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NUTRITIONAL OUTLOOK

NOVEMBER 2014
For two decades, ADVANTRA Z has safely ignited metabolism. Used in conjunction with healthy diet and exercise, this thermogenic ingredient lights the fire that jumpstarts weight-loss efforts and helps increase lean muscle, a necessity for long-term weight management.
October 25th marked the 20th year since President Clinton signed the Dietary Supplement Health and Education Act (DSHEA) into law.

DSHEA defined the category of dietary supplements in the United States and, by so doing, gave consumers free market access to the health benefits that supplements provide. But even as today’s industry stakeholders pay tribute to the two decades of DSHEA’s governance, those celebrations are shadowed by strong suspicions that some—namely, the FTC, through recent regulatory actions—are treading on the law as written.

According to industry leaders, the latest indication of FTC overstepping was when the FTC filed a legal motion for order of contempt against Bayer Corp. this fall, calling the company’s Phillips’ Colon Health probiotic structure/function claims unsupported. Bayer says the product "defend[s] against occasional constipation, diarrhea, gas, and bloating. When taken on a daily basis, it can help replenish the good bacteria in your colon and support digestive health and immune health."

According to the FTC and its own gastroenterology expert, Bayer would need randomized, placebo-controlled human clinical trials (RCTs) to substantiate such claims. But industry leaders argue that RCTs are required for drug treatment claims, not supplement structure/function claims, and that both law (DSHEA) and formal FDA and FTC guidance specifically state that dietary supplements are not to be regulated as drugs.

While structure/function claims must be supported by “competent and reliable scientific evidence,” RCTs are not required. There are a number of reasons for this, relating to the fact that supplement studies—studies proving that a product shores up general good health over time rather than curing an acute disease—are more complicated than the typical single-API drug study. Supplement studies are also complicated by such factors as subjects’ overall nutrient intake and the fact that performing studies in healthy populations requires a very long (and expensive) trial. As such, supplement firms are allowed to refer to a number of study types to support structure/function claims, including, explains the Council for Responsible Nutrition (CRN; Washington, DC), randomized clinical studies on a specific population whose results are extrapolated to the general population, epidemiological evidence, in vitro studies, animal studies, and observational studies. FTC guidance even makes clear that there is "no fixed formula for the number or type of studies required," CRN points out, and FDA does not require that studies must be done on the finished product being sold.

Industry leaders say the Bayer case is just the latest example of FTC overstepping DSHEA’s authority, as it has in consent orders past. And the slope towards unofficially rewriting supplement regulations, they say, is slippery. As the Natural Products Association (NPA; Washington, DC) said, if the Bayer case is allowed to stand, "the distinction between dietary supplements and drugs will effectively evaporate."

This is why CRN and NPA are now objecting legally in the Bayer case. In October, both associations filed amicus briefs (“friend of the court” insights that challenge the FTC’s legal actions in the Bayer case) “to try to inform the judge as to what we believe the correct standard is, because we believe the FTC is using the wrong standard in this case,” says Steve Mister, CRN’s president and CEO. Because, he points out, Bayer is not making drug claims that would require RCTs. "In this case, you’re not talking about treating an acute symptom. The product is not suggesting that when you have gas, you go out and buy the product and it cures the gas in 30 minutes. That’s not what the product says. In this case, what we see is a straight structure/function claim: defends against occasional gas, bloating, constipation, and diarrhea. Those are recognized for years in both the FTC guidance and the FDA guidance on structure/function.”

At this stage in the legal game for Bayer, there is still a chance that the court could take these associations’ objections into consideration. “We’re waiting to hear now whether the FTC would oppose that,” Mister says. If it does, “then we’d have to go have a hearing with the judge to argue why we have the right to intervene in this case and become an amicus in the case.”

If the dietary supplements industry aims to celebrate another 20 years of DSHEA, then it needs to defend the law. “I think everything about this case is a wake-up call to the industry that we need to pursue this,” says Mister.

Jennifer Grebow
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Researchers Detect New DMAA-Like Adulterant in Dietary Supplements

A “close cousin” of the recently FDA-banned ingredient DMAA has been found in 12 over-the-counter dietary supplements. DMBA (1,3-dimethylbutylamine) is a synthetic stimulant whose health effects are currently unknown, say researchers who reported the finding in an article published on October 8, 2014, in Drug Testing and Analysis.

DMBA is chemically similar to other harmful stimulants like DMAA (1,3-dimethylamylamine), say researchers from NSF International (Ann Arbor, MI), Harvard Medical School, and the National Institute for Public Health and the Environment in the Netherlands (RIVM). The U.S. FDA banned DMAA from the dietary supplements market in April 2013 following adverse-event reports, warning consumers about risks of elevated blood pressure, stroke, heart attack, and even sudden death. Regulatory agencies in the UK, The Netherlands, and Brazil have also banned DMAA.

DMBA is a synthetic stimulant whose health effects are currently unknown, say researchers.

Like DMAA, as well as ephedrine, the newly found DMBA is a stimulant. The researchers say there are no known safety studies on DMBA and that the drug has never been tested in humans, only in dogs and cats with severed spinal cords.

The researchers are calling on regulatory agencies to ban DMBA as an adulterant not approved for use in dietary supplements. “While regulatory authorities work to remove harmful stimulants such as ephedrine and DMAA from supplements, new synthetic stimulants such as DMBA continue to crop up to take their place,” said NSF International’s senior research scientist John Travis in a press announcement. (Read Travis’s article warning about emerging adulterants at www.nutritionaloutlook.com/140926/NSF.) “Without proper studies, the health impact of this new stimulant is entirely unknown. We urge manufacturers, distributors, retailers, and regulators to work together to remove this unapproved stimulant from the marketplace to help protect consumers from potentially harmful health effects.”

“It is essential to steer clear of this new drug,” added Pieter Cohen, MD, assistant professor of medicine, Harvard Medical School. “The possibility to cause harm is real.”

The researchers warn that products may list DMBA as “4-amino-2-methylpentane citrate,” “AMP citrate,” “1,3-dimethylbutylamine citrate,” “4-amino-2-pentanamine,” “Pentergy,” “4-AMP” or “extracted from pouchong tea.”

The researchers made their discovery after analyzing 14 dietary supplements, of which 12 were found adulterated with DMBA, using ultra-performance liquid chromatography tandem mass spectrometry (UPLC-MS/MS) testing. DMBA presence in the adulterated supplements ranged from 13–120 mg per serving. Consumers following the products’ recommended daily usage would ingest anywhere between 26 and 320 mg of DMBA daily.
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House Passes Designer Anabolic Steroid Control Act

The Designer Anabolic Steroid Control Act of 2014 (DASCA), which would enhance the U.S. Drug Enforcement Administration’s (DEA) authority to identify and respond to new designer anabolic steroids falsely marketed as dietary supplements, has made it through the U.S. House of Representatives and now moves to a Senate vote.

Dietary supplement association the Council for Responsible Nutrition (CRN; Washington, DC) commended the House for passing the bill and urged the Senate to follow suit.

“If DASCA is passed by Congress and signed into law by the president, DEA’s enhanced authority would help protect consumers from illegal products that could present safety concerns and will give them greater confidence that the products brought to market and sold as dietary supplements are legal,” said Mike Greene, CRN’s vice president, government relations, in a press statement.

CRN says it has been engaged in bipartisan discussions with legislators in both the House of Representatives and the Senate to underline the importance of DASCA to the supplements industry as well as consumers.

The Designer Anabolic Steroid Act of 2014 (HR. 4771), a companion bill to S. 2012, would enhance DEAs ability to enforce against supplement spikers by expanding the list of controlled substances. Reps. Joe Pitts (R-PA) and Frank Pallone (D-NJ) introduced the bill in the Senate in early 2014.

New Omega-3 Website Targets Consumers—and Market Recovery

As part of its plan to educate consumers on the benefits of omega-3 fatty acids EPA and DHA, the Global Organization for EPA and DHA Omega-3s (GOED; Salt Lake City, UT) and its newly formed Omega-3 Coalition have launched a consumer website, www.alwaysomega3s.com.

Site features include a quiz to help consumers estimate their average daily intake of EPA and DHA omega-3, a guide to choosing foods and supplements containing EPA and DHA, and basic information and scientific documentation about the benefits of omega-3s for the heart, brain, eyes, and joints.

The independent educational website is supported by The Omega-3 Coalition, a recently forged group whose goal is, in part, to help reverse omega-3s’ yearlong market decline and “change the tone of the conversation around omega-3s in the mainstream media.” Read more about the coalition and GOED’s advice to omega-3 companies in the face of current market struggles at www.nutritionaloutlook.com/140912/GOED.

GOED reported in October that the coalition completed test-marketing the full campaign and that the test market “lays the groundwork for the national rollout planned for early 2015.” The coalition is also fundraising to support its efforts, with an estimated $3.5 million raised as of August 2014.

California Prop 65 Regulators Consider Changing Warning Language

California regulators may be reconsidering the way that Proposition 65 warning statements are worded. Industry group the American Herbal Products Association (AHPA; Silver Spring, MD) reports that following a September 25 meeting with the California Office of Environmental Health Hazard Assessment (OEHHA), which oversees Prop 65, OEHHA officials showed interest in AHPA proposals to make warning statements less broad-based and more specific to certain populations.

OEHHA currently requires companies that sell products in California to carry a warning statement if the products may contain chemicals “known to the State of California to cause birth defects or other reproductive harm.” Companies must use this warning statement, even if their products contain miniscule and arguably harmless levels of the more than 850 Prop 65–listed chemicals.

Prop 65 warnings have become so ubiquitous that many argue consumers are now tuning out those warnings. For one, because the threshold for Prop 65 chemical levels is so low, many companies choose to use the warning label preemptively, regardless of whether their products’ chemicals are actually above the threshold. Some also say that warnings don’t provide meaningful information to the consumer because the warning language is vague. AHPA calls the current wording “inflammatory” and “alarming.”

AHPA, which has been very active in Prop 65 discussions, is advocating that Prop 65 warnings instead be used to warn specific populations who may truly be at risk of harm, such as children and pregnant or nursing women. AHPA proposed these “more informative” warnings to OEHHA: “WARNING: Not for use by pregnant or nursing women,” or “WARNING: Not for use by children, pregnant or nursing women, or men or women who are trying to conceive.”
Is the fish oil in your Omega-3 supplement certified sustainable? AlaskOmega® Omega-3 Concentrates are sourced from a well-managed Alaskan fishery with a 30-yr track record. Since 2005, the Alaska Pollock fishery has been independently certified to meet the highest global standards for seafood sustainability set by the Marine Stewardship Council (MSC). For AlaskOmega®, sustainability is not merely a buzzword, but the essence of our Alaskan source.

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“The AHPA proposal would make warnings for exposures to Proposition 65–listed reproductive toxicants easier to understand for consumers because they instruct that the product should not be used by those populations who could be affected by exposure,” said AHPA president Michael McGuffin in a press release. “The AHPA language would fully conform to and satisfy the intent of Proposition 65 by ensuring that consumers receive ‘clear and reasonable warning’ relevant to exposures to these substances and would dramatically increase label compliance.”

AHPA, which calls its meeting with OEHHA a “breakthrough,” says OEHHA officials asked AHPA to present specific recommendations on how to include these labeling revisions within the Prop 65 regulations. AHPA and its legal counsel are now working on drafting those recommendations.

“AHPA is encouraged that OEHHA staff is receptive to amending the regulations to provide this additional warning option,” McGuffin said. “If the regulations are amended, it would be a win for consumers and companies selling food and personal care items in California.”

OEHHA has come under criticism from many industries this year when it announced this April that it plans to overhaul the Prop 65 system. (Read more at www.nutritionoutlook.com/news/prop-65-safe-harbor-no-more.) In pre-regulatory proposals, the office suggested requiring companies list specific Prop 65 chemicals that a product contains. It also proposed creating a website that would provide consumers with additional information on chemical contents. Finally, it would ban companies from using Prop 65 warnings as a “safe harbor,” only allowing products containing chemicals above the Prop 65 threshold to use the warning statement.

Today’s Flavor Masking Must Block Multiple Receptor Sites

In September, Sensient Flavors (Hoffman Estates, IL) launched brand-new flavor-masking technology, called Smoothenol 2G, for masking bitter, astringent, and other “off” notes. According to the company, Smoothenol 2G exceeds today’s typical flavor maskers by helping to block not just one but multiple receptor sites implicated in taste reception.

As an example, David Bom, Sensient’s technology development manager, explains, “There are more than 25 bitter receptors on the human tongue, which are responsible for tasting everything from hops in beer to the caffeine in our coffee. Bitter molecules are agonists. When they bind to the receptor, they activate it, leading to an entire cascade of signaling events that agonists ultimately tell the brain are either ‘Yuck! Bitter!’ or ‘Mmmm! Yummy!’ If you block the receptor signaling, you can control that signal.”

However, sometimes blocking just one bitter receptor won’t do the trick. And that’s because taste reception often involves more than one receptor. Also, Bom points out, because bitter receptors are designed to protect the host (us), they can adapt if one specific receptor is blocked or otherwise impeded. For instance, if one specific receptor is blocked, damaged, or genetically mutated, then another receptor might step in to respond to the taste stimuli instead. Thus, “the blockade could occur at the bitter receptor itself—or at an alternate receptor downstream from the primary bitter receptor,” Bom says.

Given this, a single-molecule or single-ingredient flavor-masking solution might not be enough to successfully block taste; rather, one needs “an entire toolbox of ingredients that work together to mask ‘off’ notes and enhance flavor,” the company says.

For instance, if an ingredient like caffeine binds five receptors, Smoothenol 2G technology can provide up to five different masking compounds. Smoothenol 2G can block the bitter, metallic, chalky, astringent, and other “off” tastes associated not only with caffeine but also sweeteners (e.g., the bitter notes of Reba A), alcohol, vitamins and minerals, and nutraceuticals and functional ingredients.

The science of taste reception is still emerging. Bom says that while this multi-pronged approach to flavor masking is new to the flavor industry, it’s already old practice in the drug industry. “The majority of the time, medicinal chemists are trying to improve selectivity over multiple targets,” he says. “Other times, they either, knowingly or unknowingly, design molecules that derive their therapeutic value through the interaction with two or more receptors. A lot of brain-active medications act in this manner. In other cases, targeting multiple receptors leads to toxicity, which drives the need for selectivity.”

Group Aims to Create a Definition for Natural, and More

A brand-new group is ready to take on some of the industry’s biggest issues. Formed this summer, the Organic and Natural Health Association (ONHA; Washington, DC; www.organicandnatural.org) met the industry’s acquaintance by way of a VendorBrief presentation at October’s SupplySide West trade show in Las Vegas, NV.

