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*These statements have not been evaluated by the FDA*
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As GNC Goes, So Goes Industry?

Walking the halls of this year’s Natural Products Expo West trade show in Anaheim, CA, it occurred to me that it’s been just over a year since the dietary supplements industry first found out it was being investigated by New York Attorney General Eric Schneiderman. A lot has happened since then.

Lawmakers, attorneys general, and media continue to raise questions about supplement safety and quality. Industryfolk, meanwhile, are having their own discussions, both to acknowledge the fact that there are indeed certain bad players in industry but also to suggest how responsible industry members can strengthen their own QA/QC programs and show that the industry is doing more to address public concern. Based on my conversations at the show, it was apparent that many companies are placing emphasis on increased quality assurance.

But that may not be enough to satisfy naysayers. While self-driven quality measures are necessary, notable, and commendable, consumers and critics most outspoken against the industry want something bigger. Short of changing the laws governing supplements, critics want to see signs that the industry as a whole is unifying to make change.

Thus, in January, we saw the first signs of such movement when the Council for Responsible Nutrition (CRN) announced that the association’s membership will now be required to submit label information to the U.S. government’s Dietary Supplement Label Database. And now, GNC, the dietary supplement industry’s Goliath, has taken a dramatic step to change its own quality-control structure.

In February at the United Natural Products Alliance’s Raw Materials & Supply Chain Summit, GNC announced a new, sweeping set of GMP standards that are now compulsory for every single one of the raw-material suppliers the company does business with. Why is this such a big deal? One of the biggest topics of conversation in supplement quality is the fact that ingredient suppliers are not directly subject to FDA’s Good Manufacturing Practices regulations for dietary supplements (21 CFR 111) that supplement manufacturers face. So GNC has taken it upon itself to institute its own set of consistent, standardized GMP requirements for its suppliers, which will superecede how suppliers, individually, go about quality assurance. “We have always held ourselves and our vendors to the highest standards, and those vendors have sometimes interpreted those highest standards differently,” says GNC’s CEO Mike Archbold.

To create the new, “harmonized” best practices, the company reached internationally and across the industry for input. Archbold says, It took inspiration from more than 10 international guidelines, including those of the American Herbal Products Association’s (AHPA) Good Agricultural Collection Practices, CRN’s Standardized Information on Dietary Ingredients (SIDI) protocol, the World Health Organization, the European Medicines Agency, as well as input from former FDA auditors and GNC’s own suppliers and processors. As a result, GNC’s GMPs include manufacturing rules from 21 CFR 111…and then some. GNC’s standards reach as far back in the process to cultivation and all the way forward to handling and packaging. “This set of guidelines really is the culmination of all that work from all of those participants,” Archbold says. “The intent was to make sure that we were not missing anything in this process.”

GNC’s hope is that the rest of industry will follow suit in adopting these GMPs. To encourage this, after the company adopted the guidelines, it turned the document over to AHPA. Archbold says AHPA will act as the document’s steward for the rest of the industry, maintaining the document as it is further edited—something Archbold says he fully expects and hopes will happen as industry science, technology, and processes advance.

Archbold says GNC has reason to expect that the “major industry participants” will adopt these supplier GMPs soon based on conversations the company has had. “We’ve actually gathered everyone in the industry, from our competitive retailers to the mass-market players, raw-material providers, multilevel marketers, practitioners, even the pharmaceutical companies,” Archbold says. “So everyone has been involved in the process to make sure that all the voices are being heard.” He says that even competitors were receptive to the initiative. “We’re making sure these aren’t just GNC’s standards…because this needs to be something that’s owned by the industry,” he adds.

GNC, however, will get credit as the first company that took the initiative to bring about this change. Not long after the company announced the plan, it made the guidelines mandatory for its suppliers, even as it expects future revisions. “We felt that this was so important that the industry needed to embrace it, and embrace it quickly,” Archbold says.

The dietary supplements industry may not have a thousand miles to go toward building—or rebuilding—public confidence in the market, but a single step towards broadscale, uniform change, like this industry-wide GMP initiative, is certainly moving in the right direction.

Jennifer Grebow
Editor-in-Chief
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Can Enzymes, Probiotics, and Prebiotics Work Together in One Product?

Call it the digestive-health trifecta, the enzymatic-probiotic smash, or just the union of three booming categories. No matter the name, there appears to be a growing interest in combining enzymes, probiotics, and prebiotics in a single product. And that has enzyme firms investing in new research and exploring the formulating challenges of these pairings.

At March's Natural Products Expo West trade show, enzymes supplement company Enzymedica (Venice, FL) spoke with *Nutritional Outlook* about the potential for enzymes and probiotics to work together to enhance gut flora. Enzymedica has offered probiotic/enzyme combination products for several years, including its Digest Gold Plus Probiotics and Women's 50+ Enzyme Nutrition multivitamin, but interest in these kinds of pairings has become especially pronounced lately, says Stephanie Helton, marketing manager, Enzymedica.

"A lot of probiotic companies have started looking into ways to have enzymes in their formulas or to bring out their own enzyme lines," says Helton.

Enzymes supplier Deerland Enzymes (Kennewick, GA) has also seen more of its customers interested in combining probiotics, enzymes, and even prebiotics in a single product.

"We're going to invest a significant amount of money now to do clinical [studies] on the combinations of the products and various combinations, because of not only what we're realizing in sales, but just the feedback we're getting from the market is nothing short of stellar from this," says Scott Ravech, CEO for Deerland Enzymes.

Yet, despite the possible advantages of combining enzymes and probiotics, there has also been some resistance to the marriage of these two digestive-health heavyweights, says David Barton, director of education for Enzymedica. When Enzymedica first launched probiotic/enzyme combination products more than six years ago, Barton says some enzyme companies were opposed to the marriage and "put out statements and arguments saying enzymes destroy probiotics." He sees this as a skewed portrayal of the facts.

"What they're overlooking is probiotics make enzymes," says Barton. "Enzymes don't haphazardly destroy probiotics; otherwise, probiotics couldn't live at all. They would kill themselves. What their statement is based on is what happens in a petri dish. But in the gut, where [probiotics are] colonizing and they're having their families and they're in the right environment, they're making tens of thousands enzymes, with no problem at all."

Deerland Enzymes' Ravech agrees that combining enzymes and probiotics can lend a "very complementary" effect.

"While you get the enzymes that are driving the nutritional uptake of the food, you get the probiotics that are giving you good digestive balance and flora," says Ravech. "So I think they're just kind of a hand-in-glove fit."

Beyond just probiotics and enzymes, Deerland Enzymes is also adding its PreforPro prebiotic to these combinations to further enhance the health benefits. Of course, the product price point increases with the addition of different ingredient types, and Ravech explains it can be a balancing act to find the right potency. He describes Deerland Enzymes' thinking as a "good, better, best" approach, where enzymes alone are good, enzymes plus probiotics are better, and enzymes, probiotics, and prebiotics together are best.

"You try to find that point for which someone who can truly benefit at just the broad-spectrum digestive [enzyme] blends can just get that," explains Ravech. "Somebody who needs something a little bit more that might be inclusive of a probiotic will get to the next price point, but also to the next efficacy point. And then someone who wants the prebiotic, the probiotic, and the enzymes, where maybe they have things that are a little bit more severe in their symptomology, can take advantage of that as well."

As far as existing research into the health benefits of these pairings, Ravech says it's been relatively limited but promising so far. Deerland Enzymes is currently working on a large clinical study of the various combinations of probiotics, prebiotics, and enzymes that will continue into 2017, Ravech says.

"We're making this investment because so much more of our business is including probiotics in the mix," explains Ravech.

Another factor to consider is the types of products that are appropriate for both probiotics and enzymes. Although some spore-forming probiotics, such as Deerland Enzymes’ DE111 strain of *Bacillus subtilis*, can be heated and boiled for food applications, enzymes and non-spore probiotics don't offer the same flexibility.

"Your biggest challenge as you might expect in both cases, especially with non-spore probiotics [and enzymes], is you want to do it in a dry environment," says Ravech. "You want to make sure that all the raw materials are being looked at for their water activity, because that's what activates the enzymes is the moisture, and so if you don't have a dry state that it's going into then you could potentially start to lose potency."

For that reason, ready-to-drink (RTD) beverages are currently out of reach for enzymes. Cold-pressed bars might be a possibility, although capsules still remain the most popular delivery system for enzymes, says Ravech.

But aside from the characteristic limitations of probiotics and enzymes, Ravech explains that it's not usually a challenge combining the two in one product.

"We don't see too much negative interaction," Ravech says.
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Federal GMO-Labeling Act Defeated in Senate

Supporters of mandatory GMO labeling celebrated in March as the U.S. Senate rejected controversial legislation that would have preempted state laws that mandate GMO labeling.

The Senate legislation, which was counterpart to the Safe and Accurate Food Labeling Act (SAFE; H.R. 1599) that passed in the House of Representatives last July, was dubbed the “Deny Americans the Right to Know” (DARK) Act by opponents. It failed to reach the 60-vote mark necessary to pass the Senate on March 16 after passing the Senate Agriculture Committee by a 14–6 vote on March 1.

Rather than institute mandatory GMO labeling, as a number of consumer groups have called for, the legislation would have established a voluntary, nationwide non-GMO certification program led by USDA. It would also preempt any past or future state-mandated GMO-labeling laws, including the Vermont mandatory GMO-labeling law set to go into effect this July.

Supporters of the legislation included food industry associations like the Grocery Manufacturers Association, the Corn Refiners Association, and the National Corn Growers Association, as well as companies such as DuPont and Monsanto. Several of these groups expressed disappointment with the Senate’s vote and the possibility of “patchwork” state labeling laws.

“But opponents of the act, such as the Organic Trade Association, the Center for Food Safety, and the Environmental Working Group, were quick to applaud the vote’s outcome.

“The defeat of the DARK Act is a major victory for the food movement and America’s right to know,” said Andrew Kimbrell, executive director of the Center for Food Safety. “It also is an important victory for democracy over the attempt of corporate interests to...
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Another controversial topic in the defeated legislation was the requirement that FDA define and regulate use of the term natural, a problematic grey area that has been the source of numerous lawsuits due to its current obscurity. But with the legislation fizzling in the Senate, it looks like the murkiness surrounding natural will remain for at least the near future.

The act failed to reach closure in the Senate by a vote of 49–48. Senator Pat Roberts (R-KS) had introduced the bill.

Coke Cleared by Jury in POM Wonderful Advertising Lawsuit

More than seven years after the lawsuit was first filed, a Los Angeles jury ruled on March 21 that Coca-Cola does not owe POM Wonderful $77.5 million for allegedly misleading advertising of its Minute Maid Pomegranate Blueberry 100% Fruit Juice Blend.

POM Wonderful first sued Coca-Cola in 2008 under the Lanham Act, a federal statute that gives companies grounds to sue competitors over false advertising that creates unfair competition. POM claimed that Coke’s product (discontinued in May 2014) misrepresented the amount of actual pomegranate and blueberry juice present in the product, when instead most of the product’s blend was made from apple and grape juice. An expert for POM has since claimed the company suffered lost-profit damages of up to $77.5 million as a result of Coke’s misleading labeling of its product.

In its defense, Coke insisted its label was in compliance with FDA’s Food Drug and Cosmetic (FD&C) Act because the Nutrition Labeling and Education Act allows these kinds of juice blends to be named after the juices providing the product’s characteristic flavor. The act does not require a company name all of the juices in its beverages or list the proportions, Coke also pointed out.

The Ninth Circuit Court of Appeals and the California federal judge sided with Coke, but the case eventually made its way to the Supreme Court, which ruled in 2014 that POM can sue Coke even if the product was compliant with FDA regulations. In other words, compliance with FDA’s FD&C Act does not provide safe harbor against Lanham Act lawsuits, according to the ruling.

But following that long and potentially precedent-setting saga, as well as a six-day trial in Los Angeles, on March 21 the jury sided with Coke after deliberating for less than a day.
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Nutritional Solutions for BURNOUT

Why burnout is the next big opportunity for dietary supplements

By Mitch Skop, Pharmachem Laboratories Inc.

“I’m burned out.” It’s an expression we hear more often these days by those feeling so stressed by the daily grind that they suffer from brain fog, fatigue, loss of initiative, poor sleep, and low mood. But burnout is a real condition, characterized most often by workplace stress and subsequently compounded by other life responsibilities.

The medical community first used the term burnout to refer to physicians whose demanding, long-term shifts created dramatic, acute stress. Any worker, however, can suffer from this condition. The American Institute of Stress defines burnout as “a disabling reaction to stress on the job.” The institute also estimates that job stress costs U.S. industry $300 billion annually, as measured by absenteeism, decreased productivity, employee turnover, and direct medical, legal, and insurance fees. The institute also reports that nearly half of all American workers suffer from symptoms of burnout.¹

Consider, also, the following statistics from the National Institute for Occupational Safety and Health, part of the Centers for Disease Control and Prevention²:

- One-fourth of employees view their jobs as the number-one stressor in their lives. (Source: Northwestern National Life survey)
- Three-fourths of employees believe today’s workers have more on-the-job stress than employees a generation ago. (Source: Princeton Survey Research Associates)
- Work-related problems are more strongly associated with health complaints than are any other life stressor—more so than even financial problems or family problems. (Source: St. Paul Fire and Marine Insurance Co.)

Health Impact

According to the American Institute of Stress, when burnout occurs, it quickly incurs symptoms like fatigue, irritability, sleeplessness, inability to concentrate and focus, forgetfulness, and anxiety/panic attacks. Additionally, stressed individuals may either lose weight due to loss of appetite or gain weight due to comfort eating. Still other symptoms include involuntary teeth grinding/clenching, leading to jaw pain and headaches, and/or increased alcohol consumption or drug use.

Stressed out? Can a dietary supplement help?

Psychologically, the burnout sufferer will also become depressed, feel isolated, lose interest in intimacy and motivation, and experience feelings of uselessness and hopelessness. All this amounts to noticeable loss of productivity and increased absenteeism.

