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Nutritional OUTLOOK

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For BETTER or for WORSE?

The dietary supplements industry that exists today is vastly different than the industry that was still emerging two decades ago. During that time, the industry has gone from a fledgling enterprise still seeking legitimacy, regulatory structure, and recognition to a mainstream behemoth with sales \$41 billion strong in the United States alone, per recent *Nutrition Business Journal* estimates.

The industry has changed, but have those changes been for the better or for the worse? With success

comes scrutiny, after all, and even as supplements have grown their reach and become ubiquitous in households today, the industry also faces its share of critics and challenges on many fronts. With this in mind, and as *Nutritional Outlook* celebrates its 20th anniversary, we asked industry leaders and friends the following question: "Why is 2017 a better year for the dietary supplements industry than 1998? As an industry, how are we better or worse off than we were in 1998?"

Judy Blatman
Senior Vice President, Communications
Council for Responsible Nutrition



and places to buy. Dietary supplements are mainstream, and there is

It's hard to argue that our industry was better off 20 years ago than it is today. For one thing, the number of people taking dietary supplements continues to grow. There are more choices in terms of products and brands as well as product delivery

clear evidence that people taking supplements are generally more health-conscious than non-supplement users. There's broad financial interest in the industry, from private-equity investors to small-business owners, and from established CPG companies to high-profile retailers. All signs point to continued growth. As importantly, the industry itself is focused on accountability—to regulators and to consumers—through self-regulatory projects, such as the Supplement OWL, which lead in the long-term to an investment in our industry and better health for our consumers.

George A. Burdock, PhD
Founder
Burdock Group

Looking at industry, 2017 is a better year than 1998, as industry has matured from a plethora of cowboys (with some notable exceptions) to a self-policing industry that has embraced good manufacturing practices (GMPs) and transparency with the Supplement OWL product registry. For FDA, 2017 marks another year that the agency continues to endanger the consumer by demanding such a high threshold for new dietary ingredient (NDI) notification filing acceptance that many producers have simply gone to market, hoping to stay under the FDA radar. While FDA seems focused on claims, a practical system for vetting safe substances seems to have fallen by the wayside; it is almost as if the agency were playing chicken with public health and awaiting a catastrophe, which would force Congress to amend the Dietary Supplement Health and Education Act (DSHEA) to something giving the agency more control.



Lauren Clardy
Founder/CEO
NutriMarketing Group

2017 is a far better year for the nutraceutical industry than 1998. The depth and breadth of nutritional research is undergoing a significant transformation driven by new technologies. The advances in personalized nutrition, nutrigenomics, metabolomics, and more will continue to provide ways for companies to innovate as well as ensure a new foundation for our industry in the future. The continued progression of new and old "target compounds," botanicals, and bioactives continues to be inspiring. Our industry has matured, and we have continually raised the bar and met the challenges placed in front of us in a big way. Looking back, I am extremely proud of the steps we have



made towards GMP compliance, regulatory, and quality standards, in addition to transparency and certification advances. I want to acknowledge the American Herbal Products Association as well as the American Botanical Council for always leading our industry and "shining the light" as we maneuver the complex issues that surround botanicals. The nutra industry is better off today. The mainstream consumer has embraced our industry, and overall our culture is more accepting of the nutritional market. It's finally trendy to be involved in nutrition. What I don't want our industry to forget is an understanding of botanical medicine and functional foods and what it represents—in most cases, a rich history of time-honored use across a wide variety of accepted traditional modalities—Chinese, Greco-Arabic, Ayurveda, etc. Our problems are both short-term and long-term, and the solutions often complex. But we can't afford not to meet them head on. I am proud to be associated with such an innovative and diverse industry but one that does eventually come to work together to accomplish our goals.

Jim Emme
CEO
NOW Foods

Our industry is much better in 2017 than 20 years ago. The science and technology used today to identify ingredients, along with con-



firming the purity of these components, has never been better. An example of this is our use of the DuPont Riboprinter system to easily and accurately identify the exact bacteria in our probiotic formulae. These types of systems have also allowed companies in our industry to provide more ingredient transparency to consumers, which has helped to build trust in the products provided by our industry. Companies in our industry have also never had more options to communicate product and service information to consumers, particularly through the use of social media. New offerings and information can be easily transmitted in a very rapid manner. This results in consumers having more product choices and the ability to understand the differences each choice may offer. The more often we can provide accurate and timely information to consumers, the more we can be of benefit to them in supporting their health and nutritional goals. It's a great era to be a consumer of natural products.

