On the Hunt for Personalized Medicine

Integrative care the final pillar for delivering on the promise of genomics & deep diagnostics

In terms of market share, chiropractic continues to wane as the dominant voice of integrative medicine with largely flat revenues of $18 billion, nearly matched by massage therapy.

Sales of dietary supplements through integrative practitioners saw 9% growth in 2011 to reach $2.5 billion. Specialty formulations, base vitamins and herbs & botanicals remain the strongest product categories, while MDs ($320 million in 2011 supplement sales), massage therapy ($130 million), Ayurveda ($30 million) and osteopathy ($60 million) saw the fastest channel growth. By total sales volume, the big three—chiropractic, TCM and naturopathy—began to separate themselves a bit from a tight cluster around $450 million two years back. Naturopaths now represent 22% of practitioner supplement market sales at $540 million, approximately $70 million more than TCM and $90 million more than chiropractic.

For deeper dives into the current sales landscapes of integrative medicine, see our overviews of the ten major modalities tracked by NBJ [pages 18-21] and the trends informing leading practitioner supplement manufacturers [pages 7-9]. The discussion continues there, while this story takes a hard pivot toward the future and a look at the burgeoning field of personalized medicine.

Personalized medicine is ...

"In the past, it was good for the average to eat less salt, more fiber," says Dr. Jeffrey Bland, the recognized father of functional medicine and recent founder of the Personalized Lifestyle Medicine Institute (PLMI). "If you're trying to treat the average through generalized..."
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Letter from nbj

Craig Venter, the biologist-cum-entrepreneur who first sequenced the human genome in a neck-and-neck race with the U.S. government, had this exchange with comedian Stephen Colbert back in 2007.

Colbert: “What made you think you could do a better job with life and genetics than God?” Venter: “We had computers.”

Earlier in that segment, Venter spoke of genomics as a true harbinger of a preventive paradigm in medicine and of course he was right, but perhaps not entirely. As we stand on the cusp of another new paradigm in medicine—personalization—the secret might actually live in a thicker sauce. While genomics can begin the codework of parsing hardware from software, of parsing disease cues from our biological predisposition and expressive dysfunction throughout life, it’s the three pillars of personalized medicine—genomics, diagnostics, lifestyle—in complement that promise to build a healthy building. You need all of them talking to each other to really get somewhere.

While nutrition has an obvious role to play in the construction of this healthier structure, it’s genomics that continues to drive progress right now. Take the X Prize, a $10 million contest underway to sequence the genomes of 100 centenarians inside of a month. George Church of Harvard Medical School is the latest to enter the fray with his colleagues from Harvard’s Wyss Institute. Church is also co-founder at Knome, a software player for rapidly interpreting genetic information and the manufacturer behind KnoSys, a $125K supercomputer sold into hospitals to run this software.

Then take Life Technologies, the company behind Ion Torrent’s proton system, a scalable benchtop sequencer billed as the great genomic democratizer, capable of sequencing a full human genome for $1K. This puts the many clues of genetics inside the insurance paradigm and inside the toolkits of clinicians. Speaking to Bio-IT World about Ion Torrent’s entry into the X Prize race, CEO Jonathan Rothberg said: “It would have cost $100 million and taken 33 years to meet this challenge when the competition was announced in 2006. Semiconductor technology is transforming sequencing just as it has transformed every other industry it’s touched by driving research to ultimately improve health.”

Buckle your seatbelts, folks. Personalized medicine is fluid and on a fast curve. As genomics get more affordable, expect the metabolic diagnostics and lifestyle therapeutics—including dietary supplements—to follow in line.

Marc Brush
Editor in Chief, NBJ
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Accordingly, the terminology of personalized medicine is fluid and its definition still largely intuitive, but the impetus for all this excitement begins, rather than ends, with genomics. “Genomics in a vacuum has very little value,” says Bland. “Personalized medicine needs to be more about networked thinking over siloed thinking. The Human Genome Project was a truly revolutionary step, but we’re in the early stages of transitioning that knowledge out of the realm of the specialist. ‘The average doctor still wants to know what to do with this, what disease you get out of that genetic data.’”

“I call it lifestyle systems biology,” says Tim Avila, president of Systems Bioscience. “We can call it personalized or lifestyle medicine. We can measure genetic variation and metabolic diagnostics and lifestyle therapeutics—including dietary supplements—to follow in line.

This is the secret sauce of personalized medicine,” says Bland. “No system works in isolation, so only by putting this together as a system—genomics with biomarkers with lifestyle-based therapeutics—does it become truly valuable. You start off with a

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n tidal event like the Genome Project, and that becomes weblike with multiple points of connection. ‘Then you have an industry. Each of the pillars as a commercial entity unto itself is misguided.’

“Draw the circle of a lifestyle medicine world,” says Avila, “then cut it in half. One half is prevention. We can learn early on through genetic variation what to avoid for an individual before the presentation of full-on disease. The other half is illness, learning how to individualize medicines and therapies using the principles of functional medicine. It’s more about optimal diets and lifestyle inputs.”

Again, we have the three pillars working together. Genomics decode our hardware, phenomics assess the software through a dizzying array of more affordable biomarkers and deeper diagnostics, and lifestyle medicine provides a smarter, therapeutic understanding of connection. “Then you have an industry. Each of the pillars as a commercial entity unto itself is misguided.”

The genomics pillar

Take 23andMe. For $299, this consumer-friendly DNA analysis company will send you a spit kit in the mail. Two weeks after you mail it back, let the genotyping commence with test results clustered in two buckets—ancestry and health. Ancestry findings point you toward unknown relatives—on average 100—as well as lineage derivations from mitochondria, Y-chromosome and reference points in your autosomal DNA. The health indicators make things really interesting, with carrier status determinations for 48 mutations (cystic fibrosis, sickle cell anemia, Tay-Sachs), predisposing risk for 119 diseases (diabetes, macular degeneration), about how efficient your body is working as shown by perhaps 75 SNPs that together account for about 20% of ultimate disease risk. Note the “perhaps” and “maybe.”

23andMe uses array technology from Illumina, a market leader in computational biology with an estimated 1,500 sequencers in the field and $1 billion in annual revenues. Roche launched a hostile—and as of yet unsuccessful—$6.7 billion bid for Illumina in January. Other key players here include LifeTechnologies, a $3.8 billion company whose Ion Torrent division recently launched an affordable benchtop sequencer; Knome, with an upper hand in software and interpretation of genetic data; and Navigenomics with analytical services targeting clinicians—the professional’s 23andMe—that caught the eye of LifeTechnologies for a July acquisition.

This is the hotbed of medicine meeting technology—the data backbone of the industry—but it’s doubtful to serve as the final key to health and immortality. “Genomics—even with all its potential—really tells you nothing about the individual performance of a person,” says Dr. Bland. “The most remarkable thing we’ve learned from genomics is this—we have 20,000-25,000 genes in our human library, but hundreds of thousands of proteins. How does that work? It’s not one-to-one any more. The way we transition from genotype to phenotype is a major a-ha discovery still in the making.”

The biomarkers pillar

“Biometric measurement merged with expert opinions is the killer app for the future of medicine, and the prize is $1 billion in health spending by consumers and employees.” That’s Jim Kean, founder and CEO of WellnessFX, a diagnostics provider whose baseline package at $199 delivers twice the biomarkers of a typical physical and web time with doctors and practitioners of your choosing. The bloodwork runs from traditional measures of cholesterol like HDL, LDL and triglycerides to ApoB and LP(a), markers that begin to capture the undiagnosed risk in otherwise healthy lipid panels.

It’s deeper than you’re used to going, and it requires a new vernacular to understand and manage a host of data. It comes as no surprise then that WellnessFX is also a data visualization company, democratizing healthcare through actionable presentation of rich data at price points—they hope—that encourage you to measure and re-measure yourself. Supplement companies should take note: Given sufficient scale, platforms like WellnessFX become desirable fulfillment platforms, as well as de facto population samples for research and development.

“There’s huge focus on the pathogenic potential of gene concentrations and less about how efficient your body is working as a machine,” says Kean. “For nutrition, we see genotyping as a tool that points to generalized propensity for an individual. Since we’re
focused as a company on immediate actionability, we’re more interested right now in quickly and easily breaking down the barriers to better blood chemistry diagnostics. From the areas we picked for our baseline plan, you roll over your blood chemistry every 90 to 120 days to see how biomarkers moved. That’s why nutrition and supplements matter, and that’s why we’re so trend-oriented.

While the company sells 30 biomarkers and 20 minutes of practitioner time for $199 to consumers, it’s also active with corporations willing to offer smarter, preventive benefits to employees. “We finished a pilot program at a tech company really illustrative of the power of predictive medicine,” says Kean. Through onsite blood draws and two-week turnaround of results, WellnessFX is now able to represent that company as a biological entity and tailor messages to employee groups based on tiered results without crossing privacy lines. “Of the 100-plus employees we measured, the most interesting predictive results without crossing privacy lines. “Of the 100-plus employees we measured, the most interesting predictive results were a good genotype. "We’ll let those guys sleep out as we cheer them on from the sidelines.” The world is your oyster for data loggers, but leading companies in the space now include Fitbit—focusing on activity, sleep, diet and weight—and Azumio—sleep, stress and heart rate. Other players of note include Jawbone, RunKeeper and Withings. The big win for a quantified self lies in the ability of these wireless devices and apps to slip into the background for constant, innocuous monitoring fed seamlessly to the cloud and, ultimately, your practitioner.