The American Institute of Stress estimates that job stress costs U.S. industry $300 billion annually, as measured by absenteeism, decreased productivity, etc.
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Although dietary supplements for stress support are a long-standing category, formulated more for acute conditions, as a subcategory of stress support, burnout presents numerous opportunities to offer consumers relief.

One combination supplement, a caseozepine (milk casein) blend called Target 1, was clinically researched for its effects on individuals suffering from burnout. In addition to milk casein ingredient Lactium®, a branded ingredient from Pharmachem Laboratories, the Target 1 blend includes Extramel, a proprietary, antioxidant-rich melon extract developed by French supplier Bionov and distributed by Seppic SA (France); taurine, an ingredient believed to have energizing properties; and the adaptogenic Siberian ginseng plant (Eleutherococcus senticosus), which may increase the body’s resistance to stress, said researchers.

The double-blind, randomized, placebo-controlled study took place at the University of Bordeaux (France), where 44 participants aged 18–65 suffering from some degree of burnout were given two 640-mg Target 1 tablets to take twice daily for 12 weeks. A comparable group of 41 participants received a placebo. All participants underwent verbal interviews on their life and mental state at the beginning and conclusion of the study.

Although dietary supplements for stress support are a long-standing category, the burnout subcategory presents numerous opportunities to offer consumers relief.

At the outset of the study, all participants in the placebo and the treatment groups reported feeling at least "present" burnout exposure as evaluated on the Burnout Measure Scale (BMS-10), which rates 10 parameters such as feeling tired, disappointed with people, hopeless, trapped, helpless, depressed, physically weak, worthless/like a failure, fed up, or having difficulty sleeping. The majority of participants reported “high” burnout levels, with a few reporting “very high” burnout.

By the end of the 12 weeks, 14 of the placebo participants still had a “high” level of burnout compared with 26 at the beginning of the trial. By comparison, at the end of the 12 weeks, only two participants taking Target 1 reported a “high” level of burnout compared with 33 at the trial’s outset. The supplement group also presented greater improvement on the Maslach’s Burnout Inventory Scale.
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Formulating powerful supplements that help the body withstand and decrease physiological symptoms of burnout should go a long way in helping those specific consumers recover naturally, safely, and gently.

Human Service Survey for professional fatigue than the placebo group.

“The dietary supplement Target 1, when used in association with verbal expression, might represent a primary tool in the care of people affected by burnout in the future,” the researchers concluded.

**Individual Solutions**

It should also be noted that, individually, these ingredients can hold their own for relieving effects of stress:

**Lactium**: Lactium is a patented hydrolysate of milk proteins that contain a bioactive peptide with relaxing properties that regulate stress naturally. Lactium has been the subject of several other research studies.

A double-blind, crossover study was conducted over a 30-day period on 63 female volunteers showing at least one stress symptom. Those subjects receiving Lactium (dosage 150 mg/day) had a significantly greater improvement in stress symptoms versus placebo in the following areas: digestive, intellectual, social, cardiovascular, and emotional. The effect of Lactium was greater in subjects with a high intensity score for a major symptom at the beginning of the study.

Another placebo-controlled study conducted on 42 healthy men put through stressful, controlled situations showed that plasma cortisol concentrations significantly decreased in the Lactium group by 20.69%, whereas concentrations only decreased by 3.39% in the placebo group. The authors concluded that Lactium “displays an anti-stress activity in human subjects.”

**Taurine**: This amino acid is used to create the major inhibitory neurotransmitter gamma amino butyric acid (GABA), a deficiency of which can lead to overstimulation and the feeling of being overwhelmed. When GABA levels are low, as is typical in high-stress situations, this can result in anxiety and related issues. Much of the available GABA is unable to effectively cross the blood-brain barrier, yet taurine, a building block of GABA, can. One mouse study concluded that supplementation of taurine activated GABA receptors, leading to the minimization of excitability or nervous tension.

**Extramel (superoxide dismutase)**: One randomized, double-blind, placebo-controlled clinical study evaluated the effect of this proprietary melon juice concentrate rich in superoxide dismutase on the signs and symptoms of stress and fatigue in 70 healthy volunteers aged 30–55 years who expressed feeling daily stress and fatigue. For four weeks, these volunteers took either 10 mg Extramel (140 IU SOD) daily or a placebo. Stress and fatigue were measured using four observational psychometric scales: FARD, PSS-14, SF-12, and Epworth scale. The authors concluded that the supplement significantly improved signs and symptoms of stress and fatigue linked to performance, physical (pain, sleep troubles), cognitive (low concentration, weariness, sleep troubles), or behavioral (irritability, difficulty of contact) activity compared to the placebo.

**Eleutherococcus senticosus**: Scientific reviews of this adaptogenic plant, also known as eleuthero or Siberian ginseng, generally ascribe its abilities to alleviate fatigue, help increase energy, and support immune function.

**Lots of Promise**

Of course, other supplement ingredients exist that have been shown to provide a sense of calm, increased energy, accelerated sleep onset, and the ability to “take the edge off.” Formulating powerful supplements that help the body withstand and decrease physiological symptoms of burnout should go a long way in helping those specific consumers recover not only naturally, but safely and gently.

**References**


*Mitch Skop is senior director of product development for Pharmachem Laboratories Inc. (Kearny, NJ). His experience includes implementing and evaluating research for promising ingredients; working with formulators to develop safe, efficacious ingredients; advising customers on various delivery forms and applications; and supervising successful product launches, from securing proper certifications to branding.*
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Which healthy trends are dominating in nutrition bars?

**BY INNOVA MARKET INSIGHTS**

There are signs that dynamic growth in nutrition bar launches in recent years may now be stabilizing, with the number of introductions falling back slightly in 2015. Even so, the number of global launches Innova Market Insights tracked in the 12 months ending October 2015 was still twice as high as the level of launch activity seen five years ago. The bottom line? Nutrition bars are still very popular, and their healthy image persists, despite some adverse publicity about the sugar content of some products. Above all, the “Big Four” still command nutrition bars: “free from,” clean labels, protein, and fiber.

Europe accounts for the highest number of bar launches overall (over 40% of the global total), but this is mainly because of the large number of countries involved. Adjusting for that, the United States dominates the market overall and accounts for over a quarter of global introductions; moreover, U.S. bar companies tend to lead in terms of product development, even in a relatively mature and complex market. The bar category today encompasses a wide range of products, including granola or muesli bars and breakfast bars, as well as nutrition, energy, and performance bars.

Despite concerns over how healthy some of the products actually are, consumers are still strongly interested in the health benefits bars have to offer. Well over 80% of global cereal bar introductions recorded by Innova Market Insights in the 12 months ending October 2015 used a health positioning of some kind, rising to 92% in the United States. Just like the rest of the snack and food/drink market, clean-labelling concerns are a key focus, with over half of U.S. cereal bar launches using one or more claims relating to naturalness, freedom from additives/preservatives, and organic certification. Examples include General Mills’ two new Real Good Bars, part of its Food Should Taste Good range, made with nuts, seeds, fruit pieces, and spices, with no artificial ingredients or GMOs.

In the United States particularly, growing use of non-GMO certifications reflects rising concerns among consumers and is particularly strong in the cereals market, including cereal bars. Up to 46% of U.S. launches use GMO-free claims—over twice the global level.

Other emerging trends include the arrival of popped products in the savory bars sector, such as KIND Healthy Snacks’ Popped products, introduced last year, featuring six supergrains: amaranth, buckwheat, millet, oats, quinoa, and sorghum.

At this year’s Natural Products Expo West trade show, KIND introduced extensions to its Nuts & Spices and Fruit & Nut lines, including Dark Chocolate Almond & Mint. “Available this spring, each of the new bars is made with whole nuts as the first ingredient,” the company announced.

Other emerging trends include the arrival of popped products in the savory bars sector, such as KIND Healthy Snacks’ Popped products, introduced last year, featuring six supergrains: amaranth, buckwheat, millet, oats, quinoa, and sorghum.

The cereal bars market seems set for further growth, with health and nutrition to remain a focus alongside other factors like a premium and indulgent image and unusual flavors and ingredients. Marketers will continue to find possibilities in the use of new ingredients and formats and targeting of new usage occasions.

**Innova Market Insights** is your source for new-product data. The Innova Database (www.innovadatabase.com) is the product of choice for the whole product-development team, offering excellent product pictures, search possibilities, and analysis. See what food manufacturers are doing around the world, track trends, competitors, ingredients, and flavors. In today’s fast-moving environment, this is a resource you cannot afford to be without.
New Study Shows Cran-Max® Comparable and Effective for Urinary Tract Health

Cran-Max®: Maximum protection, minimum dosage.

Published research in the *Journal of Antimicrobial Chemotherapy* has shown that Cran-Max® was comparable and effective in maintaining urinary tract health in older women.*

Cran-Max® is the first dosage confirmed (500 mg) cranberry product delivering relief with just one capsule per day. In another published study, Cran-Max® was nearly twice as effective as cranberry extract containing 36 mg of proanthocyanidins (PAC).”

Cran-Max® has more antioxidants than a serving of cranberry juice—without the sugar. Cran-Max® is the only cranberry concentrate made using the patented Bio-Shield® technology to deliver cranberry PAC.

For more information on Cran-Max® and the entire Berry-Max® line of concentrates, visit www.pnibrands.com.

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** Bohbot J. *The Gynaecologist’s and Obstetrician’s Journal* 2007. Special Issue from the CCD Laboratory
If there’s one thing both critics and advocates of the dietary supplements industry can agree on, it’s the urgent threat posed by ingredient adulteration. The best testing methods to deal with that threat, however, remain up for debate.

New York Attorney General (NY AG) Eric T. Schneiderman drove a renewed public focus on the issue last year when he launched an investigation into makers and retailers of several herbal supplements, including devil’s claw, echinacea, and ginseng. His office alleged the supplement products were adulterated based on DNA barcode testing—a relatively new testing method that many industry experts say Schneiderman applied improperly.

The latest strategies for catching botanical adulteration combine new and old testing methods.

BY MICHAEL CRANE, ASSOCIATE EDITOR
DNA testing of botanical ingredients is “not yet the infallible hero it is in crime shows,” says Elan Sudberg.

But even if Schneiderman’s methodology was flawed, botanical adulteration remains a prevalent menace to consumer health and the integrity of the industry as a whole. The challenge facing ingredient suppliers and manufacturers today is deciding on the best combination of testing methods from a growing toolkit, including DNA testing.

“The newest kid on the equipment block is DNA analysis,” says Elan Sudberg, CEO of Alkemist Labs (Costa Mesa, CA). “However, this shiny new ball is not yet the infallible hero it is in crime shows.”

For instance, DNA barcoding has the advantage of being able to detect very small amounts of adulterants, but it has trouble discerning which part of the plant is present, explains Sudberg. For that reason, it’s best to combine DNA testing with other, “time-tested methods of analysis,” such as microscopy and high-performance thin-layer chromatography (HPTLC), he says. And when it comes to botanical ingredients, there’s no one-size-fits-all approach for detecting adulteration.

Here’s a look at some of the latest strategies for preventing adulteration, including new applications for DNA testing, as well as established tests being applied in innovative new ways.

New Tests for Cranberry

One ingredient coming under the scope of new adulteration testing technologies is cranberry. At the recent Natural Products Expo West trade show, RS Specialty Ingredients (Wellington, FL) unveiled its new Cranberry Quality Assurance (CQA) program, which is designed to help suppliers ensure their cranberry is both pure and efficacious.

Stephen Lukawski, vice president of RS Specialty Ingredients, explains that much of the cranberry adulteration he has seen comes from Asia, with adulterants like peanut skin, plum, grape skin, black bean, and black rice being used to boost the proanthocyanidin (PAC) content of the raw cranberry material. New testing methods included in CQA may make it easier for suppliers and manufacturers to catch these deceptive practices.

The CQA is based on testing procedures implemented by cranberry supplier Fruit d’Or (Notre-Dame-de-Lourdes, QC, Canada) and is now available for any cranberry supplier to adopt, says Lukawski, who is also director of global business development, sales and marketing, Fruit d’Or.

The program includes polyphenol-fingerprinting analysis, standardization of PAC biomarkers, anti-adhesion testing to establish efficacy, Matrix Assisted Laser Desorption Ionization Time-of-Flight (MALDI-TOF) mass spectrometry, and DNA sequential barcode testing.

But while DNA testing is one pillar of the program, Lukawski acknowledges its drawbacks—such as an inability to detect DNA in finished products and a failure to quantify the PAC content of the cranberry.

“DNA structure is a complex thing and it can degrade very quickly depending on the processing and the handling of the material,” says Lukawski. DNA testing is so sensitive, Lukawski adds, it can even pick up dust particles from milling machines that aren’t cleaned properly.

“So we have to use another tool in the box to really support the DNA testing, and that is the MALDI-TOF tool, the mass spectrometry equipment, because it will quantify,” says Lukawski. Fruit d’Or announced it would begin using MALDI-TOF last July to authenticate its cranberry PACs, which can ensure the PACs actually come from authentic cranberry, rather than an adulterant. The new method was developed by Christian Krueger, CEO of Complete Phytochemical Solutions LLC (Cambridge, WI).

Although some cranberry suppliers use HPTLC to detect adulteration, according to Lukawski it is not a sufficiently thorough test for the CQA. He says MALDI-TOF is a more accurate method, and HPTLC is not able to quantify foreign contaminants the way MALDI-TOF can.

The new supplier testing program is appropriate for raw cranberry materials, juice concentrate used to make cranberry juice powder, spray-dried cranberry juice powder, and even finished cranberry powder that has been encapsulated, although complex formulations with several ingredients and excipients can make DNA testing more complicated.

If the CQA proves successful at preventing cranberry adulteration, Lukawski hopes it may become a template for the testing of other botanical ingredients.

