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TOP ONLINE STORIES

Newly proposed Senate bill language pressures FDA to take action on CBD
ow.ly/JGwq50woNoC

Latest consumer survey from CRN shows highest overall supplement usage to date
ow.ly/SnJw50wwZci

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The dietary supplement industry may see its share of critics and negative headlines, but there is also plenty of positive news. Take the recent numbers shared by leading associations indicating that more consumers than ever before are buying supplements of all kinds.

These aren’t just regular stats; these are record-breaking numbers. In September, the American Botanical Council shared its latest *HerbalGram* Herb Market Report showing that in 2018, U.S. herbal supplement sales saw their strongest growth since 1998—9.4% growth over 2017. (Turn to page 12 for more details on which ingredients drove that growth.) According to this year’s Herb Market Report, 2018 marked the 15th consecutive year of growing sales for herbal supplements, evidence of consumers’ growing preference for the category.

The Council for Responsible Nutrition also had positive news to share in September. The association’s 20th annual CRN Consumer Survey on Dietary Supplements, which tracks consumer usage and attitudes towards dietary supplements, reported an “all-time high” level of supplement usage in the U.S. Seventy-seven percent of Americans surveyed said they use dietary supplements—the highest usage level reported by this survey to date. (The survey was funded by CRN and conducted by Ipsos on 2,006 U.S. adults on August 22–26, 2019.) Not only that, CRN said, “Results from the 2019 survey also reaffirmed strong consumer confidence and trust in dietary supplements and the dietary supplement industry...”

Dietary supplements are mainstream healthcare tools today, noted Nancy Weindruch, CRN’s vice president of communications. “While the industry continues to innovate, there is no denying that these regulated products have become mainstream,” said Weindruch in a press release. “More than three-quarters of Americans are taking dietary supplements each year—a crystal clear trend that serves as an indicator of the vital role supplementation plays in their overall health and wellness regimens.”

Consumers’ growing supplement usage will be top of mind as industry, critics, and regulators decide whether and how dietary supplement regulations should be updated to manage this $40 billion market. Discussions have been happening for years about whether a “DSHEA 2.0,” a revision of the Dietary Supplement Health and Education Act of 1994, is needed. (On page 14, industry stakeholders share their opinions on what changes should be made to DSHEA.)

Discussions about supplement regulations generally focus on what oversight, processes, and resources are lacking—all valid points—but it should never be forgotten that the reason to ensure the market is safe and well validated is positive: Consumers want to buy dietary supplements, and these supplements arguably help consumers take an active stake in their wellness. This is a driving point that will continue to influence the reshaping of the market for years to come and the efforts of regulators to, one hopes, rid the market of bad actors. It is also a call to action for everyone involved in the supply chain to ensure that they are putting products on the market that are safe, efficacious, scientifically substantiated and tested, and that benefit the growing consumer audience putting their trust in supplements each year.

**Jennifer Grebow**
Editor-in-Chief
Salt is not what it seems.

Think again.

It’s reasonable to believe every container of salt contains just what’s on the label. It’s even more reasonable to believe that, in today’s food-safety conscious world, the salt we buy — and put in and on our food — is pure, safe, and has gone through rigorous quality control.

Consumers, restaurants, food processors, and wholesalers are often unaware that their salt contains unwanted impurities. The worst offenders are importers that sell unprocessed Himalayan salt.

There is a loophole that many in unscrupulous importers use to sell salt that is not food grade and will never be properly cleaned or inspected before it is delivered to your facility. This is because salt can come into the country with, at most, a glancing inspection as a bulk ingredient destined for further processing but never receives the proper and necessary processing. The salt on your store shelf, in your facility or in your private label product could contain contaminants from rocks/clay to metal bits to other foreign matter.

Most importers do not know how to properly clean their Himalayan salt and are not in compliance with GMP (Good Manufacturing Practice) safety and quality standards. Some of it is downright filthy. Often, such impurities are readily detectable by the naked eye with opaque and off-color bits of foreign matter.

Pure Himalayan salt is a beautiful rosy pink salt, found in only Pakistan, and boasts a delicate flavor. It contains important trace minerals, including calcium, potassium, and magnesium. Correctly processed high-quality Himalayan salt will be in a narrow range of colors from clear, white, pale rose to brick red.

Himalayan salt that contains foreign material is much more susceptible to a recall. It is the buyer’s responsibility to be aware of exactly what is in their salt. When buying Himalayan salt, be vigilant, be aware and ask questions. Take a close look at the salt – Is it clean? Is it food grade?

You and your customers deserve the cleanest, purest, and safest salt possible.

**QUESTIONS TO ASK YOUR SALT SUPPLIER:**

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3. Is their salt Organic Compliant?
4. Is the facility third-party audited and by what certifying body?
5. What other food safety certifications do they hold?

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U.S. herbal supplement sales climbed significantly in 2018, driven in particular by the sales of cannabidiol (CBD), mushrooms, and immune support products, according to a new HerbalGram Herb Market Report published by the American Botanical Council (Austin, TX) in September. Based on U.S. retail sales data provided by SPINS, the market research firm based in Chicago, IL, and Nutrition Business Journal (NBJ), the Boulder, CO-based publication of the New Hope Network, an Informa media company, HerbalGram reports that sales increased by 9.4% in 2018 compared to the previous year. This is roughly a $757 million increase in sales and marks the strongest growth in herbal supplement sales since 1998.

In addition to an increase in overall sales growth, total retail sales increased across the three channels monitored by NBJ: mass market, natural and health food, and direct sales. Sales in these channels grew 7.6%, 6.9%, and 11.8%, respectively.

A number of ingredients showed impressive growth across channels. Elderberry, for example, found itself among the top five best-selling herbs in both the U.S. mainstream multi-outlet channel and the natural channel, according to SPINS sales data. Elderberry sales grew 138.4% to $50,979,669 in the mainstream channel and 93.9% to $25,374,666 in the natural channel. Another trending herb, ashwagandha, broke into the mainstream channel with a 165.9% increase in sales to $7,449,103, and remained in the top-ten-selling herbs in the natural channel with a 16.9% growth to $12,426,468.

While CBD did not make the list for top-selling herbs in the mainstream channel, it did rocket up to the number one spot in the natural channel, increasing in sales by 332.8% to $52,708,488. This is the second year in a row during which CBD sales grew by over 300%; in 2017, total retail sales for CBD reached $7,583,438 in the natural channel. Unfortunately, the ingredient’s regulatory status may be keeping it from breaking into the mainstream channel as most mass-market retailers are reluctant to take the risk of selling it. However, with the increasing pressure being placed on FDA by both the industry and Congress, a legal regulatory pathway for CBD may be imminent, at which point, the sales floodgates will open.

Other ingredients that showed a great deal of growth in the natural channel, pointing to potential mainstream popularity, are mushrooms, which grew in sales by 40.9% to $7,800,366. Most of these mushroom products were sold in the form of vegetable capsules and powders marketed for immunity or cognitive health. The sales growth, says HerbalGram, may be attributed to the extended 2017-2018 flu season, but the demand for products marketed as adaptogens may further stoke sales growth.

Recalls Relatively Infrequent for Dietary Supplements, Says AHPA

According to a report recently published by the American Herbal Products Association (AHPA; Silver Spring, MD), dietary supplement recalls are relatively infrequent. Analyzing recall data from FDA, AHPA found that of 803 recorded recalls initiated in 2019, 14 involved dietary supplements, or 1.7%. Compare this to 29% for medical devices, 28% for biological products, 18% for drug products, and 20% for conventional foods.

Recalls were relatively infrequent and were not a major concern in the dietary supplement market. The 14 recalls, 6 were classified as class I: “Use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.” Five products were class II: “Use of, or exposure to, a violative product is not likely to cause adverse health consequences.” The remaining three were classified as class III: “A reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.”

There were seven cases in which a drug was masquerading as a dietary supplement, and one in which a drug was masquerading as a conventional food. These were class I recalls, which were classified separately by AHPA.

“Recall data provide additional evidence of the overall safety of the dietary supplement class,” said AHPA chief information analyst Merle Zimmermann, PhD, in the report. “AHPA also regularly reviews other dietary supplement safety resources, including mandatory serious adverse event reports and recorded observations from FDA inspections, and the results suggest that current supplement laws and regulations are working effectively to protect consumer safety and ensure a marketplace of high-quality, safe products.”
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October 15, 2019, marked the 25th anniversary of the Dietary Supplement Health and Education Act (DSHEA), the U.S. law that gave dietary supplements a regulatory category of their own in 1994. DSHEA legitimized the industry and opened the door to the $40 billion market that exists today.

As the supplement industry grew within the framework of DSHEA, the challenges facing the market began to look very different from those facing it when DSHEA was still a fledgling law in 1994. More products enter the market each year—thousands more than existed back in 1994—presenting new ingredients, new formulations, new delivery formats, and new advertising claims. Consumers can purchase products from a multitude of retail channels, and supply chains for products grow more complex and global each passing year. All the while, emerging ingredients like hemp cannabidiol (CBD) are putting a spotlight on what happens when market demand for a supplement outpaces FDA’s regulatory oversight. And companies illegitimately selling misbranded or adulterated products masked as dietary supplements continue to operate under the radar.

FDA, the industry, consumers, and industry critics alike are aware of the need to maintain appropriate oversight of a market whose growth shows no sign of slowing, because one thing is for certain: consumers want access to dietary supplements. FDA is now actively looking into whether dietary supplement regulations need to be, in the agency’s words, “strengthened” and “modernized” so that FDA can effectively monitor the market. In May, FDA held a public meeting called “Responsible Innovation in Dietary Supplements,” with the mission of “giving interested parties an opportunity to present ideas for facilitating responsible innovation in the dietary supplement industry.” Industry stakeholders, advocates, and critics highlighted what’s needed, including from the agency itself. At the meeting, Steven Tave, director, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition at FDA, estimated the number of products today at 50,000 to 80,000, compared to the 4,000 products that existed when DSHEA passed.

Ahead, we asked a handful of supplement industry stakeholders about how DSHEA has aged—and what a DSHEA 2.0 should look like. What, if any, changes to the law are needed? What changes are needed in the way FDA polices the market?

At the end of the day, more consumers are turning to dietary supplements to proactively support their health and, crucially, to fill nutrient gaps they otherwise would have difficulty addressing. The hope is that the industry and its regulators can work together to address regulatory gaps, protect these consumers with a robust and well-regulated market, and ensure consumers can freely, confidently, and affordably access the products they need.

Scott Bass
Head of Global Life Sciences Team
Sidley Austin LLP

There is no question that DSHEA needs to be fixed. It was a great law and one that we
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believed should be left alone for most of the past 25 years. But the industry has changed, revenues and the number of products have increased tenfold, and sophisticated science has yielded hitherto unknown substances now being introduced with little or no safety review. Dietary supplements are an essential part of addressing the crumbling healthcare regimes around the world. They help to keep people healthy, prevent disease in some cases, and contribute to well-being. But as regulatory lines among product categories blur, and as we see aggressive companies trying to slide by the DSHEA safety protections, loopholes have to be closed. The two biggest loopholes that need fixing are the New Dietary Ingredient (NDI) safety review process and the absence of a mandatory listing of all dietary supplements sold in the United States.

Christine Burdick-Bell  
Vice President and General Counsel  
Pharmavite  

At Pharmavite, we believe the time is right for Congress to consider several important enhancements to DSHEA. This act created a framework to assist consumers in taking control of their own health through proper nutrition. It was first enacted 25 years ago, but times have changed since those pre-Internet days and we now have new challenges that were not anticipated back then. In particular, the rules concerning New Dietary Ingredients need to be updated and clarified to establish reasonable expectations for when NDI notifications are required, and to develop processes that will help stimulate innovation and promote compliance within the industry.

Pharmavite would also like to see DSHEA improved by updating the definition of allowable dietary ingredients to clearly create space for new strains of probiotics, as well as synthetic versions of botanical ingredients and other dietary constituents. Mandatory product listing would be another important step in moving the industry forward by creating greater transparency and consumer trust. That’s something the FDA has indicated it wants, but without proper enforcement it won’t benefit the FDA or the industry.

Combined with greater overall FDA enforcement of the rules that govern our industry, we believe a strengthened DSHEA would benefit both consumers and the industry for years to come. However, any modernization of DSHEA will be meaningless if the FDA doesn’t have the will or desire to enforce it, as demonstrated by its lack of meaningful enforcement against CBD supplements it has clearly declared illegal. We remain hopeful that an enhanced DSHEA can give consumers access to more safe options to help address gaps in their nutrition.

Daniel Fabricant, PhD  
CEO and President  
Natural Products Association  

DSHEA has been monumental in allowing growth for the natural products industry. But gaps remain in enforcement and structure of the current law, such as the apparent conundrum created by the influx of CBD products without an effective regulatory framework. Additionally, enforcement and communication from the FDA, such as import alerts, could more practically encourage New Dietary Ingredient notifications and lead to better industry-wide data. There’s much work to be done. We as supplement manufacturers, suppliers, and retailers must stay engaged with all branches of government—legislative, administrative, and judicial—and fight to advance DSHEA so it can provide a commonsense framework for our industry as we look toward its next 25 years.

