulation among them. The HC regulation, especially, has had a big impact on food supplement manufacturers, which are now either forced to be creative with their claims, or to back them up with substantiation accepted by the European Food Safety Authority. Good science has thus become even more crucial for new products wishing to be competitive in today’s European marketplace.”

—**Joerg Gruenwald, PhD, Founder and Chief Scientific Advisor, analyze & realize GmbH**



“From the perspective of a scientific researcher, and one who works in academia and contract research, I see an uptick in the amount of clinical trials being sponsored and funded by companies in the industry. Whether this uptick is motivated by the want for added value (intellectual property) or out of fear of litigation, I am not sure; however, more research activity is better than the opposite. Clinical validation of safety and effectiveness helps build consumer and regulatory confidence. This is a good thing.”

—**Douglas Kalman PhD, RD, FACN, CCRC, Director, Endocrinology & Nutrition Division, Applied Clinical Trials, Miami Research Associates**



“The omega-3 industry has had a tough year in 2013 with a series of negative media attacks on the business. These actually started in September 2012 with the Rizos meta-analysis calling into question the importance of omega-3s for cardiovascular indications, and continued through the year, with the most damaging report coming this summer from a study by Brasky et al linking omega-3s to an increased risk of prostate cancer. While in these two examples, and most of the other studies, the study design and results were certainly questionable, the larger issue is the irresponsible media coverage that over-exaggerated study results and published sensationalized headlines that reverberated around the world. GOED

believes these negative media stories will continue and is planning an aggressive public relations campaign to increase the positive messaging around omega-3s and establish GOED as an expert for the consumer media. We are planning to leverage our members' networks to amplify the message and provide a benefit for the entire omega-3 space.”

—**Ellen Schutt, Communications Director, Global Organization for EPA and DHA Omega-3 (GOED)**



“It has been a great year for krill: 1) Krill continues to be the number one selling dietary supplement in the mass market; 2) Krill is now the second largest omega-3 category behind fish oil, representing 14% of total omega-3 sales; 3) Krill grew 44% in all channels combined in the last year, according to SPINS; and 4) Krill is by far the most sustainable source of marine omega-3s on the market today. Encouraged by krill's performance, Aker BioMarine is currently exploring other uses for its phospholipid omega-3s in complementary markets and applications.”

—**Becky Wright, Communications & Marketing Manager, Aker BioMarine Antarctic US**

The GMO Debate: Retailers Will Move the Needle

Consumers want products labeled so they can exercise their right to choose.

“Voters in Washington State rejected a bill that would have required labeling of food containing GMO ingredients. The food industry reportedly spent more than \$20 million on advertising to defeat the measure. A similar ballot initiative was defeated in California after both sides spent close to \$100 million. This is crazy. The environmental, nutritional and agronomic benefits of GMO crops have been convincingly demonstrated. Independent, competent scientific authorities in the U.S. and Europe have repeatedly shown there are no safety issues with the use of the technology. But the mainstream press has done a lousy job—again—of presenting the facts and both sides of the debate have been less than honest in presenting their arguments.



“The food industry, hiding behind the cloak of the Grocery Manufacturers Association, pretends that labeling changes will cause a sharp rise in food prices. In reality, the big companies fear labeling will further impact the already dismal prospects for volume growth of many of their major brands.

“Regardless of the proven safety and value of GMO ingredients, it's clear that some consumers want products labeled so they can exercise their right to choose. The FDA is reluctant to take on the challenge of GMO labeling without the explicit support of Congress, and even if one of the states pass a bill to require labeling it is sure to be challenged in court.

“It seems to me that the natural channel retailers can and will move to fill the gap. By requiring their suppliers to remove all GMO ingredients the market effectively fills the role that activists want government to play. The end result will be similar to the early days of the rise of organics when Whole Foods Market embraced small suppliers and their banner attracted consumers seeking out organic alternatives.

“So why do the big food companies resist a move to non-GMO ingredients? In categories such as cereal at this time there simply isn’t enough GMO-free grain for General Mills or Kellogg’s to make the switch. And if companies start with their ‘natural’ brands, which some have done, they are sending an ambiguous message about their products to consumers. It will be fascinating to watch this evolve.”

—**Steve Allen, Screening Committee Member, Nutrition Capital Network**



“Industry continued to make positive impacts in the areas of quality and safety in 2013. GMP compliance is still an omnipresent industry issue that manufacturers and suppliers continue to grapple with. But for me, the big story is the highlighting and removal of unsafe ingredients like DMAA and now hopefully N, alpha-diethylphenylethylamine, otherwise known as dendrobium extract. These dangerous ingredients have no place in the dietary supplement industry as they are not safe or approved for use.”