Better Strategies to Fight Ginkgo Adulteration

Researchers have also recently proposed new methods to detect adulteration of Ginkgo biloba leaf extract, which remains a significant target for adulteration, according to Alkemist Labs.

“Ginkgo leaf tops our list these days, as it’s commonly adulterated with the fruit or flowers of Sophora japonica, which is easily distinguished by HPTLC,” says Alkemist’s Sudberg.
As reported in the December issue of HerbalGram from the American Botanical Council (ABC; Austin, TX), two recent studies suggest a new method to detect adulteration of ginkgo extract in commercial dietary supplement products.

A 2014 study published in Phytomedicine explored the possibility that standard testing methods established by the United States Pharmacopeia–National Formulary (USP-NF), the British Pharmacopoeia, and the European Pharmacopoeia are "not capable of detecting adulteration of ginkgo extract with free flavonol aglycones." Researchers analyzed eight ginkgo leaf retail products with high-performance liquid chromatography (HPLC) after hydrolysis, as is required by USP-NF, and before hydrolysis, which is not required by USP-NF. They discovered compelling evidence that three of the products were adulterated with flavonol aglycones, including genistein, which does not occur in ginkgo leaf.

However, the researchers noted that merely following the post-hydrolysis HPLC testing standard of USP-NF would be inadequate to detect this sort of ginkgo extract adulteration. Instead, the authors proposed, the ginkgo extracts should be assayed for flavanol aglycones before and after hydrolysis to make for a stronger method of detecting adulteration.

Another study, published in October 2015, also explored the role that the isoflavone genistein can play in helping detect ginkgo adulteration. Researchers evaluated both authenticated ginkgo materials and commercial dietary supplements labeled to contain G. biloba. While none of the authentic ginkgo materials were found to contain genistein, eight of the supplements contained genistein, suggesting they were in fact adulterated.

"This study confirms that botanically authenticated G. biloba leaf and extracts made therefrom do not contain genistein, and the presence of which even in trace amounts is suggestive of adulteration," the study authors concluded.

Researchers combined ultra-high-performance liquid chromatography-mass spectrometry (UHPLC-MS/UV) with HPTLC to evaluate the samples, which they explained "was developed as a fast and economic method for chemical fingerprint analysis of ginkgo samples."

**The American Botanical Council's new Botanical Adulterants Bulletin looks at adulteration threats facing herbal ingredients.**

Researchers analyzed the anthocyanin profile of 45 supplements containing Vaccinium fruit (cranberry, lingonberry, bilberry, and blueberry) with HPLC separation. They discovered that more than 30% of the products tested did not contain the fruit listed on the label.

But even though existing anthocyanin profiles helped researchers identify the adulterated supplements, they noted that the available purified anthocyanin standards are limited and may not be effective for verifying the authenticity of products that combine multiple fruit ingredients.
Instead, they concluded that building a comprehensive fruit and vegetable anthocyanin profile database "could immediately help advance the quality of dietary supplements available to consumers."

Stefan Gafner, PhD, ABC’s chief science officer, agrees that an anthocyanin database might help prevent bilberry extract adulteration—as long as it’s used in conjunction with proper analytical methods applied throughout the industry.

Another BAB discusses grape seed extract (GSE) adulteration, including a 2015 study that analyzed 21 GSE supplements, which are sometimes adulterated with peanut skin extract and pine bark extract to artificially boost PAC content.

Using HPLC-UV/MS, researchers discovered that nine of the products were adulterated with peanut skin extract. The troublesome findings led researchers to conclude that chromatographic techniques, such as thin-layer chromatography (TLC) and HPLC, are necessary to defend against GSE adulteration, rather than “inferior proximate assays” that some manufacturers currently rely on.

ABC’s Gafner says he was surprised to hear about GSE adulteration since GSE is a relatively low-cost material made from a by-product of the grape juice or wine industry. But, as it turns out, peanut skins are even cheaper.

“I am still surprised that someone would choose an extract from a known allergen as an adulterant,” says Gafner.

Overlooked Ingredients
Another factor to consider is the existing adulteration scrutiny for a given ingredient. While ingredients thought to be at a high risk of adulteration often receive the most attention, it may actually be more mundane ingredients that are open to the greatest adulteration risk.

“Botanicals like black cohosh and skullcap are widely recognized as being high-risk for adulteration,” says Danica Harbaugh Reynaud, PhD, global director of scientific

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Is your ingredient really grape seed extract? Or is it peanut skin?

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“Botanicals like black cohosh and skullcap are widely recognized as being high-risk for adulteration,” says Danica Harbaugh Reynaud, PhD, global director of scientific
innovation, NSF International (Ann Arbor, MI). “As a result, they are under greater testing scrutiny. In fact, we have seen very little adulteration in these botanicals as a result of this scrutiny.”

Instead, Reynaud points to widely used ingredients like black pepper, oregano, wheat grass, barley grass, and alfalfa as some of the biggest targets for adulteration because even a small amount of adulteration can help suppliers keep up with demand. If there is a high demand, low supply, and/or a high price for a certain ingredient, there may be a particularly high likelihood of adulteration.

“There is a misconception that only rare and high-priced ingredients are at the highest risk of adulteration,” says Reynaud. “We find that it is the most common and cheaper items that really are at the highest risk.”

Therefore, Reynaud recommends identity testing at every point in the supply chain and using the correct test methods. To that end, NSF International acquired Reynaud’s company, DNA testing laboratory AuthenTechnologies (Richmond, CA), earlier this year, which it says will allow for more sensitive sequencing techniques than traditional DNA barcoding methods.

But again, the key to catching botanical adulteration increasingly involves a combination of multiple testing tools. Alkemist’s Sudberg explains that while Alkemist now offers next-generation DNA sequencing equipment, it’s only when combined with tests like HPTLC that DNA testing can provide a complete picture.

“This technology combination is the most thorough and comprehensive way to be sure what is on the label is actually in the bottle,” Sudberg says.

References
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Engineered to protect what stomach acid can steal.

The human body is a thief of potency. Before your formulation can be effective, it has to run the punishing gauntlet of the digestive tract. But there is a way to protect your supplements from the corrosive effects of stomach acid. DRcaps™ capsules from Capsugel. Our innovative, acid-resistant capsules safeguard your ingredients from stomach acid, delivering them to the intestinal tract for maximum impact. In short, they're the perfect solution for liquid or powder products that need serious protection. See the DRcaps capsule difference at capsugel.com/ihc/drcaps.
Hey say you can’t judge a book by its cover—and for the most part, they’re right. But a book’s cover can say a lot about what’s on the pages within, and the same is true—or at least has the potential to be—of the packaging around a supplement or functional food.

Sure, the text on any bottle or box will tell you the obvious details about contents, ingredients, net weight, expiration date, lot number, or so on. But there’s a subtext going on here, as well, wherein subtleties and nuances of the package—from the shape of the label to the color of the cap—convey a story not just about the product inside but the health-and-wellness brand behind it.

In an age when shoppers yearn to connect with the stories underlying everything they buy, that’s a strong selling point. Moreover, it’s one more piece of evidence that a package does more than keep a bunch of capsules in place. As Brent Anderson, packaging advisor, Nosco (Waukegan, IL), puts it, “Since it’s necessary to use packaging to ensure a product gets to its destination in one piece, why not take advantage of this space for branding and storytelling?”

Captive Audience

With so much of our lives lived in “the cloud” these days, celebrating the importance of the physical package almost feels like a throwback. But we haven’t yet entered a “post-packaging” world. Websites, online engagement, and savvy marketing may be “necessary to flesh out a brand story,” says Todd Pauli, partner, The Shelton Group (Chicago), but packaging still plays the “most critical” role in telling that tale. “You’ll rarely hold the consumer more captive than when he or she is at the shelf, holding a product and trying to decide between several supplement brands,” he says. “In that moment, packaging makes all the difference in the world.”

The difference boils down to a package’s capacity to elicit emotion. Beyond just enumerating features, benefits, and nutrition facts, packaging “helps a consumer connect with a brand on an emotional level and feel comfortable with a purchase,” Pauli says. And when a package communicates this emotion clearly, it “will continue to enforce the consumer’s connection with the brand well after purchase.”

Like, for example, when that consumer reaches into the medicine cabinet every morning. “Packaging lives alongside consumers in their homes,” Anderson notes. “Any time a customer picks up a container to take their daily supplement, they interact with the brand through its packaging. That’s a great way to reinforce brand identity and engage customers over time.”

Distilling an Identity

Yadim Medore, founder & CEO, Pure Branding (Northampton, MA), considers the package “an expression of the brand, just like the physical body is an expression of the soul.” That’s pretty heavy for a pouch or pill pack, but Medore maintains that “if packaging doesn’t align with that essence, there will be a major disconnect between what the brand stands for and the meaning conveyed at the shelf.”

Which raises the question of what a brand stands for. If a health-and-wellness company hasn’t solved that riddle before settling on a preferred package, it may want to go back to the drawing board. Putting package before purpose is like putting “the cart before the horse,” Medore says. “You have to understand who you are and what you stand for before you can begin expressing the brand through packaging.”
In the supplement world, “packaging” includes not just the bottle, bag, box, or blister pack, but the pills, powders, capsules, or tablets within. That’s because each dosing format is a “package” of nutrients in its own right. And just as the package that consumers see on shelves has an undeniable effect on purchase decisions, innovative dosing formats also say to supplement users, “We’re different—and better.” Yet marketers may still wonder: Is investing in novel dosing formats worth it?

Missy Lowery, senior marketing manager, Capsugel (Greenwood, SC), sure thinks so. And she and her colleagues make the case to customers with cold, hard research. They go directly to brands—rather than manufacturers—to ask for their take on “what makes consumers reach out to their brand’s bottles over another brand’s based on their sales results and feedback from specific retail customers,” she says. “Brands can be very savvy about consumer trends.”

That’s why the branding exercises that Medore and his team conduct with customers are “holistic endeavors that look at the brand opportunity through the lens of five forces,” he says: organization, offering, trade, category, and participant. “It’s the interplay between these five forces that allows the brand opportunity to emerge in a dynamic and organic way.” And the earlier that opportunity emerges, the more self-evident subsequent branding decisions become—“because they’ll be about asking, ‘How does this decision support our brand strategy?’”

Pauli emphasizes succinctness. He says to think of the package as “your product’s elevator pitch: A consumer should be able to pick up the package and know what the product and brand are about in a very brief amount of time.”

How brief? Lu Ann Williams, director of innovation, Innova Market Insights (Arnhem, The Netherlands), cites what she calls the “3–30–300-seconds rule.” That is, during the first three seconds of a consumer’s encounter with a product package, the goal is “all about capturing the consumer’s attention,” she says—usually via front-of-pack space. “In this limited time, shoppers quickly judge a product based on the brand name, graphic design—colors, fonts, images—shape, material, price, et cetera,” she says. That’s a lot of information to deliver, “but many brands successfully reach consumers in whichever category they fit.”

Assuming the first three seconds click, the next 30 find consumers turning to the package’s back, where “mainstream brands will typically have more information about the product,” Williams continues, “while brands with a unique story will share that in a few sentences. An example appears on Coldpress (London), a cold-pressed, high-pressure-processed juice brand that Williams thinks “has a great way of explaining quickly”—and graphically—“on the bottle what it and its process is about.”

Once a package makes it to the coveted 300-second mark, it must continue engaging consumers in the comfort of their homes, where brands might keep the conversation going with “an attached booklet,” Williams says, “maybe inside a wrapper, or by referring to their website or video channel.” And how do you know you’ve made it? When your package—and, by extension, your brand—becomes part of your consumer’s day.

Stories that Sell
Lauren S. Clardy, president, NutriMarketing Group (Santa Rosa, CA), understands how critical that first, fast, strong impression is. “It’s key,” she says. “You have less than six seconds to tell the story from a visual point of view.”

But if the story doesn’t resonate, or if it doesn’t rise above others, no amount of exposure will make it stick. That’s why Nosco’s Anderson insists that brands must communicate “a story of uniqueness—what makes this product different from products within the same segment”—and one of “authenticity” that “highlights one or more areas in which your company and product stand out,” he says. “These can include aspects of...
sourcing, charity, quality, personalization, or sustainability.”

Pauli agrees that quality, as well as transparency, scientific support, “natural” cred, and “an overall contribution to a healthy lifestyle, all remain important stories brands try to tell.” But Medore cautions against focusing too narrowly on the nuts and bolts. “Too often we find our clients coming to us with functional, feature/benefit, or science-led stories,” he says. Such messages may be the bread and butter of the supplement industry, but “we know from our extensive consumer research and just from listening that a brand cannot be successful crafting its storytelling around those functional benefits alone. It’s just noise, and everybody is competing with the same language. Ultimately, a brand connects emotionally by standing for something and connecting on a much deeper human level.”

**Origin Stories**

One means of forging that connection—“especially in the food and beverage market,” Williams notes—is by taking consumers to the source. “The ability to pinpoint exactly where the ingredients were grown and harvested, sharing personal details about the growers or what the product’s significance is in that region, is a good strategy,” she says. She offers Peeze Communitea (Arnhem, The Netherlands) as “a very nice example of a tea brand sharing stories from the employees at the tea plantation where the leaves were grown.”

Organic India takes its consumers even closer to the plantation. According to Medore, this Lucknow, India–based producer of tulsi teas and herbal supplements long held the vision of turning India’s chemical system of agriculture “upside down” by devoting over 500,000 acres to organic production, creating sustainable jobs with living wages, and “helping thousands of farmers return to their sacred connection with the land,” he says. So in building its brand, the company chose not only to introduce its “authentic story to a tea category dominated by illusory, indulgent imagery,” Medore continues, but to underscore its “culture of consciousness.”

Thus it featured images of “real Organic India farmers who look you in the eye” prominently on its packages, Medore says, “connecting a circle of harmony through the farmers who care for the land to the consumers who enjoy the organic tea.” That message is apparently registering, as distribution has expanded since launch and store managers have adopted the role of brand advocates who “embrace the authentic story, thus becoming part of the circle of harmony,” Medore says.

