Nutrition INDUSTRY EXECUTIVE

2018 Natural Industry Forecast

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From renewing its focus on science, to experiencing an "Amazonian market entry," to re-thinking natural—the natural products industry forges ahead.

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Transparency in the natural products industry is becoming much more than a business ethic—especially in light of a rise in cases of intentional adulteration of supplements—what some might call a moral imperative. With the natural industry faced with dramatic price spikes from some foreign suppliers, natural companies may well wonder what the future holds regarding internet commerce versus brick-and-mortar (can anyone say Amazon and Whole Foods?). Uncertainty also exists among regulatory prognosticators as to whether the anti-over-regulatory winds in Washington will blow elsewhere, especially in states such as New York and California, which have what many might call a hyper-regulatory, or nanny-state, posture in regards to dietary supplements. Concerns about this, however, are tempered by a general upswing in consumer interest in supplementation along with a growing industry focus on science and innovation. Innovation guru, John Costa, recently wrote that it's possible that innovation is less the elemental magic of creativity and more a function of timing and stimuli carefully injected into a linear process. He said that we shouldn't wait for those eureka moments but, instead, move the process along with well-placed nudges. Here's to more nudges and more science in 2018.

NIE: What do you feel were the biggest industry issues of 2017, and why?

LeDoux: There were several major issues involving the industry in 2017. The FDA (U.S. Food and Drug Administration) appeared to take a more aggressive role along with the Federal Trade Commission (FTC) in dealing with products they deemed to be adulterated or misbranded. Seizures and fines were levied against several companies and individuals evidencing a renewed interest in achieving compliance with federal laws.

There has also been a proliferation of all things CBD (cannabidiol) but my prediction is that the federal government in actions soon to be forthcoming from the Department of Justice, will begin to reign in what many perceive as some rogue-state activities. Clearly there is room for federal oversight and regulation here, given the obvious concerns over interstate commerce, banking regulations, and other statutes on the books already.

The election of a new president in late 2016 and the resultant executive orders issued requesting reductions in regulations has been significant in our space as well. The delay in implementation of what many perceive as unnecessary changes to label presentations of nutritional facts in foods and supplements is also demonstrative of this bias.

Foreign suppliers raised prices of raw materials, in some cases by over 100 percent. Presumably this was caused by concerns over environmental pollution needing to be controlled in foreign markets such as China, but this was also caused by problems in other production facilities in Germany which suffered from facility interruptions. These price increases are now negatively impacting many suppliers and retailers who have endured price increases without the capacity to pass these along to their customers.

The internet commerce of dietary supplements and natural products is now becoming a game-changer when evaluating business models involving heavy capital expenditures and lease costs for brick and mortar businesses versus virtual companies with reduced distribution costs such as Amazon. The fact that

Whole Foods Markets was acquired by Amazon also demonstrates the blurring of commercial lines of contact points with the retail customer.

Mister: Well, I may be a little biased, but I think the launch of the Supplement OWL, the new dietary supplement registry, was one of the most significant events for the industry. It has been well-received in the first few months by product marketers and retailers alike. The Supplement OWL has the potential to be a game-changer by showing our regulators and retailers a new level of transparency about our products and their supply chains.

Beyond the Supplement OWL, the Amarin complaint before the U.S. International Trade Commission (ITC) was a disturbing development this year. Its effort to gain a monopoly on esterified EPA fish oil by declaring it to be a drug was a broadside attack on accessibility of omega-3 products for consumers. As the year closed, the ITC rejected the complaint but an appeal is in the works. CRN will continue to fight to keep these products widely available as dietary supplements.

And lastly, the direction of the new Trump Administration has recognized that burdensome regulation doesn't enhance public health, but just creates unnecessary costs for compliance. The delay in the label change regulation, the willingness of FDA to engage with industry on new dietary ingredient (NDI) master files, and the realignment of expertise within the agency all illustrate a new—and welcome—approach by FDA.

Emord: A gift to Monsanto, congressional passage of legislation to pre-empt state GMO (genetically modified organism) labeling laws was a great disservice to American consumers and the First Amendment. The Amazon/Whole Foods union invites a potential for a vast expansion in the market reach of select industry products.

