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ROAD TO 30 YEARS OF INNOVATION
SABINSA

Special Report

Sabinsa: Rooted in Tradition, Guiding the Future

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When Muhammed Majeed, Ph.D., launched Sabinsa in 1988, he had no idea that his new company would help write the latest, and possibly most exciting, chapter in Ayurveda's millennia-long story.

Far from it, Majeed just wanted climb down one corporate ladder and build another of his own design, leveraging his doctorate in industrial pharmacy and experience as a scientist at some of the world's leading pharmaceutical firms to supply off-patent generic drugs to the U.S. market.

But if the definition of luck is the collision of preparation with opportunity, Majeed had luck in spades. For at the moment when a growing Western interest in Ayurveda provided the opportunity, his scientific background and familiarity with the Ayurvedic tradition provided the preparation. And when the two collided, the lucky result was not only the Sabinsa known today, but a revolution in how the West perceives Ayurveda, and in how the entire natural products industry operates. Thirty years on, the story is still unfolding.

All in the balance

There's an irony to the fact that Ayurveda, a medical tradition in continual practice for more than 5,000 years, is currently "trending." But trending it is, thanks in no small part to the vogue for all things "natural," a booming wellness industry, and the advocacy of some very high-profile proponents.

Ayurveda's principles rest on the contention that humans, as integral components of nature, thrive when they live in harmony with the natural world. Ayurveda also suggests a balanced diet helps maintain that harmony, as well as the harmony between an individual's mind and body. The practice's Rasayana Chikitsa discipline, in particular, deploys an armamentarium of herbal and mineral preparations—think turmeric, ashwagandha, boswellia, fenugreek—toward fostering this harmony and, thereby, establishing physical, mental and even emotional well-being.

Higher standards

Though these principles were just emerging on Westerners' radars in the waning days of the Reagan administration, they'd gained enough traction to generate some early business for Sabinsa in importing Ayurvedic plant matter from India. (And at just the right time, too, for a major corruption scandal then playing out at FDA took much of the profit out of selling generic drugs.)

Yet as Majeed recalled the company's nascent botanical projects, "None of our customers were asking for standardized Ayurvedic ingredients," he stated. "They just wanted the leaves or the bark, and they wanted it crushed so they could put it in a capsule, make a tablet from it or sell it as tea."

This confounded Majeed, who, as a pharmaceutical scientist, knew that standardization of active ingredients was the only way to produce robust target samples for verifiable assays that researchers could replicate in further study. And the absence of such standardization did Ayurveda's reputation little favor among the Western scientific and medical communities of the day, which either poorly understood the system—or dismissed it outright.

Bringing science to life

That didn't just confound Majeed; it dismayed him. He'd grown up in Kerala—Ayurveda's ancestral home—and many of the plants he was importing grew in his childhood backyard. He knew that this "science of life" (the term *Ayurveda* comes from the Sanskrit *ayu*, meaning "life," and *veda*, meaning "science, knowledge and wisdom") had a demonstrable mechanistic basis. He just didn't yet have the evidence to prove it.

"These plants gave us incredible benefits that are described in the literature," Majeed noted. "But there was still very little research verification for them. And people outside India who looked at Ayurveda didn't believe there was legitimacy to it because they could not specify actual mechanisms of action for its well-established treatments."

So as far as Majeed was concerned, the only path forward was to apply his research skills and Sabinsa's resources—laying idle as FDA worked through its generic drug kerfuffle—to the task of systematically determining what Ayurvedic ingredients could do, and how they did it. "Until we could pioneer ways of extracting, standardizing and understanding these actives," Majeed said, "the whole industry would be working in the dark."

One herb at a time

The company tackled its efforts one herb at a time, discovering far more about each than was previously known, while also confirming long-held applications, explicating mechanisms of action, and identifying benefits not yet noted in foundational Ayurvedic documents.

The inaugural ingredient the company patented and commercialized was a standardized extract of the oleogum resin of *Commiphora mukul*—a relative of the Biblical myrrh—called Gugulipid®. Though Ayurvedic practitioners had been using it for thousands of years to address cholesterol metabolism, only recently had research corroborated its benefits at a molecular level.