**Green Day**

It’s no coincidence that underlying the Organic India story is a distinctly “green” motif, as a brand’s environmental outlook has become an essential element of its identity, especially in the health-and-wellness sector. Yet it’s no small irony that brands demonstrate their deep-green streak by leaning on packaging—the stuff that risks getting tossed into landfill.

“Packaging is always at the center of green discussion up to 100%, and “combining it with a second life in mind. “You want to encourage the consumer to keep the container,” Anderson says.

But choosing environmentally mindful packaging isn’t the only proof of green values. “Switching to digital printing can dramatically lower carbon footprints by reducing waste during the printing process,” Anderson offers. “And it enables companies to perform just-in-time manufacturing and reduce obsolescence.” Another way of getting packaging to walk the sustainable walk is to design it with a second life in mind. “You want to encourage the consumer to keep the container,” Anderson says.

**Transparent Packaging**

Whatever you do, don’t just pay lip service. As Jeff Hilton, chief marketing officer and co-founder, BrandHive (Salt Lake City), insists, being green “is important if it’s genuine. But don’t greenwash! Green concerns and initiatives have to come from an honest place or they won’t be accepted or embraced. Consumers will know. They really will.”
my curcumin should be adulterated
my curcumin should be synthetic
my curcumin should infringe patents
my curcumin should be unnecessarily bioavailable

my curcumin should only be Curcumin C3 Complex® by Sabinsa
my black pepper extract should be toxic
my black pepper extract should be clinically unsubstantiated
my black pepper extract should infringe patents
my black pepper extract should be confused with table side pepper

my black pepper extract should only be BioPerine® by Sabinsa
For that reason, he advises brands to provide substantiation to support certifications and claims for safety and potency. “Share scientific studies,” he adds. “Use expert third-party spokespeople to validate the brand. And make your science interesting and relevant to the consumer. Explain it in terms they’d understand and can recall.” Clardy agrees. “Transparency is the big story,” she says, “but so is underlying quality and adherence to standards. Any label claims must hold up to stability and efficacy standards.”

To see that principle in practice, look to Gaia Herbs (Brevard, NC). Medore says that the company’s Meet Your Herbs traceability program not only set a supplement-industry standard for robust tracing practices but “allowed an entry point into the brand’s storytelling, where the brand shared all the details of growing, harvesting, manufacturing, and testing through the prism of the brand’s values of purity, integrity, and potency.”

An ID on the package directs consumers to the website or mobile app to find “proof of careful cultivation, meticulous harvesting, appropriate extraction methods, and state-of-the-art validation and purity data for each herb inside,” Medore says. To support its statements, the company maintains a complete chain of custody for its products, from seed to shelf. Consumer research shows that supplement users embrace this vision, and studies that Medore and his own team conducted affirm that herbal-medicine shoppers in particular want “assurance in an industry fraught with questions, recalls, and an onslaught of negative press,” he says. Programs like this “let us prove it.”

Standing Out
Yet on a shelf packed with other products, the challenge of literally catching the consumer’s attention still remains. Mindy Wherley, brand strategy manager, Nosco (Waukegan, IL), counsels marketers to make the best use of what they’ve got. “Everything about a package, from materials and shape to copy and graphics, plays a role,” she says. “And with the printing technologies, advanced graphic design techniques, and vast material selection available on the market, there are many ways for brands to stand out, whether they’re

Back in 2010, Gaia Herbs began featuring an ID number on each of its product packages that allows consumers to obtain, via the company’s website or a mobile app, more information on the product’s origins, including where it came from; how it was harvested, extracted, and manufactured; results of product testing; and more. Fast-forward to today, and this kind of traceability is more important than ever. The company continues to feature its Meet Your Herbs program on all of its product packaging. Above, a photo of the brand’s newest products introduced at this year’s Natural Products Expo West trade show.
Contrasting colors or coatings, uniquely shaped cartons, or a distinctive die cut or decorative embellishment "can bring any minimalist design or 'green' package to life," she says. And don’t forget the power of the label. "Label shape could be used to reinforce a brand message," as can strategic use of colors, clarity or opacity, gloss or matte, texture or smoothness.

Consider the case of LifeVantage (Sandy, UT), a "science-based nutraceutical company" that Anderson notes initiated a "full-grand refresh" recently, starting with its flagship Protandim supplement. The company aimed to illustrate core values like scientific support and manufacturing excellence by rotating its name from vertical to horizontal and using a clear label substrate that creates enough transparency at the bottle’s base for consumers to view the pills within. That extra space also allows for the inclusion of a "subtle" double-helix pattern in silver-blue foil "to tie to the nutrigenomics impact of the product," adds Anderson, who credits the label's ability to "engage both the independent distributor and end user in visual storytelling" with key aspects of the rebranding’s success.

Pauli adds that NOW Foods (Sonoma, CA) launched new labels a year ago affecting its entire line of hundreds of supplements. Extensive research taught the brand that existing customers liked the familiar bright-orange labels long in use "because they know and trust the brand," Pauli says. But potential new customers saw the labels as outdated and not especially helpful in communicating the very category that the brand belonged in. The solution: a new, more "user-friendly" design "with an image for each category: botanicals, omega-3s, et cetera," Pauli says. "It was contemporary and upscale, while retaining the familiar orange color. And it’s proven very popular."

Amazing what a new "face" can do. Says Hilton, "Your packaging is your face to the consumer. It’s how they recognize you. It’s how they remember you and talk to others about you. It’s that simple. So don’t let your product hit shelves without being ready for its close up. As Hilton says, “Every brand has a story to tell. Either you and your package can tell it, or your competitors and customers will do it for you."
Only One Diet Ingredient Can Say This...

- Official Weight Loss Claims US & Canada
- Clinical Trials 14 completed since 2001
- FDA GRAS Status earned
- cGMP Certified US made
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Don’t gamble with unsubstantiated weight loss claims.

Get the tried & tested real thing:
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According to the Council for Responsible Nutrition (CRN; Washington, DC), 71% of adult women in America take dietary supplements. That sisterhood comprises a spectrum of age groups, ethnicities, economic and education levels—in short, a cohort of women so diverse that they defy any attempt to boil them down to “the typical female supplement consumer.”

Except in one sense: Every one of them has a vagina.

And increasingly, health issues involving that anatomical feature are driving women to the supplement shelf. As Maj Britt Larsen, scientific advisor, Human Health & Nutrition, Chr. Hansen (Hoersholm, Denmark), observes, “The growing availability of dietary supplements for vaginal health is assisting women’s awareness” of the subject and sparking their interest in products to manage that health.

The fact that these options even exist, and have a growing body of science to support them, is a sign of progress—both in the seriousness with which the public now takes women’s health and in the research that allows the supplement industry to serve it. As that research uncovers new relationships between nutrition and the female urogenital tract, the opportunities for supplement users and the companies that court them will only grow.

We’ve Come a Long Way

Time was when vaginal health wasn’t fit for polite discussion. Fast-forward to today, when entire websites and blogs now cover the topic. What does this efflorescence signal to Kimberly Kawa, natural-products specialist at SPINS (Chicago), a leading information provider for the natural and specialty products industry? “I think we’ve come pretty far,” she says, “considering the patriarchal system we live in.”

Those cracks in the glass ceiling haven’t shattered yet, but third-wave feminism, wellness education, the Internet’s “sharing culture,” the relentless march of research—“really, all of the above,” Kawa says—have made vaginal health a more approachable, and understandable, subject. “There’s a vast amount of knowledge available at our fingertips,” she says. “Our natural functions are now being celebrated, not shunned.”

Complicated Conditions

But what, exactly, do we talk about when we talk about women’s vaginal health? Issues surrounding menstruation and menopause are part of the conversation, as are sexually transmitted diseases like herpes, HIV, chlamydia, and the like. But setting those aside and focusing on the urogenital tract specifically, the main concerns, Larsen says, are bacterial vaginosis (BV), yeast infections or yeast vaginosis—typically Candida infections, Larsen notes—and urinary-tract infections (UTIs).

Each condition varies in the severity of symptoms, which range from the mild discomfort, odor, and discharge of BV to the itching and pain of yeast infections, as well as the pain with urination—and frequent urge to do so—that accompany UTIs.

Each condition also carries the possibility of complications. “For UTIs,” Larsen says, “there’s a risk of infection of the upper urinary tract, which will result in serious pain and
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Women’s Health

fever.” Stephen Lukawski, global director of sales and marketing, Fruit d’Or Nutraceuticals (Lourdes, QC, Canada), notes an association between BV and increased risk for sexually transmitted diseases, including HIV, gonorrhea, and herpes simplex virus type 2 (HSV-2), as well as for miscarriage and preterm labor and delivery in pregnant women.

Public and Private
Given that BV alone affects 21.2 million, or 29.2% of women aged 14 to 49—84% of whom report no symptoms—it’s hardly a frivolous matter. And given that the first line of treatment for the condition—which occurs when the vagina’s normal microflora tilt off balance—is often antibiotics, its ramifications can resonate more broadly than might at first be apparent.

To wit, treating BV as well as other urogenital infections with antibiotics—as is often done—increases the risk that resistance to those antibiotics will develop, while also introducing women to further complications like the vaginal dysbiosis or gastrointestinal imbalance that comes with antibiotic or even antimycotic use.

Research is unveiling new relationships between nutrition and the female urogenital tract.

And because these conditions are commonplace and have a high rate of recurrence, they send many women to their physicians for the requisite scrips for antibiotic treatment, thus increasing healthcare costs, sapping worker productivity, threatening the potency of our antibiotic arsenal, and making women’s lives generally less fantastic than they ought to be. The upshot: women’s urogenital health is a public and private concern.

Fed Up
Yet “many women still might not even want to discuss these issues with their own GPs, either because of the ‘delicate’ nature of the problems or because they’ve not been taken seriously when they’ve discussed them before,” Larsen says. Many women are also simply fed up with recurrent infections that conventional treatment fails to vanquish.

Still, “Many women will not accept that nothing can be done about an issue that they find important, especially those women who suffer from recurrent infections,” Larsen says. So they’re taking matters into their own hands and turning to supplements.

As Kawa notes, “Supplementation, along with dietary and lifestyle changes, can help ‘turn the corner’ or provide natural symptom relief” for women. Indeed, as awareness of vaginal-health supplements grows, women increasingly “welcome the possibility of treating these problems using natural
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means” rather than antibiotics or antimycotics, Larsen adds. However, “there are still many women who don’t know of any nutritional products in this area.”

Healthy Flora
Perhaps the first place they might find some is the probiotic shelf. As Larsen explains, “A healthy vaginal flora is dominated mainly by lactobacilli. These bacteria produce lactic acid and other compounds that keep the vaginal pH low, resulting in a hostile environment for most pathogens.” When the ranks of these good bugs shrinks, the opportunity of deploying probiotics to bring them back up to size is enticing.

Donald J. Brown, ND, managing director, Natural Product Research Consultants (Seattle), notes that women have long driven interest in using probiotics to maintain healthy gut microflora, but their understanding of the link between urogenitary health and healthy bacteria is still young. “I think it’s lagged behind the intestinal tract,” he says, “but increased interest is what we’re seeing.” That’s in part because more companies are “speaking to these issues, and that’s creating more awareness,” Brown says. Research on the human microbiome is also yielding compelling findings. “Really, the female genitourinary-tract data is running ahead of where we’re at with other parts of the body,” he notes, and part of what we’re learning is that the probiotics under investigation appear not only to improve both general and vaginal health, but to address genitourinary-tract conditions “that are particularly recurrent,” he says.

Resistance Fighters
Because probiotic benefits are so specific to individual bacteria strains, the gold standard for efficacy isn’t just clinical evidence at the species level, but evidence at the level of that specific strain. Alas scientific support for many supplements on the market can be pretty “patchy,” Larsen says, “and there’s often a lack of clinical documentation, or only very limited documentation.”

Probiotics supplier Pharmachem Laboratories Inc. (Kearny, NJ) says *Lactobacillus salivarius* subsp. *salivarius CRL 1328*, one of its probiotic offerings, has been studied for benefits to vaginal microflora for more than a decade, including for overall vaginal health and guarding against urogenital infections.

Among the proprietary strains that do have *in vitro*, animal, and “several randomized clinical studies behind them,” Larsen says, are *Lactobacillus rhamnosus* GR-1 and *Lactobacillus reuteri* RC-14, which form Chr. Hansen’s trademarked Urex complex. The complex, Larsen says, “has shown efficacy in clinical trials for maintaining a healthy vaginal microbiota within bacterial vaginosis, yeast vaginosis, and urinary-tract infections.”

Research on the human microbiome is also yielding compelling findings.

Perhaps more interesting, it’s shown efficacy in doing so without compromising antibiotic effectiveness. A year-long trial3 published in 2012 involving 252 postmenopausal women with recurrent UTIs compared the probiotic combo with antibiotics for their respective abilities to prevent such infections, while also investigating the former’s effect on antibiotic resistance. The results revealed no statistically significant difference between the probiotic and antibiotic groups in terms of UTI occurrences, but “what was really interesting,” Brown says, was the finding that every subject in...
“Our hypothesis is that cranberry must be taken every day in order to build the immune system and create a healthy microflora in the gut,” says Fruit d’Or’s Stephen Lukawski.

Brown also finds it “fascinating to note” that a year prior to publication of the aforementioned study, the same researchers published findings of an investigation into the effects of antibiotics versus cranberry capsules on UTI prevention. Though cranberry enjoys wide renown as a natural nutritional UTI intervention, the group’s results showed a higher number of UTI recurrences among the cranberry group than in those treated with antibiotics.

The researchers did, however, disclose some study weaknesses—one of them being that, at the time the study was conducted, “there was no consensus about the most appropriate method to measure type A [proanthocyanidins in cranberries],” and thus the researchers used “a high-performance liquid chromatography method.”