James J. Gormley
Natural Products Industry
Consultant
Author of *Health at Gunpoint:*
The FDA's Silent War against
Health Freedom



We're better off in some ways today. We now have federal GMPs, structure-function claims, supplement health claims, and the USDA Organic label the first two were

only taking baby steps in 1998, and the third was not even around yet. It's also better today because we're not dealing with fake fat olestra and *Codex* conspiracy ravings as we were in 1998. Olestra has since been heaved into the trash bin of food-industry ignominy, and *Codex* guidelines have not led to the end of Western civilization. Plus, in 1998, the industry was in a frenzy of selling, buying, going mass, and going public. This was, too, the same year that goldenseal was being overhyped and over-harvested into endangered status. On the other hand, 1998 was a banner year for DHA and alpha-lipoic acid research—the former of which has morphed into its own monster category today. We were also better off in some ways yesterday. Many of the biggest food and supplement manufacturers were still family owned, and the independent health food store still reigned supreme.

John Helfrick
Director, Human Nutrition
BASF Nutrition & Health

During the past 20 years, our industry has matured and worked toward our mission of responsibly providing science-based dietary supplements to support the health of all ages. As a leading industry supplier, BASF applauds our customers' increased efforts in recent years to make quality and transparency a prerequisite for doing business. In the past two decades, as



consumers have become more interested in managing their own healthcare, they have become better educated about our products. With that opportunity comes responsibility to make sure that what is stated on the label is in the product. We join our industry colleagues in continuing to deliver quality products to the 71% of U.S. adults who take dietary supplements.

Steve Holtby
President and CEO
Soft Gel Technologies Inc.

The dietary supplement industry is projected to remain strong in 2017, continuing to grow globally. That said, we seem to sustain a perpetual "black eye" from mainstream media scrutinizing how our industry is under-regulated from a safety standpoint by the FDA. DSHEA was passed in 1994, but many health officials argue that these regulations aren't stringent enough. Having been in business as a contract manufacturer of high-quality soft gelatin capsules for over 20 years, Soft Gel Technologies Inc. feels that it is the responsibility of dietary supplement manufacturers to ensure that their products contain the intended, unadulterated ingredients. We recognize that customers and consumers alike are concerned about where these products are sourced and if they are pure and efficacious. Transparency in the supply chain is achieved through a combination of extensive testing, thorough supplier qualification, and ingredient traceability, and assurance that set specifications are met each and every time. Integrity in business is key in maintaining longevity in this industry. We strive to be a reputable manufacturer and look forward to seeing what the next 20 years hold in store.

Karen Howard
CEO
Organic & Natural Health
Association

Clearly, DSHEA improved the business of selling dietary supplements and ensured

sustained growth in sales. However, relying solely on sales figures to ascertain the health of an industry is delusional. We need to measure our efforts to educate and engage our consumers who now demand access to quality products derived from transparency and traceability. We need to sponsor research that supports claims and focuses on the good, the bad, and the ugly. Let's measure nutrient effectiveness. And, let's demonstrate how continuous quality-improvement (CQI) practices safeguard against processes and contaminants that jeopardize consumer health and place the industry at risk. We need to champion the highest standards. There is no room for sloppiness, and this is no time for inclusive mediocrity. Ours is an industry rooted in the health of our consumers, so let's take a thorough look at its health. At 20, will a sense of invincibility distort our hearing and vision? Are we at risk of being overweight and undernourished? Is our work as clean as our diets? Yes, we're better off today. The question is whether we will consume and expend resources that feed our vision of supporting a healthy planet and healthy people.