Dr. Vasilios (Bill) Frankos  
Senior Corporate Advisor; Product Science, Safety, and Compliance  
Herbalife Nutrition  

After 25 years, DSHEA definitely needs some tweaking in order to improve consumer confidence in the supplement industry. The FDA should consider the following updates:

1) Mandatory label notification process: FDA and the public need to see what dietary supplement products are being marketed. By implementing simple changes to DSHEA, the mandatory 30-day structure/function claim notification can be expanded to include submission of the supplement’s label. Furthermore, this 30-day notification process would apply to all dietary supplements and not just those that make structure/function claims. The new legislation would require the notifications be posted in a consumer-accessible database that includes a unique identifier that would be placed on the label so a consumer can check if the product is complying with FDA notification requirements. If there is no unique identifier on the label, or the identifier doesn’t correspond to the product in the FDA Dietary Supplement Label Database, the consumer should be suspicious of the product.

2) Better enforcement of the New Dietary Ingredient provisions of DSHEA: [Companies selling] “me-too” NDI ingredients [but that] never submitted an NDI [notification] or don’t have the permission of the non-objected-NDI holder to market the ingredient should be blocked by the FDA from selling the ingredient. This will give more incentive to reputable companies to invest in submitting an NDI notice to FDA. Protecting the intellectual property of the NDI could also be improved through a Master File process for NDIs, such as already exists and is used for other FDA-regulated products (e.g., drugs). Of course, all this will only work effectively if FDA finalizes the long overdue NDI notification guidance, so industry can submit better notifications and decrease the high number of rejections.

3) Improve the NDI process: The process could be improved if the industry can tell whether they are using a new or old dietary ingredient. Until FDA publishes a list of old dietary ingredients, even if it is only a partial list, industry will continue to be uncertain about whether an ingredient requires an NDI notification.
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DSHEA needs to be enforced by the agency tasked with oversight—namely, the FDA. Failure to use the tools given to the agency (FDA) is not a legislative shortcoming, but rather one of potentially inadequate resources, misdirected priorities, or lack of motivation by partners inside government (think the Department of Justice) to take appropriate and timely action.

If this statute is amended, it should only be done in a way that extends the legal responsibilities for safety and purity of products throughout the supply chain. At the moment, the onus for providing safety and purity assurances falls on the dietary supplement product producer and own-label purveyors, and does not fall to the actual producers of the raw materials utilized in finished products. That is utter nonsense. Enforce the law through seizure and prosecution when appropriate. Nothing gets attention faster than seizure of assets and resources in a public way.

The biggest challenges [the dietary supplement industry faces today] come from self-inflicted wounds in the industry—e.g., allowing companies to exist that have no idea what Current Good Manufacturing Practices (cGMPs) are or why they are necessary. In order for these companies to exist, they must have customers willing to procure products made under illegal or shoddy conditions. This has to stop, and it can only be done when the FDA decides to seize products, padlock facilities, and criminally or civilly prosecute serial offenders. Perhaps the product liability insurance industry may be interested in providing significant preferred rate discounts to companies with a clean history of DSHEA compliance.

Having a license plate on a vehicle or a driving license to operate a vehicle on public highways seems like an accepted factor of modern life. Our firm does business in over 40 countries. Most other countries outside the USA require some form of registration, documentation, and notification to their government agencies tasked with consumer health and welfare, in order to provide us and our clients the legal right to make products available to consumers in those jurisdictions. Why is this such a difficult subject for the FDA to grasp? Pre-market registration is not the same thing as premarket approval. Registration with essential data points allows the agency to exercise enforcement and traceability in the event of a necessary recall for human safety concerns. The argument that ‘outliers’ and ‘criminals’ will not comply [with a mandatory product registry] lends even more credence to the wisdom of requiring some form of licensure, because failure to demonstrate one in an investigation would be prima facie evidence of guilt, and when combined with stiff fines and penalties for non-compliance, should prompt appropriate behavior. Failure to know the law does not exculpate offenders.

Failure to enforce current provisions against Internet sellers and resellers of finished products with clear content and/or labeling issues of non-compliance with the statute will continue to erode consumer confidence in this industry. Either the FDA does what it is tasked to do, or perhaps the entire function should be reassigned to another agency such as the U.S. Department of Agriculture, which has a robust Food Safety Inspection Service and is not unknown for swift regulatory action, including product seizure, destruction, and asset forfeiture in the case of proven malfeasance.

Claudia A. Lewis
Partner
Venable LLP

Many in the dietary supplement industry agree that it is time for a review and adjustment of how such
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Any Questions?

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*Based on publisher's own data.
products are regulated. It is a fact that the dietary supplement industry has matured and evolved. Indeed, with such a swiftly growing industry, it has been difficult for FDA’s policy and existing regulatory approach to keep up. A good example is how FDA recently handled the ingredients phenibut and vinpocetine. Those ingredients have been included in supplements for many years without agency comment or objection. FDA is now taking the position that the ingredients are New Dietary Ingredients and/or may not qualify as dietary ingredients and therefore cannot be sold as supplements. As we all know, the New Dietary Ingredient [provision] was implemented to be sure that ingredients that did not have a market history were safe. Rather than using the process to limit ingredient innovation, it should be used as it was intended, to confirm the safe intended use of an ingredient. This can be accomplished with a policy change and perspective within the agency.

The challenges associated with applying DSHEA to the current market are further evident with the issue of dietary supplement products resembling functional foods. Everyone wants a convenient superfood/dietary supplement. At the time DSHEA was drafted, it did not contemplate that there would be so many supplements in the form of gummies, drinks, and chews. Yet, that is what the market is demanding. Since supplements are a subcategory of foods, it seems that expanding the purview of the appropriate form of supplements could be easily accommodated via a painless regulatory fix.

Though the challenges in applying the existing DSHEA framework to the current market are impactful for industry, FDA plays an important role. We all want our food and supplements to be safe. However, it is imperative for FDA to develop a reasoned, practical approach to a regulatory pathway for dietary and food ingredients. This is very evident with the explosion of the CBD market. The juxtaposition of the federal and state regulation of CBD has proven to be very complicated. It is even more so because FDA has been clear that it questions whether CBD can lawfully be included in foods and/or dietary supplements. I am optimistic. FDA has a good history of developing its position through guidance documents and the use of regulatory procedures. I am hopeful that FDA will soon address CBD and other issues relevant to the food industry through notice-and-comment rulemaking to allow for stakeholder participation and the most fulsome record for the agency’s consideration.

**Shaheen Majeed**  
**President Worldwide**  
**Sabinsa**

Change is inevitable. Our world has changed dramatically in 25 years—the global population boom, its health (or lack thereof), technology, and significant gains in the knowledge of the universe and its contents, too. The sheer magnitude of growth our industry has seen since 1994 isn’t something that could ever have been anticipated back in 1994.

There were not many good published clinical studies on products regulated under DSHEA 25 years ago, but today there is an enormous amount of good research. It does not serve consumers that we are not legally allowed to talk about much of it, especially if [an ingredient] prevents, cures, or mitigates a disease. I think we need to revisit that.

People’s ways of accessing information were comparatively rudimentary back then, but today people research everything right from their phones. It would serve them better if we could link the research to the actual ingredients or formulas that were studied.

**Steve Mister**  
**President and CEO**  
**Council for Responsible Nutrition**

It’s time for DSHEA to create a little more transparency around dietary supplements. In the 25 years since DSHEA was enacted, the law has served consumers and industry well, balancing protection of consumer safety with assurance of access to a wide range of supplement ingredients. However, one missing component that has vexed FDA is its inability to see clearly into the market—to know which product brands are offered for sale, what ingredients are contained in those products, and what manufacturers are producing which supplements. It’s difficult to properly enforce other aspects of the law: compliance with the NDI notifications, or adverse event reporting, or proper ingredient labeling, if the agency doesn’t know which products are being sold. FDA has commented recently that it estimates there are between 50,000 and 80,000 supplements in the market, and the fact that the margin for error is 30,000 demonstrates there’s a problem with oversight. FDA can’t regulate what it doesn’t know is there.

Fortunately, there is a solution in the proposal for mandatory product listing for dietary supplements. Any product carrying the Supplement Facts label would be required to provide to FDA a copy of the label and some basic information about the product before it could be marketed in the U.S. And the database could be publicly available for consumers, healthcare practitioners, retailers, or regulators.

Skeptics worry that mandatory listing could be the first step down the slope toward premarket approval, but this concern can be addressed with strong assurances that listing, although required for all products, could not be used to prevent or slow down market entry. Like the difference between a birth certificate and a driver’s license, inclusion in FDA’s database of products could not be denied, even if the agency has reservations about a product’s legal compliance. But it would help alert the agency to the existence of safety concerns for separate follow-up investigation. In this age of corporate accountability, it’s time DSHEA caught up and shed a little light on the dietary supplement marketplace.
Creating a genuine dairy experience isn’t about adding a single taste. Such an experience has layers of depth and substance. And consumers demand the whole thing — plus a clean conscience. Unlike some solutions that lack traceability, Synergy’s are born from — and stay true to — nature. Whether they start with humanely raised grass-fed cows, or with plant-based, vegan-friendly alternatives, our solutions can be trusted to deliver it all. For simply enhancing dairy indulgence or for cleanly building it back,

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DAIRY by NATURE


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As we reach the 25th anniversary of DSHEA, it’s clear that in many ways the dietary supplement industry in general has flourished under it, as DSHEA finally provided a framework for the development of the industry that was sorely missing. This allowed for significant innovation on the ingredient side and has certainly stimulated the amount of research performed on natural products. Unfortunately, over the years, the implementation of the statute has certainly left much to be desired. Two examples that stand out are the much-delayed enactment of dietary supplement CGMP guidelines as well as the lack of clear guidance and enforcement of the New Dietary Ingredient notification requirement. Had there been clear guidance from FDA from the start on both issues, many of the challenges that have been faced by the industry could have been mitigated. Of course, from FDA’s perspective, a major stumbling block in enforcement has always been a lack of resources. Increased funding would have led to more robust enforcement and is still an issue that needs to be addressed.

While DSHEA is far from perfect, I believe that, on balance, it is a statute that the industry and regulators can work with. Enforcing the existing provisions of DSHEA to the extent possible—including more clarity around the NDI notification procedure—would go a long way in ensuring that industry stakeholders play by the rules. I don’t believe blowing up DSHEA is the answer, as that could portend additional and unnecessary restrictions on the industry and would stifle innovation. Maintaining a separate category for dietary supplements under the regulations, much like DSHEA does, is in the best interest of industry as well as consumers. These products aren’t drugs and therefore shouldn’t be regulated as such. Industry associations and self-regulatory bodies should continue to work with FDA and their own membership to ensure that the structure of DSHEA is maintained while compliance and enforcement efforts are enhanced. Ensuring that ingredient suppliers, manufacturers, and brand holders play by the rules and are held to account will go a long way in maintaining the confidence of consumers, researchers, and regulators in the industry.

Alexander G. Schauss, PhD, FACH, CFS
AIBMR Life Sciences Inc.

Between 1989 and 1992, the natural products industry was under siege. Health food stores were being visited by FDA inspectors who, without warning, removed hundreds of dietary supplements from store shelves around the country. The agency alleged these products were drugs due to label claims. Imported supplement ingredients needed by manufacturers entering through our borders experienced seizures. The media argued that supplements should meet the same standards for cGMPs and supportive evidence of safety and efficacy required of pharmaceutical products. It was in this environment that the stage was set in 1992 to introduce in Congress a separate category for ingestible products labeled as dietary supplements to differentiate them regulatorily from that of foods or drugs.

It was grassroots organizations that helped to urge members of Congress to protect the right of consumers to continue to have access to supplements without burdensome and unjustified costs. After three years of debates in Congress, DSHEA finally passed by unanimous consent of both houses and was signed into law by President Bill Clinton.

This legislation gave FDA the authority to regulate the industry according to Congress’s intent as spelled out in the colloquy and language of DSHEA. Unfortunately, on the day DSHEA finally came to the House floor for a vote, a trade association successfully convinced the chair of the House Subcommittee on Health to remove the provision that would have required registration of dietary supplement products. Many who were surprised the language had been removed from the final House version of DSHEA, and that it was not reinserted in the Senate version, have regretted that this last-minute action ever took place without first consulting with the very grassroots group, Citizens For Health, that played such an important role in urging Congressional support.

Twenty-five years after the passage of DSHEA, many are now raising the question of whether the perception of this industry would be different today had the registration provision of this legislation been retained. The United States remains the only country that does not require mandatory registration of supplement products. Would registration of supplement products have stifled attempts by individuals and companies to market products that failed to meet cGMP requirements and other provisions of DSHEA? Would urging the FDA to require registration of all supplements have avoided the stigma heard so often ad nauseam that supplements “are not regulated”? These are timely questions the industry must ask itself today.

Suzanne Shelton
Managing Partner
The Shelton Group

What could we do to make DSHEA better? My scope of work is exclusively with products regulated under DSHEA, so I think about this a lot. Most laws reveal, over time, their strengths and weaknesses, and DSHEA is no exception. One of the main things I observe is the lack of clarity in several areas:

Testing: Essentially, manufacturers have to use something that is “fit for purpose” but that is just so vague. More specific guidelines would raise the quality bar. And ingredient companies are exempt, which is kind of ridiculous, because experience demonstrates that supplement products should be tested as they move through the supply chain.

The NDI guidelines process is ridiculous with the next incarnation of guidelines in limbo and suppliers just going the Generally Recognized as Safe (GRAS) route so they can
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responsibility, many smaller, strictly e-commerce and safety. DSHEA placed the most significant onus of responsibility on the brand owner with the belief the brand owner would have the greatest reason to oversee the process and the most to lose if they failed to do so. However, with almost no barrier to entry for brand owners today, the risk of not following DSHEA’s cGMP requirements is almost equally nonexistent. There are thousands more brands and tens of thousands more products than existed at the onset of DSHEA. This burgeoning population of commerce needs more attention than the writers of this Act counted on DSHEA providing.