What difference would an appropriate measurement of the PACs in the study’s cranberry extract have made? At the very least, researchers would know for certain what was in those cranberry capsules to start with. “Cranberry research studies that have been done so far have limitations, as researchers never analyzed the starting cranberry powder to determine biomarkers,” says Fruit d’Or’s Lukawski. “It is essential to determine what is in the starting cranberry powder. Without this fingerprint analysis, you cannot have repeatable studies.”

As for the potential of cranberries to guard against UTIs, Lukawski maintains, “Any time you can find a natural alternative than taking antibiotics is a good thing, as there is so much damage antibiotics do to the microflora environment. Our hypothesis is that cranberry must be taken every day in order to build the immune system and create a healthy microflora in the gut. Taking cranberry every day, you can get rid of the bad bacteria, which sets up a clean environment for probiotics to do their job more effectively.”

Cranberries did not cause any resistance to antibiotics in the aforementioned study—an argument many make as the reason antibiotics should not necessarily be the first-line defense against UTIs. As Amy B. Howell, PhD, from the Marucci Center for Blueberry Cranberry Research at Rutgers University, commented when the study was released, “Unlike antibiotics, cranberry does not kill bacteria. The fruit contains compounds that prevent the pathogenic bacteria from sticking to the bladder wall, which is the initial step in the infection process. Interrupting the adhesion prevents the bacteria from growing and causing a UTI.”

Brown maintains, “I think there’s some really good science on cranberry. But I think that cranberry has a more limited scope. We know that cranberry has the ability to block adhesion of certain types of E. coli.” And though those E. coli types may not be the ones that cause most UTIs, “I do think that there’s a place for cranberry,” he says.

That place might be in a tag team with probiotics. “A recent study conducted by Complete Phytochemical Solutions LLC involving Cran Naturelle cranberry from Fruit d’Or and probiotics from UAS LifeSciences [Wausau, WI] demonstrated that cranberry and probiotics work synergistically, yet independently, in establishing a balanced microflora,” Brown says. The effects of the combination, which features mostly Lactobacillus species and high levels of cranberry proanthocyanidins, indicate that “cranberry has become a ‘good housekeeping partner’ with probiotics to help provide a cleaner microflora so that probiotics can function more effectively as a preventative,” Brown says. (He also sees potential in using fibers from
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fruit powders like cranberry as a prebiotic to feed probiotics.)

Gregory Leyer, PhD, UAS LifeSciences’ chief scientific officer, says the researchers are now seeking to publish the study. He speaks more on the *in vitro* pilot that looked at the effects of the combination against an “extra-intestinal pathogenic *E. coli* strain.”

Leyer notes several interesting study findings, including results that cleared up initial concerns about the viability of the cranberry–probiotic combo, which UAS is selling as a finished product called UP4 Women.

Lukawski points out that many other formulators have failed to create successful combination-cranberry products because “the water activity in cranberry can have an extremely negative effect on the strains of probiotics.” This doesn’t appear to have been a problem with UP4 Women. Here is what Leyer says, “First, given the antibacterial activity of cranberry, a question was whether the cranberry material would inactivate the probiotic bacteria, in addition to the targeted pathogenic *E. coli* strain. What we found was that the proanthocyanidins (PACs) in the cranberry powder specifically bound to *E. coli*, and not the probiotics. Second, the two ingredients act very complementarily in terms of potential mechanism of action. PACs seem to directly inhibit the invasiveness of the pathogenic *E. coli* by binding to them and essentially sequestering the organisms, rendering them much less virulent. Probiotics, on the other hand, do not have a direct, contact-to-contact interaction, but rather would aid in lessening the invasiveness by creating a less-favorable environment in the gastrointestinal system.”

On further research the companies plan on UP4 Women, Leyer says, “The benefits of single ingredients are commonly tested, but the study of the actual finished product consumed by the end-user is of great interest to us. Understanding any synergies, or lack thereof, in finished-product combinations is our focus, and this pilot *in vitro* study gave us an indication that the mechanism of actions are complementary, and not contradictory. We’re excited about adding to the body of science with additional finished-product human studies.”

**Opening Doors**

More research on that front is in order, Lukawski says, and he’s keeping his eye on the horizon for new findings. Meanwhile, Brown is enthusiastic about mounting science that confirms the ability of certain isolated *Lactobacillus* strains to survive oral administration and eventually colonize the vagina.

The previous understanding—in effect until groundbreaking research by Gregor Reid, PhD, and Andrew Bruce, MD, FRCS(C), in the early 2000s—was that strains required intravaginal application to be effective against recurrent UTIs or BV. But with Reid and Bruce’s work “opening a door that continues to be opened,” Brown thinks we’ll be seeing more companies formulating orally administered products using strains that have proven up to the challenge of the colonization journey. “I would predict that in the next five to 10 years, we’re going to see a lot more products for women that have science behind the fact that if you take them, they’re actually going to colonize the vagina,” he says.

Next up might be addressing BV with probiotics, as “the indicators are that probiotics used adjunctively not only improve outcomes in treatment, but also decrease recurrence rates,” Brown says. In light of BV’s association with miscarriage and its status as “one of those infections that’s globally significant and hard to treat,” he says, “now we’re getting into healthcare-dollar-land.”

**References**

A TV reporter is investigating supplements.

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The multivitamin gets a makeover.

BY MAUREEN KINGSLEY

Multivitamins: they may not be as sexy, glamorous, or headline-grabbing as the latest exotic herb or plant-protein superstar, but they remain one of the most popular, trusted products in the dietary-supplement market. “Multivitamins continue to be one of the top-selling products within the supplements industry,” confirms Duffy McKay, ND, senior vice president, scientific and regulatory affairs, Council for Responsible Nutrition (CRN; Washington, DC). “It is fair to say that the multivitamin is a product that really reaches mainstream America. When you consider that more than two-thirds of Americans take dietary supplements, we know that many, many of those individuals are using multivitamins as an insurance policy to fill nutrient gaps,” he adds.

Indeed, CRN’s latest Consumer Survey on Dietary Supplements, published late last year, provides some pretty solid, encouraging figures regarding multivitamin use in the United States. For instance, of the 68% of Americans who took dietary supplements in 2015, more than three-quarters took a multivitamin. Analyzed by demographic, 83% of supplement users aged 18–34 took a multivitamin, 80% of users aged 35–54 took a multivitamin, and 71% of senior supplement users (aged 55 and up) took a multivitamin. Examined by gender, the numbers are nearly equal at 79% of male supplement users taking a multivitamin and 77% of female users doing the same.

Perhaps most edifying for industry is the high level of confidence Americans have in the safety and efficacy of multivitamins: CRN’s survey showed that 85% of supplement users trust multivitamins’ safety and effectiveness.

Recent sales of multivitamins, both in the United States and abroad, reflect their popularity and trustworthiness among consumers. SPINS natural products specialist Kimberly Kawa reports that multivitamins had a good year in the United States in 2015. Total sales through natural (excluding Whole Foods markets), specialty gourmet, and conventional multioutlet channels were calculated by SPINS at just over $1 billion, with overall growth of nearly 5% over the previous year. Significant gains were made in the sales of men’s multivitamins (14.5% growth in sales via all combined channels over the previous year), women’s multivitamins (7.9% over the previous year), and general adult multivitamins (2.1% over the previous year), according to SPINS data. “Self-care is becoming more prominent as more consumers are looking to steer away from the conventional healthcare paradigm,” comments Kawa on why multivitamins’ popularity seems only to grow. “Consumers realize that the standard American diet is probably not up to par with optimal vitamin and nutrient requirements, and they are seeking primary prevention methods [such as multivitamin use] for filling in dietary gaps.”

Kawa’s comment is in line with some statements made in the newly published 2015–2020 Dietary Guidelines for Americans, which point to dietary supplements in general as being “useful in providing one or more nutrients that otherwise may be consumed in less than recommended amounts or that are of particular concern for specific population groups.” The guidelines identify vitamins A, D, E, and C, calcium, and magnesium (among others) as nutrients that are “consumed by many individuals in amounts below the estimated average requirement or adequate intake levels.” CRN’s McKay calls the newest guidelines “one of
Americans have a high level of confidence in the safety and efficacy of multivitamins. The strongest reasons for multivitamins’ popularity in 2015 were:

Data-analysis firm Euromonitor’s methodology calculates the total value of U.S. multivitamin sales in 2015 to be $5.2 billion retail value, which accounts for roughly half of all sales in the vitamin/multivitamin category. Internationally, that multivitamin sales figure increases to $14 billion. A December 2015 Euromonitor report on vitamins and multivitamins attributes growth in multivitamins to “the sustained purchases and the unit-price increase” of the products. “The price of multivitamins continued to grow as more manufacturers launched new products with different delivery formats and condition-specific formulations tailored to a specific age, gender, and other characteristics” in 2015, the report reads. “By positioning, women, including pregnant women, were the largest target segment” for multivitamins. Euromonitor forecasts continued growth for multivitamins in 2016, both domestically and internationally.

Trends in Ingredients and Formulations

In an established, saturated market such as multivitamins, brands must continually innovate to stay competitive. Multivitamin brands are doing this in a number of ways, particularly in the areas of formulations and added ingredients. Tobe Cohen, vice president of DSM Human Nutrition & Health North America (Parsippany, NJ), says that “brand owners are optimizing formulas based on evolving science and understanding of nutrient gaps.” For instance, adds Charles Barber, technical applications manager, BASF Nutrition & Health (Florham Park, NJ), “customers are especially interested in adding high-concentrate omega-3 fatty acids, vitamin B based on the compelling science around it, and vitamin D because more physicians are recommending it.”

Formulations for eye health are growing in popularity, point out Ayako Homma, senior analyst at Euromonitor International, BASF’s Barber, and DSM’s Cohen, likely the result of the Baby Boomer generation’s now advanced age. Lutein and other carotenoids are primary ingredients present in these formulations.

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Ingredients deemed “pure,” “high quality,” and “more bioavailable” are trending, too, say analysts and suppliers. SPINS’s Kawa says that “whole-food-based multivitamins have a big following and usually come with additional superfood or herbal boosts.” (See page 54 for more on whole-food supplements.) Kawa points to coenzymated or methylated B vitamins as an example of a more-bioavailable ingredient, as well as minerals bound to citrate, glycinate, malate, and aspartate instead of oxide or carbonate. She also notes a “shift toward brands using less-questionable fillers and excipients.”

CRN’s McKay sees individualized multivitamin formulas aimed at more-specific types of consumers as a current trend. These formulas, he says, are made for active athletes, for instance, or men with prostate- and heart-health concerns, or older adults: “We see companies targeting multivitamins so that consumers can say, ‘This is my multivitamin.’”

Finally, organic-ingredients supplier Or-igenetics Inc. (Brea, CA) reports continued interest in and demand for organic vitamins extracted from organic fruit and vegetable sources. “We have seen this specific organic-vitamins industry grow from a niche we created to a fully fledged industry,” says Saumil Maheshvari, marketing. “Organic—multivitamins demand has been just fantastic ever since we introduced it. This really shows the underlying consumer shift toward healthier alternatives and healthier lifestyles. More and more consumers are learning that organic food-based vitamins indeed are healthy.” (Turn to page 52 for more on this.)

Multivitamins that Deliver

Consumers desiring a tastier, “fun” way to ingest their multivitamin now have a wealth of options, as do multivitamin brands looking to distinguish themselves in online stores and on retail shelves. “Gummies have really taken off in the multivitamin category,” states CRN’s McKay. No longer marketed exclusively for children, gummies are winning over more young-adult consumers, as the products are “easier to digest and offer new and varied flavors,” says Euromonitor’s Ayako Homma.

One downside to manufacturing gummies, says McKay, is that they have physical and chemical limitations. “Some minerals

WHY YOU SHOULD ADD VITAMIN K2 TO YOUR MULTIVITAMIN

Some multivitamins are formulated with vitamin K1; other multivitamins contain no vitamin K at all. But suppliers of vitamin K2 (in the long-chain MK-7 menaquinone form of vitamin K2) continue to emphasize why vitamin K2, especially, should be a key ingredient in any vitamin mix due to its benefits for arterial and bone health.

Vitamin K2 supplier NattoPharma USA Inc. (Metuchen, NJ), along with its research partners at Maastricht University (the Netherlands) and the Vita-K supplement brand, is helping raise awareness of vitamin K2, touting its role in improving bone-mineral density, bone-mineral content, bone strength, and arterial flexibility.

“The awareness of and demand for vitamin K2 continues to grow,” states Eric Anderson, senior vice president, global sales and marketing, NattoPharma. “The publication of our three-year clinical studies showing that MenaQ7 vitamin K2 not only improved [bone health] but also inhibited age-related arterial stiffening while improving arterial flexibility have earned attention, particularly from respected practitioners.

“A growing number of compelling and groundbreaking studies showing vitamin K2 has long-term merit for all stages of life is the key force driving demand,” Anderson continues.

Sam Kwon, president of Vesta Ingredients Inc. (Indianapolis, IN), which supplies the NattoMK-7 brand of vitamin K2, says, “It is vital to emphasize that not all vitamin Ks are equal in regard to health benefits and efficacy. Consumers should be wary of this when deciding what vitamin K products they purchase.”

Compared to other vitamin K2 forms, ranging from MK-4 to MK-12 (the numeral designating the number of isoprenoid units on the molecule carbon), vitamin K2 MK-7 is “unique in that it has been shown to be more bioavailable and has a longer half-life in the bloodstream after oral intake, thus providing its benefits for a longer period of time,” Kwon says. MK-7 also outperforms MK-4, which is the other naturally occurring form of vitamin K2, he adds.

Of Vesta’s NattoMK-7, Kwon says, “Vitamin K2 (MK-7) derived from natto has been shown to be the most effective and [provide] longer-lasting benefits after supplementation due to its longer half-life in circulation. In addition, our product is 100% non-GMO, allergen free, and kosher certified.”