Adam Ismail
Executive Director
Global Organization for EPA and
DHA Omega-3s



Science is what makes 2017 better for the nutrition industry than 1998. Specifically, we are an industry that delivers products with nutrition and health benefits, and we have

seen an explosion of science in the last 20 years that has largely displaced some of the required marketing spending required of consumer product industries. This is particularly true in the omega-3 industry where clinical research in humans is published on a daily basis, but in the broader supplement industry the body of science has also grown for most products. This is one of the reasons so many more people take supplements today than



did in 1998. At the same time, this increasing penetration into households has forced the industry to become more sophisticated in every aspect of the business, from regulatory compliance to product quality to better marketing strategies. We have also caught the eye of the consumer media, and we need to be careful not to start promoting the benefits of our products before the science exists, as negative media continues to be a key challenge for the industry. So, I definitely see more opportunity in 2017 than we had in 1998—but at the same time, back then I do not think I would have predicted the steady, relatively high growth this industry has seen sustained over the past 20 years.

Loren Israelsen
President
United Natural Products Alliance



In two words: *technology* and *language*. Like everyone else, the dietary supplement and natural product industries are being carried down a digital river. Some are steering;

most are hanging on for dear life. It is a rush for those born on the river—the necessity and benefits of disruption, big data, clouds, engagement, and ideation are self-evident. I just confirmed this on Google. This new language is powerful, and those who speak it, like the languages of the past (Latin—think law and medicine), create a new medium to deliver a well-loved message, and this creates new markets. The proposed Amazon/Whole Foods deal (June 2017) would mark a new era of two cultures and languages merging. How this changes our industry will unfold in time. One thing is certain: the 2017-2037 period will be unlike anything we have ever imagined.

Andrew Jacobson
CEO
Algalif

Absolutely! 2017 is a better year for the dietary supplements industry than 1998. In the last decade, the industry experienced hyper growth globally due to a multitude of factors, including a rise in healthcare costs

and decline in quality of care, aging populations, fitness, and heightened interest in preventative health-care. Consumers have decided to take matters in their own hands and look to improve their fitness and nutrition through healthy lifestyles, including exercise and supplements. These activities will continue to drive growth in the coming decade. In addition, over the last decade, research and innovation have blossomed, driven by responsible and professional companies replacing some of the companies that relied on questionable claims. As an industry, we all should be proud of this revolution driven by our hard work on self-regulation and focus on quality. The future of the dietary supplements industry is in good health!

Frank Lampe
Vice President, Communications & Industry Relations
United Natural Products Alliance



No contest! A rapidly maturing industry is much better off now than 20 years ago. Here's why: Availability of our products to consumers is greater than ever before through a variety of distribution channels, while at the same time, the understanding that supplements can make a valuable contribution to health and wellness and reduce medical costs is at an all-time high. Additionally, notwithstanding the reasons or the source, industry is actively engaged with and moving forward to implement a number of important quality initiatives, including protocols around identification and testing that are helping instill consumer and regulator confidence. Industry outreach efforts to those regulators, including state attorneys general, are more consistent and professional than ever. Every day, it seems, more science is showing the research-backed benefits of the products. And, for the first time, senior FDA officials have reached out to engage with industry to form a collaborative partnership, while both FDA and FTC have been active



in stepping up their prosecution of bad players and removing harmful products from the marketplace. Older is wiser for the supplement industry.

Elyse N. Lovett, MBA, MS
Marketing Manager
Kyowa Hakko U.S.A.

In the past 10 years, we have seen a boom in the digital world across many generations, millennials all the way to the baby boomers. People all around the world are getting more and more information from the Internet, including information about dietary supplements. Digital media has allowed consumers to educate themselves on ingredients, claims, reviews, and science, and more recently be persuaded by those with influential power. Better or worse? I think we can say it goes both ways, as the Internet can be a source of great educational content but can also be a free-for-all of pieces of information that may not necessarily be true. Manufacturers have realized the importance of digital content and strong, evidence-based science to back up their product claims, while consumers are starting to tell the difference between what is reality versus fantasy in the digital world when it comes to dietary supplements. Digital media has also been a great platform for smaller, niche-type supplements to grow their supplement lines, creating a demand for condition-specific-type supplements like brain-health and gut-health formulations. These types of supplements are raising consumer awareness and increasing growth year over year of specific condition categories.

Saumil Maheshvari
Marketing Analyst
Origenetics Inc.