Zapp: An ingredient supplier has an interesting perspective when it comes to studying the changes within the industry. In 2017 we found a lot of companies coming to AFS with their challenges in achieving a clean label. While we all know that clean label generally refers to more natural and recognizable ingredients rather than chemical sounding, synthetic, ingredients.

What most people don't realize is that using natural ingredients can be very difficult to formulate with and are not so simple to substitute in current formulations. Therefore, to obtain the same flavors and functionalities as synthetic ingredients, manufacturers need to find the right ingredient options for their products. The biggest hurdle is in solubility and flavor. But with the right extracts, this can be achieved. It is really making clean label products particle.

Another industry issue we are seeing emerge and become more important to manufacturers is sustainability. It is difficult to ignore the planet. Consumers are becoming more aware that, in many cases, where raw materials are sourced, global living conditions are poor and the earth is easily taken advantage of.

For companies like AFS, we recognize this problem and have taken serious steps by creating our own responsible sourcing initiative that includes: sustainable growing, socially responsible sourcing and full traceability. Consumers feel it is their right to know where and how their ingredients are sourced.

McGuffin: There continues to be growing interest by larger companies to expand into the natural health product markets by purchasing brands that have built a reputation for quality and ethical business practices. This is in line with the broader trend of natural health products being adopted by mainstream America.

Some examples of this in 2017 include the purchase of AHPA members Tazo and Pukka Herbs by Unilever and Nestle's purchase of Atrium which owned several brands, including Garden of Life and Pure Encapsulations.

The Trump Administration has provided an opportunity for the industry to request changes to regulations that impact them to reduce burdens on industry while continuing to maintain protection for consumers.

Kreienbrink: The biggest issues in 2017 will remain as challenges for the coming year. These include transparency, quality, and the existence of meaningful, factual scientific efficacy studies.

NIE: Companies are drilling down into better processing, better bioavailability, better delivery, essentially better mousetraps. Is this good, and if so, why? Are there no new mousetraps any more?

Lifton: While, on the one hand, everything in nature, or naturals, already exists in some basic form, it is also true that, A, we only have identified a small percentage of what exists and is potentially active, and B, we only understand a small fraction of what we have found actually does, and C, we are finding better and better ways to improve on what we are able to both harvest from nature and harness using science.

And so, as for better mousetraps, a vast majority of the most exciting things in natural products research and development today are happening with proprietary branded ingredients, natural ingredients extracted, processed, mixed, composed or delivered in special, more effective ways.

LeDoux: This is a very interesting development, but points out the value of transparency in sourcing, supply chain processing and finished product development and production. Companies that are willing to invest on the front end of the supply chain and further invest in the science of substantiating the finished product in populations of intended use are assuming leadership roles in the industry. No longer do celebrity endorsements carry the day with the marketing messaging. The FTC has also weighed in here on multiple occasions, and in various selling channels such as multi-level marketing with the erection of some additional commercial guard rails.

The real issue here is that just claiming a better mousetrap is not going to get a "hall-pass" from the regulators or the attorneys general any more. Proof of concept and evidence of benefit conducted in a vigorous scientific method protocol are essential for having a shot at commercial success.

Emord: Contrary to media perception of the dietary supplement industry, it has always been a dynamic, ever-improving industry, providing overall better quality and service year after year. That is due to competition far more than to FDA prior restraints; the latter create anti-competitive barriers to entry and often punish those innocent of causing any actual harm to consumers, those whose only offense is a technical violation of regulation.

Zapp: When it comes to working with botanical ingredients, improvements are necessary to meet the demand for the natural and organic market. One great example is in answering the questions, how do we improve absorption both in finished products and in the body? This process starts by improved research and understanding of how specific compounds within botanical ingredients impact the human body. This leads to improving extraction methods to isolate targeted active compounds, this leads to the need for improved identity testing and verification processes to ensure those actives are really present in the finished product. Trying to improve in all of these areas ultimately leads to new discovery of botanical ingredients that can do more.

Kasbekar: Most of global surveys provide compelling evidence that better mouse traps providing advertisement claims with qualifying language and differentiating levels of scientific evidence can help

consumers understand the strength of scientific evidence behind those claims. Moreover, when a visual aid is included, consumers perceive the scientific levels more clearly and have greater confidence in their meanings. Although these surveys suggest that consumers react differently to different advertisement claim levels, it is not yet clear whether consumers understand the variations in the degree of scientific support.