NattoPharma’s Anderson says that K2 is essential for the activation of K-dependent proteins that build strong bones and contribute to cardiovascular health, but that the Western diet has created a population, “particularly children,” deficient in this nutrient. “Without adequate vitamin K intake,” he warns, “calcium cannot be properly utilized in the body to build healthy, strong bones. As up to 90% of peak bone mass is acquired by age 18 in girls and 20 in boys, this is a most advantageous time to supplement with MenaQ7.”

Currently in the United States, a few multivitamins formulated with K2 are already on the market. These include offerings from Thorne Research, Pure Encapsulations, and NutriGold.

Consumer awareness of K2 is growing, says Vesta Ingredients’ Kwon. “The global functional food market has increased in vitamin K2 products, nearly doubling in number of products launched globally from 2008–2012, according to a study by Mintel. When we compare Google search interests over the past five years (January 2011–January 2016), we see a 16% bump in ‘vitamin K’ searches and an incredible 280% increase in ‘vitamin K2’ searches, specifically. All these trends indicate that the interest and acknowledgement of health benefits associated with vitamin K2 are taking off, from the consumer to the nutritional industry,” Kwon says.

“We anticipate that these trends will only continue to grow as further research continues to verify the vital role of vitamin K2 in maintenance of health and as the public becomes more aware/educated,” he continues.
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BACK TO NATURE

For as long as most consumers can remember, the majority of vitamins and minerals used in dietary supplements have been isolates synthesized in laboratories—a trend that took off during World War II when soldiers needed a cheap and easy way to get the nutrients they needed on the battlefield. However, with the tide toward organic food and drink, demands and education around the benefits of organic, plant-based vitamins and minerals is growing, says Saumil Maheshvari, marketing, Orgenetics Inc. (Brea, CA), a supplier of vitamin, mineral, and antioxidant ingredients derived from standardized extracts of 100%-USDA-certified organic fruits, vegetables, and various other botanicals.

The difference between a synthetic vitamin/mineral isolate and a vitamin/mineral ingredient naturally occurring in plants is significant, Maheshvari says. For one thing, non-synthetic ingredients may offer faster and easier absorption into the body, with little to minimal stomach irritation.

“The body does not require synthetic isolates,” Maheshvari maintains. “What it requires is the entire, complex form. That’s why you could have as much nutrition as you need in the form of food and still be okay because your body can process it.”

Take a mineral like iron, which is crucial to prenatal health. Maheshvari says that while a synthetic-iron supplement, most often providing a high dose, is widely reported to cause stomach upset in many women, an iron supplement like Orgenetics’s Orgen-I (a nominee in last year’s Nutritional Ingredients Awards), derived from leaves of the curry tree (Murraya koenigii), does not. “Because this iron comes in a plant-protein matrix, it allows for regulated absorption into the body,” he says. Or, take L-ascorbic acid, the widespread synthetic form of vitamin C still so popular in dietary supplements. Whatever the body doesn’t absorb is excreted in the urine, but a plant-derived form like the company’s flagship Orgen-C, comprising 50% vitamin C derived from amla fruit (Phyllanthus emblica), is more effective because of the accompanying cofactors and co-nutrients, such as naturally occurring non-citrus bioflavonoids, that “work synergistically with the vitamin C,” Maheshvari says.

“You don’t need 1000% RDA of a vitamin or a mineral,” Maheshvari says. “If you have an effective form of regulative absorption, your body will get exactly the amount that it needs.”

As more consumers become educated about the nutrients they consume, more are starting to look beyond synthetic vitamins and minerals and back to nature, Maheshvari says. “There’s really been a paradigm shift in the U.S. industry, shifting to organic. It’s been seeing 10% year-over-year growth for the past 15 years…We’re very glad to be part of that paradigm shift,” he says.

DSM’s Welsh adds mints to the list of leading-edge delivery systems and says that “food-like forms” are an evolving delivery method. “Fundamentally, we see the convergence of food forms and nutritional technology,” he says.

A Long History and a Bright Future

Multivitamins have been manufactured and sold in the United States since the mid-1930s, but their ingredients, formulas, and delivery systems continue to evolve and improve, and their popularity remains robust. In 2015, such factors as the mention of a role for supplements in the most-recent revision of the Dietary Guidelines for Americans, an aging population, a millennial generation raised by health-conscious Baby Boomers, increasing consumer interest in preventative health and wellness, and the increased accessibility of products through various distribution channels all contributed to the multivitamin’s strong demand and sales.

Formulations targeted to specific demographics, such as pregnant women, active athletes, and men with cardiovascular and prostate concerns, were popular and represented marketing efforts aimed at winning specific customer types. Likewise, novel, easy-to-consume, even whimsical innovations in delivery systems set brands apart from each other and included gummies for adults, flavored chews for adults, orally disintegrating tablets, dissolvable powders, and more.

It seems that demand for multivitamins will remain high as long as scientists and medical professionals continue to identify nutrient gaps in the typical American diet; public interest in preventative and even alternative medicine continues to grow; and supplement brands continue to innovate in formulation, “purity” of ingredients, and delivery format.

Maureen Kingsley is a freelance writer, editor, and proofreader based in Los Angeles. She covers a variety of industries, including medical technology, food-ingredient manufacturing, and cinematography.

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Whole-Food Supplements

The Fast Rise of Whole-Food Supplements

Why is this category growing twice as fast as traditional supplements?

BY MELISSA KVIDAHL

Look no further than the food industry’s local, organic, and sustainable movement for proof that consumers care about where their products originate. It was only a matter of time until this curiosity extended to the supplement aisle. And when it comes to whole-food supplements, the questions are clear, says Erin Stokes, ND, medical director at Food State, makers of MegaFood (Derry, NH): “Whole-food supplements have an increased level of awareness surrounding them because people want to know the answer to the question: Where does the whole food actually come from?”

The answer, however, is sometimes a bit muddier. Like the term natural, the term whole food suffers from a lack of regulation, leaving the definitions up to each company entering the market, and clouding it with confusing terminology.

One such buzz-term is food-based supplement, which, according to Stokes, is a conventional supplement ingredient with a food ingredient added in later. “So, in this case, the nutrient isn’t being delivered in the whole food,” she explains, “but rather it’s being delivered side-by-side with a food powder.”

Whole-food supplements and ingredients, on the other hand, offer manufacturers and consumers nutrients delivered right in the whole-food ingredient as it exists in nature.

And it’s resonating with shoppers. According to Karren Jeske, corporate communications manager at Standard Process Inc. (Palmyra, WI), the whole-food supplement market grew 12% in 2012 to reach $1.2 billion, “which was twice the rate of the overall supplement industry,” she adds. “And industry experts expect the whole-food supplements category to continue to outpace growth of the total supplement industry for the foreseeable future.”

How They’re Made

The key to delivering whole nutrition begins with how the ingredients are sourced and prepped for formulation. At MegaFood, for example, oranges are frozen at their peak of freshness at the farm and arrive in crates to the lab. “We’re not getting whole-food powders delivered,” Stokes said. “We see boxes of whole oranges arrive.”

This means that whole-food ingredient suppliers and manufacturers can control exactly how the food is treated, including the drying process,” says Stokes, which at MegaFood yields small flakes bright in color and rich in flavor. “Sometimes it’s those simple things, like tasting cranberry coming right off the dryer, that are the most profound,” she adds.

Similarly, Standard Process starts with whole, raw materials like Spanish black radish and beets, explains Jeske. “We prepare these ingredients in a way that safeguards their inherent nutrition,” she says. “The vegetables are chopped, dried, and powdered under conditions that optimize preservation of important compounds, such as the sulfur-containing phytochemicals called glucosinolates. Equally important is the preservation of the plant enzyme, myrosinase, that facilitates conversion of the glucosinolate to its potent metabolite responsible for up-regulating important detoxification enzymes in the body.”

The Whole Nutrition Benefit

Compared to conventional supplements, whole-food supplements differentiate themselves with—and pride themselves on—whole nutrition. What does that mean?

“Whole-food supplements provide nutrition in a form that most closely mimics whole food,” explains Jeske. “It is in this whole-food state that nutrition is typically harnessed and presented to the body. Whole, unprocessed foods, such as fruits and vegetables, contain not only the identified ‘essential’ vitamins and minerals that our bodies require, but also other compounds, such as phytochemicals, lipids, proteins, fiber, etc., that are increasingly recognized as integral to optimal functioning of our bodies.”
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This means, for example, that a whole-food vitamin C is delivered in oranges, a whole-food folate is delivered in spinach, and so on.

"Conventional supplements," explains Jeske, "are typically produced solely with synthetic single vitamins and minerals, or isolated and concentrated compounds from food combined together into a mixture, which usually lacks any matrix or complementary cofactors inherent in food."

**Easy Digestion**

Because whole-food supplements deliver nutrients in a whole-food matrix, they are often easier to digest than conventional options, says Stokes. And that's important when many consumers complain of stomach upset or difficulty tolerating conventional supplements. "This is because we know how to digest food," she adds. "Our bodies know how to utilize whole-food supplements because they know how to utilize whole food."

Along these same lines, whole-food supplements can be taken on an empty stomach—something that can't be said of many conventional options. "As a practitioner, this tells me patients can be more consistent in taking their supplements," says Stokes. "People can be very inconsistent with their supplements, and it’s understandable. People have busy lives and are often on the go, and eliminating the hurdle of having to take it with a meal can make a difference."

**Manufacturing Benefits**

The benefits of whole-food ingredients aren’t limited to consumer nutrition and tolerance. Last year, PLT Health Solutions (Morristown, NJ) debuted a line of Vibrant Harvest Whole Food Powders, available to food, beverage, and supplement manufacturers looking to incorporate servings of high-quality fruits and vegetables into consumer products, in an efficient way.

"For example, as little as 3 g of Vibrant Harvest spinach, or as little as 5.5 g of Vibrant Harvest strawberries, can deliver a serving in a consumer product," explains the company’s director of new product development, Sid Hulse. "This low level of addition means that, if you want to, you can hide the spinach from a picky eater. But the great taste and color of Vibrant Harvest powders also means that you can feature these ingredients."

Additionally, whole-food powders can also reduce packaging, handling, transportation, and storage inputs associated with raw or frozen foods, adds Hulse. "They can also extend shelf-life and preserve the nutrients present in fruits and vegetables," he says, "limiting food spoilage and waste."

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VITAMIN Science

What recent research is teaching us about the health benefits of vitamin supplementation

BY MAUREEN KINGSLEY

Multivitamins, single vitamins, and minerals continue to demonstrate high usage and consumer confidence among Americans who take supplements, according to CRN’s 2015 Consumer Survey on Dietary Supplements. The multivitamin in particular is the most popular with supplement users, followed by vitamin D and vitamin C.

Building on this good news is the USDA and the U.S. Department of Health and Human Services’ recent release of the 2015–2020 Dietary Guidelines for Americans, which recognizes dietary supplements as “useful in providing one or more nutrients that otherwise may be consumed in less than recommended amounts or that are of particular concern for specific population groups.” Furthermore, the guidelines identify vitamins A, D, E, and C as nutrients that are “consumed by many individuals in amounts below the estimated average requirement or adequate intake levels.”

So, while the continued popularity of and general consumer and government trust in multivitamins and single vitamins remain strong, one question remains: What, exactly, are all of the specific benefits of vitamin supplementation to human health?

Researchers are actively working to answer this question, and they are looking at elements of wellness ranging from cardiovascular health to cancer prevention to cognitive performance. Ahead, we look at notable as well as recent multivitamin/vitamin studies and the conclusions reached by their researchers.

Multivitamins and Cancer

Study Title: Multivitamins in the Prevention of Cancer in Men: The Physicians’ Health Study II Randomized Controlled Trial

This large-scale, randomized, double-blind, placebo-controlled trial began in 1997 and ended 14 years later, in 2011. It sought to determine whether long-term multivitamin supplementation decreases the risk of total and site-specific cancers in men.

The study included more than 14,000 subjects (all U.S. physicians, all male) aged 50 and older. Intervention was a daily multivitamin or a placebo. The conclusion reached was that daily multivitamin supplementation modestly but significantly reduced the risk of total cancer.

Vitamin D Status: African-American, Hispanic Subjects

Study Title: Vitamin D Status and Rates of Cognitive Decline in a Multiethnic Cohort of Older Adults

The authors of this 382-subject, eight-year, observational study, published in 2015...
in JAMA Neurology, concluded that low vitamin-D levels were associated with accelerated decline in cognitive function in ethnically diverse older adults (75 years at the start of the study). These adults included African-American and Hispanic persons exhibiting a high prevalence of vitamin D insufficiency or deficiency, and individuals with normal cognitive function, mild cognitive impairment, and outright dementia.

The researchers found that study participants with insufficient or deficient vitamin D levels experienced cognitive decline in two areas—short-term memory and executive function—at a rate about 2.5 times faster than participants with adequate vitamin D levels. It remains to be determined whether vitamin D supplementation slows cognitive decline.

**Prenatal Vitamin/Mineral Supplementation**

*Study Title: The Association between Third-Trimester Multivitamin/Mineral Supplements and Gestational Length in Uncomplicated Pregnancies*

A 427-person study published online in August 2015 and in print in the *Australian Women and Birth* journal in February of this year sought to retrospectively analyze the relationship between third-trimester maternal micronutrient supplementation and gestation length of the newborn baby at birth in uncomplicated pregnancies in Gold Coast and Logan Hospitals in South East Queensland.

The findings were that women in their third trimester taking zinc, folic acid, or iron supplements in combination with a multivitamin were twice as likely to give birth beyond 41 completed weeks than those who did not take any supplement. Those not taking such supplements were found to experience a lower rate of post-date labor and require induced labor. The conclusion reached by the authors was that length of gestation demonstrates significant associations with micronutrient supplementation practices.

**Multivitamins and Stroke Mortality**

*Study Title: Multivitamin Use and Risk of Stroke Mortality: the Japan Collaborative Cohort Study*

A follow-up study published in 2015 in the journal *Stroke* of 72,180 Japanese men and women free from cardiovascular diseases and cancers between 1988 and 1990 monitored the participants until December 31, 2009, to examine the association between multivitamin use and risk of death from stroke and its subtypes.