First up? Establishing a formal definition for the word natural for a range of industries, from food and supplements to cosmetics and pet food. Lack of a formal FDA regulatory definition for natural has created lots of confusion (and jadedness) among companies and consumers over “natural” and “all natural” claims—and lots of room for class-action suits over whether or not companies use the claims misleadingly.

Why does ONHA believe it can succeed where others have failed? According to CEO Karen Howard, it’s because the association
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aims to pick up the process where others have already laid groundwork. Howard emphasizes that the intent is not to start from scratch, but rather to build on the progress other groups have made already in addressing issues key to the natural and organic industry. “The process is one that will be very inclusive,” she adds. “As we create our standards—and we can use natural as an example—we’ll be looking to the organizations with this expertise…. That is our intent: to collaborate with all of these organizations who have done this work, so we’re an added-value instead of added-work.” Howard says ONHA is targeting its membership to include the views of “consumer-based associations” such as nonprofit groups representing consumers as well as corporations and retailers. ONHA also aims to create its own third-party certification program and certification seal.

Dietary Supplements Cannot Cure or Prevent Ebola, Coalition Warns

There is no scientific data showing that dietary supplements can prevent or cure the Ebola virus or that supplements can treat, cure, or prevent disease. Industry leaders are spreading this warning among consumers as well as supplement retailers and marketers.

“As for organic, Howard says ONHA’s goal is not to compete with the USDA’s National Organic Program—“I don’t know that you can improve upon that definition at all,” she says—or any type of independent certification program, but that the association will instead play a “supportive” role in any conversations around organic. “Should there be issues with the organic label that we could be supportive of across industry, we would certainly be there for that,” she says.

First up for the new Organic and Natural Health Association? Establishing a formal definition for the word natural.

There is no scientific data showing that dietary supplements can prevent or cure the Ebola virus or that supplements can treat, cure, or prevent disease. Industry leaders are spreading this warning among consumers as well as supplement retailers and marketers.

“While there are many dietary supplements that have much to offer in terms of enhancing general immune function, therapies for the treatment of Ebola virus disease should only be recommended by qualified healthcare professionals or public health authorities,” stated the American Herbal Products Association (AHPA), the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN), the Natural Products Association (NPA), and the United Natural Products Alliance (UNPA).
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Chromium Picolinate Dietary Supplements and Diabetes-Attributed Coronary Heart Disease (CHD)

A new economic report shows that taking specific dietary supplements can provide significant individual and societal healthcare savings, by reducing the number of hospitalizations and other costly medical events associated with chronic diseases. This infographic demonstrates the cost savings that can be realized through the utilization of chromium picolinate supplements among all U.S. adults over the age of 55 with diabetes-attributed CHD.

**Potential savings**

Between 2013 and 2020, diabetes-attributed CHD medical event costs will average nearly $33 billion annually. The use of chromium picolinate at preventive intake levels by the targeted population of U.S. adults 55+ who have diabetes-attributed CHD can reduce those costs.

| Avoided expenditures with supplementation | $1.2 billion | $9.8 billion |
| Net savings after cost of supplements | $970 million | $7.8 billion |
| Savings yet to be realized if targeted population takes chromium picolinate at preventive intake levels | ~$970 million* | ~$7.8 billion* |

**The opportunity**

Chromium picolinate supplements are used by less than 1% of diabetic U.S. adults 55+, which means that 99% of diabetic U.S. adults 55+ are not taking chromium picolinate supplements. There are still significant cost savings yet to be realized through the increased usage of chromium picolinate.

**Notes:** 1. With less than 1% currently using this supplement, nearly all of the net savings have yet to be realized. Numbers have been rounded. Exact numbers can be found in the full report.


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Where Does the Multivitamin Stand These Days?

Nutritional Outlook interviewed the Council for Responsible Nutrition’s Judy Blatman on the multivitamin’s rocky few years.

BY JENNIFER GREBOW, EDITOR-IN-CHIEF

Multivitamins have faced ups, downs, and “in between” over the years. On one hand, usage remains remarkably high. The Council for Responsible Nutrition’s (CRN; Washington, DC) annual Consumer Survey on Dietary Supplements ranks multivitamins as the most popular supplement consumed by U.S. adults; in fact, more than half of all American adults report taking one.

But recent studies—most evaluating multivitamin effects on chronic disease—and subsequent media reports have portrayed multivitamins negatively. Last December, an Annals of Internal Medicine editorial minced no words. The editorial, titled “Enough Is Enough: Stop Wasting Money on Vitamin and Mineral Supplements,” states: “The message is simple: Most supplements do not prevent chronic disease or death, their use is not justified, and they should be avoided. This message is especially true for the general population with no clear evidence of micronutrient deficiencies…”

A year earlier, researchers in the Physicians’ Health Study II, published in the Journal of the American Medical Association, found that taking a daily multivitamin did not reduce negative cardiovascular events, and a later-reported cognitive arm of the study found no cognitive benefits as a result of multivitamin supplementation.

Scientific bodies also remain equivocal, stating that, currently, there’s not enough study evidence to demonstrate that multivitamins have benefits for Americans across the board. (Read more on this at www.nutritionaloutlook.com/140922/Multi.)

So, on one hand, we have consumers obviously voting for multivitamins with their dollars; on the other, a scientific community that’s still not on board. What will it take for multivitamins to get a “yes” vote from all? Nutritional Outlook asked Judy Blatman, CRN’s senior vice president, communications, for her take on the debate.

Scientific bodies state that there’s not enough evidence to demonstrate broadscale multivitamin benefits.

Nutritional Outlook: Multivitamins have seen some negative press in recent years. The message that the dietary supplement industry maintains is that multivitamins (and supplements, in general) are meant to fill nutrient gaps and shore up general good health—not necessarily to prevent broadscale disease. Has this message changed at all over the years? Is this still the primary argument supporting multivitamins?

Blatman: For as long as I can remember—and I’ve been at CRN for more than a dozen years—we have positioned the multivitamin as a safe, convenient, and affordable insurance policy for ensuring you are getting all your essential nutrients. But we’ve always positioned the multivitamin as a supplement to, not a substitute for, a healthy diet.

In terms of preventing broadscale diseases with a simple multivitamin, I don’t think there’s ever been that expectation, but it stands to reason that if you’re getting the right nutrients, then your overall health will benefit because nutrition plays an important role in good health.

In response to the negative results of the cardiovascular and cognitive arms of the Physicians’ Health Study II, many media reports portrayed multivitamins negatively. Has the way the mainstream press interprets study results and draws conclusions about the benefits of multivitamins changed in any way over the years? Would you say that the messaging is more negative these days than it is positive, or vice versa?

Blatman: The mainstream media generally takes its cue from the medical journals and the way the study authors portray the results of their studies. That’s not unique to our industry.
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The first negative wave of publicity that I experienced for the multivitamin was in 2006 following the National Institutes of Health Office of Dietary Supplements conference on the multivitamin and chronic disease where a scientific conference designed for a very specific purpose turned into a shorthand version of the conclusions. Some of the media got it right, but others couldn’t resist the temptation to turn that conference into a referendum on the multivitamin for all purposes.

“We’ve seen a particularly bad cycle of press for supplements, including multivitamins, for the past year or two, and that’s had an impact, but I don’t think it will be a lasting one, as long as we continue to be proactive in our efforts to clean up the industry and listen and understand what consumers want in supplement products.

Overall, has multivitamin usage declined? And, if so, has multivitamin usage declined because more consumers are instead taking more specialized/variety of supplements? To balance this, has the usage of dietary supplements overall gone up?

Blatman: According to the CRN annual Consumer Survey on Dietary Supplements, overall usage of supplements has remained consistent, with approximately two-thirds of American adults taking them year after year.

As our country’s adult population increases, so has the actual number of American adults taking supplements. We’ve also seen good news in that regular usage has increased from 47% in 2005 to 53% in 2013, and regular users taking a variety of supplements has increased from 22% to 35% over that same period. And, according to our survey, the multivitamin is still the most popular vitamin, with more than half the adult population taking multis.

In CRN’s September 5, 2014, comments to the Dietary Guidelines Advisory Committee (DGAC), which is currently working to draft the 2015 Dietary Guidelines for Americans, CRN advocated a multivitamin—and supplements, in general—as a good way to fill nutrient gaps when those gaps aren’t met through food intake. The 2010 Dietary Guidelines for Americans stated that “Sufficient evidence is not available to support a recommendation for or against the use of multivitamin/mineral supplements in the primary prevention of chronic disease for the healthy American population.” What do you think are the chances that, this time around, the DGAC will recommend the use of a multivitamin?

Blatman: The Dietary Guidelines process is a complicated one, and CRN understands that process and respects the work of the Committee. We’re focusing on demonstrating where the evidence-based science for multivitamins exists, and we trust that the Committee will look seriously at the science.

At the most recent meeting of the DGAC, the Committee noted that people are not meeting recommended levels for certain letter vitamins, calcium, magnesium, and folate. As people struggle to get the nutrients they need, the multivitamin should be considered as one way to get those nutrients when diet alone doesn’t work.

“We’re hopeful the Committee will expand its view of what constitutes nutrition and focus on getting nutrients not only through conventional foods, but considering other delivery methods as well.

In their nutrient recommendations, the U.S. Preventive Services Task Force (USPSTF) and the 2010 Dietary Guidelines for Americans state that the evidence to support multivitamin usage on a broad scale is insufficient. What do you think will need to happen to ensure there is sufficient evidence to support multivitamin benefits for the wider U.S. population? More scientific research on multivitamins? Is enough research being done on multivitamins? And what is the outlook for multivitamins in the U.S. in terms of consumer acceptance and usage?

Blatman: What’s interesting is how the public policy recommendations have been misinterpreted. The USPSTF did not indicate that the research wasn’t supportive of multivitamin usage; it indicated there wasn’t enough research to make a recommendation either for or against usage of a multivitamin specifically for chronic disease. And while we wouldn’t suggest that multivitamins should be specifically taken for that purpose, the irony is there is actually some promising research on multivitamins and chronic disease. The Physicians’ Health Study II found some very real benefits for reducing the risk of cancer and cataracts in a well-nourished population.

I consider the multivitamin the foundation of good health in the supplement world. It’s still a safe, convenient, and affordable way to get our nutrients in one package, basically calorie-free, and certainly with the problems of obesity in this country, it’s an option that’s perfect for many Americans.

As an industry, we need to continue to be proactive in terms of supporting well-designed science, telling our side of the story with the press and in online social and digital platforms, and separating those companies doing the right thing from those companies tarnishing our industry’s reputation. Consumers are smart and continue to look for ways to improve their health destiny—as an industry, we need to be nimble and help them find those products that will get them there.

Scientific bodies like the USPSTF focus on a scientific standard that is heavily weighted toward a drug-like evidence-based requirement—seeking several large, drug-like RCTs in order to support a public health recommendation. CRN and others in the academic community have made some headway in differentiating evidence-based nutrition and the need to look beyond drug-like RCTs when considering scientific standards for nutrients, but there’s still more to be done, particularly among scientists whose expertise is in conventional medical research. However, even as we try to change that mindset, we should still be supporting more well-designed research on the multivitamin.
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Blood Sugar in the Mainstream

Though not always positioned specifically for diabetes, product launches for blood sugar management are also emphasizing low GI and general health.

BY INNOVA MARKET INSIGHTS

Rising levels of obesity are linked to an associated global increase in the occurrence of diabetes. One would expect, then, to see a concurrent increase in food and drink products targeted more specifically at this growing consumer group. But that is not the case. In fact, diabetic foods remain largely confined to the specialist dietetic and health foods markets in most countries, while people with diabetes are encouraged to focus more generally on healthy eating, a balanced diet, and informed food choices.

Less than 0.3% of global food and drink launches recorded by Innova Market Insights in the 12 months ending June 2014 had a specific diabetic positioning. Bakery products and confectionery accounted for a combined one-third of launches, with prepared foods, spreads, sweeteners, cereals, and soft drinks each accounting for 8%–9.5%. These seven categories were responsible for over three-quarters of total launches with a diabetic positioning.

Low GI versus Diabetic

The glycemic index (GI) is extensively used as a tool to help those with diabetes manage their condition by providing a measure of the effect of foods on blood glucose levels post-consumption. Developed in the early 1980s for that purpose, in the late 1990s and early 2000s it was promoted more actively as a means of weight control, undergoing a period of massive awareness and increased use thanks to “low GI” labels on a broad range of food and drinks. Mainstream interest in GI has since fallen back. GI was featured on just 0.3% of global food and drink launches in the 12 months ending June 2014—only marginally ahead of launches with a diabetic positioning.

Mainstream interest in glycemic index has fallen back. GI was featured on just 0.3% of global food and drink launches.

North America accounted for nearly one-third of launches using a low-GI positioning, ahead of Europe, but it is in Australasia where interest is highest. The region accounts for 12% of global launches using low-GI claims, equivalent to 1.5% of total food and drink introductions across the two countries—or five times the global average share of low-GI activity. Australia, in particular, has a very strong GI symbol program, promoting the use of a GI label on a wide range of mainstream food and drink products since 2002. Not all products carry the logo, however; many simply prominently label products as low-GI, often in association with other benefits. Carman’s Dark Choc Blueberry Superfood Bars, for example, feature “low GI,” “wheat free,” and “source of fiber” claims on front of the pack, as well as a focus on the Australian provenance to add extra appeal.

Cereal products dominated GI launch activity, accounting for 22% of the global total low-GI introductions, with oat products, ancient and alternative grains, and pasta particular areas of low-GI focus. Sugar and sweeteners took second place, with 14.5% of low-GI launches, ahead of bakery products, dairy products, ready meals, confectionery, and soft drinks.

Sweeteners

The development of new and alternative sweeteners is also significant. Relatively long-established natural ingredients such as agave and monk fruit have moved into the mainstream, as have newer natural sweeteners such as stevia, recently approved for use in the United States and the EU. Some alternative sweeteners enable the launch of blood sugar–friendlier food and drinks, although launches are often also promoted to the generally health-aware.

There are a growing number of reduced-sugar or sugar-free tabletop alternatives, such as Sweet Leaf Sweet Drops in the United States, marketed as “zero GI.” These
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sweeteners are also used as alternative ingredients in a wide range of food and drink products, as exemplified by Koochikoo’s sugar-free cookies in the United States, which use monk fruit, erythritol, and stevia in different blends.

Diabetes Specific

Still, diabetes-specific products do continue launching in the specialist dietetic sector in many countries, and it is mainly in these countries where some products are labeled specifically as diabetic options. In Spain, for example, Laboratorios Esteve teamed up with Calidad Pascual in early 2014 to launch its Diabalance 15-strong range of low-GI health foods, including pasta, bread, desserts, snacks, beverages, and biscuits. In the UK, mainstream chocolate company Thornton’s also recently launched a range of no-added-sugar diabetic chocolate products and sweets.