“Genes have very little to do at any given moment with an individual being,” says Avila. “That’s just potentiality expressed through environment. Each one of us is a systems biology experiment, but we’re going through a toxic world. Give people a chance to manage their toxic burden.” Or as Bland puts it: “The toolkit is as broad as we want to cast the net. It’s every bit of information we take in from the outside world—everything we can see and feel, our exposure to radiation and pollution, the whole environment.” There are upwards of 25,000 health apps available for smart phones, with data now available to people in real time. All of this creates a “motive force” for patients to interact with caregivers and manage their own health in new and unpredictable ways, according to Bland.

The lifestyle pillar geneME is a supplement manufacturer based in Lexington, Kentucky, which offers “DNA customized nutrients” and “genetically customized supplements.” The company asks for a cheek swab, tests for 12 genes, and then builds personalized supplement formulations off a common base. “All of our products require knowledge of only these 12 genes,” says Dany Sfeir, geneME’s chief marketing officer. “We explain every single SNP and color code the information for our customers. We then formulate the right boosts to replenish what their bodies are missing according to the DNA tests.”

This means 511,000 possible combinations of ingredients, according to Sfeir.

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driven by genes such as VDR (for vitamin D receptivity), NQO1 (for optimizing CoQ10 as ubiquinone versus ubiquinol) and MTHFR (for processing folic acid and clearing homocysteine). “We believe in personalization and customization of the product,” says Sfeir. “Our DNA testing is not conducted to explore medical flacks. It’s just enough to produce better product recommendations.”

geneME operates as a direct seller of dietary supplements and skincare products, with no immediate plans to broach retail. “This industry is brand new,” says Sfeir. “We need to educate before we get into the retail space. We also need to address the privacy concerns raised for consumers by genetic testing.” Sfeir believes that these privacy concerns and the challenges of life as a first mover are the biggest roadblocks to success, even more than cost—geneME charges $175 for the one-time DNA assessment, and $129 for an average monthly supply of product. “Cost is a roadblock, but there is so much interest,” says Sfeir. “I would argue that cost is lower on our list of priorities than education, consumer acceptance and managing an ever-changing regulatory environment.”

Far removed from the world of direct-to-consumer, Pamlab—tagline: Natural Personalized Medicine—is working hard on medical foods targeting metabolic disorders and neuroscience. Based in Covington, Louisiana, Pamlab offers products like Metanx for diabetic peripheral neuropathy, Deplin for depression and schizophrenia, NeenovDHA for high-risk pregnancies, and CerefolinNAC for cognitive impairment and memory loss. “All of the science we invest in has a battery of biomarkers where we can predict a greater treatment effect,” says David Kronage, senior vice president of commercialization. “We are very interested in nutragenomics—genomics provides one marker we evaluate in disease states. Some of these genes are fairly common in 20% to 50% of the general population, and they can predict metabolic imbalances. Our depression trial has probably been the most rewarding here. Genetic and blood markers predicted a greater treatment effect for our product, and if patients tested negative for the markers, there was no effect.” Genomics plus biomarkers plus a nutritional therapy—that’s all three pillars working together.

“We are taking our model of successful products with strong clinical merit and a personalized medicine angle driven by biomarkers to begin drug discovery,” says Kronage. “We’re not large enough to market a drug effectively, so we would need to partner there.” The desire to move upstream toward drugs—and not downstream toward supplements—ties directly to greater credibility, greater access through more universal insurance coverage, and protections from the higher barriers to entry around pharmaceuticals.

According to Kronage, the big win for personalized medicine looks something like this: You identify biomarkers in an individual, communicate that information back to a physician, and promote interaction through the distribution arm of a pharmacy that allows for personalized feedback about both the condition and the product. Perhaps this is a more practical, near-term path to success for personalization within the confines of conventional care. “It’s not unforeseeable to get the labs caught up to the science, but there’s a lot of work to be done,” says Kronage. “Maybe we give away the diagnostic to find viable patients for our medical foods under insurance plans? We’re not there yet, but we know the biomarkers to look for and we can help the labs commercialize that knowledge.”

Where does all of this personalized science leave the supplement industry? Far removed from where the industry stands today, that’s for sure. Forget about shotgunning dumb combination products targeting the average. “Think of the rich array of secondary metabolites in plants that were traditionally neglected and thought to be so much flotsam and jetsam,” says Bland. “We now recognize these phytochemicals as symphony orchestrators that open up opportunities for nutrition products far more complex than what we thought possible in the ‘70s, ‘80s and ‘90s. Resveratrol, curcumin—these are phytochemicals found to have unique effects in modulating gene expression. It’s nothing like vitamins and essential fatty acids.”

And it’s not just supplements rife for disruption. “Right now we form camps and tribes—hard orthodoxies—around diet,” says Avila. “You find a trend and you ride it—raw this, paleo that—until consumers realize that it’s not optimal for them. These broad swaths of trends and fads are less useful inside an individualized systems biology. Most of our variation comes from diet and the foods that are toxic to us specifically—take gluten, or a true allergy to the full spectrum of grain protein molecules. This type of complexity rattles markets. Systems biology really helps us begin to understand what’s toxic information to each person and what’s not.”

Personalization will prove rattling to supplement manufacturers—consider the challenges of inventory management to come as single-nutrient, single-dose formulas are indentified—and regulators alike—consider the antiquation of FDA as the lines between food and drug blur. This is what happens when paradigms shift. Everything starts to rattle.

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Practitioner Channel Still a Motive Force for Supplements

Strong growth throughout for manufacturers & distributors, as medical foods begin to gain traction

It represents less than one tenth of the $30 billion dietary supplement business. Thanks to a slew of recent mergers and acquisitions, it includes only a handful of major players. But when it comes to innovation, quality and broadening the customer base, many believe the practitioner channel is where the action is.

“It may be smaller in terms of revenue, but it is in many ways on the leading edge of this industry,” says Jeremy Appleton, ND, director of professional education for Wisconsin-based Integrative Therapeutics, a manufacturer and distributor of supplements for healthcare professionals. “Large companies are recognizing that this is a space they want to be playing in.”

Growth attracts capital

According to NBj research, the practitioner channel is one of the fastest-growing channels in the industry, outpacing overall supplement sales growth year after year, even in the midst of the economic downturn. In 2006, the channel hovered around $1.7 billion. By 2011, it had grown to $2.5 billion, spiking 9.3% from the previous year while overall supplement sales rose a more modest 7%. In the past decade, the channel has grown at a compound annual rate of 7.9%, and several company executives say they expect sales to climb by double digits in 2012.

Such numbers have prompted several big players to step into the once-niche channel in a wave of consolidation that has, in some cases, also infused it with much needed capital. In 2009, global phyto-pharmaceutical company Schwabe bought Integrative Therapeutics (itself a consolidation of Vitaline Formulas, NF Formulas, Tyler Encapsulations and PhytoPharmica). In the mid-through-late 2000s, Quebec-based Atrium Innovations bought up Pure Encapsulations and Seroyal. In 2009, $11 billion holding company Altele (the owner of network marketer Amway) bought a stake in practitioner channel pioneer Metagenics. And in 2010, Diversified Natural Products (DNP)—armed with financing from Westview Capital Partners—merged with 25-year-old Thorne Research with big plans for growth in mind.

“We were interested in elevating the level of science in the natural product field and we felt the practitioner channel was the best way to go,” says Paul Jacobson, founder of DNP and now CEO of Thorne. “We have invested a ton of money—in science, manufacturing equipment, quality ingredients and staff—and we are confident it will pay off.”

Insiders and observers say the channel is thriving for an array of reasons. Time-crunched health practitioners suffering from sliding incomes are looking for alternative revenue sources. Consumers leery of headlines about tainted or ineffective supplements on the retail shelves are seeking a more reliable source. At a time when chronic conditions like heart disease, Type 2 diabetes, and arthritis impact nearly half of adults and cost roughly $1.5 trillion annually in medical costs, the medical community and the Obama administration have been looking to preventive “lifestyle” medicine—including nutritional supplements—as a potential cost-saver.

“We are in the middle of a very dramatic paradigm shift right now,” says Kyle Bliffert, executive vice president of healthcare professional brands at Atrium, which posted revenue growth of 16% in 2011 with gains in both its retail and practitioner brands. “Ten years from now, I believe our industry will be a serious part of the therapeutic tools that doctors use.”

Frustrated doctors, savvy patients

Complementary and alternative medicine (CAM) practitioners (chiropractors, acupuncturists, massage therapists, etc.) still constitute the vast majority of healthcare professionals selling supplements, with medical doctors responsible for just 13% of...
all 2011 sales in the channel, according to NBJ research.

But as lower reimbursement rates from Medicare, Medicaid, and private insurance drive salaries down, more MDs, doctors of osteopathic medicine (DOs), nurses, and pharmacists are warming to the idea. According to Medscape’s 2012 Physician Compensation Report, doctor salaries continue to decline, with some specialties dropping 12%. Family practice and internal medicine doctors are stuck at the bottom of the pay scale at around $158,000 annually.