I believe that, by far, the two most important aspects that have advanced in the dietary supplements space since 1998 are regulation and the



introduction and importance of USDA Certified Organic, which mandates audits and, as a result, has led to an increased level of consumer confidence and trust in dietary supplements in recent years. And for good reason, too. Suppliers that offer quality (and consistently prove and validate that quality) have gained ground, as have manufacturers that put quality and transparency of raw materials over their costs. The amalgamation of all these factors has led to an industry in 2017 that is much cleaner than it was in 1998 and holds itself to a much higher and more respectable standard. There now exist brands that consumers can recognize and trust for their efforts in quality assurance, transparency, and sustainability, all of which are most often identified with the USDA Organic seal. When we started in 2007, we introduced QA tests that were not required by any manufacturer, much less by law. We decided and chose from the beginning to stick to the 100% USDA Organic standards, which we have always touted as a gold standard for quality and transparency, as well as to promote environmental sustainability through organic farming. We are grateful that, in 2017, our efforts have not gone unnoticed, and that we have made some difference in the industry and the world.

Shaheen Majeed President Sabinsa Worldwide

The science behind the industry's products has improved greatly since 1998. Today, a body of science can drive sales significantly as the industry has seen with curcumin. Twenty



years ago, Sabinsa was one of the only companies producing science-based ingredients and investing in research. Today there are significantly more clinical studies on herbs, much of it university centered, and more company-sponsored research than in the past. The medical community and consumers have shown that this kind of substantiation is rewarded with acceptance. One way in which

the industry is worse off today is that there are more sophisticated ways of adulterating products. We're concerned about synthetic curcumin passed off as naturally derived curcumin, for example. That companies will still buy by price alone, knowing full well that adulteration goes hand in hand with a cheap price, is another way we're worse off. Patent infringement and "borrowing" science still goes on, and since the industry should have banned such IP theft years ago, this goes in the "worse off" category.

Will McCormack, PhD Business Development Manager Synergy Flavors

The most significant progression we've witnessed since 1998 has been the change in the regulatory environment related to the food, beverage, and nutritional supplement industries.



These stricter guidelines and regulations have resulted in a significant investment in resources on the part of suppliers and manufacturers to ensure regulatory compliance. As a supplier who as always held itself to the highest standards in terms of quality, Synergy has embraced the increased regulatory scrutiny, as it has resulted in greater levels of consumer protection relative to 20 years ago. As an example, the National Organic Program (NOP), founded in 1997, has provided the regulatory framework for the proper governance of organic product certification. Sales of organic products hit \$43 billion in 2015, achieving its largest dollar gain to date, and are still expanding (per www.ota.com). Increased consumer awareness surrounding the interaction between diet and health has resulted in an all-time high demand for natural and organic products. Twenty years ago, the library of natural raw materials available to flavor chemists and food scientists was significantly smaller than today's. This resulted in weak and underwhelming flavors, which often forced consumers to choose between health and taste experience. The expansion of the natural and organic toolbox over the last 20 years has meant that the consumer is no longer faced with the choice

between either nutritious or flavorful food and beverages.

Michael McGuffin President American Herbal Products Association



The dietary supplement industry has grown steadily over the last 20 years, and there is no indication that this trend will change. While the industry has changed in the last two decades, one thing hasn't changed: increasing consumer demand for high-quality dietary supplements that improve quality of life by promoting health and wellbeing. The overall safety and efficacy of these products has also helped supplements gain greater acceptance by the mainstream medical community, and new research continues to increase our understanding of how these products impact health and wellbeing. Not surprisingly, the growing popularity of supplements has brought additional scrutiny, and the industry continues to take proactive steps to address this scrutiny with additional transparency. Ultimately this scrutiny, and industry's ongoing efforts to effectively respond to it, have helped make the industry stronger and better prepared to meet future challenges.

Roman Nemzer Business Development Manager Vidya Herbs Inc.



