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Industry Forecast

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An expert panel discusses the latest issues affecting the nutritional ingredients industry.

The Participants Are:

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With CBD dominating much of the attention regarding the natural products industry in 2019, our panel of experts looks back at 2019 and forward to 2020, with insights on anti-supplement state actions, self-regulatory initiatives, mandatory product registries, the NDI (New Dietary Ingredient) draft guidance, DSHEA (Dietary Supplement Health and Education Act of 1994) 2.0, and more.

NIE: What were the biggest issues—whether positive or negative—for dietary supplements and ingredients in 2019, and why?

Weiss: The explosion of cannabidiol (CBD) products now in commerce, even while these products (except the prescription drug Epidiolex) are illegal, is the biggest issue of 2019. A majority of Americans aren't even aware that CBD products aren't regulated like other dietary supplements. I am a member of the Natural Products Association (NPA) Board of Directors and I'm proud of the association's work to secure a U.S. House-passed amendment that would fund FDA (U.S. Food and Drug Administration) to set a safe daily level of CBD and a set a clear regulatory framework for this popular ingredient.

Kreienbrink: The biggest disruption, which ironically is both positive and negative, is CBD/cannabis. On the positive end, CBD has undergone tremendous growth, potentially up to $20 billion. Consumers are looking to CBD as a complement to many aspects of their lives. This interest is expected to continue into 2020. The downside, however, to the growth within the CBD market is the impact it has had on other ingredients within the dietary supplement space. The market as a whole hasn't kept the pace of CBD. As a result, other supplement ingredients have declined in overall sales.

Lifton: Like it or not, CBD overwhelmingly dominated the conversation about dietary supplements and botanicals in 2019. While the loud "buzz" about CBD may have helped out manufacturers who just launched hemp and CBD products, the regulatory quagmire, FDA's lack of clarity about whether there is to be a carve-out for CBD, and a fog of over-the-top claims by a few manufacturers have, together, not helped consumers or the industry at large.

Bass: CBD is a category breaker because the political agenda for it comes from outside the natural products industry. The market is way ahead of the regulations for it.

Atwater: In 2019, there was much broader recognition by all stakeholders that […] the quality of our supplements and multifaceted solutions are critical to improve trust in dietary supplements and ingredients.

At USP, we were proud to launch our Dietary Supplements Compendium (DSC) Online in June 2019. This resource helps users navigate the DSC monographs, regulatory guidances and reference tools used around the world for the dietary supplement supply chain. The 2019 DSC features step-by-step procedures and assays to help manufacturers and ingredient suppliers demonstrate that their raw materials and finished dietary supplement products meet established specifications for identity, strength, quality, purity, packaging and labeling.

Mister: CRN sees the Codex Alimentarius proposal on probiotics as potentially problematic for the industry. The proposal would impose global criteria for demonstrating efficacy and making claims that are inconsistent with general Codex guidelines for claims substantiation for all supplements. CRN finds the proposal particularly disappointing because a few companies in the industry are trying to secure a competitive advantage by using Codex to set up a trade barrier for other companies that market similar products.

CRN recently attended the Codex Committee on Nutrition and Foods for Special Dietary Uses (CNFSDU) meeting to engage on various issues, including harmonizing probiotic guidelines. CRN and others in opposition to the proposal succeeded in getting a request by the Committee for Argentina to redraft and resubmit a probiotics guidelines proposal, which effectively suspends decisive action on probiotics for this year. Moving forward, CRN will submit additional comments and participate in a working group charged with developing and implementing a new work prioritization mechanism in 2020.

Shapiro: Clearly, the biggest issue is the explosion of CBD on to the market after Congress lifted the controlled substance status from industrial hemp. It is too early to know whether this is a positive or a negative. We have an ingredient flooding the market that FDA has repeatedly stated is not permitted to be in foods and dietary supplements. Putting the legality because of the pre-existence of the GW Pharma drug to the side, FDA recently indicated that any claim to GRAS (generally recognized as safe) status is questionable and there still appears to have been no credible new dietary ingredient notification submitted to FDA.

I am concerned that the status of ingredients may wind up being controlled by consumer class-action plaintiffs, instead of the regulatory agency in charge.

NIE: Regarding big stories in early 2019, there was a December 2018 proposal in Arizona that would have required companies to obtain a permit to market nutritional supplements like a "drug" and be subject to some of the requirements for nonprescription drugs in that state. Comments?

