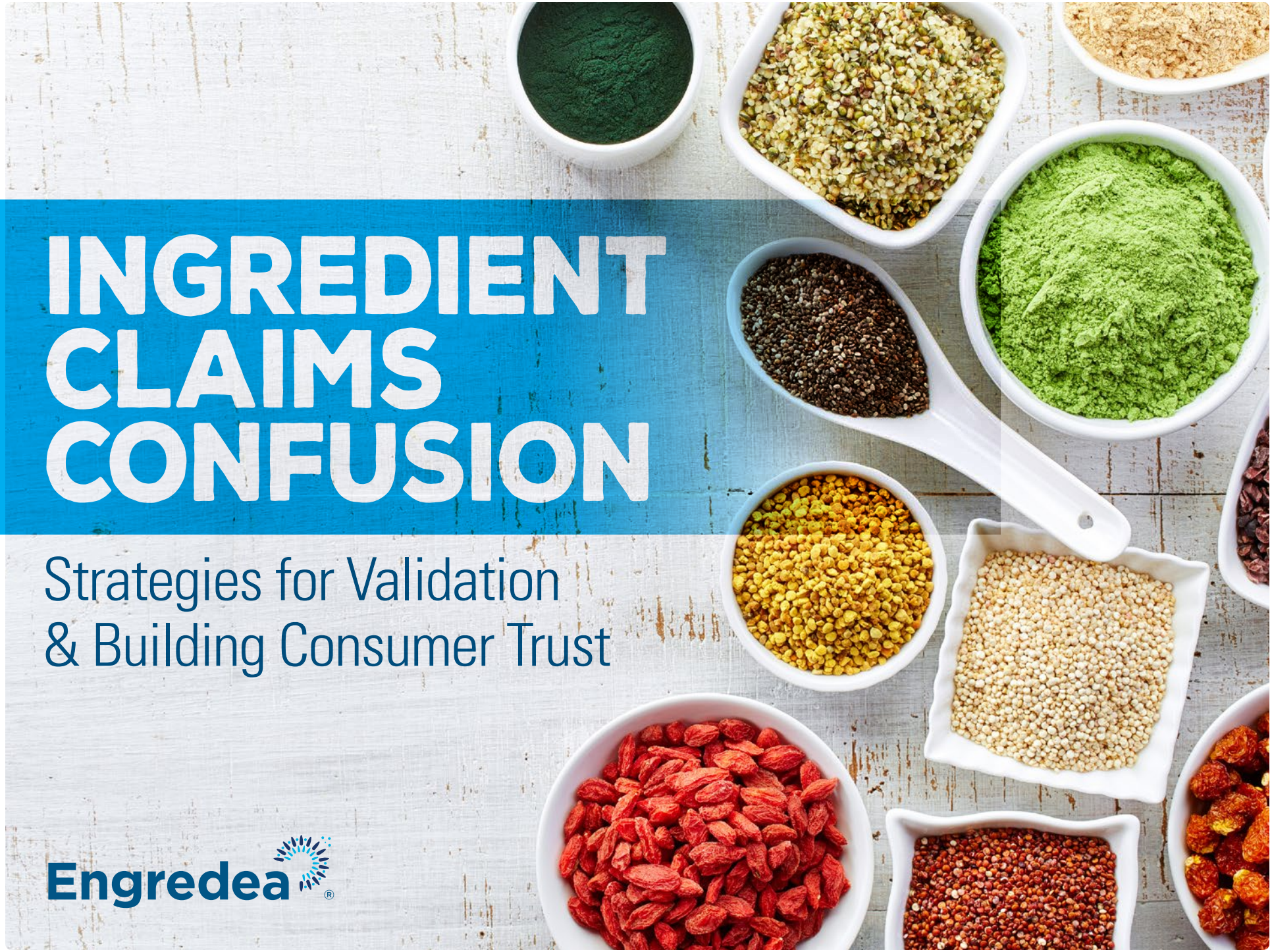
INGREDIENT CLAIMS CONFUSION

Strategies for Validation & Building Consumer Trust



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INTRODUCTION
A Paradigm Shift, an Industry Comes of Age

Can your customers trust you? It's a question every ingredient supplier, manufacturer, and retailer should be asking themselves, in the wake of a series of highly-publicized events that threaten to erode trust in the $40 billion dietary supplement industry.

Only 39 percent of supplement users currently rate the industry as "trustworthy," and the majority has doubts that product claims are honest or backed by science, according to a new consumer survey by *Nutrition Business Journal*. Retailers - still stinging from the New York Attorney General's 2015 investigation into what it called "adulterated and mislabeled" herbal supplements on store shelves — are scrutinizing ingredient supply chains more than ever. Meanwhile, regulatory agencies are also turning up the heat, with the Federal Trade Commission filing at least 14 formal complaints and sending out dozens of warning letters in 2015, accusing manufacturers and marketers of making unsubstantiated claims.