FDA [does not have the ability] to enforce the cGMPs that have been provided. The dietary supplement industry will have to self-police if cGMPs are expected to be respected. Additionally, DSHEA took for granted that the brand owner knew more about the products they provide than they do today. While the major brands are intelligent and responsible, many smaller, strictly e-commerce brands create a product suggested by a contract manufacturer with little to no understanding of what DSHEA and cGMPs are required. We, as an industry, must work diligently to ensure the actions of a few do not hinder or harm the opportunities and trust hard-earned to date. We should remain committed to the spirit of DSHEA but realize the world has evolved to require more than what DSHEA was designed to deliver.

Elan Sudberg
CEO
Alkemist Labs

DSHEA was and still is great, but it’s time to re-vamp it to further protect the supplements we take and love. This is not a reflection on the quality of its first rendition, but rather an adaptation to the current times where willful ignorance is prevalent and skip lot testing is recklessly promoted by misaligned leaders. It’s time to tighten, and make more specific, the laws that gave birth to cGMPs. The only folks who are not for more enforcement are the ones fearing more enforcement, as it leans on their bottom line. Enforcement makes our products safer and more effective. The biggest change I’d like to see is towards method-specific testing. cGMPs mandated by DSHEA failed to list specific methods for analysis of our products when FDA developed them and as a result have left a gaping hole for interpretation that the unscrupulous exploit. Updated DSHEA should ban plug-and-play chemistry sets bouncing virtual libraries around or “save the day” magic boxes using cell phones as poor substitutes for analytical lab equipment. Let’s require and enforce real chemistry with fit-for-purpose foundations.

With adequate testing, adulteration will go extinct, like some inadaptable lizard no one remembers even existed. I’ve said it before and I’ll say it again: Test test test test and then test some more. If the FDA made the top-level determination to enforce specific test methods and protocols, appeal to ignorance would no longer promote poor-quality products in our industry.

The FDA has never had a better relationship with the dietary supplement industry than it does now. I invite them to tour my lab at least twice a year. More dialogue between industry stakeholders and FDA officials is an obvious improvement in transparency from both sides.

Peter Zambetti
Global Business Development and Regulatory Strategy
Lonza Consumer Health & Nutrition

The dietary supplements industry has evolved significantly in the 25 years since the DSHEA regulations were first enacted. These changes not only include the advent of new technologies, but also new processes and numerous new ingredients and combinations thereof, as well as the globalization of supply chains and distribution. With a prolific number of new products coming onto the market all the time, DSHEA is still important to ensure consumer safety is prioritized by everyone in the industry.

Both Lonza and Capsugel have been at the forefront of supporting regulatory bodies and industry associations, in the U.S. and globally, for many years. Open dialogue between industry and regulators is key to evolving regulations to make sure they remain fit-for-purpose and in line with market changes. At Lonza, we play an active part in this process.

Our experience through serving on many trade associations in the U.S. and globally [has led us to believe that] FDA and supplement companies are aiming for the same goal: access to safe products that are marketed within the laws of that country. Understanding the regulatory requirements is key—being proactive to know exactly what’s required of you, whether you’re a supplier or manufacturer, and being ready and receptive to FDA inspections. Plus, open dialogue between industry and regulators should continue to be encouraged to make sure all challenges and requirements from both sides are put on the table and discussed.

Preserving consumer access to dietary supplements is crucial, but only for those supplements and manufacturers that operate safely and within the regulations required by DSHEA. Modernizing DSHEA, through industry consultation, and strengthening FDA enforcement will enable the continued access of safe supplements for consumers.
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Is yoga a sport? Emily Avery, USA Yoga’s women’s gold-medal champion in the 18–49 age group for three years running, would probably say so. And like her, millions of participants in “sports” such as CrossFit, Spartan Races, and Tough Mudders are redefining what it means to be an athlete, and democratizing the notion of sport in the process.

Sports nutrition products are undergoing their own redefinition in response, expanding upon the benefits they deliver, the means by which they deliver them, and the consumers whom they target. While this is forcing formulators out of their comfort zones—you’ll need more than a keg of protein powder to capture today’s sports nutrition consumer—it also heralds a refreshing dynamism for the category.

No wonder, says Josh Beaty, marketing director, NuLiv Science USA Inc. (Brea, CA), that “today’s sports nutrition is for the athlete in everyone.”

From Fringe to Front Row
The complexion of the current sports nutrition market is a far sight from what Chase Hagerman, brand director, Chemi Nutra (Austin, TX), knew just a few decades ago. “Back in the 1990s, I remember there was a small sampling of own-label distributors essentially born of bodybuilders on a mission to optimize their performance, mostly for self-satisfaction,” he recalls. By the mid-2000s as the category’s profile was rising, the critical mass started shifting to athletes looking to boost their competitive edge. “And by a decade later to today,” Hagerman continues, “sports nutrition has been becoming even more mainstream.”

How much more? Depending on whom you ask, sports nutrition products represent up to 25% of current retail sales in specialty and online dietary supplement purchases, according to Mark A. LeDoux, CEO and chairman, Natural Alternatives International (San Marcos, CA).

In fact, Grand View Research predicts a global value for sports nutrition of $24.43 billion by 2025, driven, in part, by the category’s embrace of recreational exercisers in addition to its traditional core of bodybuilders and serious athletes.

That growth tracks with heightened public awareness of health and wellness, not to mention the proliferation of high- and low-intensity gyms, “boxes,” exercise studios, and classes.

And don’t discount the role of wearables. Notes Juliana Erickson, senior marketing manager, Lonza Consumer Health & Nutrition (Morristown, NJ), “The rise of digital fitness and wearable technologies that allow...”
users to track their fitness progress is also fueling interest in nutritional products to aid performance and recovery. Indeed, says Hagerman, "For the first time since 2012, Apple reported in their quarterly earnings in June that the iPhone represented less than 50% of Apple’s revenue—reporting, conversely, 50% growth in their wearables category.”

Fueling a Broader Base

As weekend warriors don their smartwatches and start living the link between nutrition, wellness, and exercise, "they want in on these sports-nutrition products, too," says Stephanie Lynch, vice president of sales, marketing, and technology, IDF (Springfield, MO).

That’s prompting brands to formulate to a wider variety of nutritional needs. "Some companies have even discussed a potentially better name for the industry to appeal to this broader new consumer base: ‘lifestyle’ or ‘active’ nutrition,” notes Beaty.

According to Mariko Hill, product development executive, Gencor (Irvine, CA), sports nutrition consumers in general want to "reduce the impact of aging and exercise." Performance-driven users thus look for foods and supplements that build muscle, improve endurance, and boost energy, while those with a more holistic approach—"yogis and weekend warriors," she says—prioritize immunity, general wellbeing, and recovery.

"In the past, sports nutrition products were targeted at performance-oriented, young, healthy males: bigger, faster, stronger," says Larry Kolb, president of TSI USA Inc. (Missoula, MT). "Today, the consumers of sports nutrition products include women, elderly consumers trying to age gracefully, and the weekend warriors: people seeking an active lifestyle—not always to the level of an athlete—however, very committed and enthusiastic about their sport nonetheless. While performance is still driving sales of sports nutrition products, recovery and energy are major driving forces for this far broadened, everyday active lifestyle group."

In fact, recovery has appeal across the fitness spectrum. Notes Andrew Wheeler, vice president, marketing, FutureCeuticals (Momentum, IL), "The old ‘no pain, no gain’ mantra is being replaced by thoughtful training that can reduce the risk of injury. Sports nutrition consumers want products that echo that approach with claims for hydration, reducing muscle and joint soreness, and improving performance."

But as far as Hagerman is concerned, "Brands don’t emphasize vanity with sports supplements as much as they should.” Most consumers aren’t after Olympic gold, he wagers. "The vast majority are mostly just..."
recreationally active." Their goal is what he calls the "trifecta of fitness": more muscle, more strength, less fat mass. "All other functions feed into this. At the end of the day, the average consumer's biggest competition is themselves."

Understanding the Weekend Warrior
To reach that average consumer, Beaty suggests that brands innovate "in both formulation and marketing, giving consumers a reason to try something new or that they've never heard of before."

Doing so requires understanding the weekend warrior, and Emily Pankow Fritz, PhD, technical service manager for active wellness, Kemin Foods (Des Moines), considers this new breed "an interesting target" for a few reasons.

Metabolically, they differ from serious athletes in that they don't exercise intensely or consistently enough to experience the same adaptations that serious competitors do—so their energy and recovery needs will differ from those of serious competitors, as well.

Commercially, she says, "Weekend warriors might be less inclined to shop for traditional sports nutrition products positioned toward athletes." As lifestyle users, she says, "they provide an opportunity for sports nutrition brands to branch out into a wider range of supplements and products that support overall health and wellness."

Easy Does It
Which is what smart brands are doing. As Beaty says, "It's no longer just a space for protein and pre- and post-workout products."

Granted, "Protein shakes simply taste better than they used to," claims Christopher Naese, vice president, business development, Florida Food Products (Eustis, FL). "But there's also more variety and more ways to tailor nutrition to personal needs."

One such need is convenience, which formats like gummies, chews, gels, effervescent tablets, and single-serving stick packs and sachets provide. As Wheeler says, "These have the convenience factor, with portability enabling ease of consumption."

Vincent Tricarico, vice president, contract manufacturing, NutraScience Labs (Boca Raton, FL), adds that brands can win by developing packaging options that fit users' lifestyles. "So if a brand recognizes through research that most of its customers are on the go, it makes sense to package their powder in a stick pack versus a traditional tub with a scoop," he says.

Powder Power
But even conveniently packaged sports powders face competition from their ready-to-drink (RTD) counterparts. As Hagerman says, "It's been proven that convenience has a ton of merit, and it doesn't get more convenient than ready-to-drink beverages."

Still, insists Wheeler, "A great-tasting powder remains the best dose form for sports nutrition."

Hagerman agrees. "The vast majority of sports nutrition customers we work with are making powdered drink mixes," he says.

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*Based on a clinical study published in the FASEB Journal.
Active Nutrition

The bulk jugs are economical, lightweight, and easy to ship—crucial in a largely online marketplace. Powders are also cheaper to produce, making for a lower price point. And they deliver more actives per serving, Hagerman adds, “which is vital because many staple sports nutrition ingredients are dosed in gram increments.”

Snack Attack
Where convenience really hits sports nutrition is in the snack aisle. Observes Beaty, “A number of brands are innovating through the creation of not just new protein powders, but healthy snack and dessert options, like pizza crusts and cookies.” Why? “Their healthy-snacking appeal means more impulse purchases from a wider demographic than traditional supplements.”

Pointing to a Mintel finding that 94% of U.S. adults snack daily, Lynch bets that the “next big thing” will be protein crisps and other sports-snack formats. “As snacks continue to become ingrained into the American diet,” she says, “the market is ripe for nutritive snack innovations.”

But sports-nutrition supplements—read: tablets and capsules—retain a loyal following for their convenience, versatility, and easy-to-swallow format, Erickson says. “Capsules suit a range of ingredients,” she says, “and with the latest technology can address more than one health benefit in a single capsule—from sports nutrition and energy to bone and joint health.”

Go-to Ingredients
Sports nutrition brands are addressing those benefits with a number of functional ingredients—some familiar, some less so.

“Acetyl-L-carnitine, alpha-lipoic acid, casia cinnamon, chromium picolinate, citruline, creatine, glucosamine, glutamine, iso-leucine, leucine, valine, arginine, glutathione precursors, and others all have sound data showing they enhance cellular repair when used with naturally sourced antioxidants and healthy foods,” says LeDoux.

Protein remains a top draw, too. “Consumers associate protein with muscle growth, strength, and a healthy diet overall,” Wheeler says. “Traditional protein powders, like whey, comply with keto and low-carb diets while plant-based sources—pea, soy, and hemp, for example—attract flexitarian and vegan consumers newer to the sports nutrition space.”

Erickson points to studies demonstrating L-carnitine’s role in sports nutrition. “Its main metabolic function,” she explains, “is to transport long-chain fatty acids into the mitochondrial matrix for beta oxidation and energy generation—so it’s necessary for the use of fatty acids as energy, which is important in exercise and sports because fatty acids are the main fuel for endurance athletes.” Further studies show L-carnitine may enhance recovery, too, by increasing blood flow, attenuating metabolic stress markers, decreasing muscle soreness, improving recovery time, and “reducing hypoxic effects generated during exercise,” she adds.

Erickson is also bullish on marine ingredients. An unpublished pilot study found that a 25-g dose of Lonzas’s marine phytoplankton product Oceanix (Tetraselmis chuii) significantly boosted several biomarkers of exercise performance and recovery compared to baseline and control in 32 student athletes. Researchers noted high concentrations in the treatment population of superoxide dismutase, an antioxidant enzyme that protects against oxidative stress during activity, suggesting that the supplement may not only optimize physical performance, but may promote faster recovery, too, she says.

