

THE U.S. DIETARY SUPPLEMENT MARKET: AN OVERVIEW OF ISSUES AND TRENDS

A special section in the 3Q2017 issue of Asiaceutical Insights



INSIDE

Industry news 3

Member Profiles/Resources 5

Waters Corp.
CRB
Alkemist Labs
Covance
PerkinElmer

MOU Partner Profile/Resources 8

National Center for Natural
Products Research

Features

American Herbal Pharmacopoeia **9**
Preventive Controls Qualified Individual **10**
HPC Practitioner Survey **12**
Botanical Adulterants Program **13**
NBJ Consumer Trust Research **14**

Published by the
United Natural Products Alliance



Welcome.

This special section on the U.S. marketplace for dietary supplements is brought to you by **The United Natural Products Alliance.**

We invite leaders in key market sectors, countries and product categories that are willing to contribute to the responsible growth of the natural and organic health products industry to enquire about membership.

UNPA provides the following services

- **Consulting services: Regulatory, acquisitions, M&A, licensing, partnerships**
- **Education and training, including onsite training**
- **Industry leadership and guidance on key issues**
- **U.S. federal and state legislative and regulatory representation**
- **Communications, updates and other member resources**

...and much, much more!

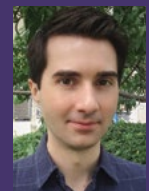


The United Natural Products Alliance (UNPA) is an international association representing

more than 100 leading natural products, dietary supplement, functional food, and scientific and technology and related service companies that share a commitment to providing consumers with natural health products of superior quality, benefit and reliability. Learn more at www.unpa.com.

In China + Asia, contact:

Daniel Mabey
UNPA Asia Representative
daniel@unpa.com
unpachina.com



In the U.S., contact:

UNPA
1075 E Hollywood Ave
Salt Lake City, Utah USA
801.474.2572
info@unpa.com
unpa.com

Herbal formulations often ignore underlying principles of traditional medicine

Finding a place for ingredients from the traditional medical systems, such as Traditional Chinese Medicine or Ayurveda, in the modern marketplace can be a difficult exercise, with formulators only paying lip-service to the principles that underlie these ingredients, according to experts in the segment, including Ezra Behar, a scientific advisory board member of the American Botanical Council; Roy Upton of American Herbal Pharmacopeia; and Beth Lambert of herbal products company, Herbalist and Alchemist. Growing interest in these ingredients has highlighted the issue.

Nutraingredients.com

Growing China supplement market also presents potential challenges

Supplement exports from Australia, New Zealand and the West to China have significantly increased recently due to the country's burgeoning middle class and a rising awareness of health and wellness. However, China's skyrocketing supplements market also presents a number of key challenges that new entrants need to be aware of, according to a new report from the Australian Trade and Investment Commission, Austrade. The report says the Chinese health food market, which includes vitamins, supplements, animal and herbal extracts and TCM, is currently valued at \$30 billion.

Nutraingredients-asia.com



UNPA President Loren Israelsen and Liu Xuecong, secretary-general of CNHFA celebrate the signing of a partnership agreement between the two organizations. From l. to r.: Dennis Simmons of the U.S. Commercial Service; State Rep. Eric Hutchings, R-Utah; Scott Pozil, U.S. commercial counselor; Israelsen; Xuecong; Bian Zhenjia, China FDA deputy commissioner; Zhao Beihai, CFDA director of international cooperation; and Liu Sonata, CFDA director of special food registration.

UNPA and CNHFA sign a joint memorandum of understanding to further Sino-U.S. industry cooperation and growth

In an effort to formalize cooperation and collaboration between the natural health products industries in the United States and China, the China Nutrition and Health Food Association (CNHFA) and the United Natural Products Alliance (UNPA) signed a memorandum of understanding (MOU) agreement in a ceremony held at the U.S. Embassy in Beijing. The MOU signing took place at the recent Sino-U.S. Health Food Summit Forum.

CNHFA and UNPA signed the MOU to promote and exchange research and technology, as well to promote cultural exchange and the safe and sustainable development of the natural and health products industry in both countries. The two organizations agreed to mutually communicate about regulations and policies to strengthen Sino-U.S. health products registration, regulation, market access and other aspects of regulatory policy.

"We are honored to be working closely

with our colleagues at CNHFA to further our mutual interests to responsibly grow the natural health products industries in both countries," said Loren Israelsen, president of UNPA. "It is our hope that this MOU agreement will stimulate further collaboration and the exchange of ideas and resources to help do this."

"We believe the MOU will promote cooperation and communication between both associations and industries. We hope through information exchange and projects, it will encourage industry development and regulatory harmonization," said Liu Xuecong, secretary-general of CNHFA.

Liu Xuecong, Bian Zhenjia, deputy commissioner of the China State Food and Drug Administration, and Scott Pozil, counselor of the U.S. Embassy in China, attended the signing ceremony, along with members of the China State Food and Drug Administration International Cooperation Department.

THE U.S. DIETARY SUPPLEMENTS MARKET: AN OVERVIEW OF ISSUES AND TRENDS

A special section in the 3Q2017 issue of Asiaceutical Insights, published by the United Natural Products Alliance



Loren Israelsen
President

Daniel Mabey
Asia Representative

Frank Lampe
Editor-in-Chief

Karen Raterman
Managing Editor

Christine Bakke
Art Director

Stephen DeNorscia
Associate Editor

UNPA
1075 E. Hollywood Ave.
Salt Lake City, UT 84105 USA
801.474.2572
info@unpa.com
unpa.com

Copyright ©2017, all rights reserved; copying or duplication of any of the content of this publication without the expressed, written consent from UNPA is prohibited.

Researchers develop DNA botanical ID technology for extracts

A new technology, building on genetic information as the basis of botanical identification, has been demonstrated in a recent research paper dealing with a common TCM ingredient. The authors, from two Chinese research institutes as well as the University of Guelph, detailed development of an identification method for *Lonicerae japonicae Flos*, or Japanese Honeysuckle, which is a common component in many Chinese patent medicines. The authors noted that

traditional medicines, especially the highly complex TCM preparations, suffer from a rising tide of adulteration.

Japanese honeysuckle is a case in point. Rich in chlorogenic acid (CGA), it is subject to adulteration with cheaper sources of CGA that have different chemical properties, according to the paper. DNA barcoding has been put forward as a method for positive botanical identification, but the authors and industry have noted drawbacks in that this method, which relies on relatively intact

strands of DNA, which may be difficult to find in materials after processing or may be absent in extract form.

