

Leaves vs roots and Davids vs Goliath: The high stakes battle for Ashwagandha

Competitors call KSM-66 marketing alarmist and opportunistic, but company CEO cites mission to protect ashwagandha market

By Rick Polito, GNIJ editor in chief

In an industry known for uniting against regulatory restrictions, companies selling ashwagandha branded ingredients are accusing the dominant player in the space of exploiting harsh regulatory matters and attacking his rivals with questionable science.

Key Takeaways

- **Ashwagandha suppliers criticize marketing** from Ixoreal Biomed as relying on unfounded claims to drive alarm about the botanical's safety.
- **Ixoreal Biomed claims** the effort is intended to protect consumers and the ashwagandha market.
- **The Ashwagandha Standards Alliance contends** reports of adverse effects are not related to use of ashwagandha leaf and that ashwagandha root is not an inherently safer option pointing to science and safety data to support this position.

Kartikaya Baldwa, CEO and founder of the company that dominates the branded ashwagandha market with a root-based branded ingredient, however, claims he is saving the botanical from a potential departure of consumers fleeing the market over safety concerns allegedly related to ashwagandha leaf.

Whichever perspective is accepted, the gloves are off.

Ixoreal Biomed, which sells the KSM-66 branded-ingredient ashwagandha, is accused of seizing on a since-stayed ban on ashwagandha leaf in India and alarming toxicity claims in Europe to poach sales from companies with branded ingredients composed of ashwagandha root and leaf. Ixoreal already dominates the

space, boasting a market share estimated to represent a staggering majority of branded ingredient sales. Half of the market is a common estimate, but Baldwa says his ingredient is included in products that account for 93% of US sales in the natural channel.

That share, Baldwa says, is large enough that he doesn't see the other ingredient suppliers as significant competitors, and his only concern is that ashwagandha leaf is a safety threat that could drive down sales for all ashwagandha brands and suppliers. Describing his company as holding a "commanding position," Baldwa explains that "Pursuing a marginal gain in market share by discrediting another part of the plant would serve neither our interests nor the industry. Our position is grounded in traditional knowledge, scientific evidence and consumer safety. Our ambition is far greater: to expand the global Ashwagandha market and strengthen confidence in the entire category."

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— Kartikaya Baldwa, CEO, Ixoreal Biomed

In turn, members of the Ashwagandha Standards Alliance dismiss safety concerns for consumption of the leaf, citing multiple studies over decades showing safety for leaf and leaf-root formulations. They charge that Baldwa's strategy poses risks for the entire ashwagandha market if consumers become wary of all ashwagandha or more governments will take action against the botanical.

"Because of that messaging, the viewpoints of different governments around the world are saying, 'Okay, well, it's got to be bad,'" says Shaheen Majeed, CEO of Sami-Sabinsa, makers of the Shagandha root-based branded ingredient. Alarms had been raised in Europe, but Ixoreal made matters worse, he says, "They added an extra layer of danger and drama."

Whatever one makes of Baldwa's intention, indications are that KSM-66 has done well in the wake of the ban and regulatory actions in Europe. KSM-66 has outpaced the market in the US, United Kingdom and German markets since the AYUSH ban directive was announced in April, according to Jungle Scout, an online sales analysis service (see chart).

Signals

FDA provides another sliver of NDI guidance

"What": The US FDA continues to dribble out New Dietary Ingredient guidance, and now with GRAS up in the air due to recent proposed changes, people are wondering when NDI guidance will create a clearer pathway to knowing when NDI notification is required. The A new incremental guidance sets expectations for the chemical identity, safety evidence, historical use data, and safety conclusions required. Put simply: "how" got closer, but the crucial "when" remains vague

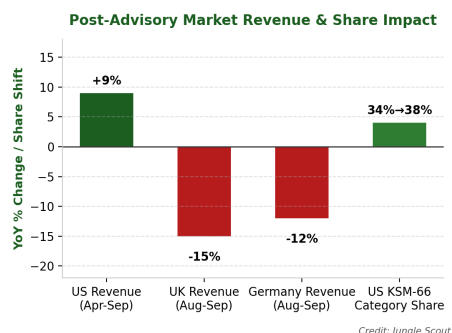
So what? When a supplier or brand pulls the trigger to launch the NDI notification process, the new guidance raises the bar on documentation of safety. This could make applications more vulnerable to FDA rejection.