Understanding consumer responses to advertisement and "mouse trap claims" is critical when designing regulations. [The] government's goal is to permit the use of a larger number of, better, easily understood, and up-to-date scientific information on advertising messages to communicate how food choice can affect the health of consumers. Policymakers should therefore try to enact regulations that will ensure that the exact meanings of claims are presented to consumers. Qualitative studies such as focus group interviews may be helpful in identifying more specific disclaimers and effective ways of delivering health messages for food or food components.

NIE: While USDA (U.S. Department of Agriculture) Organic and GMO (genetically modified organism)-free have arguably become much more pervasive and a bit more cost-effective in foods and supplements, there has been a big (perhaps) bigger push for local, especially in the produce aisle. True? If so, is this good or bad? Is local the new organic?

McGuffin: AHPA has observed a growing trend of consumers willing to pay a premium for products made from U.S. domestic and locally produced ingredients. AHPA supports organizations helping farms meet this growing demand and featured two of these groups at the AHPA Botanical Congress. The recent efforts of the Appalachian Beginning Forest Farmer Coalition (ABFFC) and Vermont Herb Growers Cooperative (VHGC) is a testament to the growing demand for locally produced medicinal herbs.

Zapp: Consumer's drive to shop "local" hits on two core values: trust and responsibility. To help align with these values, local really translates to a desire for products to be more accessible, transparent and trustworthy. But this idea of "shopping local" is really misleading as a majority of consumer packaged goods contain ingredients that are sourced from all over the world. Therefore, the real challenge is to bring the values behind "shopping local" to the consumer no matter where the ingredients are sourced for the products they purchase.

Manufacturers should ask themselves, what would it take for our supply chain to be so transparent that consumers can feel that same trust and idea of responsibility no matter where their ingredients come from? Sure, any respectable supplier should have a FSVP (food safety verification program) in place, which will provide some of that ground work.

However, consumers are really saying, "Show me, don't tell me!" Show me who is growing these ingredients as if they were my local farmer. Show me how both the environment and the local people are being cared for so that future generations can benefit from the same ingredients I am benefiting from today. That is true transparency. That is the true value of "local."

Lifton: Organic and natural have become very big and very important for the industry and for consumers.

Local, as in locally sourced ingredients and produce, has become a buzzword, that is true. And when "local" means supporting farmers, growers and communities, as in sustainable, then I think there is real muscle behind the mantra.

That's one of the reasons we've become involved in the Organic & Natural Health Association, because we're committed to the real power and promise of naturals, not just the words. LeDoux: With the

Millennial market calling for non-GMO and organic products, it is clear that the demand exists for these products. The challenge is in achieving and maintaining certification of these claims. Consequently, there is now an undeniable trend for local source production of foods, and this speaks to the tribalization of our culture which has been a mega-trend in consumer behavior for the last 10 years.

Kreienbrink: This is true. Local is certainly a positive but can be very confusing to the consumer. What is local? If you live in Chicago and you're eating fresh vegetables from California in the middle of January, is this considered local? Marketers are stretching the limits and meaning of the term "local."

Kasbekar: Is local the new trend like new organic? Yes, it is, but let's bear in mind that this is not totally new. During the pre-globalization era, our way of living was primarily local produce and local consumption. With globalization and efficient supply-chain infrastructure, we now have access to a variety of global products in a competitive market with better prices. While it is certainly a great advantage, we also have to face challenges such as longer shelf life requirements, unwanted preservatives and ingredients that need to be regulated and monitored closely to avoid health risks and frauds.

I believe in increasing awareness of organic operations that demonstrate protecting natural resources, conserving biodiversity and using only approved substances.

At the end of the day, the responsibility lies with consumers to make the right choices based on scientific evidence, their personal beliefs [about] ecological issues, price points, food and health needs."

NIE: While calcium may be an old standby, magnesium has been attracting a great deal of interest over the last several years, but is the industry doing a great job in making a case to consumers as to why we need to supplement with this heart-healthy mineral? If this is a problem, what would the lesson be?