The new technology uses a “nucleotide signature” that is unique to the target species but much shorter than common DNA. It also uses a device that should make uptake of the approach easier for industry. The researchers say it is still early for the new technology and much work still needs to be done for its wider acceptance and application. Nutraingredients-usa.com

Survey: A booming Asia market, receptive to new regulations

Three of four respondents in the first annual *Nutraingredients-Asia State of the Supplements, Health and Nutrition Survey* believe their companies will post better financial performance this year than last. The results also showed a rising awareness of health and wellbeing in the region, but while company outlooks were good, securing financing is still a challenge. The second part of the study looks at the raft of new supplement and functional food regulations introduced in the past two years, or those that are imminent. The region has seen several high-profile regulatory changes in China and Japan, with new rules soon to be enforced in India. The survey results say that the regulations have been broadly welcomed by industry in the Asia-Pacific region.

Nutraingredients-asia.com

TSI Group receives approval for first, only CFDA license for HMB

Missoula, Mont.-based TSI Group announced the approval of the first and only China Food and Drug Administration (CFDA) Manufacturing License for β-hydroxy-β-methyl butyrate (HMB) production in China. TSI’s Jiangyin Pharmaceutical facility, a wholly owned TSI Group company, received this exclusive license to produce HMB for use in Chinese food products. The approval also includes use of TSI’s HMB in a range of novel food categories, including beverages, chocolates, candies and baked goods.

China is a key market for TSI’s global muscle health growth strategy, where TSI’s mission

is to deliver muscle health benefits that enhance and maintain consumers’ healthy and active lifestyles.

“These recent regulatory approvals are significant milestones for all of us at TSI. The door is now wide open for us to deliver TSI’s world-class HMB products to one of the fastest growing markets in the world – China,” said Larry Kolb, president of TSI Group. “We know HMB can make a difference in people’s daily lives and are excited for the opportunity to positively impact muscle health for millions of Chinese consumers – from athletes of all kinds to aging adults.” **TSI Group**

The U.S. Dietary Supplements Industry 2016 by the Numbers*

Overall Supplement Sales: \$41.2 billion

Supplement Growth: sales expected to reach \$52.5 billion by 2020

Herbal Supplement Sales: \$7.4 billion on 6.8% growth

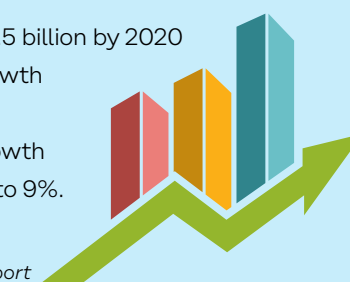
Vitamin Sales: \$12.8 billion on 4.6% growth

Sport Supplements Sales: \$5.7 billion on 8.3% growth

Practitioner Market: \$3.5 billion on growth of 7% to 9%.

*All amounts in U.S. dollars

Source: *Nutrition Business Journal Supplement Business Report*



Building laboratory capacity to ensure product safety, quality and efficacy

Due to the complexity of today's natural products, dietary supplements and Traditional Chinese Medicines (TCM), it is essential to use state-of-the-art analytical technologies, such as chromatography and mass spectrometry techniques, for drug discovery, research, quality control of raw materials and finished products, as well as verification of label claims. Working with these technologies helps bring scientific expertise to new product development and ensures compliance to legislative requirements.

Much of this can be overwhelming to many laboratory-dependent companies, but there are specialists who can help, by providing business advantages and practical solutions for companies that need analytical technologies to ensure the safety, quality and efficacy of their product. Waters Corp., in Milford, Mass., was an early pioneer in providing these services and continues to be a market leader today. For more than 50 years, Waters has been helping companies by integrating analytical standards, column and sample preparation chemistries, chromatography, mass spectrometry and data management software. Waters also helps manufacturers and labs utilize analytical solutions to identify diverse chemical compounds, meet compliance requirements, reduce operational costs and

increase productivity, according to Naren Meruva, Ph.D., Waters' marketing manager, Food and Environmental.

Industry Leadership

Waters has also taken a technical leadership role in the broader industry, with its involvement in method standardization bodies, such as AOAC and the U.S. Pharmacopeia, and with independent, third-party nonprofit organizations, for the development of analytical standards. These efforts have helped build capacity for laboratory training programs and assisted key research organizations to improve manufacturing quality standards.

For example, Waters served as an instrumental partner in a collaboration with the National Center for Natural Products Research (NCNPR) at the University of Mississippi (see article on page 8) to establish The Natural Products Training Center. Designed to promote scientific standards in the advancement of commercially viable natural products, the center offers training courses for technical professionals, scientists, regulatory, quality control and quality assurance personnel affiliated with dietary supplements and other manufacturers of natural products. Waters provided laboratory analytical instrumentation and software

Waters

THE SCIENCE OF WHAT'S POSSIBLE.®

for separation, analysis, appropriate data evaluation and management for use at the training center.

Modernizing TCM

In other areas, Waters has also worked to help bridge the gap in scientific research of traditional medicines using modern technologies. "Waters is dedicated to developing comprehensive analytical solutions for simplifying the complexity in understanding traditional Chinese medicine," said Jimmy Yuk, Waters' marketing manager for Natural Products and TCM.

"Research on the modernization of TCM conforms to the current development trend in the life sciences and the biopharmaceutical industry," said De-an Guo, Ph.D., director of the Shanghai Research Center for TCM Modernization at the Shanghai Institute of Materia Medica, in Shanghai, China.

TCM typically involves complex mixtures with many constituents, and the modernization of Chinese medicine is designed to use modern scientific means to separate and understand the actual effect of various ingredients. "The development of Chinese medicine modernization is inseparable from the analytical testing technology, especially liquid chromatography and mass spectrometry," said Guo. "As Waters Center of Innovation partners, we believe Waters' leading technology and rich experience in the field of analytical chemistry can help us achieve breakthroughs to promote TCM to the world."

For more information visit www.waters.com



Waters Corp. partnered facility at the National Center for Natural Products Research houses state-of-the-art analytical equipment.

CRB brings operational efficiencies to facility design and construction

At some point in their growth curve, most supplement and natural products companies will need to consider an upgrade of their laboratory facilities or perhaps an expansion involving a complete manufacturing construction plan. Choosing the right design and construction firm with relevant experience in key areas, such as regulatory compliance and operational efficiencies, can be the difference between a smooth, cost-effective project and one that is fraught with problems.



Keith Kettler

Selecting a company that offers a custom approach and comprehensive understanding of specific industry manufacturing needs is a good approach, according to Keith Kettler, an associate with CRB, a Kansas City, Mo.-based consulting, design and construction services firm. Founded in 1984, CRB has evolved from a three-person firm to a team of more than 1,000 professionals in 15 offices throughout the United States and Europe. The company touts extensive experience working with international partners to ensure successful completion of their projects.