For the most part, however, an increasing number of products are taking a more mainstream position targeted not only to people with diabetes but also to those with other health concerns and those concerned with general well being. Increasingly, many are also marketed on a multibenefit platform. Examples include the Free’ist range of sugar-free and no-added-sugar products launched in the UK in 2013, encompassing cookies, biscuits, wafers, chocolate bars, and jams. There are also a number of meal replacement–type products featuring rice and pasta alternatives made from konjac.

German marketer Vitanu markets its food products as sugar free but also low calorie, fat free, gluten free, and a high-fiber source.

These tend to be positioned on a number of platforms, including low calorie, low fat, sugar free, gluten free, and source of fiber, in addition to being diabetic friendly. Examples of this type of product include the Eat Water Slim range in the UK and the Vitanu range in Germany.

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Turmeric Beverages: Yellow...or Not?

Commercial beverages show just what’s possible with turmeric in drink form.

BY ROBBY GARDNER, ASSOCIATE EDITOR

Beverage manufacturers can’t ignore turmeric anymore. Published studies on the Indian root—exploring everything from arthritis relief and cancer prevention to overall health and wellness—are piling up, and turmeric is already trending in dietary supplements. The deep yellow–orange pigment of turmeric (*Curcuma longa*) isn’t as much of a problem in capsules and tablets; in beverages, however, it can be a real nuisance.

Beverage manufacturers are suddenly marketing a lot of turmeric tonics with that difficult-to-avoid yellow–orange tone—which is at least a clear indication to consumers that turmeric is in the product. Still, these manufacturers are finding interesting and unusual ways to distinguish their turmeric beverages from others, and the end result is a fun category full of combinations with other ingredients, complete with complementary flavors and colors.

These manufacturers should also know that, in an act of disruption, one ingredient supplier has developed a turmeric ingredient without the root’s strong pigment. Sabinsa Corp. (East Windsor, NJ) revealed its Curcumin C3 Reduct ingredient last year, and this curcumin powder offers higher bioavailability thanks to the presence of tetrahydrocurcuminoids, which the company says are the major metabolites in curcumin and pharmacologically superior to curcuminoids. Just as important to beverage manufacturers, however, Curcumin C3 Reduct is an off-white, not yellow, ingredient, making non-yellow curcumin formulations possible.

But, for now, it looks as though most beverage makers are embracing the yellow-orange. Ahead, we profile just some of the beverage companies diving headfirst into turmeric.

**Feel Food**
Presumably the sweetest-tasting of drinks featured here, Feel Food’s offering is a cashew milk featuring turmeric, maple syrup, candied ginger, and Himalayan pink salt. The company says this collection of ingredients creates a synergy of immune-boosting and anti-inflammatory ingredients that can even support the gastrointestinal tract. Topped with a black lid, this little guy looks good with its subtle yellow tone.

**Suja**
A whole lot of fruits and a vegetable go into Suja’s Fuel juice before turmeric, but one can rest assured: there’s a full “inch” of turmeric in each bottle, says Suja, referring to the knob-like structure that makes up the turmeric root. Suja Fuel contains cold-pressed carrot, orange, apple, pineapple, lemon, and then turmeric. It’s another sweet take on turmeric, and Suja must be doing something right. The company was named one of *Forbes*’ most promising of 2014.

**Urban Remedy**
This “low-glycemic treat” couples lemon juice and turmeric juice, with stevia for sweetening. On the nutrition facts panel, Urban Remedy calls out what are actually significant amounts of vitamin C and iron made possible by lemon and turmeric, respectively. While this beverage is part of a bigger juice cleanse, the company’s website
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notes turmeric's unique contribution based on historic uses in Ayurveda and Chinese medicine. Oh, and lemon bio-flavonoids may actually clear mucus.

**Zukay Live Foods**
Fermentation gives Zukay Live Foods a personal twist on its turmeric beverages. The three products containing turmeric also contain a medley of different fruits, vegetables, and roots. Golden Turmeric and Tropical Veggie Twist have yellow tones—made all the more possible by ingredients like carrot, pineapple, and mango—but Super Root's main ingredient is beet, which gives this drink a dark red hue.

**Organic Avenue**
Thanks to the wonders of coconut sugar, Organic Avenue can market a turmeric drink that's as sweet as it is spicy. The company's Turmeric Tonic uses lemon and ginger to round out turmeric's unique flavor in this raw and unpasteurized treat.
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In the United States, hemp is often confused with marijuana. It’s a consumer misconception that has, for decades, slowed the market potential for hemp in the food, dietary supplement, textile, and even lumber industries. The dietary supplement industry, in particular, has a lot to gain from hemp, and not just with hemp oil and hemp protein. A substance called cannabidiol (CBD) has shown nutritional potential for years, yet the taboo around Cannabis has kept CBD off the radar. Now, with hemp gaining a better reputation, it looks as though its little compound is finally poised for big market growth. And much of that growth could be in stress and anxiety formulas.

**What Is CBD?**
CBD is a phytocannabinoid that is found in industrial hemp and marijuana, which are two different varieties of the Cannabis sativa plant. The current market for CBD as a dietary supplement is based on industrial hemp, not marijuana, because marijuana also contains significant amounts of tetrahydrocannabinol (THC), a phytocannabinoid that is psychoactive and, thus, capable of making a person high. Industrial hemp contains only negligible amounts of THC—no more than, say, poppy seeds contain opiates—and so it will not get you high. The plant is, thus, safe for human consumption and useful for components including CBD.

While CBD is not psychoactive like THC, it can still have a profound influence on the human brain, but first—is CBD legal?

**Legal Status of CBD**
In order to understand if CBD is legal for sale and consumption, one must look at the legality of hemp oil, which can be tailor-made for high concentrations of CBD.

Hemp oil is listed on the U.S. Harmonized Tariff Schedule (with no restrictions on CBD content) meaning that hemp oil is a legal U.S. import. This is important because federal law prohibits the farming of hemp in the United States. Hemp can only be purchased as an import. Some state laws override this federal
law, but most of these, for now, just legalize hemp farming. At the time of this writing, Colorado and Kentucky are the only states that have laws permitting the farming and sale of hemp, and these are both very recent laws. The market for U.S.-grown hemp, thus, relies almost entirely on legal imports from established markets. Canada, Europe, and China are some of the world’s biggest hemp producers, so they control the U.S. market supply and will for at least a while longer.

As long as CBD-rich oils are imported, or farmed in states where cultivation and production is permitted by state law, CBD-rich hemp oils are legal. But they are not legal if their THC content is above 0.3%. This threshold keeps the distinction between hemp and marijuana in place.

Scientific Studies on CBD
As for how CBD works, CBD and other phytocannabinoids influence the brain by interacting with the brain’s very own cannabinoids, called endocannabinoids.

“Generally, phytocannabinoids like CBD can help to restore a more balanced ‘tone’ within the endocannabinoid system,” says Stuart Tómé, vice president of human nutrition for CBD oil supplier CannaVest Corp. (San Diego). “As such, CBD may positively, broadly affect various processes that control brain signaling, via neurotransmitter function, ion channel and membrane dynamics, inflammatory responses, and even gene expression.” It’s worth noting that Cannabis compounds aren’t the only ones capable of interacting with the brain’s endocannabinoid system. Compounds from flax and Brassica species, for instance, have shown potential to interact with the endocannabinoid system, too. With that said, why is this brain system so important?

The endocannabinoid system has broad influence over areas of the brain involved in sensations such as pain perception, movement, emotion, cognition, and sleep. For this reason, the endocannabinoid system likely
Turmeric is produced by the rhizome, or the underground stem of Curcuma longa, a plant that grows in tropical South Asia. Turmeric’s active ingredient is curcumin, enter Sabinsa’s Curcumin C3 Complex®.

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Relaxation

has big sway over some brain health conditions. A blockage of cannabinoid receptors called CB1 receptors has been linked to behavioral effects consistent with antidepressant activity. Enhancement of anandamide, the first discovered endocannabinoid, may relieve chronic pain associated with neuropsychiatric disorders. Post-traumatic stress disorder appears to involve cannabinoid pathways, too.

For all of the ways the endocannabinoid system can influence brain health, CBD’s own interaction with the endocannabinoid system could translate into some very significant health effects, and previously published studies so far offer positive indications. For extensive reading, a 2012 review of CBD studies provides a thorough overview of most of the existing human clinical trials (34 in total) on CBD for healthy and/or clinical patients. Here are some of the trials that stand out.

Anxiety
To explore the impact of an ingredient on anxiety, scientists often first look at that ingredient’s impact on cortisol levels in the human blood after ingestion. Cortisol levels are heightened when animals are under extreme duress, and when Brazilian researchers investigated the effect of CBD doses on human cortisol levels in 11 volunteers in 1993, they found that CBD decreased cortisol levels significantly more than placebo. CBD subjects also reported a sedative effect from the treatment.

Also in 1993, the same researchers compared the effects of CBD and two anxiety medications, ipsapirone and diazepam, on a group of 40 healthy individuals assigned to a simulated public speaking test. Using a Visual Analogue Mood Scale (VAMS) to assess personal anxiety before and after the public speaking test, the researchers determined that diazepam lowered anxiety before and after the test, while the ipsapirone and CBD only lowered anxiety after the test. Years later, in 2004, another team of Brazilian researchers analyzed CBD, but they upped the dosage by 100 mg (now 400 mg of CBD). Compared to placebo, subjects in this study reported significantly decreased anxiety and increased mental sedation. Brain imaging tests suggested that such effects were mediated in specific regions of the brain.

Aside from a potential influence on healthy volunteers, CBD has shown some promise in subjects with established social anxiety disorders. Two studies in 2011 yielded favorable results for CBD supplementation in this type of population. In the first study, CBD use was associated with decreases in subjective anxiety and was accompanied by (presumably significant) changes in regional cerebral blood flow. The second study tied CBD to reduced anxiety and discomfort in response to a simulated public speaking test.

Curiously, the presence of CBD alongside THC, in marijuana, has even shown potential to alleviate THC-induced anxiety and psychosis.
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Relaxation

Sleep

Early research suggests that CBD consumption can also affect sleep in a positive way—in particular, it may block rapid eye movement (REM) sleep—but such an effect may be more related to CBD’s anxiolytic (anxiety-inhibiting) properties than direct sleep regulation, per se. While the basis for this CBD-and-sleep theory is largely made in rodent studies, some research has been done on sleep-impaired but otherwise healthy humans.

In a 1981 Brazilian study, researchers at the Escola Paulista de Medicina in São Paulo assigned 15 insomniacs to a CBD dose (ranging between 40 mg and 160 mg), placebo, or nitrazepam, a hypnotic drug indicated for relief from anxiety and insomnia. With the highest CBD dose, sleep significantly increased, although dream recall was reduced, compared to placebo. The reduction of dream recall is presumably due to a reduction of REM sleep, wherein dreams are most active.

Also relating to sleep, somnolence, a state of feeling drowsy or sleepy, has been reported with CBD consumption. While the onset of somnolence may help humans sleep, such an effect should also be examined further for the sake of other CBD uses not related to sleep.

Schizophrenia

In light of the notion made earlier that CBD may attenuate the psychotic effect of THC, such anti-psychotic potential might conceivably help subjects with schizophrenia. This population can be burdened by acute psychosis, but also by anxiety.

Unfortunately, the outcomes from CBD studies on schizophrenia patients are a mixed bag. Where a 2009 German study found 600 mg of CBD to be as effective as amisulpride (an anti-psychotic drug) in reducing psychotic symptoms after four weeks, a Brazilian case series in 2006 found CBD well-tolerated but not necessarily effective for treatment-resistant schizophrenia. And of two studies conducted in 2010, one found CBD useful for managing schizophrenia, and the other did not.

Market Outlook

The ongoing CBD research discussed herein provides broad market potential for the CBD supplements already in trade today. While concerns such as stress and poor sleep may provide avenues for selling CBD oils to the general population, manufacturers can also capitalize on some much more particular health concerns. Epilepsy, a health condition not discussed in detail here, provides one of the biggest opportunities for CBD today. In fact, the state of Missouri passed a bill earlier this year that legalizes the sale of “hemp extracts” containing CBD as prescribable medicine, but only for children with a rare form of epilepsy called intractable epilepsy.

Creating demand for CBD oil shouldn’t prove difficult, but creating a pro-hemp industry around the world is still a challenge.

“There are many international markets that are well ahead of the game when it comes to CBD,” says Andrew Hard, public relations director for CBD oil supplier HempMeds (Poway, CA). “Unfortunately, the United States is a huge influence on drug policies internationally, which has probably kept these [other] markets from growing as much as they could. We’re hopeful that as the attitudes and laws towards Cannabis in the United States change, the world will adjust accordingly.”

Fortunately, the laws are already changing, and none have proved so significant for hemp as the 2014 U.S. Farm Bill. Signed by President Barack Obama at the beginning of the year, the Farm Bill contains a provision that legalizes hemp research pilot programs in states where cultivation is legal under state law. Through state and university agriculture departments, interested parties can now cultivate hemp and start to learn about its local harvest and local marketability. Since climate and soil conditions are far different in the United States than they are in, say, Canada, this research phase will help industry determine just what U.S.-grown hemp is made of. One thing about U.S. hemp is certain, though: it can be bred for high amounts of CBD.

Interested parties can now cultivate hemp in states where it is legal, but they must work in partnership with state departments or local universities.

References

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Between one-half and three-quarters of all adults in the United States report taking dietary supplements. And while nearly half of consumers (48%) purchase their supplements from well-known retail outlets, according to a report published in 2011 by dietary supplement association the Council for Responsible Nutrition (CRN; Washington, DC), more than half of them (55%) point to their medical doctor or physician as being their number-one most-trusted source of reliable information on dietary supplements.

With so many consumers looking to their practitioners for guidance on supplements, it doesn’t require a huge leap of imagination to consider that practitioners are positioned to significantly influence the fortunes of the supplement industry by recommending—or not recommending—particular supplements to their patients, and even dispensing supplements themselves.