“Doctors are really suffering on the reimbursement end and they are looking for other ways to make money,” says Ericka Adler, an Illinois healthcare attorney who is getting more calls from physicians wanting to get into supplement sales and inquiring about how to do it legally. “They are seeing a lot of their recommendations and referrals go out the door so someone else can make money off them. If patients are going to buy these products anyway, why not buy them from a doctor they trust?”

Physicians are also engaging in supplement sales as a way of buying themselves more time with patients, and getting away from an insurance-based-model that—due to poor reimbursement per capita—forces them to rush through patients.

“What enables these doctors to depart from the insurance-based model to a cash-based practice is often the income from supplements,” says Brian Blackburn, CEO of Florida-based manufacturer Xymogen.

Functional and integrative medicine continuing education programs are thriving, with the latest Institute for Functional Medicine symposium drawing more than 900 medical professionals. Meanwhile, manufacturers are giving physicians “clearer, clinically tested choices that may be easier to add to their toolbox,” says pain management specialist Robert Bonakdar, MD, co-director of the annual Natural Supplement Conference at the Scripps Center for Integrative Medicine. For those who feel queasy about stocking product in their office (which many do), companies are now offering more innovative options, like secure virtual dispensaries. And pharmacists are increasingly stocking practitioner lines, so doctors can send their patients there. “As more of their colleagues are recommending and selling supplements—and seeing good results in their patients—it creates a comfort zone and they feel like less of an outlier,” Bonakdar says.

Most importantly, patients are asking for it. According to an October 2012 survey by the Council for Responsible Nutrition, 68% of American adults now take supplements. But in the wake of negative press articles about tainted or ineffective products, some are looking to practitioners for more guidance.

“Every one of those articles ends with the same thing: ‘To be sure about the supplements you are taking, talk to your practitioner.’” notes Andy Greenawalt, CEO of practitioner supplement distributor Emerson Ecologics. “I think all the FDA scrutiny and attention will actually have a favorable impact on the brands in this channel as they tend to be of higher quality and have the resources to meet good manufacturing practices.”

**Charting new territory**
With an untapped market of thousands of skeptical physicians in their sights, many companies in the practitioner space have begun to wade into areas like oncology, cardiology, neurology, bariatric medicine, and endocrinology—historically the turf of pharmaceutical companies.

In July, Thorne teamed up with psychiatrist and brain imaging specialist Daniel Amen, MD, to launch a new line of personalized brain health supplements—combined with exercises and games—for managing cognitive health and providing “neurological supportive care.” That same month, Thorne made due on its partnership with Switzerland-based pharmaceutical company Helsinn (a minority shareholder) to launch OncoQoL, a 13-product supplement line aimed at alleviating the side-effects of cancer patients undergoing treatment. And the company plans to announce a “very big deal in the cardio space soon,” Jacobson hints.

For OncoQoL, the company has already loaded its sales force with former pharmaceutical reps to call on oncology centers. But it is being extremely careful with its message, Jacobson says, “We are not remotely coming into the oncologist’s realm saying we have a product that is better than this or that drug for breast cancer. We would not dream of going there,” he says. “These are not drugs, and we don’t intend to supplant drugs.” Jacobson estimates the company’s annual sales growth at 25%.

For 33-year-old practitioner supplement company Metagenics—which is also eyeing physicians as a growth opportunity—medical food represents the new frontier. “It’s the strongest category we have,” says CEO Fred Howard. “It allows us to differentiate ourselves from supplements and pharmaceuticals in the marketplace.”

“We are in the middle of a very dramatic paradigm shift right now.

Ten years from now, I believe our industry will be a serious part of the therapeutic tools that doctors use.”  
—Kyle Bliffert, Atrium Innovations
An outgrowth of the Orphan Drug Act of 1988, a medical food must be given under the supervision of a physician “for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.” It also must be made with General Recognized as Safe (GRAS) ingredients, and efficacy, dosing and safety must be proven in peer-reviewed literature. Companies may decide whether to require a prescription or not.

These more stringent requirements tend to ease the minds of physicians, company leaders say. Metagenics now offers medical foods for type 2 diabetes, metabolic syndrome, inflammatory bowel disease, chronic fatigue syndrome, children’s food sensitivities, high cholesterol and PMS. In 2010, it acquired Catalina Life Sciences, the maker of Bariatric Advantage, a line of supplements and medical food for weight loss surgery patients. Its Ultrameal medical food is among the top-selling products in the channel.

Brian Blackburn worked as a distributor for Metagenics for 17 years, before breaking away—and taking several Metagenics sales people with him—to form a new practitioner supplement company, Xymogen, in 2003. He said his goal then was to create products based on “evidence-based dosing” and to get away from an e-commerce trend that he believed was “undermining the exclusivity of the practitioner channel.” Xymogen was among the first to require practitioners to sign an exclusivity agreement vowing not to re-sell products online or to pharmacies, retailers or internet discounters. It also employs “internet policers,” and is developing a new labeling system which will help it to better track violators.

Today, Blackburn says the company—which focuses primarily on physicians—is the fastest growing in the channel, with revenues of $39 million in 2011 and on track to hit $50 million this year. In September, Inc. Magazine listed Xymogen among the nation’s 5,000 fastest growing companies for the fifth year in a row, and it recently built a new 136,000-square-foot manufacturing facility.

It too is now wading into the medical foods realm, with the July launch—in partnership with Acasti Pharma—of LipiChol, a medical krill oil for managing cholesterol. Blackburn says one version of the product will be available via prescription only, and he anticipates it will be reimbursable via insurance come January. “If you approach physicians in their comfort zone and their model of practice, which is writing a prescription, it makes them feel more comfortable,” he says.

Xymogen intends to roll out four other medical foods—one for depression, one for diabetic neuropathy, one for blood-sugar management, and one for gastrointestinal health—within the year. “It will be a game changer. We will be a whole new category in the playing field and prompt state health officers “discriminate” against care providers. This could level the playing field and prompt state health exchanges and private health insurers to take a closer look at covering integrative practitioners, observers say. The end result for the channel: More patients would walk in the door, where they could be introduced to supplements.

“The people who are looking for different things in their health than an alternative medical professional can provide would have easier and better access to it,” says Standard Process CEO John Nab, who estimates 60% of the company’s customers are chiropractors, with more acupuncturists coming on board thanks to its MediHerb line. “Our alternative medicine practitioners are excited about this.”

When it comes to reimbursement for supplements specifically, Nab and others see little movement in that direction for a while, as lawmakers have bigger healthcare issues to tend to. But many say they are just pleased with language throughout the Act, and in healthcare policy circles, which place greater emphasis on blending good nutrition and good medical advice to prevent disease before it starts.

“There is a growing emphasis on looking at fresh medicine—what are the new and more cost-effective approaches to bring about better health outcomes,” says John Troup, PhD, who took over as chief science officer for Metagenics in October. “Over time I think we are going to see this channel playing a significant role in solving the nation’s healthcare problems. I’ve worked in every channel and this is the most exciting one to be in.”
The leaves are blazing, the days shortening and the temperatures dipping. Autumn is here and that means lots of prep work needs to be done—but not for the holidays, as the world’s retail marketers want you to think. Now is when you should be priming your body for the upcoming season. Autumn is the time for preparing for winter,” says Dr. Tieraona Low Dog, MD, fellow director for the Arizona Center for Integrative Medicine. “If you want to sail through winter without getting sick, you have to begin to address the health of the GI track in the fall.”

The concept of “being healthy with the seasons”—as Low Dog calls it—is the foundation for Seasonal Therapeutics, a new health practitioner seminar series created by Low Dog and her longtime collaborator Dr. Andrew Weil, MD. The program pairs integrative medicine with chronobiology, the study of biological rhythms. “Many people forget that humans, like all plants and animals, are tied to the cycles of the day, month and season,” Low Dog told Natural Practitioner magazine.

Through a partnership with the whole-food supplement company FoodState, Low Dog and Weil began rolling out their Seasonal Therapeutics education to health practitioners earlier this year. The program is coupled with FoodState’s growing practitioner channel brand Innate Response, which makes 70-plus SKUs of whole-food-based supplements that more than 1,000 naturopaths, chiropractors, acupuncturists and other practitioners recommend to their patients.

“‘This company has to work with local farmers and local, organic growers in season for their inventory,’ Low Dog says. ‘If there were ever a company that wants to live in season, it’s Innate Response.’

Breaking the allopathic mold
Innate Response was born in 2004 within the walls of BioSan Laboratories (now called FoodState). Carl Jackson founded BioSan Labs in 1973 to offer the market dietary supplements made from quality, whole food ingredients rather than synthetic inputs. The Derry, New Hampshire-based company quietly made a name for itself through its retail brand MegaFood, before launching a whole-food supplements line within the healthcare practitioner channel.

Although it’s been around for eight years and is benefiting from growing consumer interest in whole food supplementation, Innate Response is a relatively small brand within the $2.5 billion U.S. practitioner supplement channel. “That may not be the case for long, however, thanks to the vision of FoodState’s new CEO, Robert Craven, who took the helm in 2011. “Innate Response is dedicated to the radical concept of wellness,” Craven says. “That’s a tongue-in-cheek way of saying that we think the practitioner space has gotten off point on the wellness concept by becoming too allopathic. Our goal is to build a platform that moves beyond the allopathic approach by addressing the root causes of problems in today’s society.”