Characterization of the resin showed it to be a mixture of diterpenes, sterols, steroids, esters and higher alcohols, the bioavailability of which comes principally from the substance's guggulsterones E and Z. Further, research had determined it effected its benefits by inhibiting cholesterol biosynthesis, enhancing the excretion rate of cholesterol and promoting its rapid degradation, among its other actions. Majeed added, "We learned that it was important that guggul extracts be properly standardized and assayed using HPLC [high-performance liquid chromatography] methods to ensure that side effects such as rashes and gastrointestinal [GI] disturbances associated with crude guggul extracts do not occur."

Armed with this clarity of understanding, Sabinsa not only had a firmer scientific basis upon which to promote its ingredient's efficacy and safety; it also had an opportunity to educate the industry and public about its benefits—an opportunity the company continues to seize for this and other products via white papers, editorial contributions, published research and scientific presentations.

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>
> *— Muhammed Majeed, Ph.D.*
> *Founder and Managing Director*

Revisiting amla's chemistry

Sabinsa's contributions to contemporary Ayurvedic science continued with its research into *Emblica officinalis* fruit, otherwise known as Indian gooseberry, or amla, and the source for Saberry®, the company's proprietary amla extract.

As Majeed explained, "Amla is used in some of the most important Ayurvedic formulas and was widely believed to have an effect because of the vitamin C content, with its antioxidant potency measured by determining the ORAC [oxygen radical absorbance capacity] value." But Sabinsa's scientists refused to accept that conclusion prima facie and, instead, investigated the extract, developing a novel HPLC method for characterizing and analyzing its constituents.

The result of their inquiry upended the science behind amla's activity by identifying a completely different set of biomarkers—namely, beta-glucogallin and mucic acid gallates, not ascorbic acid—as amla's primary actives.

"We published our findings in a peer-reviewed journal for the world to see," Majeed pointed out (*J Agric Food Chem*. 2009;57[1]:220-225). "In correcting the scientific record on amla, we prepared the ground for further study of the active component beta-glucogallin in addressing diabetes, neuropathy and other indications, with the opportunity to develop new products to benefit more people. Without the research, amla would've been seen as nothing more than a source of vitamin C."

Focus on bioavailability

In shining science's light on yet another ingredient with a rich back story, black pepper (*Piper nigrum*), Sabinsa not only captured the inspiration for its BioPerine® product, but advanced the understanding—and appreciation—of bioavailability within the nutrition industry.

"Black pepper has a rich history. Hundreds of years ago, black pepper was a precious commodity that spurred exploration to unknown places seeking new sources of this valuable spice," Majeed shared. "Wars between the major world powers were fought over control of areas in which it grew."

Part of that history is told in key Ayurvedic texts, including the *Handbook of Domestic Medicines and Common Ayurvedic Remedies*, which lists 210 compound formulations containing black pepper, and *Materia Medica of Ayurveda*, which lauds black pepper—along with long pepper and ginger—as among the three essential ingredients in several important prescriptions and formulations.

But what made black pepper more than just a seasoning? Sabinsa dug into the spice's chemistry and found that piperine, the alkaloid responsible for its pungency, is also responsible for its nutritional potency, as it increases the bioavailability of such nutrients as beta-carotene, coenzyme Q10 (CoQ10), curcumin, iron, resveratrol, selenium and others. It does this by increasing blood supply to the GI tract, aiding in the emulsification of the gut's contents, and assisting the active transport of fat-soluble vitamins across membranes.

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Adding value

Bioavailability is an established concept in the pharmaceutical sector, so Majeed, with his pharmaceutical background, anticipated its importance to the nutraceutical industry. And it should come as no surprise that when Sabinsa developed its BioPerine black pepper extract, it would go to the trouble of standardizing it to 95 percent piperine and patenting it.

In fact, Majeed asserted, "BioPerine is the only piperine product to undergo clinical studies substantiating its safety and efficacy for nutritional use. And it's also the only piperine product to secure a patent for its ability to increase the bioavailability of nutritional compounds."