The good news: From this crisis of trust has emerged an important paradigm shift, say industry veterans. In a market once heavily reliant on folklore, faith, and borrowed research, more companies are discovering that both customer confidence and competitive edge hinge on three things: Quality science, valid, well-substantiated claims, and frequent testing for purity and integrity.

What's Inside

A 2016 survey of 45,000 CONSUMERS found that "trust" is the No. 1 driver in choosing a dietary supplement brand. Price ranked fourth.

Source: Brand Keys Customer Loyalty Engagement Index

"The industry is coming of age, and companies are starting to fall into one of two camps: the one that makes solid products with real evidence that they do what they say that they do; and the one that doesnt.

— Risa Schulman, PhD, president of supplement consulting firm Tap Root.

"We are circling the wagons, and the farther we get down this path the less forgiving the stakeholders will be if your science is not up to snuff."

The pages ahead serve to offer detailed guidance on how companies can use science to position themselves firmly in the right camp and regain, or hold on to, that fragile trust. It also offers a glimpse at a new generation of sophisticated ingredients that are taking supplements into directions they haven't gone before.

As Eric Pierce, director of business insights at New Hope Network, points out: "All is not doom and gloom." Sixty-eight percent of consumers surveyed have faith that the industry is 'continuously trying to improve and make products more effective.'"

For companies who live up to that expectation, the future looks bright.

42% of supplement users think the industry ensures product claims are honest

38% think the industry is transparent about product claims

49% think products have science to back up their claims

Source: NBJ

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I. THE INTEL INSIDE

A new generation of branded ingredients put research first, commercialization next

Take one look at what's selling in the supplement industry and one overriding trend emerges: Vague, general wellness products are taking a hit while condition-specific specialty ingredients are gaining traction. In 2015, according to NBJ, multivitamin sales grew just 2 percent while sales of some specialty supplements (like probiotics for gut health or proprietary blends to support sleep or cognitive health) have been growing by double digits.

Amid this clamoring for specificity has also come a flood of branded, patent-protected ingredients that profess not only to help support a certain organ system, but specify the precise mechanism of action by which they do so.

They inevitably cost more. But they often come with a rich scientific dossier, a tightly-controlled supply chain, additional certifications (like Generally Recognized as Safe or New Dietary Ingredient status) and intellectual-property protection that discourages me-too ingredients from pirating their claims. All that can be attractive to a supplement-maker wanting to differentiate a product in a crowded market and be ready if and when federal regulators come calling.

"There are so many more products on the market today, it is becoming a necessity and a competitive advantage if you can say more than 'may support heart health' or 'contains antioxidants.' The only way you can do that is with good science."

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"There are so many more products on the market today, it is becoming a necessity and a competitive advantage if you can say more than 'may support heart health' or 'contains antioxidants.' The only way you can do that is with good science," says Schulman.

In an effort to prevent the brand erosion that can occur when consumers don't get a high enough dose and, thus, don't get any benefit, some branded ingredients even dictate what dose (based on clinical trials) a supplement maker must use in their products. Probiotic ingredient supplier Ganeden Biotech even goes so far as to take products off store shelves and test them to ensure its BC30 Probiotic strain is present in efficacious levels. Others insist the branded ingredient name be displayed prominently on the bottle.

Premium brand-holders say such added costs and requirements pay off.

In all, general wellness supplements now make up

ONLY

13.4%

of the market. "Specialty Ingredients," make up

18%

Source: Nutrition Business Journal

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"There is a very big difference in the quality of ingredients provided to supplement companies depending on where you get them," says Paul Jacobson, CEO of Thorne Research, which makes supplements sold exclusively through practitioners. He says research-based branded ingredients from companies like Chromadex and Indena have helped Thorne earn the confidence of an otherwise skeptical medical community. "They know we rely on ingredient companies that are the best of the best. Yes, we pay more. But we can trust our suppliers more."

Non-branded ingredients will, of course, remain important, says Schulman, either as back-up ingredients for blends in which a few branded stand-outs serve as stars, or as headlining herbs or vitamins with a long proven track record. But the rise of the brands has raised the bar for commodity, or generic, ingredients too. "They can also have a place as long as vendors do their homework, make good choices to sell ingredients that are well researched, and be sure that the science they are citing truly does apply to the ingredient they are selling," she says.