Craven is manifesting this “radical concept of wellness” through FoodState’s partnership with Low Dog and Weil and the incorporation of their seasonal wellness approach within Innate Response. The Seasonal Therapeutics program features education and products, but it also includes elements such as meditation and journaling that enable a practitioner’s patients to be more successful in their quest for yearlong wellness. “This program is not just about supplementing the diet—it’s about providing a platform of solutions that are all aligned for the needs of the season,” says James Doherty, general manager of Innate Response.

Along with giving them new solutions to offer their patients every quarter, Seasonal Therapeutics enables practitioners to become more proactive, says Dr. Adam Killpatrick, DC, director of product development at Innate Response. “As a doctor, I understand the need for the reactive process because patients come in and they are sick. By putting in place a proactive approach to wellness and giving their patients a reason to see them on more than an annual or even biannual basis, practitioners will be able to become less reactive.”

Building off chronobiology
Innate Response hosted its first Seasonal Therapeutic education symposium on August 25 in Boston. The one-day event featured Low Dog and her autumn curriculum, which focused on the importance of liver and digestive health in the fall. Inside the symposium ballroom, Low Dog dove deep into the science behind chronobiology and the inter-relationship of the gastrointestinal, immune...
Strategic Information for the Nutrition Industry

and neurological systems. She provided actionable advice for how they could guide their patients to better health during autumn—including through the use of meditation and gratitude journals.

Low Dog didn’t, however, pitch Innate Response. “We didn’t talk much about Innate Response inside the ballroom—we kept that to outside the room, where we had our liver and GI health products and a tasting bar for our whole food powders,” Craven says.

The Seasonal Therapeutics autumn event cost $230 and attracted more than 150 naturopaths, integrative MDs and other health practitioners, who earned CEU credits through the University of Bridgeport for attendance. “This was a test to see what would happen,” Craven says. “The test went well. We surveyed the participants and basically all of them said they would come to the next event.”

Dr. Gary Kracoff, NMD, a registered pharmacist at Johnson Compounding & Wellness Center in Waltham, Massachusetts, is one such participant. “I liked Dr. Low Dog’s approach of working along with nature and the seasons,” says Kracoff, who attended the autumn seminar with several other members of his staff. “I was impressed with the seminar content. It was very educational and there was no ‘For this condition, take this product.’ I liked that. I’m looking forward to the winter seminar next month.”

With a successful autumn symposium under its belt, Innate Response is pushing forward with the Seasonal Therapeutics platform—which it hopes to bring to multiple cities in the future. The winter event will be held in Boston on November 12, and the company is planning for how it will build upon the concept each season. “We are already looking at what we will do next autumn,” Killpartrick says. “Liver and GI health are paramount when it comes to women’s health, especially during the perimenopausal stage of life. That will be a focus next year.”

A complementary system

To support the Seasonal Therapeutics education, FoodState is working with Low Dog and Weil to formulate Innate Response-branded products that are aligned for the needs of each season. Case in point: For the autumn program, Innate Response launched Inflama-GI, which was designed to support an optimal inflammatory response in the digestive system. The supplement contains clinical dosages of ingredients such as turmeric and boswellia, one indication of the company’s new therapeutic approach. “We want to make products that are very straightforward and efficacious,” Killpartrick says. “We have pared down the number of ingredients we use in a product and use clinically relevant dosages of the ingredients we do use so that we know the product will be effective.”

Whenever possible, the Innate Response products include whole food nutrients manufactured by FoodState in its New Hampshire facility. “We believe that even with therapeutic doses of an isolate, if you deliver that in food form, it will be more accessible to the body,” Craven says. These same FoodState nutrients feed the MegaFood line of whole foods supplements, but rather than being competitive, Craven says his company’s two brands together create a complementary system that benefits both retailers and health practitioners. “We believe retail should be about foundational health and wellness—and that is where MegaFood is strong,” Craven explains. Although the MegaFood line does include a few therapeutic products, the vast majority are designed to support optimal wellness. With the Innate Response business, Craven says, FoodState strives to provide therapeutic solutions because “in the hands of a skilled practitioner, the therapeutic products can really work.”

The real value of both brands will be realized when Innate Response’s practitioners connect with MegaFood’s well-trained retailers to provide referrals, education and programming. Craven adds, “That is when sparks will fly and we will be able to truly affect a community’s health and wellness.”

Carlotta Mast
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How to Market Healthy Food—Take out the 'Health' Part

Q&A

with Brian Wansink, PhD Cornell University

Brian Wansink, PhD, is the John Dyson Professor of Marketing at Cornell University and director of the university’s Food & Brand Lab, a research group that examines consumer behavior in relation to packaged food. Dr. Wansink specializes in exploring how consumer psychological traits and product marketing together influence patterns of overconsumption and contribute to obesity.

nbj: How does behavioral science apply to the marketing of healthy foods?

Brian Wansink: One of the first books I wrote was called Marketing Nutrition. It asked: How can you take something that’s seen as sticks and leaves to some people and really turn it into a bigger enterprise and a growing market? If you’re going to take away something unhealthy you can’t just leave a void there—you’ve got to fill it with something healthy. So smarter marketing of nutrition is required because people aren’t going to give up food altogether. If you want to de-market obesity, we have to figure out how to market nutrition.

The basic way to get somebody to eat healthier, if you’re looking at supplements and functional foods, is first to find out who the real champions of that food group are. What is it about the connections consumers have in their heads about that product that make them so fanatical? After you’ve done that, it suggests what you have to focus on if you’re going to try to find other champions.

For an example, we’re doing a project for the largest manufacturer of tofu, and they’re trying to figure out how they can cause a tofu revolution in the United States. It’s not by telling people it’s healthy, because most people think it’s healthy. When we’re finding those new fanatics, it won’t be a woman in her 40s who’s already stuck in the rut of daily cooking, but it’s a woman in her 20s who’s just developing her cooking identity.

So it’s not just expanding the existing market of healthy food eaters, but moving into new markets as well. Tofu is already a key ingredient for most Asian cooking, so you don’t have to convince Asians to eat it. It’s also a key food source for vegetarians and vegans, so you don’t have to convince them either.

nbj: So you’re talking about scaling healthy foods outside of traditional markets.

BW: There’s three ways a functional food brand can grow. It can increase consumption and usage among current customers. Get somebody who eats it once a week to eat it twice a week. The second is to increase market share in the existing consumer base. If you’re at 20% share in, say, chia, you can move to 30%.

And the third thing is to try to expand to non-users. To do that, you might tell people that if you eat chia with some fruit, you’ll be full. But it won’t be to talk about the health benefits, per se. With tofu, you might say, don’t do it because it’s healthy—it do it because it’s a low-cost way to fill yourself up with protein.

There’s a “me-marketing” aspect to a lot of natural food companies. Company heads market in a way that looks good to them, not realizing that most people they want to attract are not fanatics. It doesn’t take a lot of money just to adjust those sensory and benefit expectations at the point of purchase. So these aren’t health expectations, necessarily—it’s that something is filling or tastes great or quenches your thirst or makes you a smart person.

With soymilk, you don’t want to advertise to the core that your product is lactose-free—all soymilk is. What are the unspoken benefits of your product that can reach a mass audience? So with tofu, again, consumers might be able think they’ll be seen as a little more cosmopolitan and sophisticated because it’s somewhat exotic.

They see that there’s a big trade-off—that healthy things might not taste as good, might cost more, and might require a lot of preparation.

nbj: So how do you influence consumer behavior at the product shelf? How do you get them to pick a healthy product over an unhealthy one?

BW: Our research shows that if you have three vegetables in a row, whatever vegetable is first is going to be selected 11% more often than the third vegetable. Even if you put the vegetables out at random, you’re still going to be influencing consumers’ choice. A lot of that is merchandising 101, but it’s often overlooked by retailers and restaurateurs.

The perception of how something tastes is tremendously influenced by your expectation. Emphasizing, say, the mango taste of a product over how much vitamin C it has is probably going to influence someone during a blind taste test. There’s a non-healthy dimension that you need to sell your product on, be it taste or fullness or whatever.

For new cooks, that’s an advantage. When we’re finding those new fanatics, it won’t be a woman in her 40s who’s already stuck in the rut of daily cooking, but it’s a woman in her 20s who’s just developing her cooking identity.

So it’s not just expanding the existing market of healthy food eaters, but moving into new markets as well. Tofu is already a key ingredient for most Asian cooking, so you don’t have to convince Asians to eat it. It’s also a key food source for vegetarians and vegans, so you don’t have to convince them either.
NBJ Practitioner Survey: Integrative Medicine No Longer the Alternative

Insurance coverage still spotty, but practitioners remain bullish on supplement sales—especially MDs

In 2012, NBJ conducted its third annual practitioner survey in partnership with Metagenics, Pure Encapsulations, and Emerson Ecologics. More than 500 practitioners participated in the survey. As a supplement to this survey, we also talked with 160 consumers who visited an alternative healthcare practitioner in the last 12 months.

Practitioner demographics
More than one-quarter (27%) of our survey respondents indicated that chiropractic was their primary practice, while another 18% were nutritionists/dieticians. Also well represented were medical doctors (11%), naturopaths (8%) and acupuncturists (7%).

Ninety-six percent of practitioners were licensed to practice in their primary modality, up from the 92% reported in 2011. Most notable was the nutritionist category, with a full 89% carrying licenses.