All of which amounts to one more feather among many in Sabinsa's intellectual property (IP) cap. But at the time of BioPerine's patenting, the Spices Board of India, a government regulatory and export promotion agency, wasn't nearly as enthusiastic about the company's accomplishment—at least not initially. The board feared Sabinsa's U.S. patent on the black pepper extract would hamper India's own exports of the spice by limiting which parties could use it.

Upon learning of the board's concerns, Majeed flew from New Jersey to India to allay their fears personally. Explaining that his company's patent covered not the black pepper itself but, rather, the technology that allowed it to increase certain compounds' bioavailability, he impressed upon the board's members that Sabinsa's patent could actually increase the revenue going to India's black pepper farmers above what the spice used as a seasoning alone could ever generate. "This changed the mindset of many," Majeed recalled, "and the idea of value-added spices was appreciated."

The company has gone on to research and pioneer many products that were previously not well-known, but today are mainstays of the marketplace, such as *Garcinia cambogia*, *Coleus forskohlii*, and *Curcuma longa*. In fact, Sabinsa suggests its Curcumin C3 Complex® is very likely the subject of more clinical studies than any other ingredient.

Protecting IP

Sabinsa continues to champion protection of patents and IP in the nutrition industry as a flood of competition from markets lacking serious IP controls threatens not only the reputation and profitability of innovators like Sabinsa, but the safety of nutraceutical products at large.

Several years ago, Sabinsa uncovered a scheme to sell turmeric spiked with synthetic curcumin as product standardized to 95 percent curcuminoids. Tipped off by the unrealistically low prices, the company sent samples to the University of Georgia for carbon dating and learned that many of the suspects were, in fact, spiked by as much as 80 percent. Sabinsa made sure the entire industry learned of the adulteration and even sued the companies it'd caught in the scheme.

It wouldn't be the only time the company would challenge industrial wrongdoing in court. And for a privately held firm like Sabinsa, mounting such a challenge can be a lonely—and costly—endeavor. "Public companies may not think twice about suing," Majeed noted. "But when you're digging into your own pockets to fund such actions, you think long and hard. Yet in cases where the adulteration or infringement is obvious and the organization engaging in it fails to respond to our outreach, what other choice do we have?"

The silver lining is that Sabinsa has won many of its battles, educating customers and the industry in general about the importance of honoring IP and product identity, investing in its value, and rewarding companies that target infringement.

"The trade press has reported upon our successful efforts," Majeed said, "and we've received messages of appreciation from customers and noncustomers for our work in discouraging adulteration and IP theft. Lower prices may be these bad actors' modus operandi, but we intend to stay focused on researching and generating the IP that will eventually protect our company and our customers more broadly."

The firm already boasts nearly 200 global patents that pertain not only to its branded ingredients like BioPerine and Curcumin C3 Complex, but to manufacturing and synthesis processes, preservative systems and unique product uses.

Doing well by doing good

Looking out for IP and product integrity isn't the only way Sabinsa does well by doing good. In 2004, the company hired botanists and soil experts and began contracting with farmers across India to ensure a sustainable, transparent and traceable supply of the raw materials its customers wanted. While the company didn't initiate the project as a social mission, "it quickly became one as we realized what our farmer partners needed to do their job better, and how we could teach them to produce higher-quality raw materials," Majeed declared.

To that end, Sabinsa shared advanced agricultural technologies, funded new irrigation systems and advocated for the use of sustainable farming methods. Perhaps most importantly for the farmers, the company guaranteed them a minimum price for their crops, even when harvests are poor, and committed to paying above that contracted price if the market rate were to rise.

"This helps not only our farmer partners, but Sabinsa, too," Majeed reflected. "Under most circumstances, nature and climate change—and not the farmers—are to blame for any failure to meet output needs. And by making sure that our farmers can support themselves by growing the crops we contract for, we reduce their temptation to grow something else and thus keep them in our supply chain."

The whole system gives Sabinsa oversight of their products from field to functional formulation, and puts in place the conditions for improved quality control (QC), traceability

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to origin, and a caliber of source material best fit to producing standardized extracts that are safe and effective. Sabinsa has invited customers and industry trade press members to its farms to see how it all happens.