Processes drive design

CRB's initial work was in the biotech and pharmaceutical industries, but as the company saw an increasing regulatory environment for nutritional products, it crossed over into the nutraceutical space. "We found that the processes are similar to the pharmaceutical industry regarding production of tablets and capsules, especially the technical areas of



Good facility design creates key operational efficiencies.

oral solid dosage," said Kettler. "But we also have an understanding of what is actually applicable, and we found a good bridge to apply what is necessary at a cost that is appropriate to the industry."

The company typically works with clients that are producing high-quality products. "Many of our clients are high-end brands and companies making supplements that are sold to practitioners, and they are concerned about meeting U.S. Food and Drug Administration (FDA) regulations and complying with current Good Manufacturing Practices (cGMPs)," Kettler said.

CRB provides a team of experts with the responsibility and authority to deliver a quality project, on schedule and under budget. The team applies a systematic, proactive approach to identify issues and resolve them before they become problems.

Kettler suggests there are three important elements that nutraceutical companies should look for in a design firm.

The first is Operational Improvement (OI): CRB, for example, applies the latest OI strategies to help facilities run more effectively and efficiently, with less waste and lower cost. This involves looking at equipment downtime, transportation and handling of product throughout the facility, inventory, forecasting and scheduling issues, he said.

A good example of the impact these strategies can have was with a project in which CRB was commissioned to design a new facility for a growing supplement company, based on usage of the client's existing equipment. The first design came in way over budget, Kettler recalled, so the CRB team suggested analyzing equipment



An example of a CRB-designed warehouse

usage and came up with a plan to reduce square-footage in the new facility by 40 percent. "Just because a company has three encapsulation machines doesn't mean they need three," Kettler said.

Cultural adaptations

Manufacturers and brands from outside of the United States should look for a firm that has a track record of working with international companies that can adapt culturally. CRB is particularly geared to help offshore companies looking to build or repurpose facilities in the U.S. and which are looking for lean, efficient design, Kettler noted.

Beyond design efficiencies, a design firm should also bring extensive experience working with FDA and other regulatory agencies to set industry guidance as well as design and construct facilities to meet cGMP rules for supplements and Food Safety Modernization Act regulations for natural foods and dietary ingredient producers, Kettler explained. "This involves cleanliness of the facility from the personnel to room finishes, along with procedures for cleaning, making sure that the heating, ventilation and air conditioning system works properly and that room conditions reduce particle generation from people."

The third piece is sustainability, an important aspect for nutraceutical companies, whose products embody the concepts of being good for both people and the environment. "This is where we look at reducing energy use, waste and use of water, which can lead to a lower cost of goods," Kettler said.

As a member of the United Natural Products Alliance (UNPA), CRB is concerned about the direction of industry regulations and is hoping to have an impact. CRB is always looking for ways to get involved and help with client and industry education, Kettler added. "We feel it is important to understand where an industry is going and help set those directions. UNPA was a good fit for that." For more information, visit www.crbusa.com.

UNPA testing labs, product development and equipment resources

Alkemist Labs: Contract testing laboratory



Founded in 1997, Alkemist Labs is a contract-testing laboratory of natural products, herbal medicines and omega-3 fatty acids. Headquartered in Costa Mesa, Calif., Alkemist Labs is a cGMP contract laboratory specializing in routine QC/compendial testing, method development and validation services and dedicated research services for companies throughout the food and beverage, nutraceutical and cosmeceutical markets. Alkemist offers high-throughput HPTLC analysis for botanical ingredient identity testing of whole herbs and plant extracts, with a standard five-business-day turnaround at no extra charge. In combination with HPLC, microscopy and an onsite herbarium, Alkemist offers the most reliable technical support and highest-quality services for companies to become cGMP compliant. www.alkemist.com

Covance: Product development and lab testing services



Covance is one of the world's largest and most comprehensive drug-development services companies, helping pharmaceutical and biotech companies of all sizes fulfill their research and development, clinical trial, regulatory and marketing-support needs. The company is dedicated to advancing healthcare and delivering solutions by providing high-quality, nonclinical, preclinical, clinical and commercialization services to help reduce the time and costs associated with product development. Covance is also a leading provider of laboratory testing services to the environmental, food and nutritional supplement industries and a provider of innovative, custom antibody products and services to the research community for neurological disorders. www.covance.com

PerkinElmer: Imaging, software and services solutions



PerkinElmer Inc. is a global leader focused on improving human and environmental health. The company provides customers with critical knowledge, expertise and innovative detection through imaging, software and services solutions. PerkinElmer helps scientists, clinicians and governments make accurate detections for health and safety of people and the environment. With innovative detection, imaging, informatics and service capabilities, combined with deep market knowledge and expertise, the company helps customers gain earlier and more accurate insights to improve lives and the world around us. Solutions range from more effective diagnostics and therapies to making sure that the food we eat, the water we drink and our environment are safe from contaminants. www.perkinelmer.com

National center brings academic, research perspectives to study of botanicals

July of 1995 was a big month for the fledgling National Center for Natural Products Research (NCNPR). Founded by an act of the U.S. Congress in 1988 to discover, develop and commercialize natural products as pharmaceuticals and agrochemicals, the center, at the School of Pharmacy at the University of Mississippi in Oxford, Miss., had just opened its doors.

What the future held was uncertain, even as the small staff started work to create the premier research facility for the study of natural products and botanicals.

Twenty-two years later, NCNPR, with nearly 100 on its staff, has established itself as a renowned, one-of-a-kind academic and research facility. Its partnerships with the U.S. Department of Agriculture and the U.S. Food and Drug Administration (FDA) have led to its leadership role as the only university-affiliated research center devoted to improving human health and agricultural productivity, including its work

in helping ensure the identification and quality of dietary ingredients and botanicals.

The formal partnership with FDA forged in 2001 was particularly important and led to the first International Conference on the Science of Botanicals (ICSB) that year and the creation of the Center of Excellence on Botanical Dietary Supplement Research (COE) in 2006. The center uses medicinal plant resources, from seed banks to greenhouses to field plots, to study plant chemistry in relation to genetics, botany, pharmacology, toxicology and agronomics.

The annual ICSB, held each spring in Oxford, brings together academics, researchers, scientists and natural products industry representatives from around the world to discuss issues related to medicinal plants and dietary supplements. It is the only such event each year that includes the sponsorship by and active participation of FDA, where its team members, including executives from the Office of Dietary

Supplements, share their perspectives on regulatory and research-related issues.

"The Center of Excellence has accomplished a great deal since its creation," said Ikhlas A. Khan, director of the COE and NCNPR. "We established a repository focused on medicinal plants and a 'living collection' of botanicals. We have also contributed research that has helped the FDA to make regulatory decisions."