Shapiro: One of our firm's clients was involved in the Arizona Board of Pharmacy issue. Our client was a member of NPA and AHPA (American Herbal Products Association), and they assisted us on behalf of their mutual member (an endorsement of the benefits of trade association membership).

It wasn't a proposal, but rather an interpretation of an existing regulation concerning structure/function claims that arguably and, probably unintentionally, made dietary supplement companies selling dietary supplements with claims subject to drug regulation with the state Board. Happily, with us all working together, we were able to convince the Board that dietary supplements with structure/function claims were not drugs and the regulation in question was eventually taken off the books.

While had this been strictly enforced it would have been nearly impossible to sell supplements in Arizona, I doubt this was ever the intent, which is why it was quickly resolved.

Weiss: NPA stopped the Arizona proposed regulation in its tracks. This was just one of many victories for NPA in 2019, as a part of the trade association's work to preserve consumer access to supplements, prevent government overreach and prevent nonsensical legislation.

For example, NPA recently testified in an Oregon Department of Justice hearing to discuss a health claims proposal that would confuse consumers, raise costs for taxpayers and do nothing to protect public health.

Additionally, in February, NPA defeated a proposal in the Massachusetts State House that would have prevented young people in […] Massachusetts from purchasing products like protein powder and put other popular supplements under lock and key.

Kreienbrink: I support AHPA and the NPA in keeping products free in terms of access in Arizona and elsewhere. Dietary supplements aren't categorically the same as drugs. If the measures had proceeded in Arizona, the outcome may have been an increase in costs to the end user, thus preventing access to those who benefit from dietary supplements.

NIE: In May 2019, the FDA held a public meeting on "Responsible Innovation in Dietary Supplements." The title presupposes that there is such a thing as irresponsible innovation. What was the gist (and impact) of the meeting, whether pro, con or indifferent?

Lifton: Innovation is the lifeblood of a growing industry.

Yet, we still have an NDI Guidance in revised draft form and a misty territory regarding NDI requirements, including the massive looming question as to whether the 1994 goalpost is changing regarding the list of ODIs (old dietary ingredients).

And current thinking, by some experts, is that the completion of such a master list of grandfathered pre-1994 ingredients is not possible due to several factors, including the sparsity of records from that time and due to changes in extraction technologies since that time.

Some suggest that the creating of new master list of all permissible ingredients—including grandfathered, NDI-notified and GRAS ingredients—might be a wiser path forward.

Yet new players wanting to innovate with ingredient compositions based off established nutrients are, for now at least, left with more questions than answers.

Weiss: The meeting was largely based around concepts that we expect will be a part of the NDI guidance when the FDA attempts to bring forward that guidance. Unfortunately, to date, FDA has focused more on creating the guidance than enforcing NDIs.

Shapiro: I certainly agree with at least some of the sentiments expressed. For example, I believe that FDA should allow synthetic copies of botanicals as new dietary ingredients subject to notification. If there is a legitimate benefit to health, which cannot be met solely by the natural ingredient, the public should not be deprived because of what I believe is an incorrect interpretation of DSHEA. I also believe that there should be better protection for the innovator companies that file

new dietary ingredient notification, such as import alerts to prevent potentially unsafe copycats that have not filed their own NDIs from getting into the market.

Kreienbrink: While the title can be interpreted to the extreme, implying that the industry is fraught with compromise, I think the message is really clear. The industry still has a number of bad players. It's in the interest of the industry as a whole to protect consumers from unsafe or misbranded supplements that have potential to cause harm.

Mister: CRN saw many positive suggestions presented during FDA's May 2019 meeting, including opportunities to improve efficiency in supplement regulation and incentivizing innovation, but we have not seen any action come out of it.

CRN is concerned that the FDA convened this meeting [yet] has avoided action for more than six months. We would like to see progress on the NDI notification process, especially with the idea of creating master files for ingredients that would allow companies to protect their safety data. We hope to see movement from FDA on these items in 2020.

Bass: I thought it was a major, positive meeting, and a sign that the FDA is interested in increasing access to innovation balanced by a need to protect public health.

NIE: Also, in May 2019, CVS announced the launch of its "Tested To Be Trusted" program for dietary supplements sold in-store and online via CVS, a program that requires third-party testing of all vitamins and supplements. Comments?