“Today, our robust farming network expands over 40,000 acres and involves more than 6,000 farmers all over India,” Majeed boasted. “Our fair-trade practices and support for these communities have been transformational. It’s an amazing experience for both our company and the farmers. As someone who has stood on the land of these farmers, I can promise that when they tell you that their child will be the first in the family to go to university thanks to our efforts, it is truly emotional. So we’re happy to say that we’ve expanded the program outside India into parts of Africa and Southeast Asia as we continue to look toward the future and anticipate the effects of weather patterns and climate change.”

A more recent initiative is a reforestation program, the first of its kind in the herbal industry: proactively addressing future supply shortage of a medicinal tree. Anticipating future demand as research confirms traditional Ayurvedic use for diabetes, Sabinsa learned that the Indian kino tree population is threatened. The company developed and funded a collaborative program to plant 166,600 trees on 250 forest acres over the next ten years, the first conservation program for this high-value threatened tree species in India.

Fulfilling its mission

Do efforts like these make Sabinsa a mission-driven company? Majeed would certainly say so. And the company’s original mission—to be responsible and reliable in the ingredients it supplies and the formulations it creates—“remains the same today as when we started,” he continued. “How it’s changed is in the ways in which we fulfill it, which have expanded to include contract manufacturing, extensive research, providing customers with intermediate steps in production, helping them resolve formulation and manufacturing challenges, identifying and publicizing problematic industry behavior, and advocating best practices as an industry leader.”

Lastly, Majeed emphasized the importance of disseminating what the company has learned via lectures, online content, social media and traditional publications. One major effort in this vein that Sabinsa has undertaken is a science-based lecture program called Sabinsa on Wheels, which the company has hosted in locations throughout the world. Rather than merely delivering marketing presentations, the lectures are more explicitly and intensively educational: steeped in science and attended by nutrition industry scientists, product development and formulations experts, and researchers who appreciated the opportunity to evaluate the latest findings on existing and upcoming ingredients in Sabinsa’s catalogue.

“Sabinsa on Wheels was so successful in the United States that we’ve expanded it to Australia, Europe, Japan and South Korea,” Majeed confirmed.

Room to grow

That's not the only way this company, founded in New Jersey three decades ago, has gone global. As Majeed saw the need to bring Sabinsa's ingredients—and its systematic approach to researching, developing and shepherding them—to foreign markets, the company established offices in Australia, Europe, China, Japan, South Africa and South Korea—"all markets that viewed our ingredients as either food or useful traditional medicines," he stated.

To ensure tight control on its standardization and manufacturing processes, in 1991, Majeed launched Sami Chemicals & Extracts—later renamed Sami Labs—in India's innovation epicenter of Bengaluru. Sami Labs now operates in five manufacturing sites, three dedicated to herbal extraction, one dedicated to fermentation for probiotics and enzymes, and one dedicated to supercritical fluid extraction technology. Sami Labs also hosts the global research and development (R&D) center for the Sami-Sabinsa Group, with nearly 120 scientists at work in India, 800 in the manufacturing sector and another 1,000 in associate companies conducting everything from clinical research to software development.

So to call Sabinsa just an Ayurvedic ingredient supplier vastly understates the case. Yes, Ayurvedic ingredients like turmeric and black pepper—not to mention amla, coleus, garcinia, guggul and many more—can rightfully claim their current spotlights thanks largely to Sabinsa's past and ongoing work. But Sabinsa's work has been equally important to raising the botanical industry's standards for ingredient science, safety and efficacy, and to the well-being of the farmers producing raw materials.

Sabinsa's legacy reaches beyond Ayurveda, yet it can't escape those firmly planted roots. Majeed still finds great satisfaction researching his homeland's healing tradition. "There is so much wisdom in this ancient medical system yet to be explored; the plethora of research opportunities will continue long after our time," he predicted. "What has been in use 5,000 years or more is being accurately described today, but still more evidence is needed, more pathways will be discovered and more exciting science will be yet to come."

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