LeDoux: Amazingly, the consumer knowledge of the role of magnesium is limited, even though the established and ample body of science concerning bone mineralization shows convincing evidence that calcium is best metabolized in the presence of magnesium, vitamin D and other micro-minerals such as boron. The economic question here is how does a company achieve a satisfactory return on investment of marketing messaging for what essentially is a commodity business?

Lifton: There's a lot we can do to overcome the commoditization of magnesium and its bad rep. Magnesium is just one of many examples where both absorption and tolerability can be a challenge, too. Sucrosomial Magnesium, which we offer, is a highly bioavailable complex of magnesium hydroxide providing elemental magnesium derived from the crystal-clear waters of the North Sea and which is encased in a liposomal-like structure, helping consumers to avoid the diarrhea and nausea that are sometimes experienced with conventional magnesium ingredients.

Emord: The greatest impediment to dissemination of truthful information concerning the health benefits of magnesium (as well as all other vitamins and minerals) remains the FDA. The FDA's evidence based system of review for health claims manipulatively truncates the universe of reviewable scientific evidence to such an extent that credible, science-backed claims continue to be suppressed long after the U.S. Court of Appeals in Pearson v. Shalala ordered otherwise. Rather than favor disclosure over suppression, FDA continues to favor suppression over disclosure.

NIE: Industry organizations have endorsed GMPs (good manufacturing practices) for botanicals, which is good, but this year has also been a banner year for kratom sales and adulteration with undeclared drug ingredients, such as sildenafil. What are we doing right? What do we need to do better?

Mister: Companies across the industry are embracing what some have said for years: you can't "test" quality into a product at the end; quality is the result of attention paid throughout the supply chain. The adoption of good agricultural practices and cultivation practices, and the increased focus on identity and purity throughout processing and manufacturing are evidence of that recognition. Quality issues that used to result from inadvertent errors or carelessness should be greatly reduced with this new paradigm. However, kratom, adulteration with sildenafil, and the introduction of selective androgenic receptor modulators (SARMs) all illustrate another reality: that some companies will intentionally ignore the law and put their consumers at risk.

As 2018 rises, all responsible companies should recommit to drive these outliers from the industry by refusing to deal with companies who market these products. ABC's new program urging firms to destroy illegal ingredients when they receive them is one good way to start.

LeDoux: The recent proclamation from the FDA commissioner on this matter involving kratom is welcome. The presence of adulterants or APIs (active pharmaceutical ingredients), which are undisclosed in botanical blends is essentially criminal behavior and needs to be prosecuted to the fullest extent of the law. This means the FDA and ICE/Homeland Security need to tighten the border entry points, increase random raw material testing, seize offending products and fine exporters and importers once evidence of criminal intent to create adulterated products has been established. This is a case begging for more enforcement versus more regulation.

Kasbekar: While there have been a number of FDA-enforcement actions in 2017 leading to recalls, the number of hospitalizations due to food-based illness has not reduced. The records indicate that every year, 130,000 people in the U.S. are hospitalized with a foodborne illness, and out of them, 3,000 people die. A new report from the Department of Health and Human Services' Office of the Inspector General raises some red flags about the FDA inspections program. Overall, the report concludes that the FDA "consistently failed to conduct timely follow-up inspections to ensure that facilities corrected significant inspection violations." And in 17 percent of the cases, the FDA did not conduct a follow-up inspection at all. Also, in some instances where inspectors found significant violations, the FDA took no enforcement action.

The creation of [an] oversight group within the FDA called SCORE, which stands for strategic coordinated oversight of recall execution, has played a critical role in thousands of product recalls that FDA oversees each year.

FDA should continue to adopt creative ways of expanding public notification of recalls that may affect the most vulnerable consumers, including the very young and elderly.

NIE: **Hemp madness is alive and well, in this case CBD oil. The FDA does not seem to be a fan of CBD as an ingredient in supplements, salves, balms and other non-medical delivery forms, correct? With a murky landscape of IND filings and some companies throwing in the towel, others are digging in their heels. Where do you think we will, or should, net out on CBD?**

LeDoux: My opinion is that CBD oils have remarkable benefits, but they need to be produced under strict GMP guidelines and federal oversight of the FDA. This "wild-west," state's rights approach is leading to a myriad of problems which can significantly and negatively affect users given the real potential of variability in finished products in terms of purity and potencies. There are multiple reasons that the federal government needs to oversee this in terms of production, licensure, distribution and regulation and that is what I believe is going to happen in the not too distant future.