Weiss: Third-party testing is unnecessary for products that are made under cGMPs. Testing a finished product doesn't create quality. Consumers and retailers instead should focus on identifying companies that are following cGMPs throughout the supply chain.

When it comes to supply chain and retail best practices, I'll also be looking to the Supplement Safety & Compliance Initiative in 2020, as I expect they'll be publishing a set of common safety standards recognized by some of the largest retailers, manufacturers, suppliers and other stakeholders in the industry.

Atwater: We applaud CVS for requiring third-party testing of their vitamins and minerals, which signals to us that they are concerned about the quality of the supplements sold in their stores. We hope to see other brands follow suit. Unfortunately, the percentage of products sold in health food stores that are third-party tested is very small.

However, testing alone does not ensure the quality of supplements from batch to batch. USP has successfully verified the quality of hundreds of products, by conducting GMP (good manufacturing practice) audits, evaluating quality control and manufacturing product documentation, and conducting full product testing, which helps ensure product quality from batch to batch, and we are seeing demand for the program grow. As marketplace recognition builds, we aim to expand that number into the thousands.

Kreienbrink: We are in full support of third-party verification. In the word of Ronald Reagan, we must “Trust, but verify.” Our ingredients undergo stringent quality analysis that includes heavy metal, pesticide, microbiology and irradiation testing, as well as the company’s Identilok species identification process. Identilok is our patented genus species testing process, which guarantees the highest levels of product purity, authenticity and cleanliness. We were a pioneer in creating its Identilok system in 1995 in response to a challenging industry landscape wherein no consistent process for identifying product existed. We also have a robust vendor qualification and pre-shipment sample process that includes testing every lot to confirm that it hasn’t been irradiated, that it meets United States Pharmacopeia standards for pesticide residues and that it falls below our own product-specific moisture targets.

Mister: Third-party certification programs have the potential to boost both retail and consumer confidence for products on the store shelf. CRN supports these kinds of programs, as we are concerned with the consequences of inconsistent and potentially conflicting standards among retailers. CRN has been working to harmonize standards to get retailers and manufacturers to collaborate and develop a set of standards that everyone can agree to.

We applaud organizations like GRMA (Global Retailer and Manufacturer Alliance) and SSCI (Supplement Safety & Compliance Initiative) that are also working to develop a single set of standards so all retailers and consumers can have confidence in their products.

CRN recognizes the value of multiple certifying bodies competing for business, but they all should be able to use the same measuring stick. Otherwise, manufacturers face an endless parade of inspectors in their facilities when those resources could be deployed to improving quality.

NIE: Explain how harvesting, extracting or processing advances today impact the market, and what does it open up for the future?

Lifton: Consumers want truth. Whether this means honest ingredient lists, clean packaging, truth in claims, sustainable practices—they want to be able to reduce the literal and figurative distance between what’s in the ground with what’s in the bottle. Overall, they want purity and authenticity in their supplement ingredients. So whatever methods we can harness to provide those ingredients and those products, the better.

Weiss: Many consumers are seeking “clean” products to support their health, and I think we’ll continue to see innovation that supports this consumer demand.

For instance, Nutrition 21’s Lepidamax is a proprietary, patented blend of Peruvian maca phenotypes that has been studied for safety and efficacy. To ensure proper sourcing of this high-quality, nutrient-rich maca, Nutrition 21 collaborated with the University of Peru to obtain maca that is grown and processed in optimal conditions in the Peruvian highlands. Clinical study results, published in March of 2019 in the peer-reviewed Journal of Exercise and Nutrition, showed that Lepidamax not only significantly increased energy and sexual functioning in men, but also showed an increase in strength, a key endpoint in sports nutrition.

Kreienbrink: The cleaner, more environmentally considerate ways we develop to produce extracts, the better. The cleaner more environmental way to yield extracts is always preferable, especially to today’s consumer. We place a high value on the sustainability practices of our growers. Demonstration of the plant’s long-term survival is a prerequisite for partnership. The growers must

have proven methods for correct harvestation, cultivation and seeding. They must demonstrate the avoidance of pesticide use, as well as optimal soil and water conditions. Demonstrating competency in these skills is critical in [working] with us since we place a high priority on trusting partnerships, working with some grower or collector families for three generations or more.

NIE: Should dietary supplement companies have to register the products they have on the market with FDA? Comments?