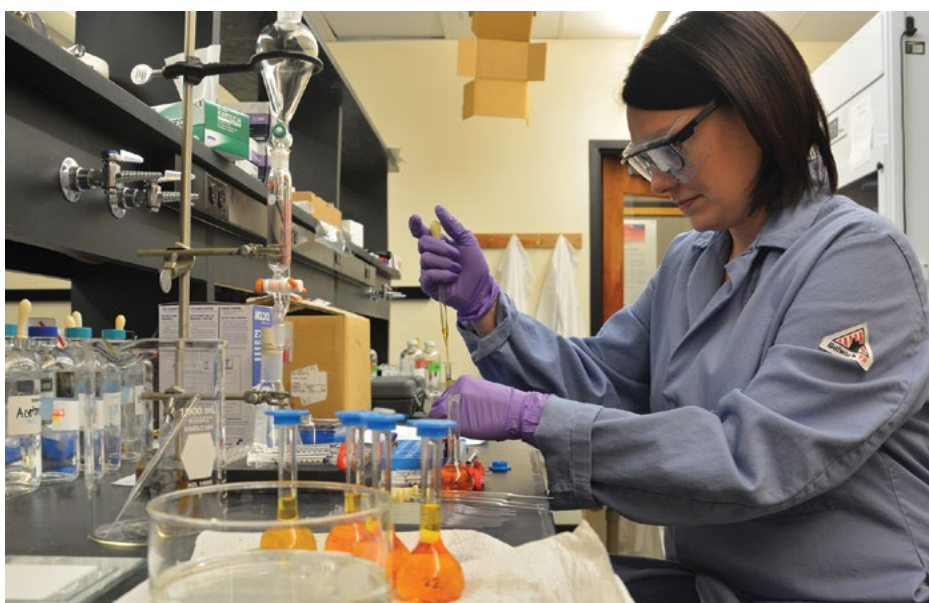
State-of-the-Art Training

Part of the work of the COE includes the training of FDA field inspectors, who are tasked with visiting and reviewing the hundreds of facilities across the U.S. that produce dietary ingredients and dietary supplements. To date, the program has trained more than 600 inspectors.

In 2015, NCNPR celebrated the opening of The Thad Cochran Research Center West Wing, part of the NCNPR complex on the university campus. The following year, the center opened its Natural Products Training Center, which includes five laboratories covering 3,000 square feet with state-of-the-art analytical equipment donated to the center by UNPA member Waters Corp., based in Milford, Mass. The Training Center provides hands-on training in plant taxonomy, laboratory analytical techniques and quality standards for botanical products, including guidance in good manufacturing practices for dietary supplements.

"This training lab was created while keeping the future of the dietary supplement industry in mind," said Khan. "This will be a great resource for people to get hands-on training and develop the skills to implement good manufacturing practices."

For more information on NCNPR, visit www.pharmacy.olemiss.edu/ncnpr.



Amber Reichley, a physical science technician, works in Charles Cantrell's USDA Natural Products Utilization Research Unit laboratory at the NCNPR. UM photo by Sydney Slotkin DuPriest.

American Herbal Pharmacopoeia promotes responsible use of herbal medicines



Roy Upton

In the mid-1990s, as the market for herbal medicines in the United States continued to grow, it was clear to noted herbalist Roy Upton that independent standards of identity, purity, quality and testing needed to be developed to ensure the safety and efficacy of botanical dietary supplements, which are relied upon by ever-increasing numbers of people worldwide.

This thinking became the primary mission of the American Herbal Pharmacopoeia (AHP). Founded in 1994, AHP works to promote the responsible use of herbal medicines. AHP accomplishes this by producing some of the world's most comprehensive and critically reviewed botanical quality-control monographs, each of which also contains a therapeutic compendium detailing the efficacy and safety of the botanical.

AHP, like other pharmacopoeial organizations, also provides testing laboratories with authenticated botanical reference materials that can be used to make sure that ingredients bought commercially are what they are expected to be.

Resurrecting classical methods

A key purpose of each monograph is to re-establish the importance of classical botanical pharmacognosy in herb-quality assessment that takes into account growing habitat, harvest practices, drying conditions and environmental impacts. This is contrary to most modern botanical assessments that primarily focus on chemical analyses.

In addition to resurrecting, rekindling, and codifying knowledge of traditional herbal and classical pharmacognosy practices,

Upton spends a great deal of time defending the rights of consumers to access herbal medicines and to see these medicines integrated into the fabric of the health care system.

"In almost every country on earth, with the exception of the United States, herbal medicine is regarded as an integral part of the formal health care system," he said. "A great example is Asia, where Traditional Chinese Medicine is a readily available option for those that choose it. America has little access to some of the most valuable systems of healing and is stuck in the conventional disease-care model. Americans literally have little access to true health care, which is well represented and is a focus of Asian healing systems."

To date, AHP has published 39 monographs fully characterizing approximately 50 different botanicals, which includes some of the most common herbal ingredients, such as *Ginkgo biloba*, American ginseng, echinacea, reishi mushrooms and cannabis. AHP plans to develop at least 300 monographs, which will cover the largest percentage of the most widely used Western, ayurvedic and Chinese botanicals that are used in the U.S.

Broad collaboration

A typical monograph can take as long as three years to complete and requires the work of many volunteers with



wide-ranging expertise, including botany, chemistry, pharmacognosy, pharmacology, toxicology and traditional healing systems. Each monograph undergoes an extensive peer-review process with contributions from collaborators throughout the world, including strong representation from Asia.

"AHP's primary role is to bring together the breadth of traditional and scientific botanical medicine knowledge, including examinations of quality, efficacy and safety, into one monograph," said Upton. "We are both rebuilding an herbal tradition that is otherwise not accessible to most Americans and simultaneously creating a model that can be emulated worldwide. In the process, we are creating a synthesis of traditional and scientific knowledge and giving equal respect to both sources of knowledge."

For more information, visit www.herbal-ahp.org.

Who's your PCQI? An Introduction to PCQI

By Loren Israelsen

If an FDA investigator or one of your major customers were to ask, "Who is your PCQI?" (Preventive Controls Qualified Individual), how would you answer?

Preventive Controls for Human Foods is one of seven provisions of the Food Safety Modernization Act (FSMA), the most sweeping reform of the food safety laws in the United States in more than 70 years. According to the Food and Drug Administration (FDA), FSMA aims to "ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it."

FSMA is also the key to a new generation of food good manufacturing practices (GMPs) based on the Hazard Analysis Critical Control Point (HACCP) principles of "anticipate, prevent and validate." Within the Preventive Controls for Human Food rule, a PCQI is required for all companies that manufacture foods and dietary supplements, outside of a couple of specific exemptions, including companies that manufacture or sell seafood, juice, low-acid canned food, and Code of Federal Regulations Title 21 Part 111-compliant dietary supplements.