About two-thirds of the practitioners surveyed were women and 42% were between the ages of 31 and 50. This year, practitioners surveyed tended to be older and to have been practicing longer than in past surveys. More than one-third of respondents have been in practice more than 20 years. Despite the older demographics in general, new practitioners are definitely entering the fold—21% have been in practice for less than 5 years. And the good news for the supplement business is that the younger practitioners are often more interested in supplementation.

As Gary Powers, CEO of Ortho Molecular Products told NBJ, it appears to be the younger doctors that are becoming more interested in supplementation. "There’s a different mindset," he said. "I think they tend to be healthier—it bodes well for the industry.”

Keeping the calendar full
In general, business is going well for the practitioners surveyed. Half of respondents indicated that patient visits were up in 2011 when compared to 2010. In contrast, only 45% of respondents in 2010 reported patient visits being up over 2009. Unfortunately, it appears that 2012 may be slowing down a bit:

**Nutritionist:** "2011 was busier than 2010 for our entire practice. At this time, 2012 seems to be a bit slower.”

**TCM practitioner:** "2011 was a much better year than 2010. 2012 is down from any year I can remember outside of my first year of practice.”

The average patient coming through the practitioner’s door is likely to be female and a member of Generation X. People in this demographic take more responsibility for their own health and adopt a systems approach to their body—treating the whole, rather than individual maladies. According to Larry Thompson, president of Progressive Laboratories, wellness centers now make up a larger percentage of his company’s customer base. These wellness centers give patients a comprehensive treatment plan with interaction among multiple doctors, rather than single practitioner visits on isolated issues.

When speaking to a group of consumers that had visited an alternative healthcare practitioner in the last year, we asked about the frequency of these visits compared to traditional healthcare practitioners. More than 80% visited medical doctors and dentists on at least a sporadic basis, while massage therapists and physical therapists were visited by more than half of respondents, primarily to meet specific needs. Among less traditional practitioners, patients were most likely to visit a homeopathic doctor, chiropractor, or ayurvedic practitioner on a regular basis.

Insurance coverage scattered
Because of continuous media coverage of healthcare reform and Obamacare, healthcare coverage is top of mind for many players in...
the industry right now. Integrative medicine practitioners—though an important group in the nutrition industry—are often the forgotten sons of the insurance market. Only 48% of the practitioners surveyed indicated that they accept health insurance (down from 53% in 2011), with 28% seeing a decline in coverage. Only 16% reported an increase in coverage.

Patients seeking nutritional advice fared best last year—28% of nutritionists and dieticians reported an increase in coverage. Conversely, the healthcare system continues to be less than kind to chiropractors, with 56% reporting a decline in health insurer acceptance. Many commented that out-of-pocket costs are often rising above office visit costs, while co-pays have increased, visits are limited, and reimbursement percentages for office visit fees are on the decline:

**Supplemental commitment**

Practitioners surveyed for this article were reached via dietary supplement companies and distributors, so it shouldn’t be surprising that a high number of respondents sell supplements in their offices. Just over four-fifths of healthcare providers surveyed sell supplements in their office, while another 35% also offer their patients functional food products for purchase. Exercise and physical therapy equipment and natural & organic personal care products are also popular—20% of respondents carry these items.

Among practitioners that do sell supplements in their office, about two-thirds recommend them to their patients at least 70% of the time. Nearly half indicated that at least 70% of their patients buy supplements in their office. Forty-two percent of these practitioners indicated that they also offer supplements for sale through a website.

Of the consumers surveyed, 14% indicated that their practitioners frequently recommended supplements while 24% did not recall a practitioner ever recommending supplements. About 70% indicated that they had purchased supplements in a practitioner’s office in the past. Beyond supplements, these patients occasionally purchased other products. One-fifth indicated buying beauty products from a practitioner, while 15% purchased workout equipment and 12% bought functional foods.

**Not in my office**

Those practitioners that don’t sell supplements in office had many reasons for not doing so, including encouraging patients to obtain nutrients through high quality food, licensing issues, conflicts of interest, overhead costs, and issues of space and inventory. Other comments:

**Osteopath:** “[W]e have not found the high quality, taste and safety (sans preservatives, colors, sweeteners) we would be proud to recommend, and we need to find a way to vend when no staff is present.”

**MD:** “Uncomfortable with mixing being salesman and an MD.”

Even those practitioners who don’t stock supplements in their offices still recommend them to patients, with 43% recommending supplements to their patients at least 70% of the time. Online commerce is a necessary tool for getting practitioners and patients involved in supplement sales. Forty percent of practitioners not selling through their offices recommend buying supplements through manufacturers’ websites, 33% recommend distributor websites, and 14% rec-
ommend their own website. But practitioners still refer patients to brick-and-mortar stores most often—65% refer their patients to natural food stores and 25% recommend supplement stores as a purchase location.

**Bringing MDs into the fold**

Many of the supplement manufacturers and distributors interviewed for this issue agree that capturing medical doctors will be a major growth driver for their business. According to Tye Smith, founder and CEO of **Natural Partners**, MDs and DOs (which many companies consider as one modality) have become the company’s second-largest practitioner group, after naturopaths. “When an MD or a DO gets this stuff, they purchase more than any other kind of practitioner,” he says.

While medical doctors continue to be underrepresented in terms of selling supplements, those that do are highly committed. Sixty-nine percent of MDs surveyed recommended supplements at least 70% of the time in 2011. Another 41% of MDs selling supplements in-office indicated that at least 70% of those patients to whom they recommend supplements purchase them in their office. The MDs that completed our survey are less likely than practitioners of other modalities to carry supplements in their office—64% stock supplements, versus 82% for all other modalities. Functional foods are the only other product with any substantial offering, at 27%.

When deciding which brands to carry, quality assurance, clinical research, and product formulation were most important to the MDs surveyed—the same three factors that ranked highest for all practitioners. Like other practitioners, MDs are torn between selling supplements at cost as an added service or selling them at an increased margin to cover costs and make a little profit. About one-quarter of practitioners sell products at 1x to 1.1x cost, and just over one-third sell them at 1.8x cost or more.

Despite being one of the most underrepresented practitioner demographics, MDs reaped the most benefits from supplement sales in 2011. For half of MDs, average supplement sales were above $50 and annual supplement sales revenue was above $10,000 for 2011. By contrast, only one-quarter of chiropractors averaged supplement sales above $50 and only 38% indicated 2011 annual supplement revenue above $10,000.

In 2011, two-thirds of all practitioners indicated that their supplements sales increased over 2010 levels, while three-quarters are expecting 2012 sales to finish up when the year closes.

**NBJ bottom line**

It’s not news at this point that practitioners are looking for partners to help provide supplements for their patients. Smart companies keep their customers abreast of the latest studies and make life easier by making their supplementation involvement a win-win partnership. Online engagement and e-commerce are vital tools for helping practitioners get on board with supplement sales.

Enjoy hearing what consumers think about our industry? NBJ’s February 2013 issue will be devoted to the natural products consumer. Help us make the most of the issue—submit your burning questions, comments, and insights to @nbjcarla.
Ayurveda’s comprehensive approach to physical, mental, emotional and spiritual well-being has formed the foundation of the Indian medical system for thousands of years. Now, this lifestyle—whose name literally means “the science of life”—is finally making inroads in the West. But how far down those roads are American consumers prepared to wander?

It’s hard to say, but as of 2007, at least 200,000 U.S. adults had used Ayurvedic medicine in the previous year, according to the National Center for Complementary and Alternative Medicine. That number is miniscule compared with those who had used acupuncture (3.1 million adults) or chiropractic (18 million)—but the numbers have likely mushroomed since then.

“Yoga has been hugely popular, and as the yoga market continues to mature and add depth, people are beginning to discover Ayurveda as a sister science of yoga,” says Kevin Casey, co-founder and chief marketing officer at Albuquerque-based Banyan Botanicals. The yoga revolution has sparked a desire for a more natural healthcare process that addresses the whole person, agrees Gunny Sodhi, operations and marketing director at Ayush Herbs in Redmond, Washington. “We’ve seen that consciousness-raising translate into sales of supplements,” he adds.

Myriad supplement companies have emerged in the retail space in recent years, including up-and-comers such as Veria, Mahima for Life Essentials, Savesta Life-sciences, and Maharishi Ayurveda.

The number of Ayurvedic practitioners is also growing. “No one can say for sure” how many there are, says Dr. Marc Halpern, founder of the California College of Ayurveda, and the author of Healing Your Life: Lessons on the Path of Ayurveda. But the number of practitioners who have graduated from a U.S. school is approaching 2,000, he says, and many more have taken short courses.

Unmasking the mystery
That doesn’t mean Ayurveda is an easy sell. “To really comprehend Ayurveda is a challenge,” says Michele Sondheimer, general manager at Boulder-based Organic India. “Not only do you have to learn about the whole philosophy itself, but it’s also like learning a whole new language.” And, she says, most American consumers don’t want to take the time to do that. “We go to the Yoga Journal conference every year. That’s a pretty primed marketplace and, even there, getting people to take the time to learn about it—unless they’re having an individual consultation or have previous knowledge—they’re really not that interested in having long lectures about it.”

But perhaps that’s not necessary. Halpern says that once consumers understand the basic premise of Ayurveda, the system is fairly intuitive. “Ayurveda is 99% common sense. For instance, who can disagree with the principle that “We all have unique physiology and, as a result, the foods we consume and the lifestyle we lead should also be unique? Ayurveda is a path for understanding what is right for you.”