Now what? Companies should start looking not just at what products they have nearing entry to the NDI maze, but probably also at what they already have on the market as GRAS. Examine altered extraction methods and other processing changes for either class, and take a close look at what's already in the dossiers. More lawyer hours might also be in the offing. It's definitely time for a GRAS (self)-audit. Now, Now What: Brands are going to lean on their suppliers dossiers even more now.

An easier pathway in China

"What": Navigating Chinese regulations has never been easy for nutrition companies, but proposed changes to the China's State Administration for Market Regulation (SAMR) may at least simplify the steps. On Oct 10, SAMR released a draft amendment to the PRC Food Safety Law that could streamline the filing and registration process for a "health food," which includes dietary supplements.

So what? Nobody needs to explain how important China is to not only the Asia-Pacific market, but to the global supplement industry overall. Success in China helps fuel success across multiple markets, and it remains a major target for US brands. Lowering the barriers to entry could provide a way for enterprising brands to add a channel to their strategy, possibly putting them ahead of competitors relying primarily on cross-border ecommerce. Brands already manufacturing in China or seeking to do so may also find innovation simpler.



Concern and consequence

The KSM-66 maker's relationship with other players in the ashwagandha market has long been strained. Natreon sued Ixoreal in 2016, claiming the company made deceptive statements about the quality of Natreon's Sensoril root-and-leaf ashwagandha product (Kerry acquired Natreon in 2022). Ixoreal countersued, and the entirety of litigation was later dismissed in US District Court.

The more recent conflicts heated up after a Technical University of Denmark study published in 2020 called attention to possible liver toxicity, hormone disruption, and other health issues from consumption of ashwagandha. Researchers set out to study ashwagandha root, but cited other studies that looked at leaf and root formulations. Denmark banned ashwagandha products in 2023.

Safety questions have since spread across Europe, with the Netherlands considering a ban on leaf-containing products and Germany and France requiring warning labels. Other European countries have instituted or are considering restrictions.

Regulatory Action Timeline (2023-2026)



The debate has sharply impacted the European market, Jungle Scout data reveals, but the matter went global in April, when the Indian Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha, Sowa-Rigpa, and Homoeopathy (AYUSH) called for a complete ban on ashwagandha leaf production and sale. Kerry, Arjuna Naturals, Sami-Sabinsa, and Omniactive Health joined four other companies in suing AYUSH and the Food Safety and Standards Authority of India, the agency responsible for enforcing such a ban. The Karnataka High Court quickly granted a stay.

Members of the Ashwagandha Standards Alliance contend that KSM-66 marketing materials have aggressively drawn attention to the ban and questions of safety concerning leaf. The critics call the KSM-66 campaign opportunism and unfair. "It's just mind-boggling how they want to bend your mind on something because it's politically motivated and economically motivated," Majeed says.

From lab to legal

Allegations of misleading marketing by KSM-66 are supported by science, ASA member company representatives say. While Sabinsa's Shagandha is a roots-only product, Majeed is adamant that arguing about leaf vs root splits the market in a way that is harmful. He questions the AYUSH ban directive, and how it's being promoted by KSM-66. He uses the way Sabinsa and other companies handled synthetic turmeric as evidence of a better option. "You don't just say, 'Oh, we should just ban all turmeric then.' No, there's a rationale to go after the people that label synthetic turmeric as natural, but you don't ban it, right?"

The safety concerns alleged by Baldwa and a small number of researchers relate to the withaferin A compound found in leaves. Withaferin A is also found in roots, but is more plentiful in leaves, though makers of the root/leaf combos say processing reduces withaferin A concentrations. They also question studies claiming risk, charging that researchers studied doses far higher than users would conceivably consume.

Baldwa takes issue with their contentions, and maintains that leaf must not be included in ashwagandha products.

Now what? If enacted, the changes could be an opportunity to review the mix of SKUs and match the potential for faster market entry and evaluate where specific product margins support the effort versus products or categories where it makes the most sense to remain focused on cross-border e-commerce. Decisions should be made both on sales growth and potential to scale.

EFSA move could speed up "novel food" approval

"What": AI-assisted review could speed up risk analysis for novel foods in the European Market.