Hagerman notes that phosphatidic acid (PA), in conjunction with sufficient dietary protein and mechanical stress on muscle, significantly activates the mammalian target of rapamycin (mTOR) signaling pathway, which regulates muscle protein synthesis (MPS). Studies involving his company’s branded Mediator PA ingredient also show a loss in fat mass, as ‘one of PA’s roles is to turn

FOLATE FOR SPORTS
Gnosis by Lesaffre (Desio, Italy) is making the case for using folate in sports nutrition supplements. Personalized-nutrition trends are leading people to products that fit specific nutritional needs, and in the case of folate, there is a population of people who would benefit from folate supplementation, especially if they want to improve athletic performance.

For example, people with polymorphisms of genotypes in methylenetetrahydrofolate reductase (MTHFR), an enzyme involved in folate metabolism, or with low dietary folate intake are at risk of hyperhomocysteinaemia, an abnormally high level of homocysteine in the blood. Those with hyperhomocysteinaemia are at risk of skeletal muscle malfunction as well as cardiovascular disease.

For example, Gnosis cites a 2016 study in which randomly selected soccer players and sedentary male students without the polymorphism in TT genotypes of MTHFR had more favorable body composition and performance measures such as aerobic and anaerobic threshold rates, compared to subjects that did have the polymorphism. MTHFR is an enzyme that allows the body to transform food folate and folic acid into the active form of folate, 5-methylfolate, used by the body’s cells. Consumers can find 5-methylfolate in products like Quatrefolic from Gnosis, which the firm says has a direct role in the synthesis of new cells and in the building and repairing of body tissues, including those injured due to physical activity.

“Whereas it is really known that folate plays an important role in human growth and development, and people need to maintain an adequate intake of folate during all stages of life—pregnancy, lactation, childhood, and aging, but also for infertility and mood—the significant function of folate for active people who practice sports should be better known,” says Lorena Carboni, product support specialist for Gnosis. “Athletes often do not assume the Recommended Daily Allowance (RDA) of folate, with potential nutritional impairment.”

—By Sebastian Krawiec, Associate Editor

Reference

—By Sebastian Krawiec, Associate Editor
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on fat metabolism and manage fat transport,” he notes.

Future of Fitness Fueling
But while most sports nutrition research to date has focused on physical performance, the effect of nutrition on cognitive “athletics” is just beginning to attract attention.

“The rise of gaming, or esports, places huge demands on the body, as players need sustained energy and mental clarity to stay focused for several hours of continuous play at a time,” Erickson points out. “While it may not be a typical sport, this challenges manufacturers to create nutritional solutions that allow longer, modified release for sustained energy and focus.”

Chemi Nutra’s SerinAid phosphatidylserine (PS) and AlphaSize alpha-glyceril phosphoryl choline (alpha-GPC) enjoy an established reputation for enhancing cognitive performance as well as athletic, Hagerman says. “Alpha-GPC is a well-regarded ‘mind-to-muscle’ ingredient due to its involvement in motor-unit activation of muscle fibers and subsequent muscle contraction, as well as its mental-sharpness benefits,” he adds.

Pankow Fritz notes that Kemin is exploring the benefits of its spearmint extract Neumentix and its FloraGLO lutein for esports athletes. Studies on the former, a natural nootropic, show improvement in choice reaction performance and sustained attention, she says, while the latter helps filter blue light, “a common exposure in this population.”

But what really has Pankow Fritz excited is the promise of personalization, which she predicts “will take on a whole new meaning in the context of exercise and sports nutrition,” she says. “The application of personalization is appearing in simple concepts like macronutrient recommendations and more complex ideas like hydration suggestions based on sweat rate, or supplementation with actives like caffeine and beta-alanine based on responsiveness and activity levels.”

While such opportunities are still in the vision stage, “companies are starting to find creative ways to personalize products and recommendations to account for training status,” she says. In the future, she wouldn’t even be surprised if the trend roped in nutrigenomics to assess the relationship between athletes’ genes and their responses to specific actives. And that’s a prospect anyone could be a good sport about.

Kimberly J. Decker writes for the food and nutrition industries from her base in the San Francisco area, where she enjoys eating food as much as she does writing about it.

References
Amino acid supplement sales are growing at an impressive rate. One market report from Radiant Insights predicts the global amino acid market will grow to $35.4 billion by 2022 at a compound annual growth rate of 5.6%.1

Sports nutrition drives the lion’s share of amino acid growth as active, health-conscious consumers look for products that can enhance their workouts. These consumers are highly motivated to find products that are backed by scientific data, which is why it’s essential for amino acid brands to have high-quality evidence of the safety and efficacy of amino acids in the context of sports nutrition.

Here are just a few studies showing how amino acids can benefit sports performance and aid in sports nutrition.

**L-Carnitine Reduces Muscle Soreness, Shortens Recovery Time**

L-carnitine isn’t a new discovery by any means, but recent research is further validating its benefits for sports nutrition. Douglas Kalman, PhD, RD, is the vice president of scientific affairs for contract research organization Nutrasource (Guelph, ON, Canada) and co-editor of the *Journal of the International Society of Sports Nutrition*. Kalman says that a number of amino acids are showing positive effects outside of muscle protein synthesis.

“Amino acids, when combined with electrolyte beverages, outperform typical electrolyte drinks in terms of rehydration and sports performance,” Kalman says. “And when you add in additional dietary sources of amino acids, there’s a reduction in perceived muscle soreness, which some people would argue is a measure of recovery. People don’t limit themselves during exercise when they don’t feel sore—they push harder.”

One study, a 2018 literature review of 32 clinical trials, found that L-carnitine supplementation facilitated exercise recovery, especially in young, healthy subjects. The review, funded by Lonza (Basel, Switzerland), also found that L-carnitine increased muscle mass, improved muscle function, and boosted physical performance in frail and elderly trial subjects.2

**BCAAs and B6 Improve Fat Metabolism**

Amino acids aren’t just beneficial for reducing muscle soreness. They can also increase the rate of fat metabolism when administered in conjunction with vitamin B6.

One randomized, placebo-controlled clinical trial followed 42 overweight and obese women (BMI of 25 to 34.9) over the course of four weeks. All participants in all conditions were assigned a calorie-deficit diet (-500 kcal per day). Participants also received either a daily dose of branched-chain amino acids (6 g) and vitamin B6 (40 mg) (n = 21), or a matching placebo (n = 21). The study authors tracked several measures of body composition, including total cholesterol, LDL/HDL cholesterol, fasting blood sugar, plasma insulin concentrations, bioelectrical impedance analysis scores, and other variables. While this study did not find a statistically significant effect of BCAA plus B6 on weight loss, it did find a statistically significant time-supplementation interaction related to waist-to-hip ratio and lean muscle concentration in the legs.3

Kalman says that amino acids have been shown to promote maintenance of lean muscle mass during exercise. “There’s data to show a retention of fat-free mass during caloric restriction,” Kalman explains. “That’s why amino acids are often used in weight-based sports like wrestling, boxing, and combat MMA.”
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Beta-Alanine Reduces Inflammation during Training

Beta-alanine is not an essential amino acid, but research indicates that it may have beneficial effects during exercise. Its anti-inflammatory properties are particularly noteworthy when considering sports nutrition applications. Clinical trial data provided to *Nutritional Outlook* by Natural Alternatives International (Carlsbad, CA) indicate that beta-alanine supplementation can help reduce muscle fatigue and inflammation during and after exercise.

One randomized, placebo-controlled clinical trial on 20 military soldiers (average age 20) examined the effects of Natural Alternatives International’s patented beta-alanine ingredient, CarnoSyn, on endurance during a restricted-sleep (five hours of sleep per night) navigational training exercise. Participants were randomly assigned to receive 12 g/day of CarnoSyn (n=10) or a matching placebo (n=10) for seven days. The soldiers participated in a five-day training mission that required them to travel 28 km/day while carrying 50% of their body mass. At the end of this mission, soldiers returned to base for a seven-day supplementation regimen before participating in a second field mission that required them to travel 10 km/day for five days while carrying a similar load. Participants’ blood concentrations of interleukin-10 were measured after the initial training period and at the end of the study.

This study, funded by Natural Alternatives International, found that CarnoSyn beta-alanine supplementation caused a statistically significant reduction in blood interleukin-10 levels compared to a placebo. The study authors conclude that beta-alanine may enhance the anti-inflammatory response during exercise.4

Amino Acid Market Set to Grow

Amino acids continue to show efficacy as workout supplements, with studies confirming their ability to increase muscle mass, boost fat metabolism, and reduce inflammation when paired with exercise. As consumers look for more natural workout supplements with strong clinical research behind them, expect demand for amino acid supplements to increase, both in the strength training market and in the healthy lifestyle market.

Mike Straus is a freelance writer living in Kelowna, Canada. He has written for publications including Canadian Chiropractor Magazine, Massage Therapy Canada, and Iconic Concierge Vancouver.

References
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The digestive enzyme market has grown significantly in recent years, and market researchers are predicting that this trend will continue. One market report released earlier this year by Reports and Data (New York City) estimates that the global digestive enzyme industry will be worth USD $1.2 billion by 2026, forecasting a 10% compound annual growth rate. Gene Bruno, MS, MHS, RH(AHG), senior director of formulation for NutraScience Labs (Farmingdale, NY), says that a growing population of senior citizens and the rising prevalence of gastrointestinal (GI) disorders are raising awareness among consumers about digestive health.

"A focus on preventative health management, as well as changing lifestyles and high disposable income, are contributing to the high growth rates," Bruno says. "By far, the most popular digestive aids are those products that provide a blend of different enzymes formulated to help digest a broad range of foods." Bruno also notes that a consumer desire to change unhealthy eating habits is taking hold, which is prompting consumers to seek out enzymes for better digestive regulation.

The National Institutes of Health estimates that 60 to 70 million Americans have some kind of digestive disease like diverticulitis or irritable bowel syndrome (IBS). Here are just some of the new trends and opportunities arising out of this increased consumer demand.

**BREAKING DOWN THE ENZYME MARKET**

**ENZYME COMPLEXES REDUCE PAIN IN STUDY**

In a double-blind, placebo-controlled clinical trial performed by Sabinsa Corp. (East Windsor, NJ), enzymes were found to reduce pain. The study followed 20 male participants engaging in standardized eccentric exercise. Participants took either one 50-mg dose of Sabinsa’s branded DigeZyme three times per day for three days (n = 10) or a matching placebo (n = 10). Relative to the placebo group, the experimental group reported a decrease in exercise-associated pain and tenderness, as well as reductions in McGill Pain Questionnaire scores (p<0.05) and a declining trend in creatine kinase and lactate dehydrogenase.
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BLENDING PRODUCTS OFFER BETTER OUTCOMES

As consumers have gained more awareness of gluten and dairy sensitivities, demand for digestive enzymes has increased. Sam Michini, vice president of marketing and strategy for Deerland Probiotics & Enzymes (Kennesaw, GA), says that enzyme products today are more concentrated than they were in the past. A greater variety of enzyme material has allowed brands to formulate more specific and more potent products, Michini says, as well as different product types.

“Interestingly, brands are starting to add supplemental digestive enzymes to their OTC product lines, which shows increased consumer demand for enzyme products,” Michini explains. “There has also been more emphasis on clinically studied enzymes. The market is no longer based solely on who can provide the most potent enzymes. It’s also about who can provide the most scientifically supported enzymes.”

Michini says that enzyme manufacturers are now changing their product formulations to better meet the needs of specific customer segments. For instance, enzyme products today are exposed to fewer allergens during fermentation, use more label-friendly standardizing agents, and have overall cleaner labels.

Marketing Claims Target Specific Consumers

Michini says that supplement manufacturers are increasingly seeking out condition-specific enzymes to support digestion for consumers with digestive sensitivities. Consumers have learned much about the causes of digestive problems in the last ten years, which is why they’re now looking for supplements to resolve their complaints.

“People who have been diagnosed with celiac disease or who have reactions to lactose or gluten will stop consuming those ingredients,” Michini says, “but they also know that they should have some ‘backup’ support in the case of unintentional cross-contamination when eating away from home.”

At the other end of the spectrum are consumers who experience mild to moderate discomfort in response to gluten-heavy or dairy-laden food, Michini says. Consumers with food sensitivities represent a growing niche for enzyme brands, and these consumers are increasingly becoming more informed about products and formulations.

Products Evolve from Single-Ingredient to Blends

While early enzyme supplements may have been single-ingredient products, modern supplements are incorporating multiple enzymes in the same product. Shaheen Majeed, president worldwide of Sabinsa Corp. (East Windsor, NJ), says that enzyme blends are becoming more popular because of enzymes’ history as digestive supplements.

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Sophisticated consumers are now seeking specific, proven multi-enzyme blends to help keep digestion running smoothly.

“People eat different foods that require different enzymes to digest, which is why consumers are looking for blends,” Majeed says. “For instance, Sabinsa’s patented multi-enzyme complex DigeZyme comprises five different enzymes: cellulase for fibrous food; lactase to manage lactose tolerance; and amylase, lipase, and protease for people who have difficulty digesting carbohydrates, fats, and proteins, respectively.”

Majeed also says that multi-enzyme blends tend to incorporate enzymes from different kinds of sources. While animal-derived enzymes previously led the market, Majeed says, the new market leaders incorporate enzymes from animal, plant, and microbial sources. He says that microbial enzymes in particular offer advantages over other kinds of enzymes. “Microbe-derived enzymes may be used at a lower dosage, provide a broader range of pH activity, and stay active at higher temperatures compared to animal-based enzymes. Microbes are used as a major source of enzymes for supplements, representing about 90% of all enzymes produced commercially for any purpose.”