BRANDED INGREDIENTS TAKE TIME

PLT HEALTH SOLUTIONS markets a brain-health ingredient Zembrin, a patented standardized extract of the South African succulent plant Sceletium tortuosum, a.k.a. Kanna. Aware of the plant's traditional use for stress relief and mood enhancement, the company spent five years selecting a specific cultivar, containing a certain combination of alkaloids, and rigorously studying not just whether it improves mood but how. Via Functional Magnetic Resonance Imaging, researchers discovered it acts on anxiety-related regions of the amygdala, inhibiting an enzyme called phosphodiesterase 4 (PDE4) and influencing serotonin receptors called 5 HT. The ingredient is now patented not only for how it's made but for how it functions in the brain.

KEMIN INDUSTRIES recently unveiled a new brain health ingredient, Neumentix, a patent-pending spearmint extract selectively bred to contain high levels of rosmarinic acid (RA) and more than 50 other phenolic compounds with neuroprotective, neurotrophic, antioxidant,and anticholinesterase activity (meaning it prevents destruction of the neurotransmitter acetylcholine). The company spent five years and $3 million on research and development, screening 5,000 lines of spearmint to come up with a variant with the precise molecular properties it was looking for. "Sometimes people discover interesting plants and see what kind of health benefits they may hold. We turn that process on its head," says Brenda Fonseca, Kemin's Global Cognition Technical Services Manager. "We do a lot of research up front to find molecules of interest. Then we identify plants that can grow those molecules for us."

BIOVA® LLC spent its first four years in research phase, studying protein-rich egg membrane for safety and efficacy, while further developing and eventually patenting two proprietary technologies: OvaPure™ for mechanically extracting the membrane from eggshells and Hydro5™ which makes the egg membrane water soluble without destroying its natural, healthful properties. The result: An entirely new category of ingredient, upcycled from a healthful material that was once a waste stream. Fast forward seven years, Biova continues its research and now has three branded ingredients: BiovaFlex® for joint health, BiovaDerm® for skin care, and BiovaPlex® for animal health.

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II. 'SOLID SCIENCE' RE-DEFINED

Federal regulators and customers are raising the bar; the industry is reaching for it

In recent years, FTC complaints against such high-profile companies as DSM, Bayer, and POM Wonderful, have illustrated one undeniable fact: When it comes to substantiating claims with science, the bar has been raised.

In 2014, the FTC issued a complaint against i-Health — the consumer products division of ingredient-giant DSM — for making unsubstantiated claims of "memory improvement" and "prevention of age-related cognitive decline" for its Brainstrong Adult supplement (made with DSM's *life's* DHA ingredient.) The company based its claims on a company-sponsored, six-month, randomized, double-blind, placebo-controlled study of 485 subjects, which found those who took 900 mg of the DHA experienced improved "verbal recognition memory scores." As Duffy MacKay, of the Council for Responsible Nutrition put it, the study was "rock solid."

But FTC argued that there are many different kinds of memory and cognition, the study only looked at a few, and DSM's claims failed to match the findings. Ultimately, i-health was forced to change its labels. For the broader industry it was a wake-up call. "What the FTC did here is make it clear up front to the folks who want to do it right that doing it right is not going to be easy," says attorney Stuart Pape, who specializes in regulatory affairs for Washington, D.C. based law firm Polsinelli. *The takeaway: Study findings, no matter how expertly conceived, must precisely match the claim.*

The POM Wonderful and Bayer cases sent other messages. In the POM case, which concluded in May of 2016, the FTC required that in the future, if POM wants to use the term "clinically proven", it must have "at least one randomized, well-controlled human clinical trial" to back it up. In the Bayer v. FTC case, Bayer was widely seen as the victor, after a New Jersey District Court ruled that it did not (as FTC tried to require) have to have two randomized clinical trials to back up its claims for its Phillips Colon Health product. (CRN argues that in some cases the drug-like standard of two RCTs is not practical or possible).

The take-away on paper: Companies must have "competent and reliable scientific evidence" to back up their claims. "The reality is," says attorney Ivan Wasserman, who specializes in FTC regulations, "If you want to say something is 'clinically proven' to influence health, one RCT is good, but you are better off going with two."

A 2013 study of 127 supplements purchased at retail found that none of the "structure/function" claims on the bottles were substantiated to the degree that FDA advises. **Only 34 percent** of the substantiation documents reviewed were human studies and most were not randomized controlled trials. **Twenty percent** of the products included prohibited "disease claims."

Source: Office of the Inspector General for the Department of Human Services

SEVEN SIGNS OF A HIGH QUALITY STUDY

Whether trying to decide whether the study you're reading is high quality, or working with a research group to design one, keep these questions in mind:

1 **IS IT A DBPC RCT?** The gold-standard is a double-blind, placebo-controlled randomized clinical trial, meaning participants are randomly selected to receive either a placebo or the compound in question and neither the researcher nor the subjects know who is getting what.