Lifestyle choices, including multivitamin use, were collected via self-administered questionnaires. During a median follow-up of roughly 19 years, the researchers identified 2087 deaths from stroke, including 1148 ischemic strokes and 877 hemorrhagic strokes. After adjustment for potential confounders, multivitamin use was associated with lower (but borderline) significant risk of death from total stroke but not hemorrhagic stroke.

An additional conclusion reached by the researchers was that regular, frequent multivitamin intake was associated with reduced risk of total and ischemic stroke mortality among Japanese people with low consumption of fruits and vegetables.

**Multivitamins, Minerals, and CVD**

*Study Title: Multivitamin-Mineral Use Is Associated with Reduced Risk of Cardiovascular Disease Mortality among Women in the United States*

The purpose of this study was to examine the association between multivitamin (MV) use and cardiovascular disease–specific death among American adults without cardiovascular disease (CVD). A nationally representative sample of adults from the Centers for Disease Control’s National Health and Nutrition Examination Survey data (NHANES III, 1988–1994; 8678 participants aged 40 years or older) was matched with mortality data reported by the National Death Index through 2011 to examine associations between multivitamin with minerals (MVM) use, MV use, and CVD mortality, adjusting for multiple potential confounders.

The researchers observed no significant association between CVD mortality and those taking multivitamins (with or without mineral ingredients) compared with those not taking them; however, when those taking the supplements were classified by the reported length of time the products were regularly taken, a significant association was found with MVM use of greater than three years (compared with nonusers) and reduced CVD mortality risk for women when models controlled for age, race, education, body mass index, alcohol use, aspirin use, serum lipids, blood pressure, and blood glucose/gyalced hemoglobin. This finding applied to women only. The study was published in 2015 in the *Journal of Nutrition*.

Maureen Kingsley is a freelance writer, editor, and proofreader based in Los Angeles. She covers a variety of industries, including medical technology, food-ingredient manufacturing, and cinematography.
Minerals

It doesn’t take much to get Max Motyka singing minerals’ praises. As a nutrition consultant based in St. Clair Shores, MI, and an advisor to Albion Laboratories (Clearfield, UT), Motyka firmly believes in minerals’ benefits, and he wants you to believe, too.

“Minerals are the catalysts or activators of innumerable enzymatic activities in the body,” he says. “Bones aren’t built without calcium, magnesium, and phosphorus. Red blood cells can’t deliver oxygen without the hemoglobin formed with iron. You can’t digest your food without hydrochloric acid—and parietal cells can’t form hydrochloric acid without the zinc metalloenzyme carbonic anhydrase.”

And that’s just the start. Muscles won’t contract without calcium, potassium, and magnesium, the latter of which is crucial for muscle formation itself. Essential fatty acids convert to their active prostaglandin form only with magnesium and zinc’s help. And “there’s more antioxidant activity in the body from the work of copper, zinc, and manganese than you can get by swallowing antioxidants,” Motyka declares. “The human body simply does not work without minerals.”

No wonder minerals have been a bedrock of supplement formulations for decades. But with trendy functional ingredients capturing headlines and hype, it’s understandable if minerals don’t always seem to get the appreciation and attention they deserve. But they should.

According to P&S Market Research,1 the global market for mineral supplements hit $9.9 million in 2014 and should grow at a CAGR of 7.5% from 2015 through 2020, thanks in part to demand from an aging population, pregnant women, and the growing ranks of the world’s urbanites. So Motyka has a point: Minerals deserve a closer look. The following shines a light on the latest research, showing how much we’ve learned about minerals’ value, and how much we have yet to find out.

Calcium: Good for the Bones, Good for the Brain
We know that poor calcium metabolism is a factor in bone loss, and we’re learning more about its role in cardiovascular disease, too—particularly with respect to endothelial health and function. But less well understood is the mineral’s relationship to forms of dementia, including Alzheimer’s disease.

According to a study2 in Clinical Calcium, higher self-reported intakes of dietary calcium were associated with reduced risk of all-cause dementia and vascular dementia—though not of Alzheimer’s—in the general Japanese population, suggesting that diets rich in calcium might help mitigate dementia risk. Notes Motyka, “This is a possible breakthrough finding in the etiology of dementia.”
There has been a lot of bad press about memory supplements.

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Zinc has been studied for its role in neurological development, but studies now also hint at a possible influence of zinc on serum lipid levels.

Zinc Travels the Gut-Brain Axis
The more we learn about the gastrointestinal (GI) tract, the more it appears to affect conditions and health states throughout the body. Such may be the case with certain neurological disorders, including autism spectrum disorder (ASD). Many patients with ASD show symptoms of GI dysfunction; given the significance of zinc in fetal GI development and morphology, maternal zinc status intrigues some researchers as a factor in ASD development.

A recent review considered zinc’s role in gut formation and a potential gut-brain link in the development of ASD and similar neurological disorders. Based on the data, the researchers present a new model for how changes in maternal zinc status might precede neurological impairments later in life. Their findings, Motyka says, “could lead to a way to prevent autism.”

Cracking the Manganese Code
Few minerals confound the scientific community more than manganese. One thing we do know, though: It’s important, in many ways. As an essential micronutrient, manganese is a key component of several enzymatic proteins, yet it’s toxic in excess amounts, making maintenance of proper intracellular levels crucial.

In a recent review, researchers examined common modes of manganese exposure, absorption, and transport, and presented the latest understanding of cellular uptake and efflux, and subcellular storage and transport. They even highlighted manganese-dependent and -responsive pathways implicated in Parkinson’s and Huntington’s diseases and suggested future research directions.

“This article points out the fine line between safe and toxic manganese intake,” Motyka says. “There’s still a definite need for more research.”

Taking the Initiative on Iodine
Iodine is a key element in infant brain development; alas, notes Andrea Wong, vice president, scientific and regulatory affairs, CRN (Washington, DC), government data confirm that pregnant and lactating women in North America run the risk of insufficient iodine intake. What’s more, recently published research from the United Kingdom reveals potentially significant societal cost savings and health benefits from iodine supplementation among pregnant and lactating women in iodine-deficient countries.

In response, the American Thyroid Association, Endocrine Society, and American Academy of Pediatrics recommend that all pregnant and lactating women supplement with a daily multivitamin containing 150 mcg of iodine. Wong says, “In support of these recommendations,” she added, “CRN recently issued voluntary guidelines that recommend supplement manufacturers include 150 mcg of iodine in multivitamins intended for pregnant and lactating women.”

Zinc: New Frontiers in Lipid Regulation
We’ve already seen how zinc may participate in neurological development. But studies also hint at its influence on serum lipid levels.

Researchers conducted a meta-analysis of controlled human clinical trials examining zinc supplementation’s effects on total cholesterol, LDL cholesterol, HDL cholesterol, and triglyceride levels. They looked at 24 studies with a total of 33 zinc interventions lasting from 1 month to 7.5 years, involving 14,515 participants in the zinc or control group, and using doses ranging from 15–240 mg/day. The conclusion: zinc supplementation significantly reduced total cholesterol, LDL cholesterol, and triglycerides, suggesting a potential to reduce the incidence of atherosclerosis-related morbidity and mortality. Noted Motyka, “This could lead to zinc supplementation becoming part of the therapy in the prevention of atherogenesis and the treatment of atherosclerosis.”

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Sex health represents one of the more controversial categories in dietary supplements. There is, unfortunately, no shortage of dietary supplement manufacturers making unvalidated health claims relating to sex drive, sexual dysfunction, and fertility. The good news is that research continues to validate purported sex-health ingredients, allowing manufacturers to have peer-reviewed, clinical data supporting the ingredients in their products.

Although minerals and other complex compounds are part of the sex-health market, a wide variety of botanical ingredients create a chunk of the sex-ingredient market, and clinical research continues to support their use in the bedroom. The following is a handful of recent science updates relating to botanical ingredients for sex supplements.

**Fenugreek Seed**

Although historically used as livestock fodder, fenugreek (Trigonella foenum-graecum), or at least the seed of the plant, is now one of today’s more promising plant ingredients for sex supplements. Its main, but not exclusive, source of manufacture is in India.

Numerous studies, many of them published quite recently, associate fenugreek supplementation in men with improvements in libido, higher frequency of sexual intercourse, increased testosterone levels, and higher sperm counts. But women may benefit from fenugreek, too. In a 2015 study from Australia, women with low sex drive who consumed fenugreek seed capsules over two menstrual cycles saw improvements in a variety of sex-related hormones, including estradiol and testosterone. Low testosterone levels are, surprisingly enough, correlated with decreased libido in men and premenopausal women.

Though the science on fenugreek is considerable, fenugreek suppliers are still trying to close gaps in their research. They want to prove repeatability of results and better understand fenugreek’s mechanism of action on human hormonal pathways. What’s known at this time is that fenugreek’s effects on sex health have to do with the seed’s complex content of saponins, some of which...
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ANTIOXIDANT (ORAC) PROTECTION COMPARISON CHART

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Research continues to validate sex-health ingredients, giving manufacturers peer-reviewed, clinical data.

help synthesize sex hormones. Anand Swaroop, president of Cepham Inc. (Piscataway, NJ), says that the fenugreek seed is where the plant’s most active constituents reside. “We have tried the other plant parts, but these contain mainly less active compounds,” he says.

Unfortunately, not all fenugreek seed extracts are made equal, and so effects on sex health may vary. Multiple recent fenugreek studies utilized extracts from two notable fenugreek suppliers, Cepham and Gencor (Irvine, CA). Cepham’s Furosap extract is standardized for 20% naturally occurring protodioscins. Gencor’s Testofen and Libi-fem extracts are standardized for a specific matrix of furostanol saponins. Both companies confirm that their extracts are unique to the market.

At the Experimental Biology conference held in San Diego, CA, this April, Cepham presented new study results showing Furosap may enhance testosterone levels and sperm profiles in men. The 12-week, one-arm, open-label study followed 50 male volunteers aged 35–65 who each received 500 mg/day of Furosap. Study parameters included testosterone levels, sperm profile, sperm morphology, libido, erectile dysfunction, mood, and mental alertness.

According to Cepham, researchers found that 85.4% of study participants showed improvements in sperm count, and 90% of participants showed improvements in free testosterone levels. Additionally, a majority of the subjects in the study experienced improvements in mental alertness and mood, and 14.6% of volunteers experienced an improvement in sperm morphology, says Cepham. Kelly Jordan, Cepham’s vice president of sales, says the company expects the study to be published.

“Overall, the results demonstrate that Furosap, enriched in 20% protodioscin, is safe and effective in attenuating testosterone levels, sperm profile, mental alertness, and overall performance in human subjects,” wrote the researchers, in an abstract provided by Cepham.

A safety parameter evaluation in the study, including extensive blood chemistry data, found no significant changes in cholesterol, hemogram (CBC), serum lipid function, triglycerides, hepatotoxicity, or nephrotoxicity as a result of the Furosap supplementation, according to Cepham.

“With these results, Furosap has set the bar high in a field crowded with other testosterone-boosting ingredients,” says Jordan, adding that the results will next be presented at the American Association of Clinical Endocrinologists’ 25th Annual Scientific & Clinical Congress in May.

Choosing your fenugreek ingredient may take some deliberation, but there are benefits at the end of it. Beyond purported sexual-health support, fenugreek seed extract is unusually sweet in taste, which should make consumer compliance a simple task. And fenugreek seed can also be positioned as a heart-health ingredient. Several recent studies link fenugreek consumption (in capsules and breads) with hypoglycemic and insulin-sensitizing properties. “The fenugreek extract powders giving the activity related to blood glucose control are typically standardized for branched-chain amino acids and galactomannans,” says RV Venkatesh, managing director, Gencor. “We are working on specific fenugreek extracts targeted at that segment of the market also.”

**Maca Root**

Maca (*Lepidium meyenii*) is known as a nutrient-packed food, but this member of the mustard family may also pack a sexy punch. Over the years, multiple studies have linked maca root consumption with increased libido in men and women, among other sexual enhancements.

Just last year, U.S. researchers concluded that 12 weeks of daily maca capsules improved self-reported sexual health over placebo in women suffering from antidepressant-induced sexual dysfunction. The long-term consumption also appeared to be well tolerated. A few months later, Czech researchers determined that 12 weeks of maca consumption improved sperm concentration and sperm motility in men, without influencing their hormone levels. More maca trials are ongoing for men and women.

Results of these and other maca trials should make manufacturers optimistic about formulating sex-health products with maca, but, as with fenugreek, the quality of raw maca supply varies across the industry. As proof, a team of Chinese researchers tested maca samples from 14 different farms in China and Peru, only to find that levels of...
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zinc, copper, and sodium in samples varied greatly.4

“Maca, like any other natural food, can vary in nutrient content, depending not only on where the ingredient is sourced, but on the quality of care the ingredient receives, as well,” says Steve Siegel, vice president of marketing and sales at maca supplier Ecuadorian Rainforest (Belleville, NJ). “It is absolutely vital for ingredient suppliers to have a close-knit relationship with local farms to ensure the quality of ingredients, as some providers may not take the steps necessary to produce maca with an acceptable nutrient profile.” So, make sure to check company history and technical documents when purchasing maca.

Ashwagandha Root

Until recently, sex-health studies involving ashwagandha (Withania somnifera) supplements have targeted the male population exclusively. Studies bode well for the Ayurvedic herb as a potential aid for improving sperm quality.5,6 And yet, a new study on females suggests that they, too, may benefit sexually from ashwagandha supplements.7

Writing in BioMed Research International, a team of Indian researchers says that women consuming ashwagandha daily for eight weeks experienced better scores on sexual-satisfaction surveys than those consuming a placebo. Self-reported improvements in the ashwagandha group included sexual interest, lubrication, arousal, and ability to achieve orgasm, as well as a significant reduction in sexual distress. Ixoreal BioMed Inc. USA (Los Angeles), which supplied its KSM-66 ashwagandha extract for the study, says the positive changes may be associated with ashwagandha’s ability to increase testosterone, but also with the herb’s calming and body-balancing effects, which have been noted in numerous other studies unrelated to sex.