If you look back on the last 20 years, a lot has happened in the dietary supplement industry. You may even call it a revolution. We're conducting research and innovation that we've never seen before. The capabilities of using natural ingredients and making them efficient, more bioavailable, and overall much more beneficial in supplements is truly tremendous. We are now better than ever able to analyze an ingredient almost to the core and pick out the most health-

beneficial compounds, extract them, and use them in all kinds of applications, from beverages to tablets to gummy bears. We're even able to naturally mask the taste if we have to with yet another innovative ingredient. Simply put, we're far more innovative than we were 20 years ago. And, we are much better in terms of sustainability and quality. Our industry's quality measures have been improving year after year so we can confidently provide the best products and promote healthy lifestyles. We should be proud of what our industry has accomplished since 1998.

Chris Oesterheld
Executive Vice President
Jiaherb Inc.

The dietary supplement industry is experiencing a lot of good changes, especially on the botanical side. Whether it be new regulations like the Food Safety Modernization Act (FSMA) or more industry requirements for botanical transparency, these are all actions that have shifted the conversation and will ultimately benefit the consumer and give players in the dietary supplement industry the opportunity to differentiate themselves. Jiaherb has taken the initiative to launch its new botanical-identification program called Herbalink. The process of identifying our material and ensuring pure and unadulterated extracts is nothing new for Jiaherb. In the last couple of years, there has been a strong push for more clear and accurate information in the form of documentation, and thus we created an efficient way of presenting all this information in a single packet of documents. These documents show each link in the supply chain, from plant to finished powder or extract.

Irfan Qureshi, ND
Executive Director, Research and
Regulatory Affairs
Healthy Directions

Looking back 20 years, the industry was only recently coming off the passage of DSHEA.

DSHEA was a big win. While that provided a platform for moving forward out of the pre-DSHEA uncertainty the industry was experiencing, many things were still ambiguous, not the least of which were the GMPs. Fast forward to 2017, and I would suggest things are much clearer. We now have the GMP guidelines and nearly 10 years of enforcement history. In addition, on the science front, things have improved tremendously with a plethora of research validating the benefits of commonly used nutraceutical ingredients and wellness practices. These two developments have served to dramatically improve industry practices and ultimately instill consumer confidence in the products we offer. Granted, there are still headwinds of uncertainty that we face as an industry, such as effective resolution of the NDI guidance and marginalizing unscrupulous players; yet, our ability to work through the challenges of the past gives me confidence that the industry has what it takes to face adversity and continue to prosper moving forward.

Judy Seybold, MS, RD, LD
Vice President, Content Services
SPINS LLC



Market trends, product enhancements, and consumers' personalized wellness initiatives have aligned to support growth in dietary supplements in recent years, culminating in a 53% sales increase in the \$13.7 billion supplement category in 2016, according to SPINS data. The U.S. population has over 50 million seniors (U.S. census data) who, with rising healthcare costs and readily accessible information, have fed the trend in self-diagnosis. One illustration is the concern with age-related inconveniences, such as joint pain, which helped advance collagen sales growth to 873% in 2016. Younger consumers have also influenced supplement sales as the plant-based diet movement has elevated the perceived need for supplementation. This



segment is also active in the burgeoning ultra-sports category, prompting enhanced support from smoothies, shakes, and other solutions. Regulatory and product changes have also fueled supplement sales. In 1998, the FDA introduced guidelines promoting product-testing transparency, ultimately strengthening consumer confidence and trust. Simultaneously, manufacturers have developed new delivery options, opening doors for new users to enter the category through gummies, chewables, and other product forms that did not exist in the past. I expect continued growth in the supplement category as today's consumers increasingly turn to trusted supplement providers for heightened quality of life and the need to reach personalized wellness goals.

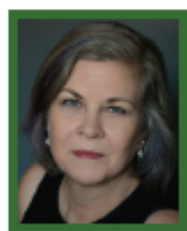
Andrew Shao, PhD
Vice President, Global Nutrition
Policy, Global Government Affairs
Herbalife Nutrition

2017 is definitely a better year than 1998 for all stakeholders (supplement industry, consumer, regulator, academic, practitioner, etc.). In 1998, the law that to this day governs the industry (DSHEA) was still quite new, and none of the aforementioned stakeholders knew how to navigate the marketplace. Today, we have new laws and regulations in place that provide guidance to industry and better protect consumers (e.g., GMPs, Adverse-Event Reporting/AERs, FSMA); we have self-regulatory efforts acting to fill gaps left by some regulations; we have a better understanding of how products work, which has led to new and unique innovations; we have a better understanding of consumer needs, preferences, and behaviors; and we have demonstrated the public health impact of supplements through healthcare cost savings. The investment in science and quality is also much greater today than it was in 1998, including from industry, government, and academia. All these advances have been paralleled by steady growth of the industry throughout the past 20 years. Most importantly, although there is still work to do, we



experience a level of transparency in the industry today that could not have been fathomed back in 1998. That alone is a huge step forward.