Storage, Ingredient Interactions Matter

Enzymes are gaining popularity as supplements, but mainstream press is calling their consistency into question. One ConsumerLab.com report published in May 2019 analyzed the contents and bioactivity of 12 different enzyme supplements manufactured by 12 different brands. ConsumerLab reported that across these products, lipase activity ranged 25-fold, amylase activity ranged 50-fold, and protein digestion ranged 100-fold. The report also found that one product that claimed to

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Three capsules per day of Deerland Probiotics & Enzymes’ (Kennesaw, GA) patented Glutalytic, an endo-/exo-peptidase complex, was shown in one Deerland-sponsored randomized double-blind placebo-controlled trial (n=11) to reduce non-celiac gluten sensitivity symptoms after one week.\(^5\) Gene Bruno, MS, MHS, RH(AHG), senior director of formulation for NutraScience Labs (Farmingdale, NY), says this study shows that peptidase complexes are effective in reducing digestive issues like stomach pain, nausea, and bloating in response to gluten ingestion.
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contain lipase didn’t exhibit any lipase activity during testing.\(^3\)

Majeed, though, says that proper ingredient processing and storage can prevent inconsistencies in ingredient concentration and lack of bioactivity. Enzymes in particular, he says, must be carefully prepared in order to retain their catalytic potential. Liquid products must be devoid of protease enzymes, Majeed says, as protease can degrade other enzymes.

“Supplements need to be formulated with components that can avoid enzyme denaturation, protect the active sites, and stabilize their function confirmation,” Majeed explains. “Along with choosing quality ingredients for formulations, brands also need reliable analytical methods to assess their catalytic activity.”

**Enzymes to Diversify in the Future**

Bruno says that the enzymes market will continue to evolve in the future, with product lines continuing to become more segmented to meet specific consumer needs. Food-specific enzymes, such as lactase and exo-peptidase complexes, are growing to meet consumer demand for specific functionality. However, Bruno notes that blends are also proving quite popular, with the bestselling products still consisting of multi-enzyme supplements that can digest a broad range of foods. While at face value these may seem like contradictory statements, it makes sense that a rising tide of consumer demand would lift all boats, single-ingredient and blended products included. As consumers learn more about digestive enzymes, expect new market opportunities to emerge.\(^4\)

Mike Straus is a freelance writer living in Kelowna, Canada. He has written for publications including Canadian Chiropractor Magazine, UX Booth, and Iconic Concierge Vancouver.

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Minerals

The market for minerals is growing, thanks to ongoing research, government recommendations, and ever-increasing public awareness of the role minerals play in good health. And as the market grows, all interested parties are changing the way they do business with it. Mineral suppliers are constantly innovating to create more trusted products that are easier to work with, and brands are answering to the constantly changing interests and attitudes of their mineral consumers. We explore the science and innovation behind today’s most popular minerals—but also the challenges in making sure your product can stand out from the rest.

Magnesium

Magnesium continues to dominate mineral sales. With poor soil health depleting the amount of magnesium available in fruits and vegetables worldwide, magnesium supplementation and food fortification has become a widespread practice. Add to that a growing body of positive clinical research on magnesium, and there are plenty of factors contributing to the market success this ingredient has enjoyed in recent years.

“Many researchers are emphasizing the importance of magnesium for wellbeing,” says Youval Saly, vice president of business development for Gadot Biochemical Industries (Haifa Bay, Israel), a specialty minerals supplier. “There has been a significant increase in sports nutrition awareness and the importance of magnesium in athletic recovery. In addition, consumers are starting to take note of magnesium’s benefits for brain health and not just the body. Aspects of mood, sleep, and migraine support are becoming emerging areas of interest as well.”

One way to distinguish a magnesium product from others in today’s marketplace may be to formulate with citrate-based magnesium. Though many existing magnesium products are made with magnesium oxide, research (old and recent) suggests that citrate-based magnesium is significantly more bioavailable.

Combining magnesium with calcium in a single product may also prove worthwhile, since the two ingredients work together to support bone health. Gadot Biochemical Industries is marketing citrate-based magnesium as well as calcium and magnesium compositions for powders and tablets in response to frequent requests from around the world.

Sea Minerals

The market for sea minerals has been around for at least a decade, but suppliers with vested interest in the category say demand has increased in recent years. Marigot Ltd. (Cork, Ireland), which supplies Aquamin brand minerals from sea water and red algae, says...
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the growth is in part a result of increasing demand for plant-based products. “The fortification of plant-based products with plant-based minerals seems to be a perfect solution,” the company says. CK Nutraceuticals (Oakville, ON, Canada), another player in the category, supplies its Deep Ocean Minerals. The ingredients are sourced from deep ocean water in Taiwan, and they are said to mimic the body’s natural mineral composition.

In sea minerals, manufacturers can get standardized amounts of macro-minerals like magnesium and calcium, but these ingredients come with an attractive, extra feature: trace minerals.

So far, Marigot and CK say they are seeing strong demand for their minerals in liquids and beverages in particular. Each has been active in pursuing clinical research on its own products. Marigot is involved in ongoing studies on joint health, arthritis, gut health, and cognitive health, and CK Nutraceuticals recently announced the publication of an independent study on its minerals and potential benefits for high-intensity running.

**Trending Delivery Systems**

For those unfamiliar with mineral fortification in the health products marketplace, potential applications include but are not limited to cereals, snacks, beverages, powder mixes, infant formulas, tablets, and capsules. In catching up with custom manufacturers, however, *Nutritional Outlook* learned that a few delivery systems are trending more than others.

“I’ve worked in the dietary supplement manufacturing space for nearly 15 years, and over the last 12 months I’ve seen a considerable uptick in demand for hydration formulas,” says Blayney McEneaney, vice president of sales for dietary supplement contract manufacturer NutraScience Labs (Farmingdale, NY). His customers are formulating beverages with magnesium, potassium, and sodium, while demand for tablets specifically has waned some.

McEneaney’s observations are confirmed by several other suppliers and contract manufacturers we reached out to for this story. In general, demand from product manufacturers is for all types of convenient, on-the-go applications. Gummies are another growing area of mineral business. Like beverages, they appeal to children, older adults, and anyone seeking convenience and/or who has trouble swallowing tablets and capsules.

**Stability and Taste**

As varied as mineral applications are, they are ultimately limited by whether or not the final product has acceptable sensory properties since certain minerals can have an unpleasant flavor and metallic aftertaste.

In response to this problem, Balchem Corp. (New Hampton, NY), supplier of Albion branded minerals, introduced a Taste Free line of Albion minerals, including calcium, iron, magnesium, and zinc.

NutraScience Labs also says it is seeing its own success by joining minerals
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EAT YOUR MINERALS: Shoppers are looking for mineral fortification in non-pill formats, requiring mineral suppliers to further improve ingredient taste.

MINERAL RESEARCH UPDATE

The library for clinical research on minerals is vast at this point, but new studies are added every month. *Nutritional Outlook* reached out to Balchem Corp. (New Hampton, NY), supplier of Albion minerals, with a request for new research that could be impacting sales and popularity of minerals. Here’s what we got:

**Zinc:** In reviewing 78 previous studies on zinc supplementation, U.S. researchers concluded that zinc supplementation in children under five years of age was associated with significantly improved growth outcomes. Not long after, a research paper broke with a proposed model for predicting growth response to zinc supplementation in zinc-deficient infants.

**Magnesium:** Sara Adaes, PhD, an investigator of neurobiological pain at the University of Porto in Portugal, writes that magnesium is a regulator of neurotransmitter signaling and that it regulates the activity of calcium channels in brain cells.

**Choline:** Though not classified as a mineral, choline is often provided in mineral supplements. A recent study concluded that maternal choline supplementation during the third trimester may result in cognitive benefits for offspring.

References

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You needn’t be an aging boomer to understand the value of maintaining healthy, functioning joints. In fact, if you’re hunting for nutritional joint support these days, you’re as likely to be an occasional triathlete or wellness-minded grad student as you are a recipient of Social Security.

That’s because, as Juliana Erickson, senior marketing manager, Lonza Consumer Health & Nutrition (Morristown, NJ), notes, “While joint health has long been a key consideration for seniors, other demographics, such as Millennials and ‘weekend warriors,’ are now taking steps to support their joints as part of their overall approach to health and wellbeing.”

Their participation in the market is changing how brands approach everything from joint-health formulation and product format to future research and development.

As well it should. As Erickson says, “Consumer needs are increasingly complex, involving convenience, evidence-based efficacy—even plant-based, sustainable solutions. As such, manufacturers are looking to formulate joint-health products using science-backed ingredients and advanced delivery technologies to differentiate in this marketplace.”

Changing Face of Joint Health
Demand for joint-support supplements is perennially solid, but the changing face of the consumer is injecting new life into the category.

According to recent unpublished proprietary research that Lonza conducted with...
Research over the past two decades has revealed that gut health is critical to overall wellness and immunity, and that an unhealthy gut contributes to a wide range of health challenges. Many researchers believe that supporting digestive health and restoring the integrity of the gut barrier will be one of the most important goals of health professionals in the 21st century.

Deerland is committed to developing the most innovative supplement products on the market for supporting a balanced gut flora, including our suite of clinically supported branded products featuring enzymes, probiotics and prebiotics.
Joint Health

the Natural Marketing Institute, joint health placed within the top-five health concerns among the general U.S. population, with 36% of respondents expressing concern about maintaining joint health and 44% willing to purchase a joint-health supplement in response—up 32% since 2009.1

The reasons why are apparent.

For one, we’re getting older as a population, and when that happens, joint complaints follow. Notes Shaheen Majeed, president worldwide, Sabinsa (East Windsor, NJ), most people over age 45 suffer from osteoarthritis of the knee, hand, and hip, making arthritis “a significant health concern in developing and developed countries, and a primary cause of joint-related health problems in the aging population.”

But today’s interest in joint support is hardly all about growing old. Witness those aforementioned Millennials.

As Erickson says, “Millennials in particular have become the driving force for shaping innovative joint-health products aimed at supporting their fast-paced lifestyles and helping with issues such as cartilage degradation, while also meeting their dietary preferences.”

Indeed, having grown up in a post-DSHEA world—the Dietary Supplement Health and Education Act of 1994 that launched the official dietary supplement industry in the U.S.—Millennials are native to a supplement shelf with more options than their parents enjoyed at the same age, Majeed adds. That being the case, he believes that Millennials view joint-health supplementation as just another aspect of taking care of their overall health.

Moved to Act

Regular exercise plays a similar role. Yet as more Millennials—and the rest of us—move our bodies, “we’ve seen an increasing number of joint issues in younger and middle-aged subjects either playing competitive sports or hitting the gym a little more than they should,” says Paul Clayton, PhD, chief scientific advisor to Gencor (Irvine, CA).

True, working out is largely to the good, but high-impact and repetitive activities place undue stress on joints, Erickson says, “leading to degradation of joint cartilage and increasing the incidence of joint discomfort among all active age groups. This motivates more consumers to seek joint-health support solutions.”
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“The number of hip and knee replacements is increasing steadily and has been for several years,” says Gencor’s Paul Clayton.

But despite the fitness boom, we’re still a population beset by overweight and obesity. More young people now qualify as obese, Clayton notes, predisposing them to joint issues before their time. “The number of hip and knee replacements is increasing steadily,” he says, “and has been for several years. This is directly related to a general increase in body weight and, most likely, deterioration of cartilage chemistry.”

The upshot: Consumers need joint support, he concludes, and they’re “beginning to understand that NSAIDs and a glass of milk aren’t going to take care of it alone.”

**Out with the Old**

But neither—at least not exclusively—will the flagship ingredient combination of glucosamine and chondroitin, which helped make Joint Juice a household name and has been a standard pairing in the joint-health category for years.

Why? Clayton points to “paucity of evidence” for its effectiveness.

Majeed mainly agrees. He says: “As the industry’s evolved from the basic glucosamine-plus-chondroitin combo formula of the early days—which didn’t work for everyone—to formulations with ingredients that address a broader range of issues, more consumers have found options that help.”

Those options work via a number of mechanisms. Some actually improve joint tissue architecture. Others inhibit the enzymes cyclooxygenase (COX) and lypo oxidase (LOX) to reduce severe pain. “Certain counterirritants, such as capsaicin or menthol, can interfere with pain’s signal to the brain,” Majeed says. “And specific biological response modifiers, such as anti-inflammatory cytokines and antibodies against important pro-inflammatory cytokines like TNF-alpha, are also used as target-specific therapies for reducing inflammation.”

**Herbal Help**

Majeed emphasizes that the joint-health literature includes a number of human studies demonstrating the pain-relieving and joint-supporting capacity of botanical extracts and isolates, among them *Arnica montana*, *Boswellia serrata*, *Cuscuta longa*, *Equisetum arvense*, *Harpagophytum procumbens*, *Salix alba*, *Sesamum indicum*, *Symphytum officinale*, *Zingiber officinalis*, *Panax notoginseng*, and *Withania somnifera*. With more consumers equating “natural” with “better,” he says, this bodes well for the herbal sector.

“In most healing modalities,” Majeed continues, “herbs are traditionally used in combination rather than singly, as any herbalist can tell you, because they approach a condition from several directions, supporting each other synergistically.”

For example, he’s bullish on the combination of curcumin and boswellia. The former inhibits COX-2, whereas the boswellic acids in the latter are 5-LOX inhibitors of the arachidonic acid pathway. “So the combination of COX-2 and 5-LOX inhibition is ideal for inflammation management,” Majeed says.