2 **ARE THE RESULTS STATISTICALLY SIGNIFICANT?** Look for a "p value" of less than 0.05. That means the investigators are more than 95 percent confident that the study results are due to the compound and not due to random chance. "If you had to defend a .09 p value to the FTC it would be an uphill battle," says Wasserman. Are those results repeatable in subsequent studies?

3 **IS THE SAMPLE SIZE ADEQUATE:** The more subtle the impact of the ingredient, the larger the sample size will need to be. "A lot of times people try to save money by having fewer subjects, then they realize later that if the study would have been bigger the results would have had more statistical significance," says Wasserman.

That said, human clinical trials are not necessarily all you need. Matt Stegenga, president of ingredient-maker Biova, believes a rock-solid scientific dossier hinges on a continuum of science progressing through a series of cyclical questions, not unlike a "chicken/egg conundrum." We certainly look at potential market application and sourcing issues, but then we get to a foundational evaluation focused on what does the material elementally consist of? Is it safe? What dose is needed? Does it work? How does it work? And, how does it work in combination with other ingredients? This requires tests done in the lab, if and when appropriate in animals, and then in humans. "As a new ingredient coming into a high-scrutiny marketplace, it is critical that you go through each and every one of these steps in depth," he says. And even after this, we encourage our customers to perform their own additional independent research on their formulated, finished product.

Schulman offers this list of questions to a company poised to go public with strong claims: "What does the totality of the science tell us, and how strong is it? Are there gaps that need to be filled to shore up a mediocre level of evidence before I can go out with my claim? What kinds of studies can fill them, and what is the cost-benefit analysis of me doing them? What level of risk is there with the current portfolio, and is it a level the company is comfortable taking on?"

One other question company leaders might want to consider as they invest heavily in research: How do you keep competitors from pirating your science to sell their own products? In the future, Stegenga believes smart ingredient developers will conduct more research but publish less.

SEVEN SIGNS OF A HIGH QUALITY STUDY *CONTINUED*

4 DO THE STUDY SUBJECTS MATCH YOUR TARGET AUDIENCE? If the study is done on obese men and you are trying to use it to substantiate a product targeted toward healthy women, this will be a problem. The same goes for when you're looking for substantiation for a brain health claim targeted toward healthy adults, but the study was done on dementia patients.

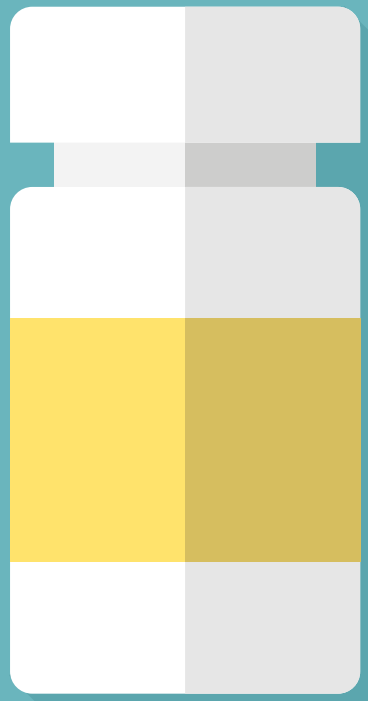
5 WAS THE ORIGINAL STUDY PROTOCOL FOLLOWED THROUGHOUT? If changes were made half way through the study, consider this a red flag. The FTC recently fined the supplier of a green coffee extract $3.5 million after charging that the study it used to substantiate its claims was "seriously flawed." Among other things, the lead investigator changed the length of the trial part way through.

6 IS THE DOSAGE AND FORMULATION THE SAME? Did the study use the same dose made the same way as what you're using?

7 IS THE INGREDIENT IN A FORMULATED PRODUCT THE SAME INGREDIENT FORM STUDIED? If an ingredient studied was produced to a patented activity, or was extracted in a specified manner, then the identical ingredient must be used within a formulation to substantiate a claim.

"Publishing for publishing's sake is counterproductive. You can keep good research in your dossier to share with your customer, and if your customer gets a call from the government asking for substantiation they'll have it. But you don't necessarily have to publish everything for just anybody to utilize."

— Matt Stegenga, president of ingredient-maker Biova



'PHARMACEUTICAL LIGHT'

Look to drug-makers for a smart research protocol

"Many companies, tempted by the promise of quick market access and lower clinical research costs at the outset, cut corners during the trial design phase,"

says Josh Baisley, PhD, associate director of clinical trials for Nutrasource, a Canadian contract research organization and consulting firm. He advises companies to use a "pharmaceutical light approach" which begins by visualizing the finished product (how it will be marketed, and in what countries) and uses that information to guide which kinds of trials to do.