Emord: As with all ingestible products, the standard needs to be the Paracelsian Principle of Harm. If CBD at the dose recommended produces adverse physiological effects, it is properly forbidden by the FDCA (Federal Food, Drug and Cosmetic Act) but only at that dose level and above.

NIE: **Way back when, mom and pop retailers were very worried about Whole Foods and Wild Oats stores opening up near them, but in many cases, net, general interest in natural went up and mom and pop sales stayed steady or even grew as a result. Now Whole Foods is again on the radar, in this case with Amazon. Now Kroger's sales are surging—is this a halo effect again or something else? What does the whole Amazon/Whole Foods thing mean for the industry short term and long term?**

Kasbekar: Amazon's acquisition of Whole Foods is not merely an expansion into the grocery business. I believe it is going to fundamentally change the way consumers buy and receive food. Amazon is following a market opportunity for [a] value vacancy that can be exploited through a digitally enabled business model.

While groceries are not new to Amazon, this acquisition is the company's first significant investment in the industry. Despite Amazon Fresh, the grocery sector is one of the last large retail sectors where Amazon does not have a significant share. At the same time, the food-delivery market represents a significant revenue opportunity.

Amazon has made its fortune by selling products at prices most competitors can't match while driving revenue through membership programs and other services.

In the short term, Amazon doesn't have to operate at a profit as other grocery retailers do. In the long term, if Amazon operates the fresh groceries business at a very low margin, while driving profitability through its Prime membership and cash from other areas, many grocery chains won't be able to compete.

LeDoux: A rising tide lifts all boats. The challenges here are remaining relevant to your consumer base. If you are running a small store or small chain, what makes you locally essential for your community? Is it education? Is it carrying locally produced products? Is it providing a value proposition that is larger than just having fair pricing? Amazon's purchase of Whole Foods is really an endorsement of brick and mortar for local communities in terms of a centralized shopping experience. At the end of the day, the consumer

wants to buy their natural products where they buy their canned goods, paper goods and household cleaners, because it is all about convenience. There is a reason that Walmart is the largest grocer in America today.

McGuffin: It is likely too soon to assess the full impact of this acquisition, but it is part of an increasing trend of large companies buying ethically focused brands that have built a reputation of providing high quality products that promote consumer health and wellbeing. These acquisitions also provide an opportunity to enhance both brands by combining their strengths. It can be a tenuous balance, but other companies have walked this line successfully in the past.

NIE: Where did we as an industry wind up with the whole ODI (old dietary ingredients) list process?

Mister: I think it's too soon to assess how FDA's efforts to create an ODI list will net out. If the FDA process only gives "safe harbor" to those ingredients already widely recognized as "old," will it be worth the trouble? What we are seeing is a new openness at the agency to try and resolve the outstanding issues around NDI (new dietary ingredient) notifications. The industry needs to reach resolution on these issues because achieving a predictable and certain process for bringing new ingredients to market is desperately needed. The climate of uncertainty around NDIs will stymy innovations. Hopefully 2018 will provide strong progress in this regard.

LeDoux: I think the ODI list process was part theater and partly an exercise in regulatory discretion. The likelihood of a list being adopted by the FDA of pre-1994 DSHEA (Dietary Supplement Health and Education Act of 1994) usage for dietary ingredients is remote at best, but the NPA just published for purchase a fairly seminal and exhaustive compilation that should withstand regulatory scrutiny should a dietary ingredient found there be challenged for suitability by regulators.

Kasbekar: We at Freyr, as a regulatory consulting company, have begun [advising] our customers about creating a risk-based analysis that entails compiling a list of every dietary ingredient in their products and then evaluating these ingredients. A detailed assessment based on the following questions is presented to the client for this purpose:

- Does this ingredient meet the definition of dietary ingredient?
- Is there adequate documentation for this ingredient's ODI status?
- Has the product undergone a manufacturing change?
- Does some food supply exemption apply, and if so, has the ingredient been chemically altered?
- Has my supplier submitted an NDI notification or is there a GRAS (generally recognized as safe) affirmation?