Suzanne Shelton Managing Partner The Shelton Group



Several things stand out as 2017 being a better year for the industry than 1998: we have more and better science showing the safety and efficacy of supplements, and we

have more individuals and companies taking a leadership role advocating for best practices. My clients may well influence my observations, but I believe there is more emphasis on proficient testing, branded ingredients over commodities, and investing in effective communication to convey product benefits. The industry is better off because consumers not only have increased access to better-quality information, but also a higher level of interest in the products our industry offers to help them stay healthier. Social media, allowing people to so easily share tips on what works for them with links to articles and studies, has fed interest in adaptogens, for example, unexpectedly fueling rapid growth in that herbal category over the last few years. Like 1998, we're experiencing a time of marketplace disruption, but rather than "super-natural" stores doing the disrupting, it's Amazon.com. It will be fascinating to see what the Amazon/Whole Foods world looks like [following Amazon's recently announced plan to acquire Whole Foods].

Scott Steinfeld CEO Trust Transparency Consulting

I would like to believe I am the same, youthful person today as I was 20 years ago, but I need only look in the mirror to realize how much I've "matured," like it or not. Some



of the same issues I struggled with 20 years ago still exist today: some matters I have overcome; and still other concerns have emerged. The dietary supplement industry suffered the same consequences of maturity as I did. In 1998, privately held health food stores were the dominant distribution channel for dietary supplement sales, and the Internet channel was only a thought. Swanson Vitamins and Nature's Wealth Company were catalog companies selling vitamins; they would not launch their online sales as SwansonVitamins.com and Vitacost.com, respectively, for two more years. Science was still emerging as an essential element to the marketing of ingredients. Vitamin E was the leading heart-health supplement as supported by the *American Journal of Cardiology*. Today, the sales channels are more sophisticated, and the science is broad, positively and negatively, in both depth and scope of products and ingredients. It is impossible to collectively say if what we have is better or worse today than 20 years ago. It is safe to say life is different today and, like it or not, it is what we have, and hopefully it is something we are proud of.

Elan Sudberg CEO Alkemist Labs

The industry is better off than in 1998 because we have 20 more years of experience in what the regulatory expectations and responsibilities are for manufacturers. The industry has experience in the pitfalls of concealment and cutting corners, and more companies have decided that the price of cutting corners is too high. However, we are worse off because while access to tools and education on GMP compliance have improved and willful ignorance has decreased, the industry's tolerance for lack of transparency for proprietary testing methods or ingredients needs work. If a test can't be reproduced because vital information is withheld, it's not legitimate science. We would see significant improvement if brands chose to source only from ingredient suppliers that



embrace transparency and reveal exactly how they made an extract to your specification. Buyers have the purchasing power to work only with contract manufacturers who embrace transparency, use high-quality ingredients, and develop test methods to back label claims. Insisting that contract labs embrace transparency share their methods, and be open to dialogue when a material fails will help take the industry where it needs to be.

Anand Swaroop, PhD, FACN President Cepharm Inc.

The nutraceutical market around the globe reached around U.S. \$205.4 billion in 2016 and is projected to reach around \$294.8 billion by 2022. This shows that nutraceutical formula-



tions, botanicals, and herbal supplements are becoming widely popular and accepted globally. A significant volume of clinical, safety, and mechanistic studies is being conducted on nutraceutical ingredients and formulations and published in peer-review journals from prestigious research institutions and universities around the world. Cepharm's research team is unveiling research-driven novel nutraceuticals from fenugreek seeds for healthy glucose regulation, women's health, and boosting free-testosterone levels in healthy volunteers. Other novel innovations include a unique *Prunus domestica* stem extract for benign prostatic hyperplasia; a state-of-the-art olive leaf extract enriched in maslinic acid for vitality, vigor, self-esteem, and strength; a standardized *Curculigo orchioides* extract enriched in 30% cuculigosides for sports nutrition, exercise, and muscle building; and many more in the pipeline. Cepharm's prime vision is continued research and innovation.