In fact, that is exactly what is happening, with more practitioners expected to recommend, and especially sell, supplements to patients in the near future. Erik Goldman, editor of Holistic Primary Care: News for Health & Healing, which sponsored the Health Practitioner Marketing Forum this past April, confirms: “There are a lot more practitioners using supplements, recommending supplements, and in some cases dispensing supplements in their offices” now
Boomers tend to believe in proper nutrition being in play for much of their lifetimes. Thence, supplementation, and prevention have continued, according to Duff y MacKay, senior vice president, scientific and regulatory affairs, CRN. Indeed, 57% of cardiology, 75% of dermatology, and 73% of orthopedics reported actually taking supplements themselves, at least occasionally, in a 2011 study conducted by Ipsos Public Affairs for CRN and published in Nutrition Journal. That personal interest in wellness and prevention, particularly among practitioners who are part of the Baby Boomer generation, plays a part in the good relationship between them and industry, says David Foreman, RPH, ND, a retired pharmacist who created and maintains The Herbal Pharmacist blog. Holistic Primary Care editor Goldman agrees, adding that although most of these Baby Boom-era doctors were trained in a “very orthodox, traditional way,” culturally, nutrition science, supplementation, and prevention have been in play for much of their lifetimes. The Boomers tend to believe in proper nutrition for good health, as well as in certain medical conditions, such as food allergies or gluten sensitivity, that were dismissed as “way out of left field” the generation before, Goldman explains. “There are definitely a lot of mainstream doctors who don’t think there is anything radical or alternative about recommending a fish oil or a probiotic at this point,” he says.

Also playing a large and growing role in the generally positive relationship between practitioners and industry is the former’s interest in seeking out new revenue streams. Foreman, Goldman, and Douglas Laboratories’ Gene Adamski, whose company sells supplements to practitioners to sell to their own patients, all cite this factor.

“More practitioners are actively coming to us wanting to explore supplementation in their practices,” Adamski says.

“More and more practitioners are actively coming to us wanting to explore supplementation in their practices,” Adamski says. “The landscape is changing in terms of how practitioners are being reimbursed,” he explains, which has resulted in some dissatisfaction among private-practice owners who feel their net income is suffering. Simply put, health insurance reimbursement is decreasing, while medical office overhead is increasing.

“Private-practice doctors are at a crossroads,” Goldman states, “where they are saying, ‘Yes, I want to stay independent despite declining insurance-company reimbursement, in which case I may have to shift my practice model.’” These shifts, he says, can take the form of simply adding supplement sales and other new sources of revenue to the practice, or they can mean leaving insurance networks altogether in favor of going cash-pay only or adopting a concierge structure, in which patients pay a practitioner annually and subscribe to his or her services. Goldman’s survey reveals that 47%—nearly half—of practitioners surveyed are “considering making a major change to their practice model within the next two to three years,” while 53% are “actively seeking new revenue streams”—such as supplement sales.

On the other hand, practitioners who do not own their own practices but instead belong to large hospital or clinic networks are generally not free to seek additional revenue streams or even to make supplement recommendations that haven’t been explicitly sanctioned by the hospital leadership, so the connection to industry among that group is less solid and much slower-growing.

Another population that is increasingly likely to recommend nutritional supplements to patients, however, is nursing professionals. Nurses and nurse practitioners “spend a lot of time with their patients, and they spend a lot of time on counseling on lifestyle and diet,” CRN’s MacKay explains. The Herbal Pharmacist’s Foreman agrees with MacKay on this point, adding that the majority of nursing professionals are women, and, nationwide, women purchase and consume more nutritional supplements than men do.

Practitioner Picks

Just which supplements practitioners are recommending and even selling to patients most is clear-cut; consensus emerged among all those interviewed for this article. Probiotics, minerals (such as iron and calcium), essential fatty acids (such as omega-3s), and letter vitamins (such as D) lead the pack, followed by multivitamins, specialty supplements (such as coenzyme Q10, recommended mostly by cardiologists, and SAM-e and chromium), and supplemental fiber. Cranberry extract is recommended quite freely and confidently by those in family practice, CRN’s MacKay adds, and he expects an uptick in practitioner recommendations of iodine supplementation to pregnant patients, based on findings laid out in a position paper published this summer by the Academy of Pediatrics about the element’s potential effect on a fetus’s cognitive development.

Recommendations and sales of vitamin D, which has enjoyed enormous name recognition and popularity in recent years, might soon “plateau,” MacKay says, based on a recent U.S. Preventative Services Task Force recommendation that physicians dis-
Medical education that includes training in integrative medicine, holistic medicine, complementary medicine, or naturopathy produces practitioners who have a relatively strong knowledge of the role of nutritional supplements in wellness and preventive medicine. U.S. medical schools that include such programs include the following:

- **University of Maryland.** The Center for Integrative Medicine (CIM) at University of Maryland was founded in 1991. Students and faculty at the center conduct research and provide patient care, and education and training in integrative medicine is offered. CIM is a National Institutes of Health Center of Excellence for research in complementary medicine.

- **University of Arizona.** The Arizona Center for Integrative Medicine at the University of Arizona College of Medicine “creates, educates, and actively supports a community that embodies the philosophy and practice of healing-oriented medicine, addressing mind, body, and spirit,” according to information on its website. Founded in 1994 by Andrew Weil, MD, the well-known medical doctor, naturopath, teacher, and writer, the center focuses its efforts in the areas of education, clinical care, and research.

- **Johns Hopkins University.** The Johns Hopkins Integrative Medicine & Digestive Center is part of The Johns Hopkins University School of Medicine, Division of Gastroenterology & Hepatology. The clinical care–focused center’s team of practitioners include board-certified physicians, licensed massage therapists, acupuncturists, psychotherapists, and nutritionists who work with patients and their other healthcare providers to address a variety of chronic conditions using an individualized approach.

- **University of Michigan.** University of Michigan Integrative Medicine (UMIM) consists of patient-care services, including the Integrative Family Medicine Clinic; research; and education. Originally supported by a five-year grant from the National Institutes of Health, UMIM operated its first Complementary and Alternative Medicine (CAM) courses for medical students in 2000. A unique feature of the CAM course sequence, according to information provided on UMIM’s website, is that it is longitudinal, extending across the entire four-year medical school curriculum.

- **George Washington University.** The GW Center for Integrative Medicine was founded in 1997 by John Pan, MD, a 1970 graduate of the George Washington University Medical School. Within the GW Medical Center, the Center for Integrative Medicine plays a central role in providing educational programs in integrative medicine, and a fellowship-training program is offered at the graduate level. The clinic combines conventional and evidence-based complementary and alternative modalities to address conditions ranging from dementias and Parkinson’s to autoimmune conditions and mental health issues.

As more major medical schools follow suit and create integrative-medicine departments and clinics of their own, the youngest generation of practitioners are increasingly likely to include such complementary modalities as supplement recommendation into their practices. The key to keeping this integrative-medicine training growing, says Holistic Primary Care editor Erik Goldman, is for these schools to maintain and grow the funding they need to run legitimate programs.

The task force “believes doctors should use a little more judgment to determine who is at risk for deficiency.” MacKay explains, “and that only those individuals should be tested. So if clinicians respond to that, then we’ll see a little less testing, but it will stabilize similarly to how calcium has stabilized: popular forever, necessary, important. But I don’t think we will see that continued upward growth and interest.”

Trailing farther behind the widely recognized and relatively well-regarded big-name supplements are enzymes (though this category is growing), so-called medicinal foods, homeopathics, and medicinal mushrooms.

The health reasons for which practitioners are currently most likely to recommend supplements to patients, according to Douglas Laboratories’ Adamski, include cardiovascular support, autoimmune support, weight loss, stress relief, vitamin deficiency based on blood work, hormone support, inflammation, and general wellness. On the horizon, he adds, will be recommendations for products geared toward women’s hormones and adrenal fatigue, and The Herbal Pharmacist’s Foreman predicts increasing interest in products for blood sugar and antiaging support.

**The How-To of Dispensing and Selling Supplements**

In Goldman’s survey, about two-thirds of practitioners are seeking new revenue streams for their practices; of these, half are considering dispensing supplements as a way of generating more revenue. The two major methods by which practitioners...
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Associate members: Supreme Biotech
Healthcare Practitioners

are “stocked” on his or her site, and patients can shop there. The practitioner takes a percentage of sales.

Connecting with Practitioners
Supplement manufacturers would be wise to strategically educate, and market themselves to, practitioners who recommend or dispense supplements to patients. As Holistic Primary Care’s Goldman puts it, “74% of the practitioners we surveyed recommend at least one specific brand of supplement to their patients. But that also means that 26% are not recommending specific brands, so there is definitely brand effort that needs to happen in this space.”

The Herbal Pharmacist’s Foreman believes that most practitioners are going to keep their distance from brands that are generally available to the public via major retail outlets such as Whole Foods or GNC. “Practitioners are most likely going to want to recommend or dispense a brand that the patient can’t get from a major retailer. They want the patients coming to them for it,” he says, which would suggest the direct-to-physician sales channel might be the most successful route for supplement makers.

MacKay adds that some of CRN’s member companies are already “very focused on” working with practitioners. These companies make “significant efforts to be at the medical conferences, using those as opportunities to educate at the appropriate sponsoring sessions.” And at these events, all practitioners—those practicing integrative medicine and those more mainstream—are targeted. Industry trade shows, he continues, represent “a tougher space, because you are competing with the drug industry for those practitioners’ attention.” In general, MacKay advises, supplement manufacturers need to maintain a “consistent, sustained presence, supporting continuing education where appropriate.”

The presence, however, will cost you. “Whether you sponsor a symposium at the American Heart Association, or you buy a booth at American Family Practitioners, it will be expensive,” MacKay warns. “Certain forms of continuing education that you are doing legitimately, that are CME (continuing medical education) approved, can be very costly and are completely stripped of any commercial benefit. If you are Company A, and you fund a continuing education program on calcium and vitamin D, for instance, none of that benefit comes specifically back to your company. It’s all done in the goodwill of everybody who sells calcium and vitamin D. That’s challenging,” he explains, “because it’s very different from the pharmaceutical model. On the drug side, if you do continuing education for hepatitis C treatments, for instance, you are going to see the benefit back to your company directly, if you have a drug in that space.”

Douglas Laboratories’ Adamski, who oversees a highly educated sales staff, emphasizes the importance of building relationships with practitioners. His team’s “number-one job every day,” he says, “is calling on healthcare practitioners, building the relationship, and educating those practitioners on the science of nutrition and what our company has to offer.”

Near-Perfect Timing
Many factors are converging that point to a continued upward tick of practitioner recommendations and sales of nutritional supplements to their patients: a glut of Baby Boomer practitioners with personal interests in wellness, preventive medicine, and nutrition; owners of private practices seeking out new revenue streams; consumers and patients who view their physicians as trusted sources of dietary supplement information; and a general, gradual cultural shift toward acceptance of some forms of “alternative” medicine—rendering them more mainstream than alternative. With some fairly rigorous—and likely expensive—targeted marketing and education efforts, supplement manufacturers and their suppliers can make headway into the growing practitioner market. The next frontier at which to arrive within this market, says Holistic Primary Care’s Goldman, is “getting
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DO PRACTITIONERS UNDERSTAND SUPPLEMENTS?

Part of forging a stronger bond with practitioners means understanding what practitioners know about dietary supplements and the industry in the first place. This summer, on behalf of krill oil ingredients supplier Aker BioMarine Antarctic US (Issaquah, WA), Holistic Primary Care: News for Health & Healing surveyed physicians, nurses, and ancillary healthcare professionals on their involvement with dietary supplements. The 362 respondents provided insight on their supplement recommendations and specifically on omega-3 fatty acids, the category of supplements respondents reported recommending most often.

Health Conditions

First and foremost, 82% of practitioners said they recommend omega-3 fatty acids for heart health. By now, many practitioners understand the link between omega-3 fatty acids and a healthy heart. But the survey indicates that practitioners are mindful of other benefits, too: 81% recommend omega-3s for managing inflammation, 80% for cognitive health and mood, 65% for joint health, and 61% for general well being.

Ingredient Sources

Practitioners may understand omega-3s generally, but do they distinguish between common omega-3 sources? While most practitioners (52%) surveyed considered themselves very knowledgeable about fish oils, they ranked themselves less knowledgeable about other omega-3 sources: flaxseed oil (35% of practitioners felt knowledge), krill oil (23%), chia seed oil (17%), and algal oil (11%).

Aker BioMarine points out that, given that nearly one-third of respondents said their knowledge of krill oil is still limited (as is the case concerning all other omega-3 sources outside of fish), it creates “an ideal educational opportunity” for the firm. (Aker adds that 41% of survey respondents felt “knowledgeable” about krill oil, and says that “clinician knowledge of krill is definitely higher than for algal or chia oil.”)

Obviously, educating practitioners about ingredient distinctions should be a priority.

Product Attributes

Do practitioners consider organic, non-GMO, and sustainability, when recommending specific supplement products? The survey ranked practitioners’ top criteria when recommending an omega-3 product: 74% consider the fatty acid composition (ratio of EPA to DHA, or phospholipid to triglyceride, etc.), followed by organic (56%), non-GMO (55%), ease of compliance (50%), cost (49%), and sustainability (46%). Other factors ranked lower: traceability (24%), vegetarian (15%), and kosher (4%).

On the apparent low concern with traceability, the survey authors state, “This was surprising, given that without clear traceability, it is difficult to substantiate label claims for many of the other criteria on the list.”

Swayed by Negative Media?

It’s no secret that omega-3 sales declined after a July 2013–published Journal of the National Cancer Institute study linked omega-3 plasma levels and risk of prostate cancer. Were practitioners also swayed by this data? Not as much as you’d think.

According to the survey, which was administered mere months after the negative prostate cancer trial made headlines, 68% of respondents said their omega-3 recommendations had not changed in the past 6–12 months; in fact, 29% reported recommending omega-3s more often.

“The findings suggest that practitioner attitudes are not as volatile as consumer attitudes, and their behavior is not as easily swayed by single studies and alarmist headlines as consumer purchasing patterns,” the authors surmise. “Clinicians are used to seeing and hearing negative trials—they are part and parcel of evidence-based medicine, and there are plenty of negative or inconclusive pharma studies. Practitioners take them in stride, put them in broader scientific context, and tend to hold a more measured view in either direction.” They also point out that there is a certain “inherent conservatism in medical thinking” that makes physicians less likely to stop recommending a supplement based on one or two negative trials; however, this conservatism also makes practitioners less likely to recommend a supplement based on just a few positive trials. Simply put, it takes more than just a few studies to convince physicians.

 Recon m m er ng How?

Another interesting finding is that a large majority of physicians recommend dietary supplements to treat (88%) or prevent (78%) a specific health condition. Law prohibits supplement marketers from making “prevention” or “treatment” product claims. “But the key point here is that many clinicians are utilizing supplements, nutraceuticals, and natural products specifically to prevent and treat diseases, despite regulatory intentions to limit communication between manufacturers and practitioners strictly to ‘healthy function’ terminology,” the authors say.

—Jennifer Grebow

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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Who Is the Blood Sugar Product Customer?

A lot of us, it turns out.