PHASE 1: These safety and tolerability studies can also help investigators learn more about how bio-available a compound is, what optimal dose is needed for impact, and how and when that dose should be given. Sometimes this phase can be skipped (it often is in the nutraceutical industry), if toxicology and dosing information is publicly available. But oftentimes it shouldn't be. "A later clinical trial may fail to show an effect, not because the effect wasn't there, but because the dosing was wrong," says Baisley.

PHASE 2: Often positioned as proof of concept, or pilot studies, these explore whether the product has clinical efficacy. If the claim is a strong one, it's best if the journey does not end here. "Ideally, they should have a dose ranging study or proof of concept study and at least one well designed randomized controlled trial," says Baisley.

PHASE 3: These are larger trials that confirm effects demonstrated in Phase II clinical trials.

PHASE 4: These are post-marketing studies.

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III. THE ART OF THE CLAIM

Once you've got the science, communicating it wisely is key

There was a time when ingredient suppliers need only communicate their science to manufacturers or brand-holders. Not anymore. "With so many people Googling ingredients, the consumer could easily end up on our web page," says Kim Colletti, Global Cognition Product Manager for ingredient company Kemin.

With the eyes of regulators, brands, and end-users on ingredient companies more than ever, many are upping their communication game. For instance, Kemin is developing a mechanism of action video for use on its Neumentix website, enabling brands that feature the product to use it, and consumers to directly view it. Kemin scientists also attend medical conferences to educate physicians and researchers on their branded ingredients, and train retailers directly.

"People are constantly talking about how little they can say, but in reality, people leave claims on the table all the time."

— Dr. Risa Schulman, President Tap Root

Both Kemin and branded-ingedient-maker PLT now also provide detailed lists of suggested claims, complete with extensive scientific dossiers, for brands who use their ingredients.

"(Crafting claims) can be a huge part of a company's product launch cycle," says Barbara David, PhD, vice president of medical and scientific affairs for PLT. "We are trying to handle some of that legwork for them."

But first, both companies put any proposed claims through a rigorous review process. In this day and age, everyone should, says Schulman. "Unfortunately, there are still well-meaning people out there who think that doing your science homework means reading webpages on the topic."

Before a company makes a single claim, she recommends convening a team of scientists, attorneys, and marketing professionals to hash out wording that is accurate, regulatory compliant, and as compelling to the consumer as possible. "Marketing is concerned with story. Legal is concerned with defensibility. Research and development is concerned with facts. So these can make for frustrating meetings," she warns.

Those writing the verbiage should read the studies in their entirety (not just the abstracts). And if they don't understand what they're reading, they should hire someone with a science-background who can. One oft-overlooked benefit of a more thorough reading of the science: You might discover claims you didn't realize you could make, says Schulman.

The Food and Drug Administration issued **80 warning letters** to manufacturers and marketers in 2015, 53 **of them for "misbranding"** products by claiming they can treat or cure.

FOUR TIPS FOR TALKING ABOUT YOUR SCIENCE

1 STICK TO 'STRUCTURE FUNCTION CLAIMS': This should go without saying, but we'll say it anyway. If you claim to "diagnose, cure, mitigate, treat, or prevent disease" you are making a "disease claim" which requires prior FDA approval and can only be made for drugs or a very select group of foods and supplement ingredients with "qualified health claims." (If you had one, you'd know it). Rather than say "cures the common cold" say "supports a healthy immune system."

2 MATCH CLAIMS TO SPECIFIC FINDINGS: Read the fine print and be sure your claims specifically match study findings. If your science is solid, this can be a huge selling point. For instance, Kemin's suggested structure/function claims for Neumentix include "Key bioactive constituents in Neumentix have been shown to slow the breakdown of acetylcholine in the brain."

3 KNOW THAT IMAGES MATTER TOO: Even if your words are expertly crafted and compliant, an image or video that subtly suggests "cure or treatment" to a consumer can get you in trouble.

4 MIND YOUR SOCIAL MEDIA: Tweets, blogs, Facebook posts, even Instagram captions, all must comply with FTC claims regulations. "Something as innocent as a supplement company liking a comment (that appears to make a disease claim) on its Facebook page can get them in hot water."

WHO SHOULD CONDUCT YOUR STUDY?

Who does your research and how they write it up matters. Here's a look at the pros and cons.

A UNIVERSITY? Working with a high-profile university researcher can lend credibility to your product among potential clients, media, and regulators. But university researchers tend to be less familiar with supplement industry regulations, says Schulman, and sometimes write the study in ways that could lead to trouble. For instance, if it makes statements that could be construed as disease claims, or refers to study populations (patients with dementia, obese individuals) that are not a good match you might not be able to use it on your website or hand it out at conferences. Universities also tend to want to (and often have the right to) publish the results whether you do or not.