And when consumers do want to take a deep dive into the system, plenty of companies stand by, ready to demystify it. “There’s a huge spectrum of where people are on their path of greater self-awareness and well being,” says Casey. “If they just want some herbs to take for a specific ailment, then we have that, and Ayurveda totally works on that level. If they’re willing to dig a little deeper, we like to be there and offer that next step.”

Buying in
There’s no question, though, that for most Americans, herbal supplements are the gateway into Ayurveda. “Turmeric is an Indian herb—it’s popularity is growing hugely because it’s being researched for so many applications,” Sondheimer says. “But is that Ayurvedic? I wouldn’t say so. Would it be an entrée into Ayurvedic principles? Maybe.”
Turmeric, in fact, is performing solidly in sales. According to NBJ estimates, turmeric supplements grew 22% in 2011 to reach U.S. sales of $80 million. Other Ayurvedic herbs are doing even better. According to market research firm SPINS, boswellia has exploded in the conventional channel, with a 152.6% increase, and a not-too-shabby 56.6% gain in the natural channel, during the 52 weeks that ended September 1, 2012. And ashwagandha is up 48.8% in naturals and 10.8% in conventional.

These retail gains correspond to equally robust growth in the practitioner channel. According to NBJ, sales of supplements through Ayurvedic practitioners grew 13% to $30 million in 2011, with sales growth of 11% projected for 2012. It’s still early in the game for this market, but it’s picking up steam as word spreads about specific herbs.

“Ashwagandha is slowly but surely becoming more widely known,” Sondheimer says. “It has a lot of applications,” including joint health, a big concern among baby boomers. Surprisingly, it outsells the company’s herbal formulas that have structure/function claims, like flexibility, she says. “We thought they would do better because they’re pretty descriptive in what they’re utilized for. But our top sellers are still the ones called by their Indian names.”

The so-called brahmi herbs (bacopa and gotu kola), as well as tulsi and arjuna are strong sellers at Organic India and Ayush. “For us, it’s our formulations that are more popular,” Casey says, noting that Banyan’s best-selling product is triphala, a traditional combination of three herbs.

But, he says, it’s not so much a matter of single herbs versus blends as how they’re marketed. Banyan’s website allows consumers to shop by category, by dosha (individual constitution) or by health topic. “People still like to shop by health condition,” Casey says. “It’s still the most popular entry point.” Likewise, Sondheimer says that Organic India’s products do best at retail when they’re sold in the structure/function sets rather than in a separate Ayurveda section. “They’re not popular enough to be browsed as commonly as people going to, say, the digestion section or the headache section. I think companies are getting much more mileage on their sales by having their products included in those particular sets.”

The biggest consumers of Ayurvedic products, regardless of how they’re sold, are women. “Women are more receptive. They’re doing more research,” says Sodhi. “I’d say 80% of our customers on the retail side are women.” (Ayush also sells a professional line to health practitioners.) Casey nails the demographic down to “college-educated women who are between 35 and 55.” But Shaheen Majeed, marketing director at Sabinsa Corp., says baby boomers are also showing interest. “With increasing lifestyle diseases, people are looking [for] safe means to regain health and live longer. Many are turning to Ayurveda.”

Majeed also says that much of what’s driving consumer acceptance of Ayurvedic herbs is science. “Increasing evidence from clinical studies has provided much support for Ayurvedic herbs in dietary supplements today.” For example, he says, “Turmeric extract has done very well, largely because of the successful clinical trials using curcumin obtained from turmeric extract for conditions such as Alzheimer’s disease, various cancers, inflammation, blood triglycerides in obese patients, arthritis, etc. The medical community is really taking notice, which is spreading to consumers.” Because consumers do respond so strongly to clinical evidence, he says, “We predict that in the future, guggul gum extract will gain attention, assuming availability of the material can be assured.” Guggul has recently shown promise in clinical trials against cancer proliferation and heart disease.

**Sustaining momentum**

But Majeed brings up an important issue. “It is important for the industry to acknowledge that natural resources are limited, and proper and planned cultivation of these herbs may help to create sustainability of these materials.”

Banyan’s Casey agrees. “We see sustainability as a critical issue. Ninety percent of the herbs used in Ayurveda in India are wild harvested. As Ayurveda continues to increase in popularity around the world, it’s definitely an issue and it’s affecting quite a number of herbs.” Both Sabinsa and Banyan have cultivation programs to assure regular supply of Ayurvedic herbs, and Casey says Banyan has stopped selling herbs that it’s particularly concerned about, such as jatamansi and sandalwood. And guggul (or guggulu, as it’s sometimes called) may be next on that list. “It’s a resin, so it needs to be harvested correctly for the tree to survive,” Casey says. “The trees are being overharvested. It’s threatened in certain areas of India.”

Majeed says purity is another concern with guggul. “The resin contains several compounds, but the active ingredients are the guggulsterones. “When purchasing guggul products, it is vital that the extract be assessed for purity and appropriate standardization.”

It’s not just guggul that requires stringent processing oversight, though. “Sometimes elevated levels of lead are found in Ayurvedic herbal products. This is where commodity-based sourcing of raw material can be problematic,” Majeed says. “Cheaper material is not likely to be grown and handled to minimize lead levels that can come from soil and the environment.”

**Putting it in practice**

If responsible players in the industry can overcome these obstacles with a thoughtful approach, the category could be poised for substantial growth. It might even get a boost from the Affordable Care Act, too—if the profession can get out of its own way. A provision in the act supports the development of the health care work force—to include “licensed complementary and alternative medicine providers.” The only problem is, there currently is no licensure of Ayurvedic practitioners.

Savvy marketing will also help grow the profession, says Ayushi’s Sodhi. “The yoga revolution happened because it was backed by strong marketers,” he says, specifically calling out Bikram Choudhury’s hot yoga system. “He adapted something unique and people were seeing results from it. I think for Ayurveda to do the same thing, there needs to be someone knowledgeable, who has credibility—not to sell, but to educate.” He hints that Ayush will be partnering with “the appropriate medium to make it more mainstream,” but says it’s too early to disclose that partner.

The more that Ayurveda becomes part of Western culture—whether as a result of yoga immersion, marketing or clinical studies—the more opportunity the practice and the products have for expansion. The only limiting factor may be the profession itself.
Integrative Medicine by Modality: Growth across the Board

Chiropractic sees new life for first time in years, while MDs finally join the fold

Integrative medicine continued to expand into new realms over the past year and a half. Its success could be attributed in part to its growing exposure in mainstream health.

NBj analysis shows an increase in service revenue across all ten integrative medicine disciplines tracked. Total growth in the last year was 4%, up from 2% growth in 2010. And, after three years of loss, chiropractic—integrative medicine’s largest revenue generator—is on the rebound and seeing a significant improvement in revenue and membership.

More and more people are looking for an integrated approach to medicine, and these practices are becoming more common in mainstream medicine. Naturopaths are enlisted to take on diabetes, a major chronic ailment unsatisfactorily addressed by allopathic methods. The U.S. Military is using chiropractic and acupuncture as a form of pain relief instead of prescribing addictive drugs to wounded soldiers and veterans.

And another way in which integrative medicine could potentially become mainstream is through the Patient Protection and Affordable Care Act. If left in tact, non-discrimination language in the act would require insurance companies to include complementary alternative medicine in healthcare coverage.

“Instead of being outside the power structure and banging at the gates, there are key places in the areas of research, healthcare delivery, prevention, public health, and the work force where, for the first time, these disciplines and providers are explicitly included.” —John Weeks, Integrator Blog

**CHIROPRACTIC**

**Service revenues:** In 2011, chiropractors brought in $18 billion in service revenue, accounting for 36% of total integrative service revenue. Revenue growth was at 2%, which is a notable rebound from -2% in 2010. There was also a small increase in the number of chiropractors to a total of 80,000. This population had been slowly decreasing since 2007, when membership again stood at 80,000, so 2011 was a turnaround. NBj predicts service revenue and practitioner increases over the next three years.

**Supplement sales:** NBj estimates show that roughly 69% of all chiropractors sell supplements. Supplement revenue stood at $450 million in 2011, a 4% increase from 2010. Chiropractic only accounted for 18% of total integrative medicine supplement revenue, down in share from previous years. NBj predicts that growth will remain low in coming years.

**ACUPUNCTURE**

**Service revenues:** The number of acupuncturists increased 4% to 41,000 in 2011. While acupuncture only accounts for 1% of all practitioners in integrative medicine, they brought in 10% of the total service revenue, at roughly $4.9 billion. From 2010 to 2011, acupuncture added new revenue of $130 million, or 3% annual growth, which is lower than previous years. NBj predicts that growth will remain low in coming years.

**Supplement sales:** Approximately 54% of acupuncturists sold supplements in 2011, a small increase from the 53% in 2010. Total supplement revenue was $170 million last year, an increase of 8%, or $12 million. Acupuncture accounted for 7% of the total supplement revenue in integrative medicine.