BY JENNIFER GREBOW, EDITOR-IN-CHIEF

November is National Diabetes Month in the United States, and the latest statistics out of the Centers for Disease Control and Prevention are alarming, to say the least. At least 9.3% of the U.S. population has diabetes (diagnosed and undiagnosed), according to the CDC’s 2014 National Diabetes Statistics Report. Diabetes cases cost $245 billion in annual direct and indirect medical expenses in the United States in 2012, and there were 1.7 million new diabetes cases in 2012 alone. (See page 20 to read more on some of the costs associated with diabetes.) Although diabetes is a rampant global disease, one fact to remember is that, at least for some, preventive steps can be taken.

Prevention is especially relevant to those with prediabetes—people with high blood sugar levels that haven’t yet scaled up to the condition of diabetes. The CDC estimates that 37% of U.S. adults suffer from prediabetes.

For these individuals, there may still be time to take back the reins of blood sugar management and try to steer levels back to a healthy range through weight loss and increased physical activity. Proactive individuals can also consider adding dietary supplements and healthier foods and beverages to the mix to help manage blood sugar and, combined with lifestyle changes, hopefully sidestep a slide into diabetes and its associated adverse conditions, including heart disease, stroke, and blindness.

Approaching Blood Sugar Effectively

To recap, a body maintains healthy blood sugar levels thanks to the hormone insulin. Insulin helps transport glucose from the blood—keeping blood sugar levels in a healthy neighborhood—to muscle, fat, and liver cells where glucose is used for energy.
among other critical functions. A diet high in quickly digested carbohydrates—the refined sugars and starches that break down easily into glucose and yet comprise a large portion of today’s Western diet—causes blood sugar levels to quickly spike post-meal, otherwise known as a high-glycemic response. Under healthy conditions, the body’s pancreas would produce and release more insulin to the blood to deal with glucose spikes; however, those with diabetes and prediabetes have insulin insensitivity, and the body’s insulin response cannot effectively handle the glucose challenge. As a result, blood sugar levels remain in a prolonged state of hyperglycemia, potentially leading to a range of adverse health effects. Most (90%-95%) of people with diabetes have type 2 diabetes, a state that can be spurred by excess weight, a lack of physical exercise, and a diet too rich in refined, quickly digested carbohydrates that keep the body in this hyperglycemic state.

Dietary supplements and healthier foods and beverages attempt to help bring blood sugar levels back in the balance, and they can do so in many different ways. Slowly digested, low-glycemic starches and sugars—as opposed to blood sugar–spiking, high-glycemic starches and sugars—can help avoid rapid glucose spikes. Still other approaches include no-sugar and low-sugar formulations, ingredients to control sweets cravings, and ingredients to influence carbohydrate metabolism. Product marketers should remember, however, that there are many types of potential customers for blood sugar products, and connecting successfully with the target customer depends on the right approach.

**Food and Beverage**

“Many consumers do not want to buy foods and beverages that are positioned to a disease state,” says Pam Stauffier, global marketing programs manager for Cargill (Minneapolis). As such, a lot of food and beverage marketers these days avoid a “direct” diabetes angle. (See page 26.) While some do mention diabetes directly when describing their products—see Abbott’s Glucerna nutrition bar line and the Diabalance food line in Spain—still many more tend to focus on generally healthy attributes. Indeed, these types of claims may appeal to a group (especially those with prediabetes) that doesn’t necessarily consider itself “diseased” but that is encouraged by practitioners to improve health and wellness in general through healthier diet and lifestyle choices.

“Currently, the leading label claim for blood sugar–targeting products is indeed the low/no/reduced-sugar health claim,” says Joseph O’Neill, president and general manager for Beneo Inc. (Morris Plains, NJ). “The reason behind this is that sugar reduction is relevant for everyone.”

“The most important thing to realize is that [people with diabetes and prediabetes] are not different from others in their general attitudes towards nutrition,” adds Barbara Katz, president of HealthFocus International (St. Petersburg, FL), a market research firm specializing in health and nutrition. This past April, the company released a report, “The Consumer Side of Diabetes,” with insights on how people with diabetes and prediabetes view nutrition and which product attributes they seek, based on survey results from 1200 U.S. consumers.

“In our study, over half of people with diabetes fell into a group that we call ‘Middle of the Road,’ defined as people who are aware that diet is important to health but for the most part who eat what they want. Sometimes that will be a salad, and sometimes it will be a pizza with extra cheese. But it all evens out to be not too bad,” Katz says. Only 11% of people with diabetes fall into a group that HealthFocus terms “Health Managers,” those that manage their eating habits to focus specifically on addressing an illness.

Belgian ingredients supplier Cosucra categorizes blood sugar–product consumers in three groups. (The company supplies the blood sugar market with its non-digestible, low-glycemic chicory fiber Fibruline, which not only offers a source of soluble dietary fiber but also lends sweetness without impacting blood glucose levels. Cargill sells Fibruline on behalf of Cosucra in the United States under the name Oliggo-Fiber.)

First, Cosucra says, there are people with diabetes and prediabetes. These people “are ready to buy premium products with proven benefits” and “understand messages of glycemic index/glycemic load and blood sugar management.”

Then there are “lifestyle consumers,” who don’t necessarily want “diabetes” products but who are seeking overall good health. These “lifestyle consumers” respond to specific messages of “maintains healthy blood sugar levels,” “reduced sugar,” “X% less sugar,” and other scientific messages, as long as those messages are understandable.

And, finally, there’s the mass-market customer, who won’t pay a higher price for a product; more likely this customer is looking to lose weight and is thus drawn to more general claims of “low sugar,” “reduced sugar,” or “no added sugar.”

“At Cosucra, we think that claims related to blood sugar levels, such as the one the European Food Safety Authority (EFSA) recently accepted for chicory-derived inulin, could appeal to [those with diabetes and prediabetes] but also ‘lifestyle’ consumers,” says Sabrina Marnet, product manager, chicory ingredients.

Following petitioning from chicory inulin suppliers Beneo, Sensus, and Cosucra, EFSA issued a positive opinion this past January linking non-digestible carbohydrates, in place of sugars, with a lower postprandial blood glucose rise. Cosucra suggests marketers use consumer-friendly wording such as “When replacing a minimum of 30% of sugars by Fibruline chicory inulin in foods/drinks, you induce a lower blood glucose rise after their consumption compared to sugar-containing foods/drinks,” paired with visual aids for further explanation.

For people with prediabetes, there may still be time to take back the reins of blood sugar management and try to steer levels back to a healthy range.
Also, remember that people with diabetes and prediabetes still want to enjoy their food just like anyone else. For instance, “lifestyle” consumers in particular may be more attracted to moderate (30% or less) versus drastic sugar reduction, according to Cosucra. These customers, Cosucra says, are looking for more “balance.”

When polled on what they look to avoid in foods, HealthFocus survey respondents noted these as the top five: sugar, carbohydrates, added sugar, sodium, and saturated fat—basically, attributes that any health-minded food shopper might seek. On the flip side, the survey respondents indicated that they do seek good sources of protein, fiber, and whole grains—again, desirable features to many a shopper.

“If there is a difference amongst people with diabetes, it is that they are even more taste-focused than other groups and more concerned that healthy foods won’t taste good,” HealthFocus’s Katz says. “So, with that background, the best way to communicate with them is with the assurance that they aren’t going to be making a taste sacrifice with your product.”

Thankfully, today’s formulators have a robust toolbox with which to make delicious foods and beverages friendlier to blood sugar status, thanks to innovative ingredient suppliers. Low-glycemic options can substitute high-glycemic starches and sugars, often times without sacrificing taste or texture. (From a formulator’s point of view, sugar provides essential, functional bulking properties that are not always easily replaced.)

Ingredient supplier Beneo offers numerous options to lower the glycemic effect of foods and beverages. With the ability to replace high-glycemic sugars, the company’s chicory-derived, non-digestible prebiotic inulin and oligofructose fibers act as low-intensity sweeteners and a source of fiber and satiety, all without impacting taste. “Used in combination with high-intensity sweeteners, they even help to mask undesired off-notes,” O’Neill says.

Beneo also supplies isomalt, which O’Neill describes as “the only sugar replacer derived from sugar beet” that can substitute sucrose 1:1, while maintaining texture. Isomalt is not fully digested, lessening its effect on blood sugar, and can also be applied to direct-compression dietary supplement tablets and sugar-free mints.

In addition to sugar replacers, Beneo provides Palatinose, a low-glycemic, slow-release sugar that, compared with high-glycemic sugars, provides the body with a sustained source of energy over a longer period of time. “The carbohydrate energy enters the body in a slow, low, and sustained way,” O’Neill says.

In addition to supplying the tasteless, odorless, and texture-neutral Oligo-Fiber chicory inulin, Cargill’s Xtend sucromalt is a slowly and fully digestible sweetener syrup that impacts neither glycemic index nor product texture, the company says. Cargill also offers Isomaltidex isomalt for glycemic-friendly formulation.

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**Dietary Supplements**

Whereas even the casual food shopper will likely stumble upon a reduced-sugar food in his or her lifetime, dietary supplement consumers tend to know what they are looking for from the start: blood sugar support. HealthFocus International survey data indicate that nearly a quarter of people with diabetes say they always/usually take supplements targeting blood sugar management.

“In supplements, consumers are seeking direct ‘support,’” says Mitch Skop, senior director of new product development for Pharmachem Laboratories Inc. (Kearny, NJ).

“The supplement market is definitely more direct in its approach to the blood sugar market,” agrees Max Motyka, MS, RPh, director of sales and marketing for Albion, Human Nutrition Division (St. Clair Shores, MI). “This is...obvious looking at the way the supplement market names and describes its blood sugar products.” Indeed, the supplements shelf is rich with “blood glucose support” formulations.

Most blood sugar–supplement shoppers are also familiar with claims of supporting healthy blood sugar. “Due to FDA/FTC regulations, which consumers are now used to since 1994, the claim ‘supporting healthy blood sugar’ is well understood,” Skop says. Even for mainstream customers new to the supplements aisle, “we still believe that such a claim is not ambiguous; conversely, it’s rather crystal clear. It is also truthful and non-misleading,” he adds.

More supplement shoppers are learning about the way in which different blood sugar ingredients work. For instance, an ingredient that inhibits carbohydrate breakdown and glucose absorption by the blood, such as Pharmachem’s Phase 2 Carb Controller white kidney bean extract, is “predominantly” understood, according to Skop. While many shoppers seek Phase 2 for weight-management purposes, they may be interested to know that a 2009-published study in The Open Nutraceuticals Journal suggests that the ingredient also helps to inhibit hyperglycemia. More recently, in a study published in 2011 in Nutrition Journal, researchers further determined that Phase 2 may help reduce postprandial blood sugar spikes.

“Products that act on glucose can do so in a number of ways, but for simplification I like to classify them into two categories,” says Jocelyn Bérubé, MSc, scientific director, health and nutrition, InnoVativ (Rimouski, QC, Canada). “There are products that act on sugar before it gets into your body, and others that act on how your body uses glucose once it is in the body. It really follows what happens after a meal. Glucose gets in the blood (from digestion), and then your metabolism gets glucose out of the blood (to make energy, or fat, or something else). If you want to act on the in phase, you can, for example, slow down the digestive enzymes that cut large starch and sugar molecules into single glucose. You could also inhibit the transport of that glucose across the intestinal wall.” However, he continues, “If you want to act on the out phase, you could facilitate insulin release or secretion, improve the sensitivity of cells to insulin, increase conversion of sugar to either glycogen or fat, and many other things. This will all have the effect of lowering blood glucose more rapidly.” But, according to Bérubé, growing consensus in the scientific community is that increasing insulin production through artificial means may not be the best route because the body could potentially
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Blood Sugar Management

end up becoming more desensitized to insulin. “The best strategy, and the one with the most beneficial impact on health, is really to work upstream by reducing the entry of glucose into the body,” he says.

This April, InnoVactiv’s InSea2 ingredient launched in a new carbohydrate-inhibiting supplement, Cebolixs, by Euro-Pharm International. InSea2 contains phlorotannin polyphenols, derived from the brown seaweed species *Ascophyllum nodosum* (kelp) and *Fucus vesiculosus* (bladder wrack). InSea2 helps to inhibit the enzymes that spur carbohydrate breakdown: alpha-amylase and alpha-glucosidase. By inhibiting these enzymes, human studies show InSea2 can help to modulate both starch and sugar digestion, and the result is lowering blood glucose levels (by up to 48.3%), while also lowering blood insulin levels and increasing insulin sensitivity, right after first use of the product.

Pharmachem also supplies Prenulin, a proprietary combination of Chromax chromium picolinate and a unique form of L-arabinose. A 2011 *Nutrition Journal* study demonstrated that Prenulin consistently and significantly lowered circulating glucose and insulin after a 70-g sucrose challenge, without adverse effects. “It operates in two separate modes,” Skop explains. “L-arabinose, derived from the corn plant, acts as a sucrose ‘blocker,’ which reduces the digestion of sugar. Chromium picolinate (Chromax) helps metabolize the sugar that is ingested in a more healthful way.”

Bill Levi, vice president of strategy and business development at Nutrition 21 LLC (Purchase, NY), the manufacturer of Chromax, points to more than 51 human clinical studies and FDA qualified health claims confirming Chromax chromium picolinate’s effectiveness in helping to maintain healthy glucose metabolism. This includes clinical studies showing superior absorption compared to other chromium forms. Nutrition 21 is now highlighting further dimensions of diabetes impact, including a link between high glucose levels and risk of dementia, recently highlighted in the *New England Journal of Medicine.*

Chromium, as well as supplement ingredients like *Gymnema sylvestre* and cinnamon, are commonly understood, Albion’s Motyka says. But increasing research is also paving the way to a larger market presence for magnesium, zinc (especially for those with type 1 diabetes), and alpha-lipoic acid, he says. Albion supplies the following minerals for type 2 diabetes and prediabetes, in the form of bioavailable bisglycinate chelates: magnesium (including a buffered form), zinc (both bisglycinate and arginate chelates), and chromium nicotinate glycinate.

Magnesium, which is a key cofactor for enzymes involved in carbohydrate metabolism, as well as a key factor in insulin sensitivity, “is of prime importance,” Motyka says. Deficiency has been linked to both insulin resistance in obese children and increased risk of type 2 diabetes in adults. Unfortunately, of all minerals, the U.S. population is most deficient in magnesium. And zinc, he adds, plays a key role in fighting insulin sensitivity by helping to prevent the malfunction of the protein amylin, which otherwise results in “shutting down” insulin-producing cells. Those with diabetes, however, tend to have more trouble absorbing and utilizing zinc.