The European Food Safety Authority's risk assessment process and standards have long been tedious and extraordinarily slow for botanical extracts, precision-fermentation ingredients and other products classified as novel foods. Any improvement would be welcomed by innovation-focused ingredient providers and brands,

So what? The long waits may have discouraged EU-based brands from innovation and kept international brands from introducing trending ingredients, leaving the EU beyond the US and more open markets in consumer product adoption. Any reduction in approval timelines that typically stretches across years could refresh the market, though claims regulation remains a challenge.

Now what? Executives should examine their product portfolio looking for not only trending products that may now get on European shelves more quickly, but also to consider which of those products could be easily shaped to pass strict claims restriction. None of this means shifting away from more open and promising markets but it does suggest adding Europe to the strategy sooner than in past years.

India's sugar crackdown comes for childhood nutrition

"What": The Food Safety and Standards Authority of India (FSSAI) proposed regulations to bar the use of sucrose and fructose in specialized early-life nutrition and pediatric wellness.

So what? India is a major and rapidly growing market on its own, but the move reflects a broader Asia-Pacific regulatory crusade against hidden sugars in functional food and beverage. Regulators are addressing sugar in functional gummies, powders, and pediatric formulations in one of the fastest-growing supplement regions. How that plays out across regional markets will likely be influenced by what happens in the important India market.

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— Thomas Brendler, Plantaphile

Noted ethnobotanist Thomas Brendler calls such pronouncements unfounded. Brendler, who has spent 30 years studying herbs and botanicals, reviewed numerous studies to come to the conclusion that the leaf is safe. "We basically looked at all the clinical trials that have been published and looked for safety-related endpoints and adverse event reporting. And regardless of what you were looking at—root, leaf, root *and* leaf—the outcomes are pretty much identical."

Others claim that cases of toxicity are rare and may be related to existing conditions or other case-by-case factors. Brendler does not address that theory directly and instead focuses on a compendium of data that he says should give consumers and the supplement industry complete confidence in ashwagandha. "I am not saying that there are no adverse events. I'm also not saying that there has not been documented liver toxicity. What I'm saying is that the evidence that is being presented in what is in the public domain does not allow for a causality assessment."

Again, Baldwa questions such findings, alleging that there are no studies looking at toxicity in the leaf alone, though Brendler says there are. Ashwagandha Standards Alliance member companies do not sell pure leaf products, producing root or root/leaf combinations instead. Baldwa counters with claims that sellers in the commodity market are selling leaf-only powders due to the material being cheaper, and that it thus remains an issue in the market no matter what other branded ingredient makers are selling.

Leaf, he says, has no place on the market.

"Harvesting the leaves takes seconds; extracting the deeply embedded roots requires considerable effort, yet Ayurvedic physicians placed particular importance on the root. That distinction deserves serious consideration," Baldwa says.

A campaign gets questioned

Though the KSM-66 allegations can be direct, Baldwa denies aggressive business tactics in his interview with GNIJ, the first interview he has granted on the dispute with the Ashwagandha Standards Alliance members. "I hold no animosity towards any company in this industry. Different approaches are inevitable, and I respect those contributing to its progress. We have no reason to question others to establish our own credibility. Ultimately, product quality and consistency determine lasting trust," he says. Baldwa consistently returns to the argument that the KSM-66 marketing is intended to call out the leaf safety issue and not to build market share.

Some of those other executives, however, bristle at the KSM-66 marketing campaign, describing Ixoreal as staging a direct attack on their quality and credibility and dismissing strong scientific evidence of safety for root-leaf formulations. The KSM-66 website makes Ixoreal's position plain in a "Be Wary of Ashwagandha Leaves" headline. The same page states that "Leaves Contain Potentially Harmful Compounds" and accuses makers of leaf/root extracts of economic exploitation: "Increased usage of leaf material also decreases the profits of the hard-working farmers and deprives ashwagandha fields of the much-needed compost for the next growing season."

While the ASA member companies are not named in the KSM-66 marketing and Baldwa includes commodity ashwagandha powders in his criticism, Arjuna Natural Vice President of Operations Chase Johnston and others have taken issue with the marketing strategy. Johnston calls the messaging "propaganda" that causes "turmoil in the market."

Majeed calls Ixoreal marketing less mission and more about selling product. He questions the company showcasing regulatory restriction as a selling point: "They use the AYUSH ban at their show. They have a paper printout in a glass, like a show-off piece saying, 'Oh, look, here's the ban.'"