A CRO? With Contract Research Organizations, you typically own the data so they publish only what you ask them to. Many have an encyclopedic knowledge of supplement industry regulations so they write up results in a way that you can use in marketing without worrying. The downside, says Schulman: They tend to be less likely to publish in top tier journals, and – because they deal with so many different kinds of ingredients – may not have the condition-specific expertise a university researcher has.

PUBMED? Beware of what Schulman calls "the PubMed punch up." Someone involved with developing the marketing copy takes the name of the ingredient in question and a health benefit, puts it into the search box in PubMed, clicks "enter" and uses the results to claim that "hundreds of studies" support them. "If this is true, there is nothing wrong with these statements," she says, "but most often things are hairier than that." If you are going to use PubMed (ideally as a background or adjunct to your own research), pay close attention to what kind of study it was (animal or human) the dose and type of ingredient used and precisely what benefit it's linked to, she says. "When I see statements like 100s of studies show ingredient X works, I read 'I am sensationalizing my science'."

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TRACKING INTEGRITY

Companies are scrutinizing raw botanical materials more than ever, but which test is best?

In February, 2015, N.Y. Attorney General Eric Schneiderman publicly accused GNC and three other retailers of selling fraudulent products, after DNA barcode testing found 19 of 24 herbal supplements on their shelves contained DNA that was either unrecognizable or from a plant not on the label. Instead of spotting echinacea, St. John's wort, ginkgo, valerian, ginseng, saw palmetto and garlic, the tests spotted rice, asparagus, wild carrot and other compounds the media referred to as "cheap fillers and house plants." Amid the massive public black-eye, the Natural Products Association and the Council for Responsible Nutrition cried foul, arguing that the testing method was flawed. Ultimately, Schneiderman conceded that GNC was in compliance with current Good Manufacturing Practice guidelines which require companies to use "scientifically valid methods" to test identity. GNC, nonetheless, promised to set an example for the industry, by embracing DNA fingerprinting. "We believed that embracing a new quality test and DNA barcoding could validate product quality, change the mindset of our critics, correct their misperceptions, and improve confidence," said GNC spokesman Greg Miller.

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— GNC spokesman Greg Miller

But Elan Sudberg, of Alkemist Labs, says it's not so simple. He and other testing experts say that while DNA barcoding, no doubt, has a place in the "pantheon of testing methods when performed by trained experts," it has shortfalls and should not be relied upon, in and of itself. It's not a good fit for extracts, he says, because the extraction process often damages or removes genetic material. It's also vulnerable to contamination — a fleck of pollen or a stray skin cell from a lab worker could render a sample contaminated. And DNA fingerprinting can't distinguish between a root, a fruit, or a leaf, or determine whether a plant is unripe or rotten. "DNA testing does nothing to assess quality," he says.

In some cases, simple, "organoleptic" or microscopic practices can work better to answer the question at hand. In other cases, chemical fingerprinting methods like high performance thin layer chromatography (HPTLC) or High Performance Liquid Chromatography (HPLC) suit best.

FIVE TIPS TO ENSURE WHAT'S ON THE LABEL IS INSIDE THE BOTTLE

1. At each change of hands in the chain of custody, employ an identity test.
2. Make sure your vendors keep raw material reference samples (from before processing) on hand so if testing fails to identify what you're looking for you can go back and determine why.
3. Tell your testing company how you make your product, including what extraction methods you use. This might influence how they conduct the identity test.
4. If the species name isn't a critical differentiator (for safety or efficacy reasons) and you cannot confirm beyond a doubt that you have the right species, consider leaving the species off the label. Plants tend to hybridize and can sometimes contain DNA from similar species (without impacting its health properties), says Sudberg. "I think there are a lot of materials floating around that are not in fact the species they say they are. DNA testing is going to uncover that and if that happens, you have potential label infractions."
5. Don't "pixie dust": The more ingredients in a bottle, the harder it is to test for identity, says Sudberg.

"None of them are 100 percent fool-proof. If you really want to be air tight and buttoned up do all three."

— Will Rowe, Canadian testing company Nutrasource Diagnostics

PLTs Barbara Davis, points out that identity testing is just one step in the comprehensive traceability and management system it uses to assure its clients that its ingredients are made with integrity, quality, and efficacy. "Science is an integral part of the process, from farm to shelf," she says.

As botanical supplements become more sophisticated – some cultivated to perpetuate naturally occurring distinct chemical fingerprint with a distinct, scientifically-backed mechanism of action.

This is perpetuated through a natural seed-to-shelf control cultivar, insuring a targeted activity.