Research is in the early stage for a grape seed extract ingredient Polyphenolics (Madera, CA) introduced this year for healthy blood sugar maintenance. Announced in April, MegaNatural-GL differs from the company’s flagship grape seed extract ingredient, MegaNatural-BP, which aids in healthy blood pressure. Although both ingredients are founded on grape seed extract, “MegaNatural-BP...has
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a molecular structure which enters the blood-stream quickly. MegaNatural-GL, on the other hand, maintains its characteristics in the digestive tract, where it can have the greatest benefit,” explained president Anil Shrikhande, PhD, in a press release. Pilot studies at the University of California, Davis, conducted in healthy subjects and subjects with metabolic syndrome suggest MegaNatural-GL may help increase insulin sensitivity and glucose metabolism, especially after dinner, a time of day during which the body’s ability to manage glucose may be lowest, compared to the morning.

Consumer Education
The high prevalence of diabetes and prediabetes opens the door to possible assistance from dietary supplements, foods, and beverages. But, as InnoVactiv’s Bérubé points out, there is still a great deal of education needed to help consumers understand diabetes in general, as well as its triggers and the role that nutrition can play. HealthFocus International secends this, stating, “There appears to be a high lack of awareness among people at risk in regards to their overall health and diabetes risk.” Cosucrais Marnet adds, “Indeed, products specifically targeting diabetes are not spreading in the mainstream market, as mass-market people do not understand the ‘scientific’ messages present on those products”—which makes targeted marketing all the more relevant.

“One important aspect that people have to understand is that we spend most of our waking hours in a postprandial (post-meal) situation,” Bérubé adds. Once we’re done eating, it usually takes around two hours for postprandial glucose levels to return to fasting levels (such as when you first wake up). But if insulin resistance is present and insulin signaling is not optimized, bringing those blood sugar levels down can take a lot longer. So, instead of being in a postprandial glucose state for, say, six hours of the day following each daily meal, we may spend as many as nine or more hours awake in a post-meal, elevated-glucose state. And that doesn’t even count spikes that occur after snacking.

Sadly, Bérubé says, people may not even notice the fluctuations between glucose highs and lows, meaning that many don’t even realize the rigors we put our bodies through simply by indulging in high-glycemic foods throughout the day. (People with diabetes, by contrast, often experience symptoms such as dizziness when their blood sugar levels are too low, so they may be more aware of when levels change.) Likewise, we don’t realize the damage that we’re doing. Of hyperglycemia, Bérubé says, “It is like ‘rusting’ the body by adding glucose molecules on many different proteins like hemoglobin, collagen, enzymes, and others, which then lose part or their entire functions.”

Don VerHulst, MD, chief science officer for InBalance Health Corp., believes more focus is also needed not just on the symptoms of high blood sugar but on the cause—in his words, “toxic belly fat.”

“The enemy is what I call toxic belly fat,” VerHulst says. “Excess abdominal fat is what causes insulin resistance, which leads to dangerous, higher blood sugar. Although traditional medicine, which I am trained in, has become very good at keeping blood sugar levels within an acceptable range, it often ignores the cause of the problem. You see, high blood sugar is a symptom, not the cause, of the problem.” He says InBalance’s InBar nutrition bars and dietary supplements, alone or in conjunction, can help consumers manage their weight and glucose levels and provide “a simple solution to what can seem like a complicated health issue.”

Pharmaceutical firm Boston Therapeutics, together with marketing firm Benchworks, is working on a blood sugar awareness campaign for its new carbohydrate-blocking dietary supplement, Sugardown, whose ingredients include galactomannan. The plan will include an active social media and public relations reach-out, as well as a partnership with PreDiabetes Centers around the United States, to grow awareness around Sugardown and the importance of maintaining healthy blood sugar levels throughout the day.

“We believe that there is more need to explain the role that a dietary supplement plays in helping patients manage their health,” says David Platt, PhD, CEO of Boston Therapeutics. “We believe that consumers need to understand how Sugardown works. That is why we are providing as much education as possible.”

Opportunities to Help
Although more education is needed to drive the blood sugar market, there’s one, certain market driver that doesn’t appear to be going away anytime soon: the high number of people trending towards diabetes who need to take preventive steps. As Nutrition 21’s Levi puts it, currently “the sale of blood sugar supplements does not match the size of the population of people who are insulin resistant.”

InnoVactiv’s Bérubé says that while the blood sugar category can be challenging, the number of blood sugar products will continue to grow as consumers get the message to cut sugar and high-glycemic food intake.

“Products with unjustifiably high amounts of sugar keep receiving a lot of criticism, and the sugar level of food and beverages is about to become much more important,” Beneo’s O’Neill says. “Consumers know that they need to focus on their health, but they often struggle with changing their habits or following one diet after another.” Dietary supplements and foods and beverages that allow customers to eat more healthily without sacrificing enjoyment are tools we can all consider. After all, Bérubé says, “Blood glucose maintenance is a building block that should be part of any health-maintenance strategy.”

References

Capsules and Tablets
Bosch has been manufacturing capsule fillers for over 40 years. As testimony to Bosch reliability many of these early machines are still in use by our customers. What is less known is that Bosch now offers a full line of tablet presses.

Tablet Presses
With the purchase of Manesty Bosch entered the tablet press business. Manesty has long been known for making excellent tablet presses that brought about many industry leading innovations. Bosch hopes to build on the groundwork set by Manesty and continue to improve on tablet press design. Currently Bosch offers options from laboratory scale to high-speed production systems.

Capsule Fillers
Bosch continues to be on the forefront of capsule filler design with innovative machines that have the right blend of size, function, and flexibility to fit your operation. Bosch offers three classes of capsule fillers, the Capsylon for budget minded buyers, the traditional GKF models for expanded flexibility and features, and the HiProTect series offering full containment and wash down for the highest level of operator safety. Whatever your capsule filling need Bosch has you covered.

Checkweigh and X-ray Inspection
Bosch offers a full assortment of inspection systems including the new KKK universal capsule inspection system designed to ensure the correct weight and detect any defects or foreign particles. For 100% gravimetric checkweighing, Bosch offers the KKE checkweigh systems that weigh each capsule and provide feedback to automatically notify you of any issues or automatically adjust the filling parameters of certain GKF models.
The dietary supplement and healthy food and beverage markets are flush with great products, making it increasingly difficult for brands to communicate the unique attributes that set their products apart from the competition. Keen packaging design has emerged as an important product differentiator in the natural sector, but it’s not without its caveats. Using packaging to court natural shoppers can be tricky, especially when it comes to maintaining the delicate balance of providing shoppers with enough product information without overwhelming them, not to mention creating a distinctive brand message that still fits within the industry’s regulatory framework.

Crafting the Right Message

The single biggest challenge when designing packaging for the supplement market is creating a unique selling proposition, says Kevin Smith, founder of boutique packaging, website, and graphic design firm Smash-Brand (Eden, UT). “Sometimes there are ingredients or benefits that are protected by a patent or backed by some exclusive university study, but for the most part, many manufacturers are able to put the same ingredients into the product with low or no barriers to entry,” he says. “This makes the industry highly competitive and the products very difficult to differentiate.”

This is a critical instance in which package design aesthetics really matter, Smith says. “If the consumer doesn’t really know the difference between two or more products and believes that either product could address their needs, they will choose based on price and package design,” he says, adding that consumers often subconsciously assume that products that have better packaging are of higher quality. “In the end, manufacturers can command a higher price point for products...just by having high-quality packaging design.”

Fortunately, natural product shoppers tend to be well educated about the types of products they want (and don’t want). For that reason, Matt Cave, brand strategist at brand identity and package design company Edmundson Martin (Boca Raton, FL), says consumer resonance can’t be distilled down to a one-size-fits-all solution for brand identity and package design. “Natural products shoppers, first and foremost, are looking for the truth. What are the health benefits? What’s in the product? Who makes it? Are...
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they good people? Is the manufacturing and distribution of the product sustainable?” he says.

Yael Miller, partner at food packaging and branding company Miller Creative LLC (Lakewood, NJ), asserts that supplement branding hasn’t been very progressive as a category, which should theoretically make it easier for brands to stand out if they differentiate on a fundamental level. However, he says, brands must respect consumer expectations by conveying efficacy—i.e., taking cues from the pharmaceutical category but without making drug claims—while still affording space for natural/healthful visual cues.

Informative Design

High minimums and expensive dies for injection-molded plastic continue to make traditional round bottle and screw-top closure designs the most cost-effective packaging option for supplements. Still, some companies are flexing their creative muscles to make the most of the adaptable aspects of this packaging format.

“Information can still happen by marrying the use of design on the outer label with bottle and cap color and by using less-common bottle shapes,” says Smith. “The most cost-effective design is to be creative in your approach to using stock packaging so that the end product feels very much like custom-designed packaging.”

Stock bottles and caps are available in an array of colors, and labeling deco options are almost infinitely customizable. Molly Fuehrmeyer, graphic design manager for packaging firm TricorBraun (Oak Brook IL), says packaging color selections continue to trend brighter and in some cases even include tactile features to stimulate the consumer both visually and tangibly. “Adding some kind of tactile/texture feature or matte versus gloss effect to the shrink sleeve or to the label goes that much further to capture the consumer’s attention and get them to pick the product up off the shelf,” she says. “Marketers know that if they can get the consumer to pick up the product, they have a greater chance of securing the purchase.”

For some companies, color serves a very specific purpose. Herbal extracts brand Herb Pharm (Williams, OR) recently debuted a

Fibregum™ line of products is an all-natural and GMO free source of 90% soluble dietary fiber from carefully selected acacia tree gum. Fibregum™ is clean label and appeals to consumers because it’s 100% vegetable origin and available in organic grades. Clinical studies have demonstrated the numerous health benefits of Fibregum™ and its prebiotic properties at a daily dose of 6-15 grams.

Fibregum™ is progressively fermented by probiotics in the intestinal tract without discomfort, making it the perfect replacement for other dietary fibers that consumers report can create gas, bloating and flatulence.

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brand-wide, color-coded packaging redesign (pictured below) capped off by a new logo. All products are sorted into color-coded categories according to function: Immune Support, Nervous System, Energy & Vitality, Respiratory System, System Restoration, Cleanse & Detoxify, and Optimal Well-Being. The company says the new formatting makes it easier for retailers to merchandise each product by category and also delivers at-a-glance convenience to consumers.

“We hear from so many people saying they have both a need and interest in healing herbs but simply don’t know where to start,” said Michael Gillette, Herb Pharm’s director of marketing, via press release. “With our new color-coded labels and corresponding descriptive categories, we are making it easy to match an individual’s health need with an effective, medicinal herb, while also encouraging the experienced herb shopper to broaden their use of herbs to other areas of their personal health.”

Supplements firm Vitalah (Santa Cruz County, CA) also tapped into a more inviting color scheme for the new packaging for its Oxylent effervescent multivitamins, pictured above. “By using new colors and graphic elements on the front of the box, we made it easier for our customers to spot their favorite flavor at a glance,” says CEO and founder Lisa Lent.

Beyond its colorful visuals, the packaging does something unique: it balances a wealth of product information while remaining consumer friendly. Each of the product carton’s side panels describes in detail the doses and benefits of each key ingredient, including superoxide dismutase, magnesium, zinc, selenium, potassium, stevia, calcium, CoQ10, and vitamins B, C, and D3. Consumers will no doubt find handy visual graphs demonstrating how the products’ minerals (mineral chelates from supplier Albion Human Nutrition) are better absorbed compared to standard minerals.

Delivering meaningful product information in a visually appealing package is something that Lent says is difficult to achieve but important for forging trustworthy consumer relationships. “Conveying information to our consumers is a primary driver of our packaging design decisions, since packaging is the means of communication that gets closer to consumers than any other,” she says. “But, at the same time, too much text can be overwhelming and actually dilute the message we are trying to convey. It’s crucial to remember that aesthetics communicate just as words do—we can convey our core brand values visually as well as verbally.”

Also, according to SmashBrand’s Smith, the unfortunate level of health claims abuse cited by regulators, with questionable companies making unauthorized product health claims, should definitely make firms more wary to communicate product benefits the right way. “In the end, we try to focus on a big impact of one or two main and
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Packaging

DOES CONVENIENCE PACKAGING COME AT A PRICE?

Convenience packaging—single-serve and blister packs for supplements—are still trending. “People are on the go and will pay more money for that convenience,” says SmashBrand’s Kevin Smith.

These types of “planned” serving packaging formats are ideal for daily usage supplement regimens, says Richard LeBlanc, principal at B12 Packaging design firm (Dallas, TX). “Consumers are more distracted than ever before by their daily lives,” he says. “Anything the brand can do to simplify this is key.”

The trend, however, is tempered by an overarching sense of environmental responsibility. “Most of these packaging types tend to create more waste, and especially with the market segment that cares about healthier natural products, they tend to also care about saving the landfills and waste,” Smith says.

Differentiated benefits, “he says. “Because there is a lot of distrust in the industry, you can actually gain a lot of consumer trust just from the packaging by not exaggerating or making unrealistic claims on the packaging.”

A New Design Direction

When it comes to on-package graphics, Jonathan Ford, founding partner and chief creative officer for design firm Pearlfisher (New York), says marketers are turning to new inspirations. “We have definitely moved away from the wholesome and earthy and also the rigidly functional,” he says. “Clean and clinical…came to the fore, but we are now just starting to see a necessary shift that creates a new aesthetic…which is refocusing on the individual body and its optimization.”

He also says that while “healthy” market segments historically paid greater attention to female consumers, more brands are using packages designed to appeal to men. Pouches, like those for sports nutrition brand Manfuel, “are still popular when targeting the male consumer,” he says. (See photo on page 64.) Also, “We are seeing traditional bottles, boxes”—like those designed in-house by supplements brand Nano Labs, pictured at left—and vials also coming back to the fore as we emphasize attention to detail, the handcrafted, and the sense of the personal touch.”

He points to two projects his agency recently executed, for Strong Vitamins (see page 62) and Plenish juice (pictured above), for which the goals were to express freshness and quality using visuals and simple language. “The central idea [for Strong Nutrients] uses the metaphor of birds for each product—with, for example, a swan representing beautiful cell regeneration,” Ford says. The Plenish line was designed to be “bold, simple, and focused on cause and effect.”

“Both Strong and Plenish are disrupting and cutting through the existing look and feel of the category,” he continues. “It’s not necessarily about including results or substantiation, but finding new visual and verbal ways to clearly, simply, and honestly express the end benefit to ensure relevance and resonance.”

“Aesthetic preferences have changed towards more streamlined and ‘clean’ design, versus lots of heavy color, words, and content,” says Miller of Miller Creative. He notes that gradients and shiny effects continue to be dropped in favor of “flatter” design details. “This subtly conveys honesty in marketing and less ‘smoke and mirrors’ typical of large consumer brands.”

In the end, it’s about finding a personalized way to connect with consumers. “It is the responsibility of design to create new definitions and spaces, to help brands establish and own a new visual rhetoric and positioning and optimize the communication of these brands,” Ford says. “And these two needs are now starting to pull together and be realized as we begin to see a new generation of brands finding new ways to marry product with experience and forge a new level of customer connection.”