Now what? The message to brands and suppliers is simple: cut the sugar. The process to accomplish that, of course, may not be simple at all. Natural sweeteners exist, but parents might bristle at anything that suggests an added layer of processing. Producers need to look at the most "natural" sounding sweeteners and keep an eye on emerging sweetener technology. In the meantime, monitor both the timing of regulatory changes and what strategies competitors are examining. Transparency will win, of course.

European & APAC looking hard at sleep and energy ingredients

"What": Conversations at Vitafoods Asia suggest formulators in the EU and APAC markets are increasingly interested in non-habit-forming actives for sleep and putting a greater focus on the search for non-stimulant energy boosters.

So what? High-dose melatonin has already drawn regulatory restrictions and additional scrutiny in Europe and consumers worldwide are increasingly skeptical of caffeine-heavy energy formulations. Both circumstances could open the door to product development based on herbs and botanicals not as closely associated with sleep and energy.

Now what? Product development and innovation in both condition categories deserve a greater focus. Both energy and sleep are condition markets where new ingredients can easily catapult to trend status, and getting there faster can be an advantage, particularly if the ingredient can be delivered in a branded extract/format. That doesn't mean brands and ingredient suppliers should step away from the standards, but a strategy encompassing more options is an obvious need.

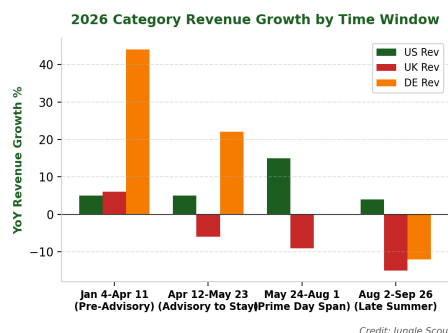
"There's a whole cautionary tale about, 'Hey industry, we let this happen on our watch. We allowed somebody to spread a huge amount of money to get everybody's heads nodding to the same tune, and we didn't check the music.'"

— Kenn Israel, Beyond Brands

Kenn Israel, nutrition practice leader at Beyond Brands and an industry veteran, has no ownership stake in the ashwagandha market, but says he is incensed by the KSM-66 campaign. He accuses trade media of offering an overly friendly platform for Ixoreal's claims. "There's a whole cautionary tale about, 'Hey industry, we let this happen on our watch. We allowed somebody to spread a huge amount of money to get everybody's heads nodding to the same tune, and we didn't check the music.'"

Again, Baldwa claims to have no business agenda against his branded ingredient competitors and explains the KSM-66 marketing as a campaign to save ashwagandha from safety questions before they can spread across markets beyond India and Europe. He points to careless production of kava as having destroyed a promising market, and calls the KSM-66 campaign an effort to prevent a similar fate for ashwagandha, charging that kava leaves were used when roots were the safer option. "Kava offers a sobering lesson in how safety concerns can undermine confidence in an entire botanical category. The consequences extend well beyond individual businesses. Innovation must be matched by responsibility and consumer safety."

Israel is unconvinced that the KSM-66 mission is so well-meaning, calling trumpeting regulatory scrutiny as a marketing tool an example of bad intentions. "It was seen as an opportunity, and then it became this leaves-vs-roots thing. It was sort of opportunism that went wrong here."



Ayurvedic axioms

Science exists at the center of the leaves-vs-roots debate, but traditional use emerged as a significant factor in the AYUSH decision. The argument against leaves may be potent among ayurvedic practitioners. Whether that matters to a shopper at a Brooklyn Whole Foods is far from clear.

It matters a lot to Baldwa. "We are not more wise than these doctors," he says, referring to ancient practitioners who developed ayurvedic medicine. Many competing suppliers, however, primarily market their products as more science-forward than ayurveda-forward. Any modern extract, including KSM-66, it could be argued, is a departure from tradition.

Even limiting the discussion of ashwagandha to ayurveda may be misleading. Ashwagandha has also been used in traditional medicine in the Middle East, the Mediterranean and Africa.

Still, KSM-66 marketing calls out competitors for stepping outside tradition. Marketing language like "Companies using leaves are experimenting on consumers with plant parts that traditional medicine intentionally excluded for 4,000 years" could be considered overstated, if not misleading. Evidence exists that leaf-based preparations have been used in ayurvedic medicine for acute conditions.