—**Ed Wyszumiala, General Manager, Dietary Supplement Programs, NSF International**



“Along with the good news of industry growth, we also saw an unacceptable number of FDA warning letters for firms failing to follow GMPs and for adulterated products marketed as supplements. We are living a tale of two industries: mainstream, responsible companies routinely producing high quality products—and some less reputable ones who flout the law. The good guys need to take back the industry, demonstrate how they put their consumers’ interest first, and hold a spotlight up to less responsible players. Let’s be known as the industry that invests in its products for long-term growth. This next year presents an opportunity for companies to invest more in rigorous research, consumer education and to help FDA identify the bad actors and take action against those companies hijacking our reputation.”

—**Steve Mister, President & CEO, Council for Responsible Nutrition**



“The saying ‘There is strength in numbers’ rings true to me. That’s one of the reasons why industry trade associations like CRN play a critical role in industry growth. Associations provide a platform for responsible, like-minded companies to help shape the future of an industry by supporting critical agendas with the power of consensus. Membership in an association is an investment in the future, but it’s an investment worth making. Effectively dealing with the challenges our industry will face in the years ahead will require the collective efforts of many companies. Stand up for our industry by joining with other responsible companies who believe that our products positively impact the health and well-being of our customers.”

—**John Blair, CRN Chairman and Senior Vice President, The Juice Plus Company**



“Over the past year, the dietary supplement industry has seen a variety of obstacles and opportunities. On the legislative front, 2014 will serve as a crucial time for all of us. As the industry grows, NPA is diligently working to seek new champions in Congress. We’ll also be focusing on the Dietary Supplement Caucus, as we enhance relationships with current members and foster new relationships. The NPA advocacy team plans to better educate lawmakers on the issues that matter most in the dietary supplement space, while proving to industry stakeholders why NPA needs their support to continue onward.”

—**John Shaw, CEO and Executive Director, Natural Products Association**



“There is every indication that 2014 will be very similar to 2013 for the herbal products industry. Consumers’ demand for herbal products is likely to increase despite the vocal criticism of industry opponents. The herbal products industry can build on previous years’ success by continuing to focus on meeting demand for high-quality products. The American Herbal Products Association (AHPA) will continue to support the industry by helping companies perfect compliance with the Food and Drug Administration (FDA) current good manufacturing practice (cGMP) regulation, helping them submit new dietary ingredient notifications for new, innovative ingredients, and promoting submission of serious adverse event reports (SAERs) to demonstrate the low rate of adverse events caused by supplements. AHPA will also continue its work with FDA to address the issue of illegal products spiked with undeclared pharmaceutical ingredients that masquerade as dietary supplements.”

—**Michael McGuffin, President, American Herbal Products Association (AHPA)**



“Industry firms continue to seek company and product public relations exposure. While they may think a product or service has enough of a news hook, several key points to keep in mind are: when developing a press release or website, remove the words ‘leading’ and ‘number-one solution’; if your company is green or sustainable, make sure you can prove it; as a B2B business, social media must go beyond LinkedIn; for those who have company Twitter or Facebook accounts, the number of Twitter followers or Facebook likes for a brand is not commensurate with how wonderful your company is; and finally, don’t do anything PR can’t measure.”

—**Sheldon Baker, Senior Vice President, Baker Dillon Group**



“The state of the industry for dietary supplements is strong and growing, especially at Life Extension. We believe the use of dietary supplements will continue to grow as millions of Americans discover the disease treatment model is not working for them and realize using preventive, nutritional, integrative approaches will significantly enhance their quality and length of life. Life Extension is unique as we are largely an information company providing several products and services including cutting edge, research-based dietary supplements and functional foods as well as the Life Extension magazine, Disease Prevention and Treatment book, clinical research, blood testing and membership.”

—**Luke Huber, ND, MBA, Vice President, Product Innovation & Scientific Development, Life Extension**



“Three factors will continue to drive nutraceuticals: science, demographics and communication. Advances in science and technology will deliver better product solutions in the form of relevant consumer products (efficacy, safety, validation, formulation). The changing demographics favor increased interest in natural (non-Rx) wellness solutions and psychographic index supports continued acceptance. And ultimately success or failure depends upon a better understanding of how to connect these two factors to the end user (consumer); this, in my opinion, is the under appreciated difference between a product and a success.”

—**Peter Leighton, CEO, Abunda, Inc.**



“Consumers have become increasingly more sophisticated and expect their supplements to have solid scientific evidence of efficacy and action; they also expect the ingredients to be pure, without excess benign compounds wasting space in the supplement—and in their bodies. The industry is evolving rapidly with ingredient leaders continuously re-investing in science and technology, increasing the bar for value and quality.