The Preventive Controls (PC) is the process, and the PCQI is the person or persons trained to devise, implement and execute the preventive controls developed through a food safety plan.

Who needs to have a PCQI?

If you produce, transport, distribute, warehouse or sell any products that require a Nutrition Facts or Supplement Facts label on products sold in the United States, you are strongly advised to complete PCQI training. See "Who is required to have a PCQI on staff" in the "Frequently asked questions about PCQI" at right for a complete list of PCQI training requirements.

How PCQI training works

1. Companies designate at least one individual responsible for the preventive control food safety plan and its implementation.
2. A PCQI is required to have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or as otherwise qualified.
3. The standardized, curriculum-based course is 2.5 days with active student participation.
4. Class size is capped at 15 people per instructor.
5. The coursework is standardized and approved by an independent body, the Food Safety Preventive Controls Alliance (FSPCA), a non-profit organization recognized by FDA to oversee PCQI training.

6. PCQI graduates receive a certificate of training, *which is specific to the PCQI*, not the company. Thus, if your PCQI leaves your company or is on leave for any reason, you need to designate and train another PCQI.
7. The PCQI is now responsible to create, implement and maintain compliance through the food safety plan that begins with PCQI training.
8. Each facility (not company) must have at least one PCQI.
9. A food safety plan is specific to each product type, and it is not uncommon for one facility to have multiple food safety plans.
10. The compliance date for PCQI implementation is dependent on the company size, and large companies were required to have a PCQI on staff as of September of last year.
 - Large companies (>500 employees): September 2016
 - Small companies (<500 employees): *September 2017*
 - Very small companies (<\$1 million in annual sales, but this includes the value of your inventory): September 2018

UNPA offers PCQI trainings

Clearly, thousands of conventional food and dietary supplement/dietary ingredient companies require training to be in compliance with these federal regulations—a huge task. In response, UNPA offers PCQI training in specific locations as well as onsite training for individual companies. Please visit www.unpa.com/ABOUT/Education-Training for information on upcoming UNPA PCQI trainings.

There are other parts of FSMA that require a qualified individual with separate training, such as the Foreign Supplier Verification Program (FSVP). We will be offering FSVP training starting in the fall of 2017.

UNPA has set FSMA compliance as a high priority. We are doing all we can to provide the tools, the training and the resources for industry companies to be FSMA compliant. Our goal is to have a 100-percent FSMA-compliant membership within the next 12 months. We hope we can help you become FSMA compliant, too.



Loren Israelsen is the president of the United Natural Products Alliance and has been deeply involved in the commercial, political and regulatory issues facing the global dietary supplement industry since 1980. He also served as general counsel and president of Nature's Way Products Inc.

Frequently asked questions about PCQI

Compiled by the UNPA staff

What is a PCQI: PCQI (Preventive Control Qualified Individual) is an individual(s) on your staff whom you've designated to be responsible for the preventive control food safety plan and its implementation. It's a requirement of the Food Safety Modernization Act (FSMA). A PCQI has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or as otherwise qualified.

What is FSMA: FSMA (Food Safety Modernization Act) is the most sweeping reform of the nation's food safety laws in more than 70 years. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it, based on Hazard Analysis Critical Control Point (HACCP).

What is Preventative Controls for Human Foods: Preventive Controls for Human Foods is one of seven provisions of FSMA and the key to a new generation of food Good Manufacturing Practices (GMPs), based on the HACCP principles of "anticipate, prevent, validate."

What are Preventive Controls: The Preventive Controls (PC) is the process, and Preventive Control Qualified Individual (PCQI) is the person trained to implement the preventive controls developed through a food safety plan.

Who or what falls under the PCQI requirement: All food products, wherever they are from, that are consumed in the United States. Note: Some companies are exempt (seafood, juice, low-acid canned food, and Section 111-compliant dietary supplements).

Who is required to have a PCQI on staff: A food company, brand holder or contract manufacturer that manufactures, packages, holds or distributes a food product using a Nutrition Facts panel is required to have a PCQI. This includes manufacturers of natural food products and functional foods, such as protein shakes and 'power' bars.

In the U.S., dietary ingredients (raw materials) are classified as a food, and therefore suppliers of these ingredients are subject to the full requirements. These suppliers include companies providing botanical powders used in dietary supplements, such as echinacea, ginkgo, and others. Any company selling or distributing a finished dietary supplement product would be expected to qualify their suppliers of these ingredients to ensure they are compliant with the new regulation.

Companies and products using the Supplement Facts panel are required to ensure that all of their ingredient suppliers—including all foreign suppliers—have at least one PCQI on staff. Therefore, it is highly recommended that each finished supplement manufacturer or distributor be fully educated about PCQI so that they can qualify their entire supply chain as required by FSMA to eliminate or prevent hazards from being introduced into the food supply.

Does every manufacturing facility need to have a PCQI: Yes, each facility (not company) must have at least one PCQI. It's important to note that each product must have its own Food Safety Plan in place.

What is a Food Safety Plan: A Food Safety Plan (FSP) is specific to each product type, and it is not uncommon for one facility to have multiple food safety plans. The PCQI is now responsible to create, implement and maintain compliance through the food safety plan that begins with PCQI training.

When do you need to have a PCQI on staff: The compliance date for PCQI implementation is dependent on the company size:

- Large companies (>500 employees): September 2016
- Small companies (<500 employees): *September 2017*
- Very small companies (<\$1 million in annual sales, but this includes the value of your inventory): September 2018

When is the next PCQI training offered by UNPA: Please visit www.unpa.com/ABOUT/Education-Training for information on upcoming UNPA PCQI trainings. UNPA is now offering onsite corporate PCQI training, which offers an efficient and cost-effective means for companies to get their staff and even their supply chain in compliance.

Are there additional required trainings to meet the compliance standards: Yes, there are other parts of FSMA that require a qualified individual with separate training, such as the Foreign Supplier Verification Program (FSVP). UNPA will be offering FSVP training starting fall 2017, as well.

Is the PCQI training standardized: Yes, the coursework is standardized and approved by an independent body, the Food Safety Preventive Controls Alliance (FSPCA), recognized by FDA to oversee PCQI training.

Practitioners show increased engagement with botanicals and supplements

Highlights of *Holistic Primary Care's 2016 Practitioner Survey*

The desire for non-pharmaceutical alternatives to promote health and prevent or ameliorate disease has driven growth in all segments of the dietary supplement and natural products industries, most notably in the healthcare professional segment.