Joanna Cosgrove is a Media, PA–based writer who has covered the dynamic dietary supplement and functional food and beverage industries for more than 15 years.

The plan for Plenish packaging was to be bold, simple, and focus on cause and effect.

“You can gain a lot of trust from packaging by not exaggerating or making unrealistic claims,” says Smith.

PHOTO: BY NANO LABS; PHOTO BY PUNYIR

Differentiated benefits, “he says. “Because there is a lot of distrust in the industry, you can actually gain a lot of consumer trust just from the packaging by not exaggerating or making unrealistic claims on the packaging.”

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When the FTC released updated guidelines for sussing out fraudulent weight-loss claims in print, television, and radio ads earlier this year, the agency asked media outlets to do a “gut check” before running dubious product spots. But for supplement makers in the busy weight-management space, the move felt like more of a gut punch.

After all, FTC’s “Gut Check” initiative—which singles out specious weight-loss claims for special media scrutiny—represents only one of several roadblocks that tripped up a supplements sector valued at some $60.5 billion in 2013, according to Marketdata Enterprises Inc.

Consider, for example, the settlement FTC reached with four weight-loss product marketers in January wherein the companies—Sensa, L’Occitane, HCG Diet Direct, and LeanSpa LLC—agreed to collectively refund $34 million to consumers for making what the Commission says were deceptive claims. Or consider the June Senate subcommittee hearing on consumer protection that lambasted television personality Dr. Mehmet Oz for touting as “magic” and “miraculous” weight-loss supplements like green coffee bean extract, Garcinia cambogia, and raspberry ketones that critics claim lack sufficient science—let alone magic or divine intervention—to justify their promises.

Perhaps the capstone was comedian John Oliver’s spoof of that very hearing, in which he spared no one—not the celebrity doctor, the government, nor industry as a whole—his wit. As Council for Responsible Nutrition (CRN; Washington, DC) president and CEO Steve Mister—who himself testified at the hearing—says, “Satire is not your friend in that situation. So I wouldn’t be surprised if it affected consumer confidence in the weight-loss category.”

But it hardly killed it. With more than two-thirds of American adults overweight or obese, according to National Health and Nutrition Examination Survey (NHANES) data, demand for weight-management supplements is in no existential danger. And with research on ingredients continuing apace, there’s reason for both consumers and industry to have hope. The trick to maintaining this momentum will be to keep an eye on the science and steer clear of the wild claims that attracted negative attention in the first place.

In the Crosshairs

Industry watchers agree: the weight-control sector is under increasing regulatory scrutiny. Looking back over the past few years, Mister concedes, “Yes, we are seeing more cases and more investigations focused on weight management.”

John E. Villafranco, partner, Kelley Drye & Warren LLP (Washington, DC), sees a similar pattern. “At this point, the FTC appears to be active and back to a more usual pace in announcing cases on health-related advertising—and weight-loss advertising, in particular,” he says, noting several recent “gut check” settlements whose FTC consent orders included permanent bans. “The bans either prohibit certain types of claims or prohibit individuals or companies from participating in the weight-loss industry at all,” he says. “And while bans are nothing new, there seems to have been an uptick in the use of bans recently.”

Also appearing with some frequency are consent orders barring companies from making weight-loss claims without the support of at least two well-designed randomized controlled clinical trials (RCT). This two-RCT requirement “pervades all of the FTC actions these days,” Mister says, and is “not limited to weight management.” Overlaying a “drug-like” benchmark atop the Dietary Supplement Health and Education Act’s (DSHEA) more flexible standard for competent and reliable scientific evidence, the two-RCT requirement has some in industry wondering if we’re witnessing regulatory mission creep.

(Read more on page 10.)

Silver Linings

But Mister isn’t especially concerned about the requirement’s effect on the weight-management category in particular, and the reason why underscores once again that weight management, despite the recent kerfuffle, is in a healthy spot.
Jost Chemical Co. is highly rated as the go-to source for high purity mineral salts for nutritional, clinical nutrition, pharmaceutical and other specialty applications. Our FDA registered site manufactures 250+ products under cGMP that routinely meet very low levels on Pb, As, Hg, and Cd. Jost also developed technology to produce ultra-pure calcium salts with Al levels of 5 ppm or less. Our products meet USP/EP/JP/FCC requirements and are Kosher and Halal certified. Contact Jost for assistance in meeting custom purity requirements.
As Mister points out, "Weight management is an area where you can do a 60-day, even a six-month trial with human subjects." While such studies require rigorous design, execution, and data interpretation, they are, he says, "relatively easy to set up. And that's why I think if you talk to those we'd consider experts on weight management, they would probably not think it unreasonable for a company making these claims to do clinical trials on these products.

And if the products perform as hypothesized, that news will only buttress any claims and redound to the good of the category as a whole. As Villafranco sees it, if FTC applies its consent-order authority justly, it "can strike the right balance to require a reasonable level of substantiation while avoiding setting the bar so high that the many existing good actors in the weight-loss industry will no longer have the incentive—or financial capability—to innovate, create, and market new products."

And make no mistake: good actors are out there. While some weight-management claims "really are egregious," Mister says, and the billions of dollars spent on the products rightfully has FTC cautious of fraud, "we do believe that there are legitimate ingredients in the dietary supplement space that can help consumers with weight management, whether by increasing metabolism, providing a sense of satiety, or providing other benefits," he says.

**Word to the Wise**

That's why CRN "applauded" FTC's activities in its June testimony before Congress and "encouraged them to do even more in this area," Mister continues. "It does a real disservice to legitimate marketers of legitimate ingredients when you have people out there promoting ingredients that simply cannot work the way they're being advertised."

So what's his advice to legitimate marketers hoping to remain within FTC's good graces? Mister has a checklist of best practices, starting with the exercise of assiduous ingredient oversight. As he explains, simply by being in the weight-management space, product formulations are already in the crosshairs. That makes it imperative "that you're doing really good analysis on your incoming ingredients to make sure that what you think you're putting in your products is actually what you're putting in them," he says.

And as strictly as you scrutinize your ingredient certs, scrutinize your science. Ask yourself: Is it, in fact, "competent and reliable" evidence? Do the data cover human subjects? And what about dosing? "If the daily serving I'm recommending is 12 mg and the studies are all done using 100 mg, it becomes hard to say that the evidence supports use of the product," Mister says. "So make sure there's a good, strong link between the study and the product in terms of ingredients and levels."

*Continued on page 76*
Introducing Nitrosigine®, an FDA accepted new dietary ingredient for use in pre-workout products for sports nutrition. Nitrosigine® is a patented complex of bonded arginine silicate, scientifically engineered to deliver benefits to consumers engaged in fitness training programs. Manufactured in the U.S., Nitrosigine® is a safe, non-stimulant ingredient that’s easy to formulate into new and existing sports nutrition products.

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Congressional hearings and FTC scrutiny notwithstanding, this really is an exciting time to be exploring the weight-management landscape. For proof, look no further than the innovations sweeping thermogenics. As Bob Green, chairman, Advantra Z Inc. (West Caldwell, NJ), puts it, “We’re very confident in the future of the thermogenic market because manufacturers have only begun to tap the potential of thermogenic ingredients.” Stimulating the body’s thermogenic potential “is a proven method of not only weight loss, but also for increasing fitness and energy,” Green says. And if an ingredient can do that without negative side effects, “the opportunities for innovative consumer products are limitless.” Start exploring right here:

Advantra Z

Green points to two large, long-term human clinical trials as vindicating his company’s Advantra Z bitter orange extract (Citrus aurantium) as a safe and effective thermogenic ingredient. A randomized, placebo-controlled, parallel-group, double-blind study published in 2013 in the Journal of the International Society of Sports Nutrition found that eight weeks of supplementation with a multi-ingredient weight-loss supplement (Prograde Metabolism) containing Advantra Z—along with raspberry ketone, caffeine anhydrous, OmniActive Health Technologies’ (Morristown, NJ) capsaicinoids ingredient Capsimax, and others—enhanced body composition, reduced hip and waist girth, and increased energy levels in overweight men and women when administered as part of a weight-loss program including caloric restriction and exercise.

Another study, published in 2013 in Food Chemistry Toxicology, found that Advantra Z and its dominant amine p-synephrine produced no adverse effects on systolic or diastolic blood pressure, blood chemistry, or blood cell counts, nor any adverse effects on cardiovascular, hepatic, renal, or hemopoietic system function at a dose of up to 98 mg daily for 60 days. Of note, Green says, this was “the longest research study with the highest dose of bitter orange as a single-entity product conducted to date.”

ActivAMP

One strategy for boosting thermogenesis is to get out and exercise, which acts on the enzyme 5’ adenosine monophosphate-activated protein kinase—AMPK, for short—to, broadly speaking, “determine whether available energy is utilized to meet immediate requirements or stored for future use,” explains Paul Clayton, PhD, chief scientific advisor, Gencor (Irvine, CA). “Activated AMPK also increases fat burning via beta oxidation and inhibits cholesterol synthesis by down-regulating HMG CoA reductase and fat formation by down-regulating acetyl CoA carboxylase.”

Exercise being easier said than done, the possibility that a thermogenic ingredient could trigger a similar cascade of cellular activity is tantalizing. According to a 12-week randomized, double-blind, placebo-controlled trial of 80 overweight participants published this year in Obesity, it appears that Gencor’s ActivAMP, an extract of the herb Gynostemma pentaphyllum, may do just that. Study results showed statistically significant decreases in body-fat mass, percent body fat, body weight, body-mass index (BMI), and total abdominal fat area in the experimental compared to the placebo group.

“AMPK is often called the ‘master metabolic regulator,’” Clayton notes, “and it switches on the same fat-burning and energy-producing metabolic processes that exercise does.” It appears that the actives in the Gynostemma extract, a class of saponin compounds called damulins, account for the supplement’s AMPK activation.

Coleus Extract

According to Anurag Pande, PhD, vice president, scientific affairs, Sabinsa Corp. (East Windsor, NJ), “For better success of long-term weight-loss maintenance, one has to understand the various factors affecting it. One prime factor resulting in poor long-term weight-loss maintenance is an adaptive decrease in thermogenesis.”

That is, the less caloric energy one consumes in pursuit of weight reduction, the more the body adapts to the energy deficit by reducing its energy needs and expenditures. “One way to overcome this adaptive decrease is to stimulate thermogenesis,” Pande continues. He notes that clinical studies demonstrate the benefits of Coleus forskohlii extracts in maintaining long-term weight loss via thermogenic enhancement.

Forskolin, a diterpene that’s a key active in Coleus extracts, “stimulates the enzyme adenylyl cyclase and subsequently increases levels of cyclic AMP, or cAMP,” Pande explains. In adipose tissue, cyclic AMP helps release fatty acids, “facilitating fat breakdown in adipose tissue,” he says. In so doing, “cAMP may actually regulate the body’s thermogenic response to food, increase the body’s basic metabolic rate, and increase utilization of body fat.” Not bad for an herbal extract.

Sinetrol

At Fytexia, in Vendres, France, they’re betting that the famously healthful Mediterranean diet bears some responsibility for the region’s famously slender inhabitants. “If you go to the South of France and ask people how they stay lean and healthy,” notes Romain Thévenot, sales manager at Fytexia, “they will tell you about their well-balanced diet based on multiple fruits and vegetables.”

Those fruits and veggies are packed with polyphenolic antioxidants, and Fytexia developed its Sinetrol XPrur product to capture their potential to promote weight management. It is a proprietary combination of citrus extracts from specific varieties of blood orange (Citrus sinensis L.), sweet orange (Citrus sinensis L.), grapefruit (Citrus paradisi Mac-fad), and guarana (Paulinia cupana Kunth), with a total polyphenol content of 90%.

Thévenot notes two published clinicals showing that the product promotes lipolysis by inhibiting phosphodiesterase, “helping [users] lose fat without any controversy about
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Continued from page 74

In the more recent of the two studies, a 12-week randomized, double-blind, placebo-controlled human intervention trial published in 2013 in Phytotherapy Research, subjects who took the extract twice daily with meals exhibited significantly decreased body weight, fat mass, and waist and hip circumferences compared to the placebo group. The release of free fatty acids into plasma was also significantly higher in the treatment group, further supporting the extract’s proposed lipolytic mechanism.

Continued from page 72

And mind the messenger, particularly if you’re leaning on testimonials or endorsements. For example, Mister says, “If five people who’ve lost five pounds in 30 days are going to become spokesmen for your product, the FTC says that you need to show that their results are typical of what the average consumer can expect.” And in accordance with FTC’s Operation Full Disclosure initiative, launched in September, you’ve got to disclose that information clearly and conspicuously—not in mouse type on the insert’s back page.

That done, you can breathe easier when it comes to crafting product claims. Nevertheless, Mister urges marketers to avoid FTC’s “red flags”—claims so suspicious that their very presence should prompt that aforementioned “gut check.” Any promise that a product will help users shed 2 lbs or more per week for a month or beyond without diet or exercise should set off bells. So, too, should promises of substantial weight loss regardless of diet; products that purport to block the absorption of fat or calories; claims of a safe loss of more than 3 lbs per week for more than a month; products that promise all users will lose substantial weight; promises of weight loss via topical application; and any promise of permanent weight loss. Nothing, after all, is permanent.

“Companies in this space should absolutely look at those areas and make sure they steer clear of them,” Mister says. It doesn’t hurt to lawyer up, either. As he sagely advises, “It’s always a good idea to get outside counsel to review your labeling and claims in advertising.”

View references at www.NutritionalOutlook.com/1411/Weight

Kimberly J. Decker writes for the food and nutrition industries from her base in the San Francisco area, where she enjoys eating food as much as she does writing about it. Contact her at kim@decker.net.
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Testing to the Limits
Texture analyzers and rheometers for quality control

BY ERIC CHIANG, BROOKFIELD ENGINEERING LABORATORIES

Rheology is a topic fairly broad in scope. In general, it is the study of the flow behavior of materials, including both elastic and viscous properties. In the consumer packaged goods industry, rheology can be used to determine how materials move during processing, what their flow characteristics are like in packaged form, and, finally, how they behave when used by the customer.

In the nutraceutical and food industry, rheology is important because these products encompass both liquids (such as beverages) and solids (like powders). When it comes to product testing, rheometers, as well as texture analyzers, help to ensure quality and consistency in production, as well as assist during evaluation in R&D studies. These detailed test methodologies enable food scientists to understand and correctly predict flow behavior in order to monitor the effect of changes in formulation on product performance. Let’s take a look at how specific nutraceuticals are tested for flow properties, including the test methodology and equipment used to make relevant measurements.