“NattoPharma’s concept is to deliver a superior-quality vitamin K2 backed by clinical evidence and that is competitively priced. MenaQ7 is clinically proven to spare bone loss and improve bone strength. Further, MenaQ7 is patented and clinically proven to improve cardiovascular health, including improving arterial flexibility (and thus regressing age-related stiffening). NattoPharma is the only vitamin K2 manufacturer that has invested in human research that demonstrates therapeutic health benefits.”

—**Tom McMahon, Sales Manager, NattoPharma Inc.**



“In 2014, we expect a continued convergence of two very significant trends: increased supplement use and increased consumer education. Nearly 75% of American adults take nutritional supplements; both generations X and Y are emerging with the highest increase of use. Correspondingly, we expect more consumers to research ingredients even while in-store from their mobile devices. We know that some 70% of millennials have smartphones and we can see that they are drawn to safe and effective evidence-based products. For Horphag, this means further expanding upon our catalog of research on Pycnogenol to help demonstrate the extract’s health benefits to this engaged consumer base.”

—**Sébastien Bornet, Director of Global Marketing, Horphag Research**



“The last 12 months have been witnessing a growing industry mainly due to the trend of naturalness, which has swamped all areas of consumer goods and particularly dietary supplements, food and beverage industries. The nutraceuticals market is particularly affected by this global trend and offers strong opportunities for botanical extracts. Through their diversity and their numerous health benefits, they can be considered as ingredients of choice for a wide range of applications. The challenge for the industry is to continue to guarantee and protect these natural resources, keeping in mind the requirements of consumers in terms of natural and sustainable origin, quality and scientific support.”

—**Mathieu Dondain, Director of Marketing and Communication, Nexira**



“‘Co-opportunity’ is the perfect word to sum up my perspective on the recent past and short-term future. As a leading supplier, we have often said that our customers rely on us for more than just ingredients. That’s never been truer than it is today. Economic and regulatory pressures plus growing consumer demand for safe, healthy and tasty foods mean we must work smarter together—as customer and supplier. With each new or improved supplement, food or beverage, BASF sees a co-opportunity to help ensure market success throughout the entire product cycle. Together we must tackle the ‘newtritional’ needs of our growing population with beneficial and sustainable products.”

—**Samy Jandali, Vice President, BASF Nutrition & Health, North America**



“We are launching our new corporate identity, PLT Health Solutions, to reflect our evolution and embrace our CPG clients’ requirement that ingredients meet rigorous scientific, regulatory and quality assurance standards. Our clients carefully scrutinize the clinical data, ask for guidance on what they can say about ingredient benefits, and require that we vouch for our manufacturer partners’ competence. They expect assured supply whatever it takes and want a supply partner able to address their global requirements. As this complexity has increased, our continuous focus is on strengthening our partnerships with our clients and the solutions available to help them grow.”

—**Paul Flowerman, President of PLT Health Solutions Inc.**



“At Ganeden Biotech we continue to see that consumer preferences are shifting from probiotic supplements to probiotic functional foods and beverages. Global sales of probiotics are expected to reach \$31.1 billion by 2015, with functional foods and beverages accounting for 90.1% of total probiotic sales. We feel that the main cause of this shift is the desire to reap the benefits that probiotics provide, while consuming your favorite snack bar or drinking your morning coffee; taking another pill is no longer necessary.”

—**Michael Bush, Senior Vice President, Ganeden Biotech**



“OmniActive has focused much of its 2013 efforts on educating the industry as a whole about the importance of early and consistent lutein intake to help maintain proper eye and general

health over a lifetime as part of our Lutein for Every Age campaign. A new set of vision concerns is emerging as a result of early and heavy use of computers and other electronic devices. In addition, growing scientific evidence suggests lutein and zeaxanthin play a key role in healthy visual function across all ages. People tend to not think about their vision health until it is too late. That is why we at OmniActive launched the Lutein for Every Age campaign, to help individuals understand how they can take a proactive approach to maintain eye and general health over a lifetime through supplementation and healthy diet and lifestyle choices.”

—**Hiren Doshi, Vice President, OmniActive Health Technologies**

“There has been continued growth in the dietary supplements category as consumers seek ways to proactively manage their health and wellness. The trend toward personalized nutrition is leading to new diverse categories of products targeting life stages and unique health benefits. This has led to the emergence of new categories of products targeting key health concerns among consumers, including cognitive health and digestive health. Products such as Flintstones Brain Support and Schiff’s Digestive Advantage are pushing innovation in these emerging categories. Meanwhile DSM has introduced new high potency life’sOmega to the omega-3 category, which expands options for consumers seeking vegetarian sources of omega-3s in smaller delivery format (pills, gummies, etc.).”

—**Bruce Brown, Director of Marketing, Human Nutrition and Health, DSM Nutritional Products, NA**

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