Kreienbrink: While I feel that mandatory registration is prohibitive, I'm not opposed to voluntary listing. Some consumers are interested in understanding the derivatives of their supplements. The listing could provide guidance for those types of consumers. It may serve a secondary purpose in preventing those with misleading or compromised ingredients from participating in the market. Either way, the listing can be suggested or recommended, but I don't think it's useful to create a requirement. I would rather see more effort being placed into third-party verification of ingredients to increase validity.

Weiss: This topic has been debated at our NPA board meetings and there are some good arguments both for and against an FDA product registry. While I'm not opposed to it, it's unclear how it benefits the consumer or the industry. It certainly adds a level of additional costs to both industry and FDA, which is ultimately paid for by the public. Ideally, the resources that are spent by industry on state-level regulatory overreach would be more efficiently used to cooperate with FDA, if the state-level issues were pre-empted.

Bass: Without mandatory listing, no other industry-strengthening regulations will be possible.

NIE: In 2019 there was no shortage of studies with aberrant or misreported findings. Case in point, on Nov. 8, 2019, a supplementation study by de Boer and colleagues claimed that supplementation with vitamin D3 and omega-3 fats didn't protect prevent or treat kidney disease in people with type 2 diabetes. Comments?

Bass: It's very concerning that these strawmen are erected and then supplements are then falsely claimed to be ineffective.

Lifton: Regardless of the merits of this study, if any, this is yet another stalking-horse scenario, which reminds me of the case of St. John's wort some years ago when St. John's wort was shown to not help with major depression when, in fact, it was never suggested as a product that could be used for that. The same thing with kidney disease in diabetes.

If dietary supplements could speak, in this case, they would say "Not my circus, not my monkeys."

NIE: What do people mean when they say DSHEA 2.0? It always used to be said that we should be very careful about opening up DSHEA, because, once it is opened up, it can easily be compromised or weakened. Does DSHEA itself need to be "updated" or does the FDA need to update its application of the law or its enforcement priorities?

Weiss: We should be careful about what we wish for, since we might get it. DSHEA was a long hard fight and it still isn't fully implemented by FDA. Once fully implemented, maybe some tinkering might be needed.

Bass: Until recently, I have been against opening up DSHEA. But the proliferation of new ingredients makes it a necessity that we have a robust NDI review process. That system is broken now. Kreienbrink: DSHEA is always going to evolve. It fills an important role in providing regulatory authority to the FDA, while also supporting consumers with access to safe and high-quality dietary supplements. I think we should all hope (and expect) that the focus on transparency will be meaningful in reshaping DSHEA's initiatives. The only ones that would suffer by this are the less than reputable player in the industry.

Shapiro: I do not believe that it is necessary to "update" DSHEA. I think that the law as currently written should work extremely well.

Lifton: If newly crafted regulations better embody the spirit of the law, then yes, it might make sense to update it. Some aspects of the law were already outdated shortly after it was enacted—the emergence of the internet and online sales is just one example. Still, industry and consumers should navigate these waters very cautiously, as a new DSHEA may wind up not being the promised land we're sailing towards.

NIE: What are your big natural products industry predictions for 2020?

Lifton: Consumers will shop even more with their values in 2020, whether those are personal values (such as sustainably harvested and non-GMO), product-expectation values (such as minimally processed and free of artificial ingredients), or health-goal-oriented values (condition specific, diet specific or otherwise personalized).

Kreienbrink: Hemp, hemp and more hemp. I say this in part jest. We truly feel that 2020 will be a big year for growth in the category. We also expect a continuation of growth in the plant-based ingredient category.

Bass: My prediction is that CBD will move forward as a regulated product outside of the drug approval.

Atwater: New dietary supplements are entering the market at an accelerating pace. In the past 25 years, the dietary supplement industry has grown from $4 billion with 4,000 products to $40 billion with more than 50,000 different products. Given the scale and variety of products being introduced

and the increased globalization of the supply chain, plus increased FDA regulatory oversight, we predict in 2020 we will see continued growth of third-party verification and retailer quality programs. Additionally, we may see new legislation discussed and introduced given The Dietary Supplement Health and Education Act is 25 years old and new quality mechanisms have been created since then.

Weiss: I am a believer that consumers are more educated now than ever before about self-managing their own health and wellness. This bodes well for companies that are producing high-quality, safe and efficacious dietary supplements and functional foods. Of course, this all starts with the ingredients, so the demand for science-backed ingredients will continue to grow in 2020 and beyond. NIE