According to recent research from *Nutrition Business Journal*, practitioners accounted for 9% of overall supplement sales across all channels in 2015, generating approximately \$3.5 billion in revenue. Though the channel still represents a small slice of the total sales, *NBJ* says it has maintained steady growth rates of 7% to 9% over the last decade, outpacing growth in all other channels.

This is attracting new clinicians to the space, with more than half of the survey's responding clinicians reporting they are new to the practice of integrative medicine.

Brand Opportunity

Practitioner brands have traditionally built their businesses around the needs and practice models of chiropractors, naturopathic physicians and "alternative" medical doctors (MDs). While these categories are likely to remain cornerstones of the channel, it is now clear that other practitioner groups, specifically mainstream MDs that sell supplements, are growing in influence, scope of practice and size.

The practitioner channel is also an increasingly attractive proposition for supplement and natural product brands, offering strong growth, premium pricing, relatively few competitors and an opportunity to leverage basic science.

With these themes in mind, *Holistic Primary Care's 2016 Practitioner Survey* here shares a small sample of top-line findings to help industry stakeholders better understand practitioner engagement and make more informed, data-driven business decisions.

In this year's cohort, a majority of practitioners are in solo or small-group practices and more typically require cash payment rather

than taking insurance. Nearly half of the respondents report they are considering major changes to their practice models and looking for new streams of revenue, including dispensing supplements.

It is not surprising that a large majority of these practitioners (more than 80%) are engaging in nutrition counseling to some degree. Their interest in botanical medicine has been growing within the sector over the last decade. Two-thirds of this year's respondents (64%) say they utilize herbs in their practice, up from 53% in 2015 and 23% in 2013. The reasons for this shift are not entirely clear but likely reflect patients' desires for non-pharmaceutical treatment options, as well as growing scientific support for herbs such as turmeric.

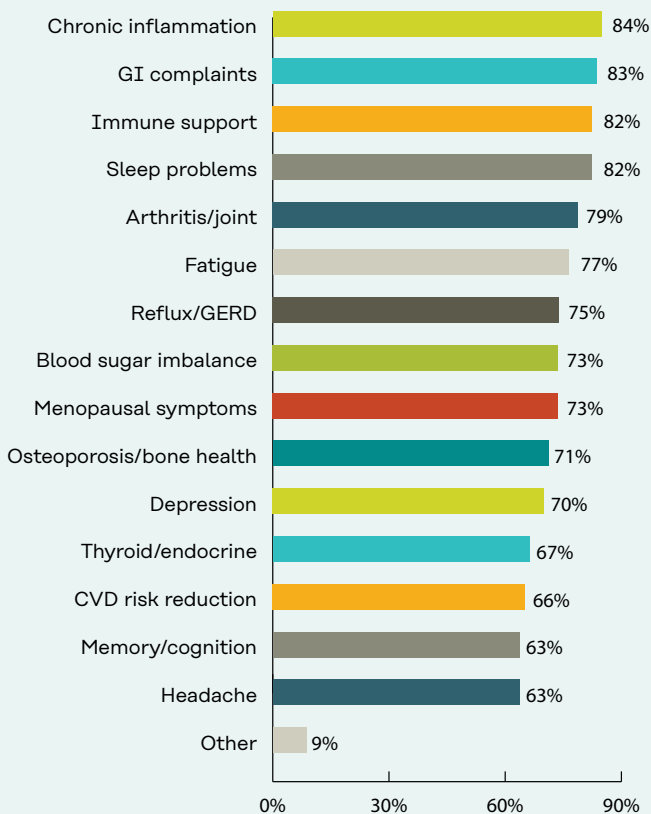
Use of herbs is strongest among naturopaths (95%), but 61% of the conventionally trained MDs, 53% of chiropractors, and 50% of registered dietitians (RDs) are using botanicals to some degree. Use was much higher at 77% among non-RD nutritionists.

Prevalence of dispensing supplements varies by practitioner type: It is highest among naturopaths (87%), chiropractors (86%) and non-RD nutritionists (81%).

One of the most troubling findings this year is that nearly 60% of responding practitioners are not familiar with the landmark law governing supplements in the U.S., the Dietary Supplement Health and Education Act of 1994 (DSHEA). Among those who do recognize DSHEA, confidence in the law is weak, with only 9% calling it effective in ensuring supplement safety and protecting the public, and 19% saying the law needs major revision.

For more information about HPC's practitioner surveys, visit www.tpcforum.com/practitioner-survey.

Conditions for which practitioners use supplements



Collaborative program seeks to help remove adulterated botanicals from supply chain

A partnership among two leading non-profit organizations and a major university in the United States seeks to educate and inform the herbal and dietary supplement industry about adulteration of botanical ingredients, whether accidental or intentional, and to help industry identify and remove adulterated ingredients from the supply chain.



Mark Blumenthal

The American Botanical Council (ABC), the American Herbal Pharmacopoeia (AHP) and the University of Mississippi's National Center for Natural Products Research (NCNPR) partnered in 2010 to create the ABC-AHP-NCNPR Botanical Adulterants Program (BAP).

With year-to-year growth in the botanical supplements market, the herbal and dietary supplement community has become increasingly aware of suspected and confirmed practices of adulteration of botanical raw materials, extracts, essential oils and finished, botanical-based consumer products.

Adulteration instigated the industry-funded BAP, which serves as an important self-regulatory mechanism

for industry to address adulteration problems through education rather than federal regulation.

Adulteration of botanical ingredients can be accidental or deliberate, as a result of poor quality-control procedures, lack of adequate training, and/or the intentional adulteration of plant-based products for financial gain.

Detecting Adulteration

"Our objective is to educate industry members about the presence of adulterated

botanical materials and how to detect and avoid it," said Mark Blumenthal, founder and executive director of ABC and director of the BAP. "Our publications are used by many industry members when developing specifications for their botanical ingredients to help ensure high-quality products, properly labeled for consumers."

The BAP is a long-term, multi-party coalition of botanical quality and identity experts in university research groups, third-party analytical laboratories, government agencies, trade associations and industry companies, who examine the extent of suspected adulteration of herbal materials, particularly adulteration



Black cohosh is one of the herbs with a BAP Laboratory Guidance Document

that is economically motivated. The goal is to confirm the extent of adulteration in the United States and global markets, determine which official or unofficial analytical methods are currently available to help detect the presence (or absence) of a suspected or known adulterant and to provide comment and guidance on the relative strengths and/or weaknesses of differing analytical methods. The results of these investigations are published in a series of reports and are available at no charge on the BAP website.