At Full Strength
Many vitamins come in hard-capsule form. Testing the tensile strength and extensibility of hard gelatin capsules is crucial to ensure that capsules can withstand the rigors of production and use.

When formulating a nutraceutical, one key element a manufacturer needs to consider is whether the nutraceutical is compatible with a capsule’s gelatin shell. Certain substances may negatively react with the gelatin and cause it to fail. Another common failure in a gelatin capsule is a highly hygroscopic filling, which may absorb water from the capsule shell, in turn causing the shell to become brittle and prone to breakage under mechanical strain.

A texture analyzer is the instrument of choice for evaluating mechanical properties of tensile strength and extensibility (capability to be stretched). The device shown in Figure 1 is called a capsule loop tensile fixture (CLT) and can be used with a texture analyzer (Figure 2) to quantify the mechanical strength of the capsule shell. This combination of equipment enables manufacturers to identify and quantify the effects that different fillings will have on the strength and stability of a capsule.

The CLT fixture is used to break apart the shell of hard gelatin capsules and, in so doing, enables manufacturers to quantify how much strain the capsules can withstand. The sample capsule is placed over two small pins, which are then pulled apart while the load force is recorded.

Sample preparation must be carefully controlled and involves the following steps:

1. Store the hard gelatin capsule overnight at room temperature
2. Separate capsules into two halves (body and lid) and empty the contents
3. Select the smaller half of the capsule (lid) for testing

During the test, the upper half of the CLT fixture moves away from the lower half at a speed of 1.0 mm/sec or slower until a trigger
force of 10 gm is detected. (The trigger force is the minimum amount of force that must be detected before the instrument starts to measure and report the tensile load.) Once the test commences, the capsule is stretched with increasing force to a point where the sample can no longer support the applied force and breaks. The amount of force measured at the breaking point is an indication of the hardness of the sample.

A typical plot of the tension test showing force load versus time is illustrated in Figure 3. Note that there is a double peak for each test; this double peak indicates that there is some amount of stretching or extension that occurs just before the capsule breaks. The area under the curve for a similar graph, which plots force load versus distance, is a measure of the work required to break the capsule wall.

Figure 4 shows the data summary for four test runs. Note that the software used to control the texture analyzer can also compute helpful information such as the average value for peak load and the standard deviation. The test results show that this method is suitable for testing the tensile strength and extensibility of hard gelatin capsules. In order to yield reproducible and repeatable test results, manufacturers must adhere to the test procedure, sample preparation, and equipment setup. In our test case, several tests were done on the hard gelatin capsule, and all test results were within 10% tolerance, indicating that this capsule has sufficient tensile strength and extensibility.

The following preparatory steps must be observed in order to ensure repeatability and reproducibility:

1. Use similar ends of the hard gelatin capsule cap
2. Ensure identical sample temperatures during testing

**Flow with it**

Methods used to test the flow properties of liquid and semi-solid nutraceutical and food ingredients require use of a rheometer. Rheometer measurements typically include both yield stress and viscosity flow curve. The rheometer shown in Figure 5 uses a cone spindle to shear the sample material in order to quantify these two properties.

### Texture analyzers and rheometers are quality-control tools for consistency in production and R&D.

- The peak load-deformation at peak load for all four gel capsule sample tested is shown in Figure 3.
- Figure 4 shows the test results comparing all four hard gelatin capsule sample tests.

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Figure 4. Test results comparing all four hard gelatin capsule sample tests.
mences. The associated torque value at that instant in time is a measure of yield stress. The second test involves rotating the spindle with increasing speed and measuring the viscosity at each speed. The typical flow behavior for nutraceutical materials is “pseudoplastic,” meaning viscosity decreases with increasing shear rate. Examples of yield stress and viscosity flow curve are shown in Figures 6 and 7.

Controlling Quality
There are many reasons to use texture analyzers and rheometers as quality-control tools for consistency in production and R&D. Good practice, as shown in these examples, ultimately ensures product consistency between different batches, shifts, and plants, thus guaranteeing a consistent product, no matter where it is manufactured.}

Eric Chiang is product manager, texture analyzers, at Brookfield Engineering Laboratories (Middleboro, MA), whose viscometers/rheometers have been the world standard in viscosity measurement and control of liquids and semi-solids for 80 years.
Alzheimer’s Patients Consume Saffron for a Year

Unsurprisingly, Iran just birthed another study on saffron, one of the country’s biggest cash crops. While researchers at Tehran University have studied the purple flower many times before, their latest study on saffron and Alzheimer’s disease appears to be the longest yet on the topic.

For a full year, 68 Alzheimer’s patients consumed daily capsules containing saffron (30 mg) or memantine (20 mg), a prescription drug for Alzheimer’s. Every month, they submitted to cognitive tests—the Severe Cognitive Impairment Rating Scale (SCIRS) and the Functional Assessment Staging Test (FAST)—to help researchers measure any cognitive decline during the study. After a year, researchers did not detect any significant difference between scores of either group, suggesting that saffron may be as effective as the Alzheimer’s drug in slowing cognitive decline.

This study on patients with moderate-to-severe Alzheimer’s disease follows two previous saffron trials on mild-to-moderate Alzheimer’s. In those trials, saffron slowed cognitive decline compared to placebo or donepezil, a drug intended to treat dementia. Researchers involved in these studies suspect that saffron may be effective against cognitive disorders because it may inhibit the overgrowth of amyloid β in the human brain. Interested manufacturers can procure saffron extracts in liquid and powder forms from saffron extract suppliers such as Nutraceuticals International Group (Paramus, NJ).

Follow-Up on Omega-3s and Prostate Cancer: Inconclusive

Following up on the not-so-favorable results of a study that found omega-3 consumption may be linked to increased prostate cancer risk, the *Journal of the National Cancer Institute* brought together a handful of investigators involved in recent, similar prospective studies to analyze all of their data together.

The combined analysis included 5098 subjects who were diagnosed with prostate cancer during studies, as well as 6649 control subjects. The average follow-up time for each study was five years. Data dated as far back as the 2007 Physicians’ Health Study and as recently as the 2013 SELECT trial, the results of which suggested increased prostate cancer risk.

In this new meta-analysis, while researchers observed elevated risks of prostate cancer in the highest quintile of EPA and DHA fatty acid consumption, a cause-and-effect relationship was not established for either fatty acid, and heterogeneity was found amongst the studies. Interestingly enough, stearic acid was inversely associated with prostate cancer risk, and data on the remaining 11 fatty acids under investigation bore no connection to prostate cancer.

“There was no strong evidence that circulating fatty acids are important predictors of prostate cancer risk,” concluded the team. “It is not clear whether the modest associations of stearic, eicosapentaenoic (EPA), and docosapentaenoic acid (DHA) are causal.”

**Why Krill Oil Is More Stable than Fish Oil**

By now, manufacturers and even some consumers are familiar with the argument that krill oil is more efficiently absorbed than fish oil. Another distinction, however, is that krill oil is also more stable than fish oil. A team of researchers now believes it has more evidence of just what causes krill oil to be more stable during storage.

Krill researchers in Scandinavia placed krill oil samples in storage at 20°C or 40°C for 28 and 42 days, and they measured markers of oxidation as well as levels of antioxidants over time. With an increase in storage temperature came increases in fat oxidation and browning reactions, which were to be expected. But as oxidation increased, the researchers also identified an increased presence of antioxidative compounds called pyrroles, which appear to result from reactions of particular compounds during the browning stage.

While krill companies are well aware that krill’s contents of astaxanthin and tocopherol help keep krill oil stable over time—and more so than fish oil—the new data indicates...
that there are still other compounds that can protect krill oil from rancidity during storage. This gathering of antioxidant-like compounds may also mean, as some researchers have suggested, that krill oil is better suited for functional foods and beverages where it is not as easy to mask the flavor of unstable, rancid oil.

This latest study on krill oil stability used Rimfrost krill oil from Olympic Seafood AS (Fosnavaag, Norway).

Watermelon Has Lycopene, Too

Tomatoes enjoy nutritional fame for, among other useful compounds, their rich sources of lycopene. But watermelons have lycopene, too—and theirs might even be more effective.

Hoping to get a better understanding of watermelon nutrients, a team of Korean researchers compared tomato lycopene and watermelon lycopene using a series of assays designed to assess the antioxidative and anti-inflammatory potential of each lycopene. Compared to tomato lycopene, the lycopene in watermelon showed greater antioxidant activity in scavenging radicals such as DPPH and superoxide anion. The watermelon lycopene showed significant anti-inflammatory activity, as well. On human cells, it lowered expressions of common inflammatory biomarkers, such as inducible nitric oxide synthase (iNOS) and cyclooxygenase (COX-2), and in dose-dependent fashion.

The full results of this study are available in the International Journal of Food Science & Technology, and they should come as welcome news to manufacturers of watermelon juices and watermelon extracts, although watermelon rind-based extracts will likely be low in lycopene. While watermelon juice can provide a tasty means of delivering the fruit’s lycopene content, researchers have warned of the possible loss of lycopene (and red color) during watermelon juice production. To mitigate this potential lycopene loss, a non-centrifuge juicing process may be best for these fruits.

Watermelon is a valuable fruit for its many other nutrients, too, such as vitamin A, vitamin C, potassium, beta-carotene, and the amino acid L-citrulline.

Chlorella Is High in Vitamin B$_{12}$ (Methylcobalamin)

Although chlorella (Chlorella vulgaris) is already sold in health food stores around the world, researchers are still just learning the makeup of this single-celled green alga. A study out of a national research institute in India provides a little more information about chlorella’s vitamin B$_{12}$ contents.

Researchers at the CSIR-Central Food Technological Research Institute in Mysore, India, quantified chlorella’s vitamin B$_{12}$ and identified it as the methylcobalamin form of this essential nutrient. Their data is based on multiple microbiological and chemiluminescence tests that they used to record vitamin B$_{12}$ levels between 26.84 ± 2μg and 29.87 ± 2μg per 100 g of dry-weight chlorella.

These finding should improve chlorella’s standing as a useful source of nutrition, but the ingredient has many other nutrients, including minerals, vitamins, and amino acids. Scientists have recently reported a lack of published human trials on chlorella, but some optimism can be had in what trials have been completed, including a very recent placebo-controlled trial on chlorella’s potential to improve lipid profiles in obese adults.
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(Signed) Tim Baudler, Brand Director
9/30/14

Raw Material Sales
Job Description
We are a distributor of bulk raw materials (vitamins, dietary ingredients, chemicals, herbal extracts). We are seeking a seasoned experienced sales professional from this specific field. The primary responsibility of the sales person is to increase sales by selling the company’s raw material ingredients to clients. The sales person reports directly to the President.

Desired Skills & Experience
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- Independently develop processes to obtain leads and effectively execute the delivery of the company’s unique selling propositions to prospects.
- Identify prospects where company’s products and services can be sold;
- Target and obtain appointments with prospective new clients, often travel required;
- Contact potential clients to assess their individual needs and demonstrate how Company’s products and services can meet or exceed these needs;
- Develop and submit comprehensive proposals based on individually or team assessed needs of potential clients;
- Maintain accurate up-to-date sales pipeline and forecasts;
- Ability to perform other duties as assigned by the President
- Understanding of the dietary supplement industry within the B2B scope;
- Strong sales skill, likeable personality;
- Proven ability to achieve goals;
- Solid mastery of the processes, technologies and tools of the sales practices;
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Experience: Mid-senior level
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Guayusa Is More Than Caffeine

The South American leaf is a growing choice for tea and drink launches. But what’s in guayusa besides caffeine?

BY ROBBY GARDNER, ASSOCIATE EDITOR

I
n the hustle for clean-label caffeine ingredients, tea and energy drink makers are starting to get their hands on guayusa (Ilex guayusa), a holly plant and close relative of yerba mate (Ilex paraguariensis). This South American leaf contains caffeine—less than coffee, and more than green tea—but there’s a deeper story to be told for guayusa, and much, but not all of it, is centuries old.

Folklore
Guayusa is a plant full of amusing folklore. Before developed markets discovered guayusa, indigenous people living in or near the Amazon jungle, where guayusa still grows exclusively, gave this plant a mystical role in daily life.

According to guayusa powder supplier Ecuadorian Rainforest LLC (Belleville, NJ), guayusa was known locally as “Night Watchman,” due to its awakening ability (which we now understand as being at least partly related to guayusa’s caffeine content). Some traditional healers contend that drinking guayusa tea can help ward off snakes, because snakes can sense guayusa’s presence. On the lighter side of things, guayusa tea is still just a morning ritual for families.

The little details of guayusa’s origin are tucked into what experts say are just small regions of the Amazon rainforest, where the rainforest lies closest to the Equator, but because manufacturers around the world now have at least limited access to guayusa, opportunities do exist to share guayusa’s very peculiar history with shoppers thousands of miles away.

Contents
Storytelling aside, the nutritional contents of guayusa are, at the end of the day, what make guayusa most marketable.

“The great thing about guayusa is that it’s more than just caffeine,” says Randy Kreinbrink, director of marketing for guayusa powder supplier BI Nutraceuticals (Long Beach, CA). As much as industry is just beginning to unravel the components of guayusa, it appears certain that guayusa at least contains flavonoids, polyphenols, saponins, caffeine, and L-theanine. Found in other plants such as green tea, L-theanine is widely regarded for its relaxative effects on the brain, and its presence in guayusa may explain why numerous suppliers characterize guayusa as having a “calm energy.”

Suppliers often characterize guayusa’s caffeine buzz as a “calm energy.”

Leaf Stages
For all of the appealing compounds that can be found in guayusa, one need only steep guayusa leaves. But the optimal conditions for steeping guayusa have not yet been decided on. This uncertainty is what keeps guayusa powder supplier Applied Food Sciences (Austin, TX) hard at work.

“If you just boil the leaves, you’ll get the tea,” says Jackson Zapp, vice president of marketing for Applied Food Sciences (Austin, TX). “But, we’re looking at the green leaves, the withered leaves, the different stages of the plant, and we’re finding what different compounds are in each of these stages.”

Early trial and error at Applied Food Sciences suggests that there are indeed phytochemical differences in each of these plant conditions. Manufacturers eager to one day use guayusa for nutrients other than caffeine will have their choice between a range of tailor-made guayusa ingredients. And as phytochemical contents change in the plant, so does guayusa’s flavor. “The more you wither the leaf, the more you’re going to get a traditional black tea flavor,” says Zapp.

Guayusa Powder
In this early stage of global guayusa trade, ingredient suppliers have settled on guayusa powder, wherein the guayusa leaves are dried, sterilized, and milled into a water-soluble substance. Regardless of the form guayusa takes in finished health products, though, guayusa leaves are sure to find a comfortable place amongst the green teas, coffee beans, kola nuts, and guarana seeds of today’s caffeine market.
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