An investigation into whether three months of supplementation with curcumin and boswellia extracts could affect plasma levels of oxidative stress markers, inflammation, and glycation in 47 healthy male master cyclists found positive effects in glycoxidation and lipid peroxidation, Majeed says, “indicating the potential for combining curcumin with boswellia to achieve joint-health benefits.”

His company combined both its branded *Curcumin C3 Complex* and Boswellin, a standardized extract of *Boswellia serrata*, with ginger to create NiLitis SR, a sustained-release biayer tablet designed for joint health. A published study involving adult subjects with knee pain found that the combination produced “a very positive effect on knee discomfort,” Majeed says.1

**Boosting Anandamide**

Beyond herbs, Clayton is excited about palmitoylethanolamide (PEA), an endogenous fatty acid amide produced as a repair response to damage, stressors, discomfort, and inflammation.

He describes it as “an autocoidal substance directly involved in exercise-induced hypoalgesia” and calls it “very promising, indeed.” Structurally related to anandamide, the body’s inherent pain regulator, PEA may potentiate anandamide’s effects and inhibit fatty-acid amide hydrolase, which breaks down anandamide.

“PEA also helps stimulate production of the body’s endocannabinoids, which help regulate sleep, immune-system response, relaxation, pain, and more,” Clayton continues. “PEA is not only revolutionizing joint health but is proving beneficial within the recovery, relaxation, and sleep categories and exhibits a remarkable series of pharmacological similarities to CBD.” (CBD is the cannabidiol cannabinoid in hemp.)

Like curcumin, PEA is minimally dispersible in aqueous environments, including the stomach. Gencor and its sister company Pharmako Biotechnologies (New South Wales, Australia) developed a dispersion technology called LopiSperse that helps fat-soluble ingredients like PEA disperse more freely for better functionality and bioavailability.

The company’s dispersion-enhanced PEA ingredient Levagen+ displays improved pharmacokinetics, Clayton notes, and a recent arthritis study demonstrated its abilities further. His advice: “Keep an eye on this one.”

**Collagen Still Strong**

Collagen may not be a new entrant to the joint-health field like PEA, but it has history, familiarity, and continued innovation on its side.

Erickson points to clinical evidence showing that her company’s undenatured type II
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collagen product UC-II supports joint comfort, flexibility, and mobility by activating the body’s natural repair mechanisms.

When taken orally, she explains, it travels to Peyer’s patches, specialized lymphoid follicles in the small intestine, where it interacts with the immune system, triggering regulatory T-cell stimulation and further production of cytokines that circulate to affected joints. “Upon arrival,” she continues, “these cytokines induce knee joint resident chondrocytes to begin producing more type II collagen and other constituents that compose the structural matrix of the knee joint.”

Erickson suggests brands combine the ingredient with curcumin in her company’s DUOCAP capsule-in-capsule technology. The format can deliver a small collagen dose in the inner capsule and curcumin in the outer. “This enables consumers to benefit from the two ingredients’ synergies in a single supplement, while helping brands differentiate their products in a crowded and competitive market,” she says. “Synergistic ingredient combinations and advances in delivery technologies are really pushing joint health to new horizons.”

**Future Forward**
She can say that again.

“Methods and technologies keep evolving to improve the duration of discomfort-reducing supplements, site-specific actions targeting particular joints, and delayed and continued delivery systems to improve efficiency and reduce the number of doses,” Majeed says. Gels, liquids, oral formulations, and systems like his company’s bilayer tablets “have been developed to address the above issues.”

On a more forward-looking path is research into stem-cell approaches, Clayton adds, as well as work at the St. Petersburg Institute of Gerontology that he claims “provides a fascinating and much more user-friendly alternative” to stem cells. Scientists there are working with organ-specific growth peptides that “could provide the ideal and ultimate joint-health approach: the regeneration and replacement of damaged cartilage and related tissues,” he says.

It’s exciting work, but it remains in the distance. So for the time being, Clayton says, “We’ll still need the more acute types of supplement products that provide almost instant relief”.

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Here’s an unfortunate truth: every year, FDA identifies dozens of products illegally formulated with sildenafil, more commonly known by the brand name Viagra.1 When unscrupulous product manufacturers and ingredient suppliers are pushing drug ingredients into the dietary supplement’s intimacy category, how can legal and responsible companies stay competitive?

To start with, these companies “should try to compete with these spiked ingredients by utilizing the most potent and proven ingredients shown to enhance libido through the latest research findings,” says Brien Quirk, director of R&D for Draco Natural Products (San Jose, CA).

It’s also important to ensure consumers manage their own expectations. “In traditional herbal medicine cultures where they have utilized herbs for libido, especially in traditional Chinese medicine, they recommend the use of the herbs over an extended period of time and not to expect instant results overnight,” cautions Quirk. “Consumers might be thinking these should work within minutes or hours, but we know that in traditional Chinese medicine the understanding is that something out of balance needs to be brought back into harmony for the body’s normal function to be restored.”

The means of improving sexual health with natural, plant-based ingredients can be varied. Draco and other ingredient suppliers hold portfolios of ingredients backed by ancient historical use as well as cutting-edge research. It’s just a matter of finding those that fit a product’s platform. The following are a few standout natural ingredients for which sexual health research continues to evolve.

**Maca**

Indigenous Peruvians have eaten maca (Lepidium meyenii) for more than 2000 years, but outside of Peru this root is used more as a dietary supplement. In recent years, scientists have linked maca consumption in animals and humans to potential benefits such as aphrodisiac properties, better sperm health, and improvements in physical strength. It makes sense, then, that a market for maca dietary supplements exists, especially in the male health category.

Adding to the growing body of research, a team of researchers in Florida recently completed a maca trial on men and women. They found that men who consumed maca for one month demonstrated improvements in hand strength, self-reported fatigue, and self-reported sexual function compared to those who only took a placebo.2 The effect was not evident in women, which the researchers speculate may be related to maca’s possible influence on hormones, and three subjects (two men and one woman) withdrew from the study after reporting increases in acne. The researchers say the improvements reported in fatigue and sexual function are consistent with previous research.

The active maca ingredient used in this study was Lepidamax, a proprietary maca ingredient from Nutrition 21 LLC (Purchase NY).
Fenugreek

Fenugreek seed (*Trigonella foenum-graecum*) is often promoted for male and female sexual health. Though newly published research on the ingredient for either use is sparse, outside of a study finding positive effects with fenugreek in a combination product for women, there is news to report in terms of how fenugreek is being marketed to consumers.

Paul Clayton, PHD, chief scientific advisor for the fenugreek supplier Gencor (Irvine, CA), says that his company is witnessing a trend away from unsubtle “performance” claims and towards more rounded concepts based around wellbeing. In men, fenugreek has repeatedly been shown to increase testosterone. “Testosterone exerts multiple benefits in men, and, while sexual performance is important to many, the related improvements in self-image, mood, alertness, drive, fertility (via improved sperm morphology), and general health make up a very attractive package,” Clayton says.

For all consumers of fenugreek seed, a new safety review brings added confidence to the ingredient’s safety. Researchers in Pune, India, looked at more than 400 studies published on fenugreek seed and filtered them for those that measured ingredient toxicity factors. Twenty studies met their criteria, and the results suggest “a broad margin of safety for long-term duration (of use).” The review, it’s important to mention, was limited to research on fenugreek seed and no other parts of the plant, such as whole plant or leaves.

Tongkat Ali

For centuries, men in Southeast Asia have consumed the root tongkat ali (*Eurycoma longifolia*) for purported aphrodisiac properties. Some research on animals supports this theory. Lately, however, tongkat ali research appears focused on other, somewhat related health factors: hormones and muscular strength.

A new clinical trial suggests that tongkat ali consumption for two months improved power output during exercise while also increasing testosterone in men. Though tongkat ali use was associated with increasing testosterone, resulting ratios of testosterone-to-epitestosterone remained under the 4:1 threshold held by the World Anti-Doping Agency, meaning that tongkat ali is a safe ingredient for athletes. In an interview with HP Ingredients (Bradenton, FL), supplier of LJ100 concentrated tongkat ali extract, the company affirmed the ingredient’s overall safety.

“[Tongkat ali] is classified under the World Health Organization, Global Harmony System, Classification of Chemicals, in Category 5—no toxicity,” said HP Ingredients CEO Annie Eng. “This safety factor is so large that *Eurycoma longifolia* water extract is very safe for human consumption, under normal conditions of use, whether as an herbal tonic or clinical remedy.”

There’s still much to learn about tongkat ali. Last year, Malaysian and Indian researchers were studying eurycomanone, an active compound for which tongkat ali extracts are often standardized for. They found that, when consumed orally, the compound may permeate animal tissues only in small amounts, yet such small amounts may still be enough to exert desired effects of the compound. And more recently, researchers in China identified four new phenolic compounds in tongkat ali.
**AYURVEDIC BLEND**

With a multi-ingredient approach to sex health supplementation, Dolcas Biotech LLC (Landing, NJ) and Tenshi Kaizen Private Ltd. (Bengaluru, India) recently announced a partnership to sell Fortiquin, a unique formula made of L-arginine and four Ayurvedic botanicals (mucuna, cynara, trigonella, and ashwagandha) intended to have a positive effect on male sexual stamina. The two companies say their approach, based on low doses of synergistic ingredients, is "informed by the ancient healing system of Ayurveda" in its approach to similar dysfunctions. Results of a new study on sexual function in men are forthcoming, they say. Fortiquin was introduced to the U.S. market this fall at the SupplySide West trade show in Las Vegas.

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**Damiana**

Consumers may not be very familiar with damiana (*Turnera diffusa*), but a market for the woody shrub does exist in male and female sex health. Damiana is backed by a long history of use in Mexico, dating back to ancient civilizations, where its leaves have been used for sexual performance.

Published research on damiana is limited, but at least one company has plans to invest in new research. Pharmactive Biotech Products (Madrid, Spain) supplies Liboostr damiana leaf extract for global markets. Its previous consumer study found men and women satisfied with the ingredient, and this is helping to spur investment in more research. The company’s damiana leaf extract is standardized for flavonoids and acacetin, a particular compound of interest, and it has a recommended daily dosage lower than that of other damiana extracts on the market today.

At least in men, damiana may be a sexual aid in its potential to support vasodilation capacity.

**Shilajit**

Though purified shilajit, a rock exudate from the Himalayas, is now being touted for potential cosmetic uses, research continues on the ingredient for male physical and sexual health. This past spring, U.S. researchers associated more than 60 men to consume shilajit to improve their health. This is helping to spur investment in more research. The company’s damiana leaf extract is standardized for flavonoids and acacetin, a particular compound of interest, and it has a recommended daily dosage lower than that of other damiana extracts on the market today.

At least in men, damiana may be a sexual aid in its potential to support vasodilation capacity.

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**Saffron**

On its own, saffron (*Crocus sativus*) has potential as a sex health ingredient. A recent Iranian meta-analysis of saffron and erectile dysfunction studies was unable to make a broad determination due to methodological flaws of the studies included, but data from the studies compiled still compelled a review team to conclude, “Overall, saffron seems to exert valuable impacts on erectile dysfunction.”

In recent years, saffron studies have also yielded positive outcomes in cases relating to eye health and psychological health.

Despite market potential for saffron-only supplements, Nexira’s (Rouen, France) approach is to combine saffron with fruit polyphenols for a potentially synergistic benefit. The company’s formula, called EnoStim, can be made into tablets, capsules, and liquid shots. It was recently the subject of a recent trial on nearly 100 men in which EnoStim use was linked to significantly better erections and sexual satisfaction.

Nexira says that in Europe, saffron benefits from the following health claim: "Improves erections and relaxes muscles."
Any Questions?

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*Based on IMS data as of November 6, 2018. Based on 4 total industry magazines. Print only.*
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There was a time when a snack wasn’t considered the most important meal of the day. But these days, snacking means much more. “Snacking occasions have increased throughout the day as folks continue to lead a more mobile, on-the-go lifestyle,” says Jack Acree, executive vice president of Saffron Road. As more consumers turn to snacking to fill the ever-increasing gap between meals, or even as meal replacements altogether, manufacturers must ensure they are able to serve a larger snacking audience with products that cater to a broader range of food sensitivities.

Allergen Free
Making certain consumers have access to healthy, allergen-free snacks is important. According to Foodallergy.org, 32 million Americans have food allergies, 1 in 13 of whom are children. Accounting for 90% of food allergies are milk, eggs, fish, shellfish, peanuts, tree nuts, wheat, and soybeans. SPINS (Chicago, IL) reports that sales of allergy-friendly foods grew 20.4% year over year in the 52 weeks ending January 17, 2019. That’s $228.5 million in sales. Within the allergen-friendly space, the cookies and snack bars category grew 22% to $44 million.

Brands like That’s It, which manufactures snack bars made entirely of fruits, are capitalizing on the demand for allergen-friendly snack foods while also fulfilling a desire across the entire marketplace for cleaner products with as few ingredients as possible. Other brands like Saffron Road, while not producing solely allergen-friendly foods, are providing consumers the tools they need to determine which products they can eat. Saffron does this through an allergen search feature on its website.

“We get a good amount of communication from customers asking questions—some very specific—as they might be allergic to certain spices, and we wanted to make a feature that was as consumer-friendly as possible. [In] this information age we’re in, we have the information and can make it easily available to our consumers,” says Acree. “Another key component of what we try to do as a company is to be transparent. While a vast majority of our items are gluten free, we want people to understand that not everything is gluten free because we don’t want them to buy a Saffron Road product by mistake” thinking that it automatically is.