Brian Tanzer, MS, CNS Manager of Scientific Affairs The Vitamin Shoppe

Over the past several years, we have seen a shift in product formulation to include ingredients, dosages, etc., that are supported

by scientific research. I think we are past the days when consumers believed that the more ingredients in a formulation, the better the formula must be. Today, consumers have greater access to information than ever before. In addition, many supplement companies are more transparent about a product's formulation than they were even five years ago. Consumers have become very suspicious of so-called "proprietary blends," so industry has responded with cleaner labels, fewer ingredients, and meaningful dosages. Ingredient manufacturers are investing more money in clinical research these days as a way to give their products more credibility and to help differentiate their ingredients from similar products on the market. Given the dietary supplement industry's competitive landscape, companies must continue to incorporate advanced technology (i.e., innovative delivery systems) and test these technologies through rigorous science. We are moving into the age of "less is more" when it comes to product formulation.



David Trosin
Director,
Global Business Development,
Dietary Supplements
NSF International

The dietary supplement industry has seen a great deal of growth and maturity in the last 20 years. A lot of effort has been made toward self-regulation as well as implementing the necessary changes to comply with required GMPs. While there is always work to be done, one of the best ways the industry is demonstrating compliance is through accredited third-party certification of products and independent GMP facility registration. These are the most effective and efficient ways to assure high-quality, safer products for consumers.



Marc Ullman
Of Counsel
Rivkin Radler

As regulatory counsel, from my perspective the industry is vastly better off, as it is now subject to a well-defined set of regulations with predictable consequences for non-compliance. Two decades ago, we were still waiting for FDA to take steps toward implementing any kind of rational enforcement scheme following the passage of DSHEA. Most importantly, we have a robust set of GMPs governing every aspect of how our products are produced. As a result, industry products are better, something which benefits both the consumer and industry.

John E. Villafranco
Partner
Kelley Drye & Warren LLP

While it is hard to say if the industry is in a better place now than in 1998, it is clear that the landscape has changed dramatically. In the



past two decades, numerous new laws and regulations have gone into effect, including the allergen and AER laws, FSMA, and GMPs. We also saw a federal court in *Pearson v. Shalala* make clear that the First Amendment prohibits FDA from regulating non-misleading health claims that are qualified by reasonably worded disclaimers. Congress got into the act by forming the Dietary Supplement Caucus in 2006; the NAD-CRN initiative began its excellent work in 2007; and beginning in 2010, a Democratic-led FTC sought to impose novel and extremely rigid substantiation standards on dietary supplement advertising. Where does all that leave us today? I suppose one thing we can say with confidence is that the regulatory outlook for 2017 is better than it was one year ago. With the Republican administration and Republican-led Congress, there is much greater certainty that DSHEA will remain in place. There is also hope that at key agencies, new leadership will seek to avoid undue burdens on responsible industry. FDA, for instance, may see fit to integrate more industry input into its final NDI guidance. At the FTC, the acting chair, appointed by President Trump, is more skeptical than her predecessor of rigid substantiation standards. She or a different permanent chair may return that agency to a more appropriate interpretation of the "reasonable basis" standard.

Joseph J. Weiss
President
Nutrition 21

The focus on quality, efficacy, and consumer confidence is much higher now for the industry than it was 20 years ago. Market forces and regulatory issues have moved the industry in the right direction, and we are stronger for it. ☐



Vincent Tricarico
Vice President of
Contract Manufacturing
NutraScience Labs

We are much better off now than we were in 1998. For one thing, science-driven innovations continue to demonstrate the effectiveness of supplements. The ever-increasing wealth of knowledge, which can be easily accessed in today's digital world, has created a more-informed consumer. These more-informed consumers have highlighted the importance of traceability and efficacy within our industry, and have pushed manufacturers to create and maintain a system that—from raw material to bottled product—demands the highest standards and the best quality. These changes have helped more people than ever before discover the potential benefits of smart supplementation.