BAP publishes Laboratory Guidance Documents that identify the most suitable analytical methods for detection of certain adulterants and authentication of specific botanical materials in all the available forms. Positive assessments of analytical methods are based on a thorough review of available methods from official compendia and other reliable sources, in addition to the relevant methods in the published, peer-reviewed literature. Currently, four Laboratory Guidance Documents have been published on bilberry fruit extract, black cohosh, skullcap and grapefruit seed extract.

BAP also publishes a series of reviews on adulteration of specific botanical ingredients, called the Botanical Adulterants Bulletins, to keep industry personnel and laboratories informed of adulteration problems in a timely manner. There are currently 10 bulletins published covering the adulteration of various popular herbs in international commerce.

"Compared to our extensive Laboratory Guidance Documents, the Bulletins are a more rapid means of confirming suspected and/or alleged adulteration and have become the key publications in the program's educational activities," Blumenthal said.

To access the BAP documents mentioned above and for more information, visit cms.herbalgram.org/BAP/index.html. All the BAP information is free-access; registration on the ABC site is required.



A TALE OF CONSUMER TRUST

U.S. consumer perceptions about supplements are mixed, but it's still a call to action

By Rick Polito

Trust is a block, even a cornerstone, in the foundation of any industry. In supplements, it is the foundation.

That foundation, *Nutrition Business Journal* (NBJ) consumer research suggests, has some cracks. Whether they spread, or the mortar weakens, becomes the biggest shadow darkening the industry today. How that foundation can be strengthened becomes the biggest question.

But the troubling nature of the results cannot be questioned at all.

NBJ and New Hope Network surveyed 500 people. Among the most troubling responses for supplements was the category's "trust" ranking among various industries and professions. The question was posed as, "How trustworthy are the following industries or institutions?"

Supplements did not fare well.

Respondents rated supplements' trustworthiness above only big business and the U.S. Congress. Only 39 percent rated supplement makers trustworthy or extremely trustworthy. Nobody paying attention would expect supplements to wedge into the upper rungs with police and small business owners, but to see the supplement industry ranked below broadcast news, and more importantly, pharmaceuticals, is troubling, indeed.

What it tells Martha Rogers, author of the book *Extreme Trust*, is that the industry needs something like a bucket of cold water thrown in its face. It could be just the beginning. Trust was a marketing mission before. With consumers getting access to more information than at any time in history, trust has to be a reality built into every link in the supply chain and every step in the manufacturing process. Fail that test, said Rogers, and "the age of transparency means

that (the industry's trustworthy ranking) will be lower than this sooner or later."

Tipping point?

Indeed, the numbers suggest a certain precariousness to the public's trust. Just 47 percent of supplement users think the industry has strict control of what is in their products. Only half think the industry follows strict regulations. Worse yet, the share of supplement users that think supplements are safe because supplement makers are following strict quality and testing guidelines is just 39 percent. A troubling 59 percent think there could be undisclosed ingredients in their supplements.

Those numbers aren't necessarily tipping points, but they certainly look like tipping points.

Whatever they look like, they suggest urgency to Mike Archbold, former CEO of

retailer GNC. In November 2016, Archbold and GNC announced an industry coalition to establish safety standards and proposed a product database and mandatory good manufacturing (GMP) certification to make it onto GNC shelves. He wanted to see more action and less discussion. "When do we need to do it? To me, it's right now," Archbold said. "This can't be a multi-year protracted process for us to get there."

Too much of the discussion, Archbold complained, has been inside the industry. The story, coupled with concrete action, has to go out to the public. "There might be those in the industry who would say we already do this, and we're good. Well, if the consumer doesn't believe it then that's the reality. Consumer perception is reality."

That perception sounds a complicated alarm. Only 43 percent of those surveyed believe the industry has clear and honest motives, and 45 percent think the industry is honest and upfront about product benefits. At the same time, an incongruous 68 percent think the industry is continuously trying to make those products more effective, and 66 percent believe the industry is trying to improve the quality of ingredients. Slightly

fewer, 64 percent, believe the industry is attempting to make products safer.

Those results may be mixed, but they are also encouraging, Rogers said. Making the industry better is better for every manufacturer, she said. If people believe the effort is real, they may accept more of the good news the industry can share. Referring to the 50 percent of consumers that think the industry follows strict regulations, Rogers contends that "if we could get that number up to 90 percent ..., "trustworthiness would be "a given."

"In a perfect world, it's not even a differentiator anymore," Rogers said.

That benefits the whole industry, with the companies leading the effort possibly benefitting the most, she said. Leaders in transparency and trust are going to be recognized, and with recognition comes familiarity. That familiarity is a valuable commodity. "One of the things that we learn in communications is that familiarity all by itself makes people feel better about something," Rogers said, offering the scenario of a small town with three restaurants, one of which has a billboard on the highway. Stop for a meal and "the one

that you saw the billboard for is probably the one you will go into because at least you've heard of it before."

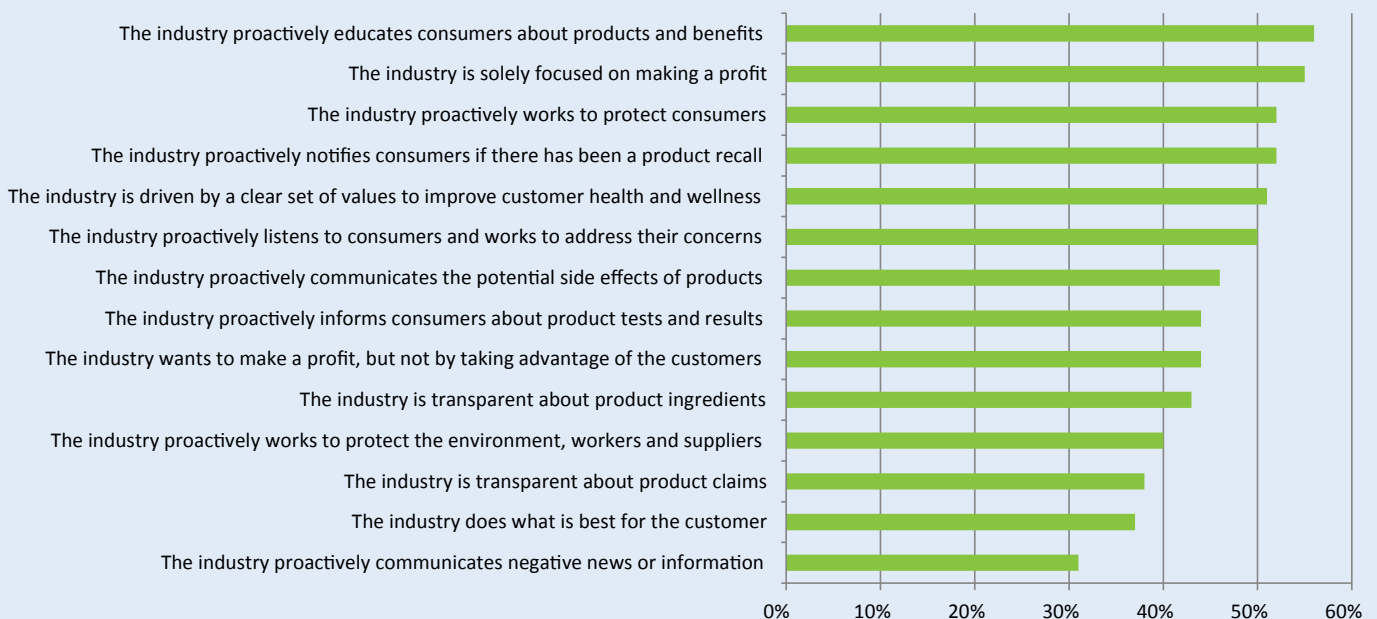
Tying familiarity to high-profile efforts at industry wide reform creates a powerful combination and offers a spot on the first wave in a rising tide that could grow the entire industry.