Science and strategy

Baldwa's argument on science is based largely on the high concentration of withaferin A in the leaf material. However, production for ingredients like Kerry's Sensoril and Arjuna Natural's Shoden includes processes that remove excess withaferin. The brands openly share fit-for-purpose testing methodology documenting how the marker is quantified,

Abbott spins off nutrition brands

"What": Abbott announced on October 21 that it intends to spin off its global Nutrition business into an independent, publicly traded company by the end of 2027. The new company will have approximately \$8.5 billion in annual sales, 16,000 employees and 14 manufacturing sites, and Similac, PediaSure, Pedialyte, Glucerna and Ensure. The move follows a broader restructuring trend among large healthcare companies, which have separated or divested consumer-health and nutrition assets to sharpen their strategic focus. The timing is significant. Abbott's Nutrition business has faced manufacturing and supply challenges, litigation related to infant formula, and recent sales pressure. Reuters reported on October 21 that Abbott also lowered its 2026 sales-growth outlook.

So what? As a standalone public company, Abbott Nutrition will need to demonstrate its own investment case, growth strategy and ability to allocate capital effectively. The challenge is to sustain the benefits of scale while operating independently. The brands are powerful assets, spanning infant, pediatric, medical and adult nutrition, but brand recognition alone will not resolve questions about market share, manufacturing resilience, litigation exposure or the pace of innovation. The new company will need to show investors where incremental growth will come from: emerging markets, high-protein products, healthy aging, metabolic health, medical nutrition, hydration or new product formats. Abbott's decision aligns with a broader pattern in which diversified healthcare companies separate businesses with different growth profiles, capital requirements and innovation cycles. The move raises a larger question: are established nutrition brands and ingredient businesses better positioned to grow inside diversified healthcare groups, or as specialized companies with dedicated leadership and investment priorities?

Now what? Competitors will assess where the new company may increase investment or change its approach: watch adult nutrition, pediatric nutrition, hydration, metabolic-health products and emerging markets. Ingredient suppliers should revisit commercial plans for Abbott's nutrition portfolio, determining which ingredient platforms support the new company's existing brands and where it may focus plans for growth. Investors need to examine separation terms, standalone financial disclosures, capital structure, management priorities and post-separation growth targets. The critical question is whether the new company can



Brendler's safety pronouncements have been echoed by the American Herbal Products Association Chief Science Officer Holly Johnson, who declared that adequately tested leaf-root combinations are "absolutely" safe, during a recent episode of Naturally Informed, saying "There is a fundamental difference between crude, uncharacterized leaf powder and a scientifically processed, highly standardized extract where specific constituents are monitored and controlled for safety."

Like Johnson and Brendler, Trish Flaster is another ethnobotanist who points to safety data for leaf-root combinations, but Flaster also calls for transparency by suppliers or finished product brands that are selling ashwagandha leaf as root or not being clear about what plant part is used. It's a matter of transparency, she says, not safety. "A lot of people have been using leaf, but they haven't been labeling it. So, in reality, their product is an adulteration. However, if they would just say 'root and leaf', it's not a problem."

Putting it to the test

Though it does not appear in ASA marketing, industry insiders have privately and not so privately questioned how legitimate KSM-66 ingredient authenticity and concentration might be. Majeed questions the 5% withanolides claim, saying "Achieving 5% withanolides is neither easy nor inexpensive, so suppliers should be transparent and honest about how they reach that concentration at such a low cost."

Part of the problem, Majeed and others say, is that KSM-66 is delivered with insufficient transparency on testing.

Ixoreal has not released their methodology and limits testing to a select set of laboratories. Baldwa points to inspection by USP, FDA and other agencies and organizations as proof of quality. "We have 47 certifications. Show me a single company in this industry that has got 47 third-party quality certifications."

Releasing the testing methodology, however, is not in Baldwa's plans. The CEO calls the testing method a trade secret to protect brand equity. "KSM-66 embodies years of research, investment and proprietary expertise. Protecting that intellectual property is both our right and our responsibility. Scientific transparency should never be confused with surrendering confidential knowhow. We welcome legitimate scientific scrutiny, but speculation is not evidence. Our

confidence rests on the quality, consistency and scientific foundation of our work, not on responding to every allegation," he contends.

"You can send our ingredients, any of our 120 ingredients that we supply, to any lab in the world."

— Shaheen Majeed, Sabinsa

Competing brands say that Baldwa's position raises questions.