Gluten Free
The gluten-free category remains important, though it has matured a great deal since it boomed in 2012. “I think there was a gluten-free bubble where folks were buying gluten free solely because of the fact the product said it was gluten free, and they had it in their mind that it was healthier. For the most part, I believe those days are over,” says Acree.

Consumer awareness around gluten free has also matured, with more people nowadays identifying whether or not “they have something as serious as celiac disease or very specific levels of gluten intolerance,” Acree adds. Consumers who do not suffer from celiac disease, which affects only about 1% of the population, are finding that they may in fact be gluten and wheat intolerant and that even though they won’t get sick from eating gluten, they can avoid gluten through elimination diets and feel better not having it in their diet.

Categories like gluten free are evolving and now overlapping with other popular categories such as paleo, which is a diet that has nothing to do with intolerance but instead the perceived healthiness of particular foods. According to a SPINS 2019 “State of the Industry” report, paleo and grain-free food and beverages are showing the fastest growth in conventional retail. Paleo-positioned foods grew 48.8% to $294 million in conventional retail sales compared to the previous year, and grain free grew 81.5% to $139.4 million in conventional retail sales compared to the previous year. The biggest impact was in the chips, pretzels, and snacks category, where paleo-positioned products grew 163.5% to $41.1 million in sales and grain-free snack sales grew 258.3% to $29.7 million.
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Adulteration quiz! Test your knowledge.
Ingredient adulteration is never a fun topic to address. It is, however, a real threat to the dietary supplement industry and the reputable actors within it. Analytical testing methods for verifying ingredient purity are continuously refined, and there is an ongoing effort to make these services more affordable for raw material suppliers and product manufacturers. The reality, though, is that there will always be parties looking to gain an unfair advantage and elude common testing methods. Misrepresenting products with cheap alternative ingredients is a threat to industry integrity and can even cause harm to the public.

The Botanical Adulterants Prevention Program (BAPP) was created to educate responsible parties about adulteration risks in the botanical marketplace as well as best practices for avoiding adulterated products and properly validating pure products. BAPP is composed of scientific and industry experts from the American Botanical Council (Austin, TX), the American Herbal Pharmacopoeia (Scotts Valley, CA), and the University of Mississippi’s National Center for Natural Products Research. We caught up with BAPP to learn about some of today’s most at-risk ingredients.

**Saw Palmetto**

Saw palmetto (*Serenoa repens*) extract is popular in men’s health dietary supplements. Studies suggest that this ingredient may support prostate and urinary health. Though saw palmetto has its own distinct chemical profile, it shares some chemical similarities with cheaper plant oils, such as palm, canola, and coconut. This scientific discovery has led unscrupulous players to sell saw palmetto extracts that are diluted with these cheaper oils if not outright replaced entirely.

BAPP notes that while saw palmetto adulteration can occur in any global market, the U.S. is at reduced risk because saw palmetto’s farming origin is in the southeastern U.S. Asian markets are at a heightened risk of receiving adulterated saw palmetto, since they are further away from the true saw palmetto source.
Grape Seed Extract

Grape seed extract is highly regarded as a powerful antioxidant. This byproduct of the wine industry contains large amounts of polyphenolic compounds that can protect human cells from damage caused by free radicals. One class of polyphenols is proanthocyanidins (PACs). PACs are found in grape seed extract, but they are also found in cheaper ingredients such as peanut skins. Adulteration of grape seed extract with peanut skin represents a quality and safety concern, since peanut skins may provide the same allergenic risk to humans as peanuts themselves.

While laboratory analysis methods can identify PAC content within a sample, raw material testing methods are often not sophisticated enough to distinguish one PAC source from another. Short of investing in more precise tools, grape seed extract thus remains an issue in the industry. Manufacturers and marketers of grape seed products are encouraged to inquire with their suppliers and institutions like BAPP about which methods are most reliable for verifying grape seed extract.

Because cranberry extracts are also standardized for PAC content, the same risk applies here.

Turmeric (Curcuma longa) is one of today’s most popular dietary supplement ingredients. This rhizome is often identified by its vibrant yellow color, but looks can be deceiving. Synthetic yellow dyes can create the appearance of turmeric in raw materials or products where turmeric content is low or totally absent. In cases of turmeric adulteration with yellow dyes, lead chromate is often the adulterant of choice, and that creates a serious human safety risk. Numerous scientific studies have found adulterated turmeric as a potential source for lead contamination.

Turmeric may also be subject to adulteration in a taxonomical way. While the *Curcuma longa* species is the most studied of turmeric, some suppliers and brokers have reportedly sold off other *Curcuma* species as turmeric. Turmeric is also at risk of adulteration with cheaper, synthetically produced petroleum-derived ingredients passed off as natural curcumin. More turmeric suppliers are employing the use of carbon-14 testing to validate that ingredients are naturally derived.

The adulteration risks with turmeric in dietary supplements may extend to turmeric spice and curry powder. Fortunately, reliable methods for detecting turmeric adulteration are available and actively used.

Blue Skullcap

Sales of skullcap (*Scutellaria lateriflora*) are small compared to those of the aforementioned ingredients, but there remains a market for wild-harvested and cultivated skullcap. Adulteration issues should be taken seriously, no matter the scale of impact.
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Adulteration

With skullcap, adulteration can be accidental or intentional. Because of similarities in appearance between skullcap and germander (*Teucrium* spp.), which are both in the mint family, skullcap may be misidentified in the wild or deliberately misrepresented in the marketplace. What’s most concerning is that consumption of germander can have toxic effects on the human liver.

In a detailed report on skullcap adulteration, BAPP notes that commercially available analytical tools can easily detect skullcap adulteration with germander. The primary adulteration issue with skullcap can thus be avoided by responsible parties.

**Cordyceps**

Cordyceps fungus (*Ophiocordyceps sinensis*, syn. *Cordyceps sinensis*) has been extensively and globally studied for potential uses relating to sexual health, cardiovascular health, respiratory health, and antimicrobial activity, among others. Unfortunately, the ingredient is often replaced with other fungi ingredients in the marketplace, namely other *Cordyceps* species.

Because the market for cordyceps is significant in volume and cordyceps are expensive, there are ongoing efforts to improve the efficacy and lower the cost of scientific methods for analyzing and verifying true cordyceps. Recent studies suggest there are also unique levels of safe-to-consume organic arsenic in true cordyceps. These findings appear to warrant an additional course for laboratory identification of cordyceps in the supply chain.

**Ashwagandha**

Ashwagandha (*Withania somnifera*) is well represented in the botanical marketplace. The Ayurvedic ingredient is marketed for applications such as inflammation management, energy support, and sexual stamina. While lots of available research on ashwagandha is based on the plant’s root and root extracts, there is still a contingent of the industry that supports using ashwagandha for its aerial parts, including leaves and stems. All of these parts of the plant contain withanolides, which are active compounds used for gauging ashwagandha purity. The precise amounts and types of withanolides in each material, however, can differ.

Both aerial and underground parts of ashwagandha are allowed in the marketplace, but many interested parties believe it is best practice for suppliers and marketers to specify the ashwagandha materials used in their ashwagandha raw material and finished products. On the other hand, declaring an ashwagandha product as being derived from root if it’s in fact derived from leaf would constitute intentional misrepresentation.

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Seeding Growth

Consumer demand is bringing black seed into the mainstream, with a number of functions driving its growth in the marketplace.

BY MIKE STRAUS

Black seed (Nigella sativa) extract’s reputation is growing at an impressive rate, with a variety of new products coming onto the market to meet consumer demand. Mainstream consumer health media outlets are now starting to put the spotlight on black seed—which also goes by the name black cumin—citing its favorable results in clinical trials.

Weight loss, immune function, and blood sugar health are just some of the functional appeals that are driving consumers to adopt black seed. As consumer awareness around black seed grows, expect demand for more convenient and diverse product formats to grow as well. Here are just some of the must-know studies about black seed demonstrating its functional benefits.

Rooted in Ancient Wisdom
Black seed is relatively new to the west, but it has a history as a food ingredient, condiment, and supplement in India and Southeast Asia that dates back to the time of Hippocrates. Shaheen Majeed, worldwide president of Sabinsa (East Windsor, NJ), says that black seed is cited as a panacea in the Bible, in Islamic writings, and a variety of Asian and ancient Roman texts.

“Black seed has been used since antiquity for a variety of purposes, like cardiovascular support,” Majeed says. “Modern clinical trials have shown that black seed or its extracts,
essential oil, and other major components can improve mitochondrial function, lower cholesterol, and improve insulin resistance.\(^1\)

Until about 25 years ago, black seed was unknown in the west. The growth of scientific literature around black seed has prompted consumers to adopt it for both human and animal health. Black seed is now coming to the fore in the western market, with Global Market Insights predicting that annual domestic sales of black seed oil alone will reach USD $25 million by 2025.\(^1\)

**Black Seed Market Set to Grow**

The black seed market is staged for significant growth in the coming years, driven by consumer demand for cardiovascular supplements and natural products with long histories in folk medicine. The journal *HerbalGram* estimated last year that black seed sales grew by over 200% in 2017\(^4\). This trend upward could continue.

As black seed’s popularity grows, consumers will demand more specialized and diversified products with specific functional claims. Savvy brands can benefit by marketing black seed products for specific functional concerns like blood sugar support or cholesterol maintenance.\(^5\)

**References**


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**As consumer awareness around black seed grows, expect demand for more convenient and diverse product formats to grow as well.**

**Black Seed Extract Modulates Immune System**

Mark Mueller, founder and chief innovation officer of Botanic Innovations (Spooner, WI), started investigating black cumin seed oil’s immune-boosting properties in the mid-1990s. Mueller partnered with medical researchers at the University of Minnesota to conduct animal trials on black cumin seed oil and black raspberry seed oil.

“As our findings confirmed and expanded on what others had discovered,” Mueller says. “As we developed relationships with scientists and doctors, we learned more about the properties of black cumin. We have study data showing that our [branded] Organic Black Cumin Seed Nutri-Powder supports heart and immune health.”

One 2015 randomized, parallel-assignment, triple-blind clinical trial\(^2\) examined the effects of black seed oil or a placebo on 80 asthmatic participants between the ages of 18 and 65. Participants were randomized to receive either 1 g per day of black seed oil (n = 40) or a matching placebo (n = 40) for four weeks. The participants were assessed for scores on the Asthma Control Test and testing for blood eosinophils, pulmonary function, and total serum immunoglobulin E at baseline and at conclusion. Ten participants from each group withdrew prior to the study’s conclusion.

After four weeks, the black seed oil group exhibited a statistically significant improvement in Asthma Control Test scores, a statistically significant reduction in blood eosinophils, and a non-significant improvement in forced expiratory volume. The study authors concluded that black seed oil supplementation improves asthma control.

**Metabolic Effects Proven in Animal Trials**

Black seed has long been thought to have beneficial effects on metabolic function, but now, studies are validating its impacts on blood sugar, cholesterol, and blood pressure. One 2018 study\(^3\) examined the efficacy of black seed oil in regulating metabolic function in mice on a high-fat diet.

The trial followed the mice for 20 weeks, dividing them into 1) a control group on a regular diet (n = 5), 2) a second control group on a high-fat diet (n = 5), and 3) an experimental group on a high-fat diet that also received TriNutra’s (Ness Ziona, Israel) branded black seed oil standardized to 3% thymoquinone content for the final eight weeks of the trial (n = 5). The mice were assessed for fasting blood glucose, blood pressure, oxygen consumption, liver inflammation, body weight, antioxidant markers, and protein and fat concentrations.

The researchers found that thymoquinone supplementation regulated mitochondrial function, lowered fasting blood glucose and blood pressure, and increased oxygen consumption in obese mice. If these findings are validated in human participants, it could open up opportunities for black seed extract as a metabolic-regulation and weight-management supplement.

Mike Straus is a freelance writer living in Kelowna, Canada. He has written for publications including Canadian Chiropractor, *Massage Therapy Canada*, and UX Booth.

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**OCTOBER 2019**

**NUTRITIONAL OUTLOOK**

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Ashwagandha (Withania somnifera) is one of the most important adaptogens in the Ayurvedic medical tradition. Its use dates back some 3,000 years. Ashwagandha—roughly translated as “horse-like” from the Sanskrit language—is a true powerhouse for vitalizing the body and mind. The effects of this herb are truly multifaceted.

Ashwagandha is traditionally classified in Sanskrit as rasayana, which means having the ability to defend against disease, arrest the aging process, revitalize the body, increase its ability to resist illness, and enhance mental well-being.\(^1\) Emerging research on ashwagandha in humans continues to show a broad range of benefits, and this is spearheading the popularity as well as steady overall growth of this herb. Per data from market researcher Innova Market Insights and ashwagandha supplier Arjuna Natural Ltd. (Kerala, India) in April 2018\(^2\), new product launches featuring ashwagandha between 2013 and 2017 increased by approximately 18%, with growing interest in different delivery forms, including beverages.

Recent data from human clinical trials suggest the broad therapeutic activity of ashwagandha extracts in diverse health conditions. These research results affirm ashwagandha’s stature in Ayurvedic medicine as a tonic herb and indicate that it will continue to be an important natural option for supporting the health of numerous systems of the body.

**Improved Strength and Enhanced Recovery**

One of ashwagandha’s well-known benefits is its revitalizing property. A recent double-blind, placebo-controlled study was conducted to explore whether an ashwagandha...
extract can improve strength training and recovery.