Tribulus

Not all sexual-health botanicals come from the roots. In the case of tribulus (Tribulus terrestris), the most active concentration of relevant compounds is found in aerial parts of the plant. And according to Chinese, Greek, and Indian traditional medicine, this portion of tribulus may be used as a sexual stimulant.

Human clinical trials on tribulus may be scarce, but recent results may help validate traditional uses for tribulus. In an April 2015 study8 from Egypt, 30 men with indications of low testosterone production were assigned to three months of daily tribulus consumption, which was associated with improvements in total and free testosterone, as well as better scores on questionnaires concerning erectile health. A 2016 study9 on menopausal women found tribulus supplements were associated with self-reported improvements in sexual arousal, desire, lubrication, and ability to achieve orgasm, compared to placebo.

Human clinical trials on tribulus may be lacking, at least compared to some other ingredients, but there are still plenty of global suppliers for the ingredient, such as HP Ingredients (Bradenton, FL), which markets a tribulus extract standardized for a particular concentration of saponins.

Synergizing Ingredients

A single botanical ingredient may be attractive enough for consumers seeking sexual-health supplements, but more complex formulas may provide greater uses, such as multiple or even synergistic benefits. The market for sex-health supplements is extensive, and the small handful of ingredients covered here is just a taste of what’s already on the market. Draco Natural Products (San Jose, CA), for instance, offers a long list of Chinese herbs, many of which pertain to sexual health. “We are able to combine these into potent, efficacious, traditional Chinese medicine formulas that are highly unique and proprietary,” says Draco R&D
director Brien Quirk. "They offer several advantages to the mass market’s popular botanicals, such as epimedium or tribulus, if a company wants to launch a new product and be able to have a competitive advantage with existing products."

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Turmeric and White Mulberry Blend May Reduce Joint Discomfort


New preclinical study results suggest Romatol, a blend of turmeric extract and white mulberry extract from Unigen (Seattle), may be able to reduce joint discomfort in rats. Researchers found that Romatol supplementation resulted in a significant improvement to pain resistance compared to placebo and achieved similar results as an ibuprofen treatment.

Romatol contains a blend of extracts from turmeric (*Curcuma longa*) rhizome and the root bark of white mulberry (*Morus alba*). In a press release, Unigen acknowledged that Romatol is still being tested for its capabilities in aiding joint support, and that it is just one of “multiple new joint-health ingredients in their pipeline.”

“Joint health is a category that continues to be dominated by a few ingredients, and we would like to see that offering expanded, adding value to Unigen’s clients,” said Grant Bergstrom, vice president of sales and marketing, Unigen.

The study involved rats with carrageenan-induced paw edema that were treated with either 200 mg/kg of ibuprofen, a placebo vehicle control, or Romatol doses of 100, 200, 300, or 400 mg/kg.

Researchers found statistically significant improvements in pain resistance and paw edema suppression in animals treated with Romatol, compared with the placebo group. The highest dose of Romatol (400 mg/kg) was also found to have a similar effect as the 200 mg/kg dose of ibuprofen.

Additionally, an *in vitro* aspect of the study to evaluate inflammation found that Romatol showed a dose-dependent inhibition of enzymatic activities of cyclooxygenase and lipoxygenase. It was also found to act as a bradykinin receptor B1 and B2 antagonist.

“UP1304 [Romatol] could potentially be considered as a dietary supplement product for the management of arthritis,” concluded researchers.

UC-II Collagen More Effective for Knee Osteoarthritis Symptoms than Glucosamine Hydrochloride Plus Chondroitin?


A study published in *Nutrition Journal* finds that UC-II, an undenatured type II collagen ingredient, may be more effective at relieving knee symptoms of osteoarthritis than a placebo or a combination of glucosamine hydrochloride and chondroitin sulfate. Supplied by InterHealth Nutraceuticals (Benicia, CA), UC-II is a collagen supplement derived from chicken sternum cartilage that has shown promise in past studies for joint function.

The multicenter, randomized, double-blind, placebo-controlled study was conducted at 13 centers in southern India and included 191 volunteers aged 40–75 years. Participant criteria included moderate-to-severe osteoarthritis by physical examination in one or both knees, and knee pain for at least three months prior to the start of the study.

For 180 days, subjects were randomized to consume a daily dose of 40 mg UC-II, 1500 mg glucosamine hydrochloride plus 1200 mg chondroitin sulfate, or a placebo.

The study’s primary endpoint was the change in total Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) from baseline to day 180, with secondary endpoints including WOMAC subscales, the Lequesne Functional Index (LFI), and the Visual Analogue Scale (VAS) for pain.

At the end of the 180-day trial period, the overall WOMAC score for the UC-II group was significantly reduced compared to the placebo and the glucosamine/chondroitin combo groups. The UC-II group also experienced significant changes in all three WOMAC subscales: pain, stiffness, and physical function. Compared to baseline WOMAC subscale scores, the UC-II group experienced a 41% reduction in the pain scale, a 40% reduction in the stiffness scale, and 39% reduction in the physical-function scale, according to InterHealth.

Researchers concluded that UC-II “significantly improved knee function in [osteoarthritis] subjects by day 180, compared to placebo and to [the glucosamine/chondroitin combo], and was well-tolerated. Based on the data presented herein, we believe that additional research is warranted both to confirm and to define these findings more extensively.”

MSM and Boswellic Acids Comparable to Glucosamine for Osteoarthritis Relief, Study Suggests

New study results out of Italy suggest a combination of methylsulfonylmethane (MSM) and boswellic acids may be as effective as glucosamine sulfate for alleviating symptoms of knee osteoarthritis.

Writing in *International Journal of Immunopathology & Pharmacology*, researchers reported that while MSM and boswellic acids have been found to show positive effects on osteoarthritis symptoms in the past, this is the first study to compare the efficacy of MSM and boswellic acids with glucosamine sulfate for knee osteoarthritis.

The study included 120 participants with a mean age of 59.2 +/- 13, all of whom had osteoarthritis of the knee and reported frequent joint pain for at least six months prior to recruitment. Participants were randomized to consume either 2.5 g of MSM and 3.6 mg of boswellic acids in a sachet twice per day or 1500 mg of glucosamine sulfate in a sachet once per day. The supplementation period of the study lasted 60 days.

Researchers assessed efficacy of the treatments with a visual analog pain scale (VAS) and the Lequesne Index (LI) for knee joint function, as well as the patient’s need to take anti-inflammatory drugs. Participants reported for clinical visits to evaluate these measures at the outset of the study, at the end of the supplementation period, and six months after the beginning of the study (four months after the end of the supplementation period).

At six months, VAS, LI, and use of anti-inflammatory drug scores were significantly reduced in both the glucosamine group and MSM and boswellic acids group compared to baseline, with a tendency toward better values for the MSM and boswellic acids group. Aside from the fact that both treatments showed a significant improvement to osteoarthritis knee symptoms, researchers also noted that the effects seemed to persist for four months after suspending supplementation.

“This study suggests the potential effects of MSM and [boswellic acids] in knee [osteoarthritis] patients in pain management, functional recovery, and the reduction of intake of anti-inflammatory drugs,” wrote the researchers. “The point that this new combination of integration (MSM and [boswellic acids]) has presented results comparable with [glucosamine sulfate] could confirm validity in the treatment of [osteoarthritis].”

Researchers noted that further study is still necessary to better understand the effects of long-term MSM and boswellic acids administration.

**New Safety Data Published on Weight-Management Ingredient ForsLean**


A study on the safety of ForsLean, a patented Coleus forskohlii weight-management ingredient from Sabinsa Corp. (East Windsor, NJ), is now published in the *International Journal of Pharmacy & Pharmaceutical Research*. The article’s lead author is Sabinsa founder Muhammed Majeed, PhD. ForsLean is standardized to 10% forskolin content.

The researchers performed three types of studies post-oral ingestion in Wistar rats: acute, sub-acute, and chronic toxicity. During the two-week, single-dose test, rats were given a single 2000 mg/kg body weight dose of ForsLean and then examined once daily for toxicity, behavior, and pharmacological effects thereafter. The researchers also performed a four-week sub-acute oral toxicity test in which the rats were given daily doses of either 100, 300, or 1000 mg/kg body weight. Finally, in a 180-day chronic oral toxicity test, the rats were given a daily dose of 500 mg/kg body weight or 1000 mg/kg body weight.

The researchers reported no deaths, no organ damage, and no significant changes in hematology or serum biochemistry. Body weight changes were said to be normal. Even the high dose of 1000 mg/kg body weight did not lead to any significant toxic effects in the rats, they said, leading them to conclude that the no observed adverse effect level (NOAEL) for ForsLean is 1000 mg/kg body weight daily.

“Coleus forskohlii root is a well-established ingredient with a long history of safety. Even for such well-known herbs though, additions to the scientific literature are always welcome, and this article serves to increase our understanding of the appropriate use of this important herb and its extracts,” said American Herbal Products Association (Silver Spring, MD) president Michael McGuffin in a Sabinsa press release announcing the test results.

“Our award-winning ForsLean brand is set apart from other suppliers of Coleus forskohlii with our safety publications, patents, and human clinical studies,” said Sabinsa marketing director Shaheen Majeed in the press release. “Substitutions just don’t have those advantages.”

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**RESEARCH BUZZ**

**Rosemary and Green Tea Blend Preserves Meat Color, Flavor, Says Kemin**

A bright red color is often the first thing consumers look for when purchasing meat and poultry, and a new study suggests a blend of rosemary and green tea extract may be just the thing to preserve that ideal coloration.

Kemin Food Technologies (Des Moines, IA) recently shared results of a study, which found that while it’s rosemary and green tea extract blend is better at preserving the color of ground beef than rosemary extract alone. The color-stability study was conducted at the University of Nebraska–Lincoln meat lab in February 2015.

Researchers treated 0.725-lb portions of coarsely ground, 81% lean beef with either rosemary extract alone, a rosemary extract and green tea extract blend, or no treatment. The meat was then stored in a simulated retail display for 10 days, with color measurements taken with a HunterLab ColorFlex Colorimeter.

Researchers noted that further study is still necessary to better understand the effects of long-term MSM and boswellic acids administration.
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CRAZY for Coconuts

Coconut oil’s sales are surging thanks to its appeal as a healthier replacement for butter.

BY MICHAEL CRANE, ASSOCIATE EDITOR

As more consumers seek out nutritious alternatives to butter, margarine, and traditional cooking oils, up-and-coming oils, from avocado oil to pecan oil, are quickly shooting up the sales charts. But one of the biggest breakout ingredients in the category is coconut oil, thanks to its solid nutritional profile and easy use as a butter substitute.

U.S. coconut oil sales reached more than $239 million in 2015, according to SPINS. And while that’s still less than the total sales posted by category leaders canola oil and soybean oil, coconut oil sales climbed 31.3% in 2015 compared to the previous year. Canola and soybean oil, on the other hand, saw sales decrease by 5.7% and 9%, respectively, during the same period.

“Interest in organic virgin coconut oil has been rapidly growing over the past decade,” says Meg Carlson, president and CEO of Prosperity Organic Foods. Since 2012, Prosperity Organic Foods has been marketing its MELT Organic products—featuring virgin coconut oil, hi-oleic sunflower oil, and flaxseed oil—as a “luscious butter improvement that is truly good for you.” (Recently, the company even introduced a probiotic buttery spread containing the Ganeden BC30 Bacillus coagulans probiotic strain.)

“Consumers have become educated about the nutritional profile and benefits of eating organic virgin coconut oil rather than GMO-derived vegetable oils like soy and canola,” explains Carlson.

Perceptions of Saturated Fats

One marketing challenge for coconut oil may be its high saturated fat content, but not all saturated fats are created equal, says Carlson. The saturated fats in Prosperity’s organic virgin coconut oil do not elevate LDL cholesterol and are rich in medium-chain fatty acids, which have been researched for benefits to metabolism and thyroid activity, explains Carlson.

Consumers seem to be getting the message, as Prosperity Organic Foods has “already seen a significant change in the perception of saturated fats,” Carlson says.

John Roulac, founder and CEO of Nutiva, agrees that consumer perception of saturated fats has changed since Nutiva began selling coconut oil back in 2003.

“As thousands of doctors now know, there’s no direct connection between saturated fat and heart disease,” Roulac explains.

Nutiva’s coconut oil sales have “exceeded all expectations,” says Roulac, and in January the company debuted a new organic buttery coconut oil.

The potential positive health benefits of coconut oil are also outweighing any negative perception of saturated fats, suggests Mary Ann Siciliano, national sales manager for oils supplier Arista Industries (Wilton, CT). She points to the “unique combination of fatty acids, antioxidants, and phenol compounds” in Arista’s organic extra virgin coconut oil, which makes it a popular choice for consumers looking to improve cholesterol levels or lower the risk of heart disease.

Works Like Butter

One of the biggest factors in coconut oil’s favor is undoubtedly its ability to easily substitute for butter in a variety of applications. With a similar melt point as butter and unobtrusive flavor, it works on everything from popcorn to steamed vegetables, says Nutiva’s Roulac.

“Organic extra virgin coconut oil can tolerate higher heat than many other oils,” explains Arista’s Siciliano. “It has a smoke point of around 350 °F, and it is great for sautéing and frying. It can be used in place of shortening or butter in a variety of baked goods, including cakes, candy, cookies, pastries, and pies.”

It’s no wonder then that coconut oil is giving canola and soybean oils a run for their money.

References

1. Data includes natural supermarkets (excluding Whole Foods Market), specialty supermarkets, and conventional multi-outlet channels. Comparison of 52 weeks ending 12/27/15 with 52 weeks ending 12/28/14
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