This critical process has prompted some companies to vertically integrate so they have control over every step of the supply chain. For instance, HG and H Pharmaceuticals, which supplies PLT with its Zembrin ingredient, developed its own seed bank and painstakingly monitors planting, drying and harvesting to ensure full traceability. To assure each batch contains the unique chemical fingerprint validated in clinical trials, PLT uses HPTLC, HPLC, and DNA testing. Additional tests look for shelf stability, and the absence of microbes, heavy metals and other contaminants.

Going forward, Sudberg believes more and better testing — as long as it is applied appropriately — can play a key role in resolving the industry's trust crisis. His advice: "Test test test and test again. Because what matters most in the end is what's in the bottle, not the shipping container."

A TESTING PRIMER

MICROSCOPY: One of the oldest and most effective techniques for assessing identity and quality of botanicals. Can confirm species. Can assure the right plant part (leaf, root, stem,) is present. Can identify contaminants. In combination with other sense-based or "organoleptic" methods (smell and taste), can also assess ripeness and other quality measures. Can't identify specific phytochemicals and can't distinguish between two similar species.

HIGH PERFORMANCE THIN-LAYER CHROMATOGRAPHY (HPTLC): This state of the art method measures the phytochemical fingerprint of the plant and compares it to a reference sample. Ideal for confirming the presence of active phytochemicals. Can be used for extracts or raw botanicals in whole or powdered form as well as finished products. Can't always distinguish between two similar species. Considered the "gold standard" stand-alone method for identifying botanicals in finished dietary supplements, according to NPA.

HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC): A more powerful and expensive form of chromatography, it is better at determining the quantity of certain phytochemicals. For this reason it can sometimes distinguish between two species (bilberry vs blueberry), based on their phytochemical profiles.

DNA FINGERPRINTING: Looks at the presence of genes and compares this genetic fingerprint to a reference sample. Can distinguish between closely related species (bilberry v blueberry) and can detect minute amounts of genetic material. Can't distinguish between leaves, roots, or fruits, ripe or unripe.

CONCLUSION: THE PAYOFF

What can all this top shelf science buy companies in the end?

William Rowe, president and CEO of Nutrasource, envisions a day when dietary supplements in the United States are required to go through some sort of pre-market approval process to assure they are safe, efficacious, and of high-quality (as they have been since 2004 in Canada). "Both consumers and regulators are showing a preference for reputable science, high quality products and supply chain transparency," he says. "It's no longer a matter of if, but when."

If and when that day comes in the U.S., companies who have done their due diligence will have a head start. In the meantime, they're already making their way into Canada and other countries, where more rigorous pre-market approval also comes with more freedom to make stronger claims. "Canadian companies can do far more aggressive clinical trials in sicker patient populations and make far more aggressive claims than in the U.S. domestic market," he says.

Science-backed supplement companies are also being eyed by pharmaceutical companies, wanting to give their customers what they want (less expensive, efficacious solutions with fewer side effects) without spending the time and money to develop a prescription drug. Whether they're looking for an ingredient supplier or looking for a brand to buy, those pharma companies tend to be more discriminating when it comes to science.

"The big hot zone for us is taking natural compounds on a pharmaceutical pathway," says Rowe. That pathway could lead to a premium dietary supplement, but it also could lead to a medical food (a growing category of products which are often reimbursable by insurance).

Even if no major regulatory changes are made in the United States, companies have one other over-riding reason to painstakingly validate their claims and the integrity of their ingredients :

"In the end, it's peace of mind we are trying to deliver here," says PLTs Barbara Davis.

"The consumer can identify the supplements they know to be effective and can trust. They are the reason we are in this business to begin with."

ALKEMIST LABS

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Alkemist Labs is an ISO 17025 flexible scope accredited contract-testing laboratory specializing in plant authentication, botanical ingredient identification and quantitative analytical services to the Food & Beverage, Nutraceutical and Cosmeceutical industries. Located in Costa Mesa, California, Alkemist Labs offers a wide range of specialty research services to evaluate the identity, purity and quality of botanical raw materials, dietary ingredients, and finished products. Alkemist Labs also offers an array of critical tools for botanical identity verification, including their complete line of Composite Reference Botanicals (CRBs), phytochemical reference standards from Extrasynthese of Lyon, France as well as AHP-Verified Botanical Reference Materials (BRMs), easy to purchase through the Alkemist e-commerce section of their website.

biova

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Privately held and globally distributed, Biova LLC is the market leader for water soluble egg membrane (WSEM) ingredients offering proven health benefits. Our advanced R&D has yielded multiple patents, including the Hydro5™ process that creates Ovacore™—the only 100% USA-made, commercially available WSEM product. Ovacore-based ingredients—BiovaFlex® for Joint Health; BiovaDerm® for Skin Care; BiovaPlex® for Pet Health—deliver uniform activity profiles (e.g. > 85% protein) and offer multiple delivery options for expanded product lines and greater market potential.