Collective dysfunction

Peter Wennstrom at the Healthy Marketing Team agrees with the potential for the rising tide, but says the effort that drives it has to be tidal itself. It can't be one company trumpeting its efforts. It has to be the whole industry working together or even category leaders doing the heavy lifting without emphasizing their brands. Several companies are in a position to do that, he said. It's to the industry's and the companies' benefit. "If the proverbial pie grows and you are the market leader, then of course your share grows the most."

That doesn't make it simple. Wennstrom's company has a global focus, and he sees mistrust of supplements in most markets. He just sees it more in the U.S. customers. "It's a bigger problem in the U.S., because you have bigger villains there,"

To what extent do you agree with the following statements about the supplement industry?



Source: NEXT & NBJ Survey conducted Q1 2016

Wennstrom said, referring to America's megacorporation business culture. He also observes an endemic case of paranoia. "You always suspect there are schemes and plans behind your back."

Part of the answer, Wennstrom believes, is emphasizing quality of ingredients over claims. The battle for claim supremacy has "commoditized" a market that should be built on quality and integrity, Wennstrom said. Though *NBJ* data suggests brands can have a significant trustability advantage—67 percent rate premium brands as trustworthy or extremely trustworthy—Wennstrom doesn't see the relationship between brand and customer as exceptionally strong in supplements. He recalled a study that looked at the strength of the relationships between customers and brands that ranked supplements against other categories. "Batteries have a stronger relationship than supplements in the U.S.," he said.

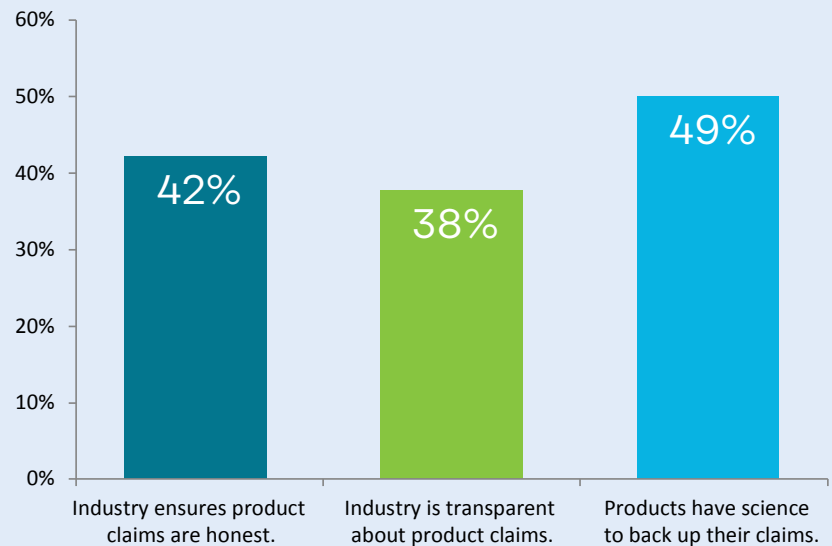
Promoting quality over claim, Wennstrom added, is the way to bake that bigger pie. It can't be companies promoting their brand over others, either. Telling the quality story across the whole industry is "not cheap," he said, but it's essential. "If you don't get your act together, your piece of the pie shrinks."

Signed and sealed

For Rogers, the quality story has to be written in shorthand. That could be the retailer—"I depend on Whole Foods Market to kind of pre-screen stuff for me," she said—but she would like to see it right on the label. She is surprised that third-party certification made so little difference for consumers in the *NBJ* survey, but says the story has to be told quickly and simply. "If we were able to give consumers one clear thing that made it possible for them to know the difference between 'This one is ok' and this one 'might not be ok,'" that's all we are going to be able to teach people."

The *NBJ* survey respondents ranked third-party certifications or seals second to last among attributes that drove their supplement purchases, just above sales or promotions. For Rogers, that

Supplement users thoughts on product claims



Source: NEXT & NBJ Survey conducted Q1 2016

means the education effort has not been well developed.

That's part of what Michael O'Hara at Underwriters Laboratory (UL) is seeing. UL is developing an information system to allow customers, retailers and manufacturers to see, among other things, what's in the products and where it was sourced. UL is famous for its seal, but a certification program is not in the plans.

Perhaps people don't base decisions on the seals because they don't know what they mean, O'Hara contended. Whatever the reason, the seals have not changed the game. "Some of these programs have been around for 12-plus years. Have they solved the problem that the industry is facing? I don't know," O'Hara said. "It doesn't seem like it."

O'Hara said UL's information platform plan, that may happen in conjunction with the Council for Responsible Nutrition's product registry or GNC's database, could offer deeper information more appropriate to a digital age. "It's a new story to tell," he said.

Whatever happens, O'Hara added, it has to be industry wide. "If it is companies across the industry that support that, you've got many different channels to promote the

good work. You've got more hands to pull and push."

That fits Archbold's thinking. Having every product in a registry or database highlights credibility for every manufacturer. "That's a giant leap forward," he said. It's also part of a new storyline that could build trust. The story has to be true and it has to be told. Steps have been taken, but pushing the tipping point in the other direction will mean more work and more voices telling the story.

Nobody is going to listen to that story when it's just a plan, Archbold said. That's merely a conversation inside the industry. It only becomes a story when it becomes true, when it goes beyond intention into evidence and action.

The time to get started was years ago. The time to lean in is right now, he said.

"Change is coming," Archbold said. "And the best way to deal with it is to initiate that change."



Rick Polito is the editor-in-chief of *Nutrition Business Journal*, an executive market-intelligence publication produced by New Hope Network, a division of Informa Exhibitions. For more information, visit www.newhope.com/nbj.