No matter which way the list is analyzed, the objective is to have a picture of the company's current exposure and an understanding of steps to take to minimize potential risks. This will help locate ingredients that may require an NDI notification so that a company can be fully prepared to submit a notification if it is determined to be ultimately necessary for regulatory compliance.

While the past year has not provided greater insight into the long-term effects of the 2016 NDI Draft Guidance, it has been helpful to have the time to digest the revisions and strategize future compliance.

While there is no sign as to when the FDA will finalize the NDI Draft Guidance, the industry […] has started to determine how it will comply when the decision rolls out. It is expected that there will not be any major changes in the final guidance, so the best step is to begin planning now to minimize potential pitfalls.

NIE: What are your big predictions for 2018, in terms of category growth, specific supplements and ingredients, challenges and opportunities at wholesale and retail?

Mister: 2018 promises increased growth and acceptance of dietary supplements for promoting better health. The industry will make a strong case for allowing recipients of SNAP (Supplemental Nutrition Assistance Program) benefits to purchase a multivitamin with those benefits. This platform will allow us to raise awareness of the realities of nutrient insufficiencies, particularly among low income Americans, and the role supplements can play in alleviating them.

Developing research on nutrigenomics and individualized medicine will help us better understand unique nutrient requirements and lead us toward more individualized supplement regimens. Probiotics will continue their growth, along with overlooked nutrients like choline, iodine and magnesium. And lastly, even as the scrutiny from states attorneys general may be waning, private class action litigation directed at the industry will continue. Fortunately, several influential courts have signaled that they will require evidence of real harm to allow these cases to move forward.

Zapp: Complex flavors [are] on the rise—in foods and beverages, we have had noticed a number of manufacturers requesting more complex flavors, like turmeric. Generally, the ayurvedic tastes of India tend to be on everyone's radar and ingredients like ginger and turmeric are heavily sought after right now in new product development and R&D.

As food changes and adopts more of a clean-label footprint, the landscape of supplements is slowly evolving to follow suit. Many large sports nutrition and supplement companies are now requesting organic ingredients to "green-up" their labels. Especially in sports nutrition, labels used to be dominated by hard to pronounce branded ingredients: "the more the better." Today, we are seeing products being developed in this space with fewer, but more specific ingredients. Organic tends to be a big emphasis and we can expect that to continue in 2018.

Kasbekar: The industry is constantly trying to introduce a variety of products catering to different customer segments. For example, there is an increasing demand for the vegan variants of nutraceuticals targeting the global vegetarian population. Omega-3s, traditionally extracted from fish, have been developed with vegan variants obtained from algae and flaxseed oil. There are also surveys that emphasize the increasing demand for vegan-based protein supplements.

I believe some of the niche segments such as anti-aging, energy boosting, skin care, digestive care may continue to grow in 2018. There are predictions for high growth in categories such as fortified water, fortified noodles, sports and energy drinks, etc.

LeDoux: I think 2018 will see the advent of CBD regulations at a federal level. I think that Congress will be more receptive to the role of supplements in disease prevention or management, and the value of having supplements and healthy foods as a component of the WIC (Women, Infants and Children) and SNAP programs for people in need. Furthermore, I think more and more large companies of all sorts will be making investments in this space and increasing consolidation because the consumer demand is real and growing.

Challenges that remain will be spotty enforcement of economically adulterated goods, or "supplements" with undisclosed APIs that are illegal per se, and the industry needs to hold the regulatory agencies accountable for enforcement.

I also think there will be some changes involving anti-doping of athletes, enhancement of concussion prevention protocols in contact sports such as football, and more work done on providing supplements to

the fastest growing segment of the population, namely the aging Baby Boomers, who remain influential and affluent as they head for their sunset years.

Lifton: In terms of challenges, intentional adulteration of dietary supplement formulas and ingredient mixes has become a big problem where we need much more enforcement in 2018, not more regulation.

Plus we need a better argument to counter the anti-supplement narrative than “Drugs are much more dangerous than supplements.”

As we double-down on self-regulatory initiatives and support agency efforts to make the marketplace completely inhospitable, and even hostile, to the bad actors operating on the periphery of the industry, we must do a better job—and here’s the opportunity—of spreading new, science-backed messaging to get the word out on the ability of dietary supplements and functional products to improve health and make life better for so many people.