Majeed calls limiting the number of labs and employing a proprietary methodology a red flag. "You can send our ingredients, any of our 120 ingredients that we supply, to any lab in the world," Majeed says. "That's not the case with KSM."

Johnston is equally adamant about the use of a proprietary testing method by any brand. "You could make up any product; standardize it; say anything you wanted; and it could actually have nothing in it; and you could still show whatever percentage you wanted."

In contrast, Arjuna is very open about their methodology, Johnston says, calling it transparent and available for evaluation. "It's open. If you want to use it and you want to set it up in your lab, we'll help you set it up, no problem."

Science and regulatory consultant Blake Ebersole, who is both a founding member of the ASA and a spokesperson for the group, calls the lack of transparency a huge issue, especially for a company claiming safety concerns. Ebersole contends that if there is a safety issue, it is consistency and quality. If the connection to ashwagandha supplement consumption in the Denmark study is valid, he says, the cause would be more likely a question of substandard products than the use of leaves.

"We don't want to scare the market. We want to calm the market. We want to be honest with people and not bring up unnecessary scares that could take a \$1.5 billion industry back down to \$200 million in two years."

— Blake Ebersole, Ashwagandha Standards Alliance

Knowing what is in a product and how it is tested will be how ashwagandha will be declared safe, Ebersole says. The leaf vs root debate is a

generate a stronger growth and profitability profile than it could within Abbott. The new company's performance could influence additional separation, acquisition or consolidation involving established nutrition and consumer-health businesses. A standalone Abbott Nutrition could also become a major strategic buyer, a partnership platform or a future acquisition target.



distraction from the real work at hand in the wake of Europe's restrictions and AYUSH's ban directive, he insists.

"We want to correct the market and protect the market. We don't want to scare the market. We want to calm the market. We want to be honest with people and not bring up unnecessary scares that could take a \$1.5 billion industry back down to \$200 million in two years. That hurts farmers, suppliers, supply chain, consumers, brands. You're hurting everybody."

Majeed and Johnston point to consistent quality for Sabinsa and Arjuna Natural, and both claim transparency on their testing methodology. Earlier this month, Alkemist Labs announced Kerry's Sensoril had achieved an Alkemist Assured seal, something Sabinsa achieved in May. Alkemist CEO Elan Sudberg used a LinkedIn post to call on other ashwagandha suppliers to match Kerry's commitment: "My challenge to every other ashwagandha brand: follow suit. Let's make verified quality and transparency the expectation across this industry," Sudberg wrote.

In a company statement, Kerry called quality a better marker of safety than the issues coming up in the leaf vs root debate. "As with all science-backed botanical solutions now widely recognized across the global wellness market, the safety debate should be focused on the science and product quality as opposed to the plant itself," read the statement, which also called out "misinformation about the safety profile of ashwagandha."

Shared concerns

Israel, Ebersole, and the ASA member company executives interviewed for this story share the concern about consumers seeing ashwagandha as unsafe, something Baldwa acknowledges in his arguments. The other companies, however, don't agree on where the totality of the threat comes from.

The KSM-66 marketing, people like Majeed and Johnston contend, is not helpful. Even if the concerns over leaf are valid, consumers may not read past the safety warning headline to learn the difference between roots and leaves. Consumer perception likely lacks such nuance. "I don't think they get to 'leaf dangerous, root safe.' I'm not sure that that [difference] absorbs. In Europe, it's 'ashwagandha is dangerous,'" Israel says.

Trade associations have taken note. Following the AYUSH action, the Natural Products Association arranged a call with Cara Welch, director of the FDA's office of dietary supplements. Baldwa, Majeed, Johnston, and other executives were all on the call. According to Majeed, Welch had no appetite to follow AYUSH's ban directive.

Such a call could be called urgent but not unusual. When safety issues are raised, supplement industry brands and ingredient suppliers typically circle the wagons. When the threat comes from outside the industry, competitors unite.

In the amplified leaves vs roots debate, the wagons are still circled. The difference is that one wagon has found a place on the outside of that circle.

Baldwa seems comfortable with where he parked his wagon. He is proud of his position.

"We have never needed to diminish others to establish our own standing. Scientific differences don't merit personal attacks. Our commitment remains to research, quality and responsible innovation. We aspire to make Ashwagandha one of the world's most trusted botanical ingredients. Leadership, to me, means raising industry standards, not lowering the conversation."