In the study1 led by Tim Ziegenfuss from the Center for Applied Health Sciences (Stow, OH), young, recreationally active men were asked to consume 500 mg of an ashwagandha extract—Sensoril from Nat- reon Inc. (New Brunswick, NJ)—or a placebo daily for 12 weeks. Baseline measures included body composition, muscular strength, power, endurance, and a 7.5-km cycling time trial. These were repeated after 12 weeks of supplementation and an upper and lower body resistance training program.

At the end of the study, significantly greater gains were seen in the ashwagandha group compared to placebo in average squat power and bench press performance. Further significant improvements were evident in 7.5-km cycling times and perceived recovery scores, indicating that this extract improved both upper and lower body strength and has potential benefits for exercise recovery.

Healthy Thyroid Function
Ashwagandha has traditionally been used in the Ayurvedic system of medicine for supporting thyroid function. Subclinical hypothyroidism, a condition in which thyroid stimulating hormone (TSH) levels are elevated, is estimated to occur in 3%-8% of the general population and is often devoid of obvious thyroid deficiency symptoms.

To evaluate the effects of ashwagandha supplementation on individuals with subclinical hypothyroidism, researchers in India conducted a double-blind, placebo-controlled trial in 50 individuals between the ages of 18 and 50 with elevated TSH levels between 4.5 and 10 micro IU/L. Participants supplemented with 600 mg of ashwagandha root extract—KSM-66 from Ixoreal Biomed (Los Angeles, CA)—daily or a placebo for eight weeks.

Serum levels of the thyroid hormones TSH, T3, and T4 were assessed at baseline and at the end of the study. Levels of all three hormones were significantly improved in those supplementing with ashwagandha compared with placebo. Ashwagandha extract was able to normalize thyroid function in individuals with subclinical hypothyroidism.

Enhanced Testosterone and DHEA Levels
A further Ayurvedic indication for ashwagandha includes supporting vigor and vitality. In a recent double-blind, placebo-controlled crossover study2, Adrian Lopresti and colleagues from Murdoch University (Perth, Western Australia, Australia) aimed to assess ashwagandha’s effects on fatigue, vigor, and hormone levels in aging men.

Fifty-seven overweight males aged 40-70 with mild fatigue were asked to supplement with ashwagandha—as Shoden beads from Arjuna Natural Ltd. providing 21 mg of withanolide glycosides per day—or a placebo for eight weeks. Treatments were then crossed over for an additional eight weeks.

Improvements in fatigue, vigor, and sexual as well as psychological well-being were reported over the supplementation period in the ashwagandha group; however, the difference in these changes versus placebo did not reach statistical significance.

Ashwagandha supplementation led to a statistically significant increase in testosterone versus placebo (14.7%) as well as in salivary levels of DHEA sulfate (18%). Low testosterone levels occur in those with mood disorders, obesity, cardiovascular disease, and type 2 diabetes and are associated with reduced quality of life, while some studies indicate that DHEA levels are a predictor of longevity in men. Higher DHEA levels are also associated with enhanced mood and reduced fatigue. Thus, ashwagandha’s beneficial effects on these hormones may lead to improvements in quality of life in aging men.

Improved Cognitive Health
An additional traditional use of ashwagandha is for supporting memory and cognitive function. To explore whether ashwagandha supplementation can improve cognitive health in individuals with mild cognitive impairment, Dnyanraj Choudhary from the Indian Red Cross Society (Pune, India) led a double-blind, placebo-controlled study in which 50 adults were asked to supplement with 300 mg of an ashwagandha root extract twice daily—KSM-66 from Ixoreal Biomed—or a placebo for eight weeks.

A battery of cognitive tests was used to assess changes in cognitive function, including memory, executive function, and attention. These measures included the Wechsler Memory Scale III, a validated tool assessing several types of memory; the Wisconsin Card Sorting Test and the Eriksen Flanker Task to assess executive function; and the Trail Making Test and Mackworth Clock Test to assess attention and information processing speed.

At the end of the study, significant improvements were evident with ashwagandha supplementation in immediate and general memory, executive function, sustained attention, and information processing speed. These results indicate that ashwagandha may be an effective intervention for enhancing cognitive function in adults with mild cognitive impairment.

Irfan Qureshi, ND, is vice president, product development and quality assurance, for Healthy Directions.

References
The 1990s were an important decade of innovation that saw a remarkable medical discovery about the human body called the endocannabinoid system (ECS). The ECS can be described as an intricate physiological system utilizing cannabinoids produced in the body (endocannabinoids) and the receptors they attach to. At the helm of this unearthing was the work of Raphael Mechoulam, PhD, of The Hebrew University of Jerusalem and several colleagues at the National Institute of Mental Health in the U.S. Due to politics and the stigma attached to cannabis and cannabinoids, ECS research was previously buried, and many of the findings about the plant’s medicinal value was diverted outside of the U.S.—a true medical travesty. Fortunately, research and education is slowly disassembling this unjustified besmirchment, and we are just beginning to appreciate the ECS and its role in health and disease, even as marketplace obstacles abound for hemp cannabinoids.

The ECS refers to a complex network of receptors found on all cells that accept cannabinoids (CB1 and CB2), as well as the endogenous cannabinoids we produce in the body (such as the endocannabinoids anandamide and 2-AG) and the enzymes involved with their production and degradation—what some call our “endocannabidiome.” In addition to anandamide and 2-AG, other lipid-based molecules have also been classified as endocannabinoids due to their effects on cannabinoid...
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Acting as the conductor of our body’s physiological symphony, the ECS’s signaling pathways are in constant communication with every organ system and globally act as the modulator of activity to maintain balance and well-being (homeostasis). At the organ level, once endocannabinoids attach to our receptors, they influence important regulatory mechanisms that govern major physiological processes, including stress, anxiety, pain, inflammation, insomnia, ocular health, bone repair, neurological well-being, and cancer, to name a few. Essentially, the ECS is implicated in the adaptogenic control of the most vital processes, thus creating stability in the body.

There are times when we do not produce enough endocannabinoids and must rely on dietary cannabinoids (phytocannabinoids) to help support the ECS. Hemp is the richest source of these phytocannabinoids. And while phytocannabinoids hold great promise for health and as a viable market, the market currently faces numerous challenges that have been difficult to surmount.

**The Value of Phytocannabinoids**

Nutritional and botanical medicine is barely more than a century old. As we grasp the incredible roles the ECS plays in keeping us in balance and its involvement in disease prevention and treatment, we will learn to appreciate how hemp-derived phytocannabinoids will play pivotal roles in nutrition and medicine. This is further supported by the enormous amount of research published on the manipulation or support of the ECS in neurological, inflammatory, cardiovascular, and ocular conditions; bone disorders; as well as cancer. There is overwhelming evidence that our endocannabinoid system is a target of choice for many diseases that may be suitably treated with hemp phytocannabinoids.

While the ECS and phytocannabinoids have been studied in detail, the clinical value in many disease models requires continued research and clinical trials. The hemp plant (*Cannabis sativa L.*) contains over a hundred different phytocannabinoids which collectively provide a full spectrum of supportive activity. Research demonstrates that this shared participation among the phytocannabinoids is responsible for optimal dose ranges and better clinical outcomes when compared to singling out any particular one cannabinoid such as cannabidiol (CBD).

While CBD has recently grabbed the spotlight primarily due to GW Pharmaceuticals’ CBD-based FDA-approved drug, its effects can be greatly enhanced by support from the rest of the phytocannabinoid family. This has been a major tenet of botanical medicine and was beautifully described as the ”entourage effect” by Dr. Ethan Russo.

Dr. Mechoulam, mentioned at the beginning of this article, also said it best when he stated that, “Biochemically active natural products are in many instances accompanied by chemically related though biologically inactive constituents. Very seldom is the biological activity of the active constituent assayed together with inactive ‘entourage’ compounds. Investigations of the effect of the active component in the presence of its ‘entourage’ compounds may lead to results that differ from those observed with the active component only.”

It’s important to underscore the intricate interplay of CBD and other important phytocannabinoids with various receptors in the body. While CBD has tremendous medical benefits, it cannot support the entire ECS on its own—period.

**The Status of Dietary Phytocannabinoids**

Unfortunately, despite the value of phytocannabinoids to health that research is unveiling, phytocannabinoids and their fate in the marketplace still face some major obstacles.

From a legal standpoint, the question remains whether CBD is legal. Federal and state laws continue to be at odds with each other, and the situation continues to be confusing for the marketplace. Citing the 1994 Dietary Supplement Health and Education Act (DSHEA) governing dietary supplements in the U.S., FDA’s position on not allowing specific phytocannabinoids as dietary supplements has not changed. DSHEA clearly states that if a substance was not in commerce prior to 1994, it cannot be grandfathered in as a dietary supplement: strike one against CBD. The law also states that if a natural substance becomes an FDA-approved drug before it is sold in the natural marketplace, it can no longer be sold as a dietary supplement: strike two against CBD in light of GW Pharmaceuticals’ FDA-approved CBD drug. It seems that companies either are ignoring or don’t understand these federal regulations. Unless FDA is going to change or dismantle DSHEA, the language in DSHEA does not support qualifying or qualifying CBD on a label as a dietary supplement.

The more important class of naturally occurring phytocannabinoids in hemp and their effects on the ECS now find themselves embroiled in this unfortunate situation. Cannabinoid companies all anxiously await FDA regulations that they hope are soon to follow and may change the market picture for phytocannabinoid products.

To make matters worse for phytocannabinoids, some companies are illegally labeling products and passing off marijuana hybrids as industrial hemp. How FDA, the U.S. Drug Enforcement Administration (DEA), and the USDA deal with these ”Frankenstein” strains remains to be seen. Prior to the Farm Bill’s passage in 2018, farming of hemp was banned in the U.S. for over 80 years, and no domestic-sourced hemp has been available. These new hybrid strains are not true industrial hemp and have no history of human consumption. This is in direct opposition to true industrial hemp strains that do have decades of human consumption outside of the U.S. and are available for growers. We have yet to see how government agencies view this issue.

Another problem for phytocannabinoids stems from the introduction of CBD isolate to the marketplace. In our opinion, if you concentrate a substance in a plant to 70%, 80%,
or 90%, the isolated substance is viewed very differently from the plant it came from. Such is the case with CBD isolates. Considering the fact that CBD isolates were not on the market prior to 1994 as either a food or dietary supplement and are in an FDA-approved drug, FDA would likely consider these in violation of federal law. It’s also unfortunate to see companies touting 70%-80%-90%-plus CBD oils as full-spectrum oils. Not only would those concentrations place such products being close to drug status, how is it that companies try to convince the market that concentrations that high come from a true botanical spectrum oil? Buyer beware.

Clouding the Value of Phytocannabinoids and the ECS

To think that a single magic-bullet component like CBD is responsible for all of the clinical benefits of hemp’s 100-plus phytocannabinoids is sorely shortsighted. This is no different in the many botanicals on the marketplace—there are many ginsenosides in ginseng, many curcuminoids in curcumin, etc. What case can anyone make in thinking that the clinical benefits of hemp are due to only one phytocannabinoid when there are close to 100 cannabinoids known to exist in the plant? What case can anyone make thinking that CBD can fully support the ECS on its own? Undoubtedly, CBD and the rest of the family of phytocannabinoids naturally found in hemp represent some of the most important, clinically relevant phytoneutrins that have come to the marketplace since the market’s inception.

With more research and clinical trials, our understanding about the role of the ECS and beneficial hemp phytocannabinoids play in health and disease is paramount. The fate and evolution of this sector will hopefully transcend market and regulatory battles. We must embrace the bigger picture: that phytocannabinoids and the health of our ECS will play an increasingly important role in the health landscape to come.

Carl Germano, CNS, CDN, is a NY Board Certified Clinical Nutritionist and vice president of Verdant Oasis, a developer of exclusive, high-quality hemp products through vertically integrated operations, from seed to finished products. He holds a master’s degree in clinical nutrition from New York University and has over 37 years of experience in product development and education for several of the largest vitamin supplement companies in the trade, including Solgar, Country Life, Bluebonnet, Ajinomoto, and others. In addition, he has been instrumental in bringing cutting-edge formulas and phytocannabinoid ingredients to a variety of markets, including dietary supplements, medical foods, and functional beverages. He is a prolific author with several bestselling trade books including The Misled Athlete, Nature’s Pain Killers, The Osteoporosis Solution, The Brain Wellness Plan, and his most recent, Road to Ananda: The Simple Guide to the Endocannabinoid System, Phytocannabinoids & Your Health.
ADULTERATION Quiz

Test your knowledge, based on the article on page 4.
Answer Key online at http://bit.ly/adulterants

1. Which botanical extract, often used for men’s health, is at risk of being adulterated with cheaper plant oils such as palm, canola, and coconut oil?

2. Which botanical extract is at risk of being adulterated with peanut skin, posing an allergen risk to potential consumers?

3. Due to its difficult supply chain, this fungi ingredient would benefit from high-quality and cost-effective laboratory analysis to ensure identity.

4. Because of this ingredient’s characteristic color, unscrupulous suppliers will adulterate its supply with synthetic dyes.

5. Due to its similarity to another herb called germander, this ingredient is at risk of being misidentified in the wild or deliberately misrepresented. This is particularly dangerous because consumption of germander can be toxic to the liver.
We are excited to announce our fifth Maggie Award from the Western Publishing Association for our article "Scaling Up Stevia."

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We are excited to announce our fifth Maggie Award from the Western Publishing Association for our article “Scaling Up Stevia.” Thank you to all our readers for making this award possible!

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