A recent peer-reviewed, randomized, double-blind, placebo-controlled crossover study showed just 450mg/day of BiovaFlex was associated with improved range of motion and increased physical activity. Plus, subgroup analysis showed reduced back pain (as one might experience from exercise and/or daily activity) after just 5 days. BiovaFlex features ≥ 88% protein standard.

BiovaDerm's natural ratio of collagen, elastin, desmosine, isodesmosine and peptides is clinically shown to reduce the appearance of fine lines and wrinkles.

BiovaPlex for canine, feline and equine applications, is rich in nutritional building blocks and offers high palatability with low inclusion rates.

All Biova ingredients are 100% USA-made, kosher and halal certified, self-affirmed GRAS & manufactured in a certified cGMP facility. A focus on sustainable production, anchored by vertical integration with some of the largest US-domestic egg producing and processing partners, assures Biova an unmatched supply of raw material—the right combination of access and capability to drive opportunity and growth worldwide. We invite you to compare and discover why Biova is The Clear Choice℠.

Neumentix™ PHENOLIC COMPLEX K110-42

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Website:
www.kemin.com
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Kemin develops high quality, science-based ingredients for use in the dietary supplement, and functional food and beverage markets.

The global company offers a diverse line of clinically-tested ingredients to support cognitive function, eye health, sports performance and overall wellness. All ingredients are naturally sourced and held to rigorous quality standards.

Kemin's innovative leadership in the dietary ingredients industry helps to improve human health and nutrition globally.

Neumentix™ is a proprietary Phenolic Complex that is sourced from patent-pending, non-GMO lines of Kemin's purpose-grown spearmint (KI110 & KI42) that has been clinically studied and shown to help support working memory and cognitive performance in adults. It contains high amounts of rosmarinic acid and other important phenolic compounds.

In a 90-day randomized, double-blind, placebo-controlled, clinical trial to assess the effects of Neumentix™ on cognitive performance in men and women with age-associated memory impairment, people who took 900 mg Neumentix™ showed a 15% improvement in overall quality of working memory, a 9% improvement in accuracy in spatial working memory and reported that they got to sleep easier and faster at night compared to subjects who took placebo.

Neumentix™ support for cognitive performance may be related to the mechanisms of action associated with the constituents that are part of the Phenolic Complex. Bioactives in the Phenolic Complex such as rosmarinic acid and salvianolic acids are reported antioxidants and have demonstrated acetylcholinesterase inhibition, neuroprotective and neurotrophic properties.

(References available upon request.)

nutrasource

Website: www.nutrasource.ca
Contact: Jennifer Andrews, Marketing Manager
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Nutrasource is a full service contract research organization and consulting firm specializing in navigating complex regulations on behalf of dietary supplement, food, cosmetic and pharmaceutical companies. With locations across North America, our experienced team partners with sponsors to bring products to market through strategic product development, regulatory and clinical trial consulting and analytical and bioanalytical testing.

PLT HEALTH SOLUTIONS

Website: www.plthealth.com
Contact: Dr. Barbara Davis PhD, RD,
Vice President, Medical & Scientific Affairs
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PLT Health Solutions (Morristown, NJ) is a discoverer, developer, and marketer of high-quality, scientifically-supported ingredient solutions for the natural products, food & beverage and cosmeceuticals markets. Our goal is to bring innovative and impactful solutions that help our consumer products customers develop new concepts, new products and grow successful brands. Today, we deliver solutions across a number of health & wellness platforms that respond to existing and emerging consumer demand. Delivering these solutions includes marketing over 20 proprietary branded ingredients that are considered either market or scientific leaders in their categories – as well as the supply of high quality botanicals, extracts, raw materials and functional materials that support the development of our customers' formulated products.

PLT360 is a business-wide commitment by PLT Health Solutions to developing ingredients that our customers can be both confident and proud to supply to their own customers — knowing that these ingredients are safe, of high quality, efficacious and harvested and manufactured in a sustainable way. Going beyond traditional quality control programs, PLT360 examines every aspect of an ingredient that we supply to deliver a best-in-class solution in a program that tracks Ingredient Integrity, Quality, Sustainability and Efficacy.

The Efficacy pillar of PLT360 places an emphasis on delivering high levels of efficacy and the most positive consumer experience in every ingredient the company offers. For many ingredients, PLT conducts a multi-targeted, on-going program of scientific evaluation to support customer marketing activities and develop differentiation and intellectual property. Scientific dossiers and 3rd party reviews are a part of PLT's Efficacy efforts. An important component of PLT's scientific support of ingredients is our ability to translate research into commercially significant value statements for consumers. A strong program presenting information on efficacy can also help PLT's customers address the concerns of government and regulatory agencies.