“In the news: A recent meta-analysis funded by the National Center for Complementary Medicine shows acupuncture is the highest seller of supplements.” —NBj

“Instead of being outside the power structure and banging at the gates there are key places in the areas of research, healthcare delivery, prevention, public health, and the work force where, for the first time, these disciplines and providers are explicitly included.” —John Weeks, Integrator Blog
and Alternative Medicine (NCCAM) provides evidence that acupuncture may be helpful for chronic pain. The study looked at nearly 18,000 people in 29 randomized, controlled tests and examined the use of acupuncture on chronic headache, shoulder pain, back pain, neck pain and osteoarthritis.

The study found two components influence the effects of acupuncture. The first component is needle location and depth. The other component includes factors such as a patient’s expectations of treatment, the contextual result of an acupuncture procedure, and placebo effects.

“It’s an important study because there’s been a lot of controversy about whether acupuncture is actually beneficial,” Dr. John Killen, deputy director of NCCAM, told NBJ. “This study doesn’t completely answer all those questions but it indicates, with an entirely different methodology, that acupuncture is a useful modality in treating chronic pain and that its effects are very complicated and need to be understood.”

### Traditional Chinese Medicine

**Service revenues:** Traditional Chinese medicine (TCM) has remained a fairly consistent modality. It increased 2% in both service revenue and membership in 2011. TCM has had an annual growth rate of 2% in membership for the last four years. There were roughly 37,000 TCM practitioners in 2011, a growth of 700 members since 2010. Service revenue was $5.5 billion, and accounted for 11% of the total service revenue in integrative medicine. TCM has accounted for 11% of the total since 2006.

**Supplement sales:** Supplement revenue increased by $25 million to $470 million in 2011, a 6% annual growth rate. NBJ estimates that 81% of TCM practitioners sell supplements and contribute 19%—the second highest of all modalities—to total practitioner supplement sales. This share is down from 21% in 2008 and is expected to continue to decrease.

**In the news:** A recent Australian study found traces of DNA from toxic plants and endangered animals in Chinese herbal medicines. The research sampled 15 types of traditional Chinese medicines. By using next-generation DNA sequencers and checking against databases, they determined which plants and animals the DNA came from.

The study identified 68 families of plants, including a poisonous herb that can cause bladder cancer, and several animal species such as goats, water buffalo, domestic cows and the critically endangered Saiga antelope. Over three-quarters of the samples tested for animal DNA contained genetic material from animals not listed on the packaging.

In better news, the first traditional Chinese herbal medicine obtained registration under the EU’s new Traditional Herbal Medicine Product Directorate in March. The product is Di’ao Xin Xue Kang, or Japanese yam root, which is used to treat myocardial ischemia. Several Chinese pharmaceutical companies hope this will open up a pathway for more herbal medicinal products in Europe.

### Homeopathy

**Service revenues:** NBJ estimates that there were 13,000 homeopaths practicing in the United States in 2011. That number is up 6% over 2010—the second-highest growth rate among all modalities. Homeopathy recorded service revenue of $1.1 billion in 2011, accounting for 2% of total integrative medicine revenue. Revenue grew by 7% from 2010, when the total was $1 billion.

**Supplement sales:** Roughly 93% of homeopathic practitioners sell supplements, the second-highest percentage of all modalities. However, homeopathy only represents 6% of total practitioner supplement sales, as it has for the last four years. In 2011, homeopathy recorded $150 million in supplement revenue, with 10% annual growth.

**In the news:** In 2011, consumer sales (both retail and direct) of homeopathic products saw a 9% increase to about $980 million. Nearly half of these sales came through mass market retail, with natural & specialty retail accounting for 32%. According to Peter Gold, communications director for the National Center for Homeopathy, there’s also a sense from manufacturers that there’s been a change in buying patterns, as homeopathy becomes a more consumer-centric product class.

The growth in sales is in part due to the push for expanding consumer knowledge.

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The NCH has expanded to social media platforms such as Twitter and Facebook—where they are averaging 30,000 visitors per week. The NCH also saw a 14% website growth in the last year.

Within the past year homeopathy has also received several accolades, including that of the infamous Dr. Oz, who did a positive piece on the effectiveness of the practice. Luc Montagnier, who in 2008 won the Nobel Prize in medicine, also did research and interviews that confirmed homeopathic practices.

**MISCELLANY**

**Service revenues:** In 2011, miscellaneous integrative service revenue reached $870 million, accounting for roughly 2% of the total revenue in integrative medicine, including health clubs. Service revenue and practitioner population both increased by about 3% from 2010 to 2011. NBJ estimates that there were 26,000 practitioners in this category and numbers are predicted to increase.

**Supplement sales:** This category represents only 3% of all the supplement revenue in integrative medicine. In 2011, supplement revenue was at $66 million, a growth of 16% from the previous year. This was the second highest growth rate among all modalities in 2011.

**In the news:** Just as fitness clubs are clamoring to be seen as health & wellness centers, wellness companies want in on the fitness angle. This blending offers opportunity for a wellness companies to attract health club members while they are working out.

**In 2011, naturopathy brought in $540 million, a 10% increase from $490 million in 2010. Naturopathy has the highest amount of supplement sales in the integrative medicine industry, representing 22% of total practitioner supplement revenue.**

**In the news:** According to Coquina Deger, editor of the newsletter for the Association of Accredited Naturopathic Medical Colleges, there has been an increase in the number of applicants and students accepted to accredited naturopathic programs. New enrollment increased from 265 students in 2002 to 606 students in 2011.

More importantly, there has been a push for adjunctive care of diabetes by naturopathic doctors. According to the Centers for Disease Control, in 2010, 19 million people age 20 years or older were newly diagnosed with diabetes, and a total of 25.8 million people were thought to be affected with diabetes in the United States. With such high numbers of incidence, naturopaths could potentially have a substantial impact on the disease.

Naturopathy treatment for diabetes includes a low carbohydrate diet filled with good proteins. The treatment also calls for antioxidants and nutritional supplements, according to the American Association of Naturopathic Physicians.

**AYURVEDA**

**Service revenues:** Service revenue grew to $200 million from $180 million in 2010, a 9% growth rate. However, Ayurveda service revenues are comparatively low, and contribute less than 1% to the total integrative medicine revenue. Same goes for Ayurvedic professionals—again, less than 1% of total integrative medicine practitioners. But Ayurveda did see 11% growth in practitioners, the highest of all modalities, with 2,000 practitioners in 2011.

**Supplement sales:** Supplement revenue reached $30 million in 2011, and has been increasing by double digits for several years. The growth rate in 2011 was 13%. Almost all Ayurveda specialists sell supplements, at 95%—the largest percentage of any integrative modality. However, there are significantly fewer practitioners than in most modalities.

**In the news:** Ayurvedic supplements are making clear gains at retail, but several issues still hold back widespread adoption of the discipline. While language in the Affordable Care Act promises non-discrimination in insurance coverage for any licensed CAM practice, there’s just one problem for Ayurveda—there is no license yet. “It is the goal of the Ayurvedic profession to seek state licensure,” says Dr. Marc Halpern of the California College of Ayurveda.

But how that will happen is anybody’s guess. The National Ayurvedic Medical Association (NAMA) is developing a national competency exam (as well as standards for education), but within the profession, there are deep rifts about who exactly should be qualified to practice. “There is the traditional Indian Ayurvedic doctor, allopathic physicians and the Western-trained Ayurvedic practitioner,” Halpern says. “Each group has its own perspective and sees through their own eyes with limited vision. All three groups are working with NAMA and participating in the curriculum and examination committee. It will take determination to succeed and the courage to compromise to resolve these areas of difference.”
in the news: Keep your wits sharp DOs—the American Osteopathic Association (AOA) has changed its certification requirements for licensed osteopaths. As of January 1, 2013, doctors of osteopathy seeking re-certification will have to undergo what the AOA calls a Practice Performance Assessment, where the practitioner evaluates his or her practice against national standards to create a plan for continuous improvement.

Continuous certification may sound like a burden for DOs, but the AOA insists that such programs are becoming a standard of care and are essential for preserving and legitimizing the profession.

The AOA may also be concerned about an aging DO demographic. According to NBJ’s 2012 Practitioner Survey, only 10% of DO respondents reported their age as under 40, while over 20% of total integrative medicine providers surveyed were under 40 years old. This difference in demographics may suggest a waning population of new osteopaths and a need to keep aging DOs at the top of their game.

Service revenues: Combined, there are an estimated 3.5 million nurse practitioners and medical doctors, of which 2.7 million are NPs and 760,000 are MDs. In 2011, NP integrative medicine service revenue grew by 4%, while MDs brought in $165 million in new revenue. NBJ predicts that both nurses and MDs will see a steady increase in integrative medicine service revenue over the next few years.

Supplement sales: MDs and nurses have few practitioners selling supplements. Roughly 4% of MDs and only 2% of nurses sell supplements. Supplement revenue is also low for nurses, who earned $70 million while MDs earned $320 million. Of all the fields in integrative medicine, MDs had the highest growth rate in supplement sales in 2011 at 17%. Growth rate in revenue for nurses was 12%.

In the news: MDs have traditionally been viewed as the final frontier for the practitioner supplement market, but according to company heads, that frontier is now within striking distance:

Larry Thompson, Progressive Labs: "Historically, our best customers tend to be the NDs, DOs, and DCs, but we’re going to start putting a significant emphasis in looking at the MD side of the house."

Tye Smith, Natural Partners: "[MDs and DOs] is now our second-largest category of clients. That never used to be the case. They have always been, on a per capita basis, the largest purchasers. When an MD or DO gets this stuff, they purchase more than any other kind of practitioner."

Kyle Bliffert, Atrium Innovations: "We have seen over the last few years and we continue to see more new MDs entering the space and being more open to using certain supplements. They’re very good clients because once they embrace the idea, they typically will do so in a more universal situation. For instance, if they believe that vitamin D will be helpful for their patient population, they’re going to want to sell vitamin D to the majority of their patients. A naturopath will stock a greater variety of supplements, but won’t sell at the same volume."

MASSAGE THERAPY

Service revenues: In 2011, massage therapy earned $16 billion in service revenue with growth of 5%, an increase of $790 million. With the second-highest revenue of all the modalities, massage therapy represents 32% of total integrative medicine service revenue. There were 363,000 massage therapists in 2011, an increase of 7% of the 2010 population. The membership growth rate has been declining since 2009, and NBJ predicts that it will continue to slow in coming years.

Supplement sales: NBJ estimates that 10% of all massage therapists sell supplements. Those earned $130 million in supplement revenue in 2011. The annual growth rate was 14%, increasing revenue by $20 million. Massage therapy accounted for 5% of all supplement revenue in integrative medicine.

In the news: According to the U.S. Department of Labor in 2010, employment for massage therapists is expected to increase 19% from 2008 to 2018, faster than the average for all occupations. This statistic is especially interesting considering the current U.S. economic situation, where business closures and layoffs force thousands into vocational colleges and secondary careers.

According to the American Massage Therapy Association, today’s massage therapists are most likely to enter the profession as a second career.

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Inside the Mind of a former FDA-er

Q&A with Jason Sapsin, Polsinelli Shughart

Jason Sapsin, JD, MPH, is an attorney at Polsinelli Shughart, where he leads the firm’s FDA practice. Sapsin was formerly associate chief counsel in FDA’s Office of Chief Counsel, where he advised the agency in pursuing seizures, injunctions and product recalls against drugs, supplements and adulterated foods. Sapsin’s thoughts and comments do not reflect FDA’s position either during or after his tenure at the agency and are entirely his own.

nbj: How do you characterize this longstanding tension between FDA and the supplement industry?

Jason Sapsin: The dietary supplement is supposed to be one component of a balanced and healthy lifestyle. In my mind, the greatest tension that you see between industry and the agency is a result of marketing practices and approaches to dietary supplements that have drifted from what those products are at their core. At their core, supplements are traditional, well-studied and can reasonably be expected to provide health benefits over the long term. When you get away from that—and the pressures of the marketplace seem to almost force companies toward aggressive descriptions of the immediate virtues of their supplements—you run into the potential for more conflict with the agency.

nbj: How could industry better engage FDA?

JS: I think industry tends to look at the agency primarily as a market regulator. I think the agency internally views its market regulation as ancillary to its primary function as the protector of public health.

nbj: How do you characterize this longstanding tension between FDA and the supplement industry?

JS: It wasn’t FDA that carved out supplements as a separate regulatory category. Congress created a new regulatory category in an effort to temper FDA regulation and respond to market pressures. Some of this pressure was for good and laudable reasons—to help people be healthier—but there were also other pressures coming from business interests perceiving economic advantages in a less restrictive regulatory environment. It took off from there. Those two motivations have been present all along. There are folks who view supplements primarily as a way to advance health and welfare, and another group of folks—I think—who view them primarily as a commercial opportunity. And they compete. They compete for space in the market. I think that the opportunity to make pharmaceutical-type profits without making pharmaceutical-type investment is simply too appealing for some people to pass up. That does not imply that everyone in the industry feels that way.

nbj: Industry sometimes bemoans the recent ramp up in enforcement as blindsiding. Do you agree?

JS: I think it’s a little disingenuous to claim that FDA hasn’t bothered industry for years and now all of a sudden FDA is changing the rules. This is a classic argument. Business interests which, frankly, have been thwarting and resisting enforcement, now turn around and claim they’ve been caught by surprise. The agency has probably been interested in playing by a relatively rigorous set of rules for a very long time—they just haven’t necessarily been allowed to do it. When political factors, public health and safety factors, and economic factors combine in the right way, the agency finds itself in the position to finally enforce the law more effectively. I think some of the complaints we hear now from industry are in reaction to that.

nbj: What’s your take on last year’s NDI guidance?

JS: It’s not clear to me that the guidance says anything all that different from what was originally contemplated. It’s just bringing it to the forefront again. I see the NDI guidance as, in part, an attempt to say—Look folks. Here’s what dietary supplements are supposed to be about. Let’s refresh our understanding of the fundamental premises on which this entire structure for the regulation of supplements was built.

Source: Nutrition Business Journal estimates ($mil., consumer sales)

U.S. SUPPLEMENT SALES AND GROWTH, 1997-2012E
“Dietary supplements, in terms of large-scale experimentation, strike me as a little bit comparable with the chemical revolution in food. Supplements have such tremendous potential to bring people better health and improve their lives, just as those first efforts did.”

—Jason Sapsin, Polsinelli Shughart

We don't really require proof of safety for supplements in the United States. The idea is to use grandfathering and NDIAs as proxies for a formal, scientific determination of safety. The idea is to give the industry a way of providing the public, and the regulators charged with their protection, a reasonable basis upon which they can conclude that the product is safe without having to undergo formal trials. I would disagree with the allegation that industry is suddenly being exposed to an undue burden of demonstrating safety. I think it's fairer to say that the requirement is simply to show that substances put into some products are sufficiently well known that we can take it for granted that they are safe. That's a very different animal.

**nbj:** Given supplements' record of largely safe use, is safety a real concern for FDA?

**JS:** There are a couple of issues related to safety. Outside the basic question of whether a supplement is being properly and safely produced, a big concern is that consumers can be put off their guard under the belief they might treat a serious health condition, themselves, with supplements. I'm sympathetic to the benefits of diet, exercise—fundamental, healthy things that we're not so good at doing in this country. Any of those are probably more important over your entire life than whether you have access to the greatest, most novel pharmaceutical statins available. But there will be people with conditions, borderline or serious, who need that pharmaceutical statin. Those people need a product that has been subjected to a vigorous evaluation so they know it will work. They also need competent medical advice. That's at the heart of the agency's concern about claims for supplements—people either not seeking treatment, or believing there is a cheaper, equally effective alternative to a medication and medical advice. That may be the case, but the public health professional's point of view is this—Let's find out. Let's at least have the manufacturer demonstrate that. If a manufacturer wants to make that demonstration—compile the evidence to show that their product will safely and effectively treat a potentially serious medical condition—then frankly they're probably going to need to market a drug. My concern is that some in the industry seem willing to go with a lower quantum of proof than the agency would accept. There are good arguments on both sides of that debate. There really are, but FDA's mission first and foremost is to protect the public's health.

**nbj:** So why the growth in supplements, despite this poor reputation with regulators?

**JS:** We all want the elixir of life. We all want the alchemist's stone, the thing that's going to make our bodies anything they can be. This especially appeals to people when they approach middle age, when they happen to have the most disposable income. Supplements meet this need, this strong drive to stop time a little bit and improve the quality of the time you have left.

It's hard for us to think in the very long term. We want to see a cause and effect, and we're not good at thinking about cause and effect over years or decades. I push the button, the bell rings. That's the promise of too much of the modern dietary supplement industry.

**nbj:** This sounds like a cyclical struggle between free markets and social safety nets.

**JS:** I wouldn't want to overstate the similarities here, but there is a tie to the early part of the 20th century and the explosion of interest in the modern field of chemistry. They tried stuff, and sometimes it didn't really work out. Dietary supplements, in terms of this large-scale experimentation, strike me as a little bit comparable with the chemical revolution in food. Supplements have such tremendous potential to bring people better health and improve their lives, just like those chemicals did. If you're business-minded, your impulse is to not keep the promise and potential of supplements away from the public. When you believe in what you're doing and you see the global need for better nutrition and the wide-open playing field there, you can focus too much on that upside.

The public health regulator has to focus elsewhere. When you're looking at health and safety, you're not dealing with something you can fix after the fact. It's not like a TV set. It's not a normal consumer product. If the TV breaks, they give you a new one or fix it. You can fix the problem after the product launches. With health and safety, you can never really “fix it” after the product has launched. In a very real sense, you can never go back. Even if you can physically restore someone after a serious illness or injury, there are emanating waves of damage to the person, their family around them, their caregivers, their dependents. The stakes in health and safety regulation are incredibly high. It doesn't get any bigger than that, in my mind.

The point isn't that the supplements industry should not be innovating or trying to deliver greater health benefits to the consumers who want them. The question is how. Over what time frame? To what purpose? Are there reasonable constraints on the means we use to get there?
NBJ is now accepting nominations for their 2012 Business Achievement Awards. Categories include scientific achievement, organic excellence, education, deal of the year, management achievement, and many more! Learn more about NBJ’s 2012 Awards at newhope360.com/nbj

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NBJ Supplement Business Report

The newest iteration of NBJ’s Supplement Business Report will launch October 1st. It includes a comprehensive overview of the supplement industry, SWOT analyses of industry leaders, market trends and insights in the category and so much more. Use the report to analyze the competition, develop strategies and focus business efforts.

For more information, visit http://newhope360.com/research/2012-supplement-business-report