



AND  
LISTENING  
LEADING

 **CRN**

COUNCIL FOR RESPONSIBLE NUTRITION

*The Science Behind the Supplements*

**2018 ANNUAL REPORT**



# Thank you, members!

This year's annual report comes with a healthy dose of pride. The CRN team accomplished so much toward our mission in 2018, and I trust you will agree, browsing these pages, that we made the world a better place for the dietary supplement and functional food industry as well as for our consumers who depend on our products as mainstays in their wellness regimes.

But none of our success would be possible without you, our member company executives, who share not only in our wins, but in our work. With your input and your engagement, not just your membership dues, we thrive and make the most impact. You'll see in this report specifics of how CRN responded in 2018 to member feedback received via a late-2017 survey, alongside our other achievements for the year.

Thank you for your participation. We look forward to continuing to grow the association and to doing even more with your help.


Please don't hesitate to reach out to our staff, listed on the back of this report, with your questions or comments. We love hearing from you.

Also, we invite you to see us face-to-face at one of our many in-person events held throughout the year—especially our premiere educational and networking events, *The Workshop: CRN's Day of Science* and *The Conference: CRN's Symposium for the Dietary Supplement Industry*, taking place Nov. 6–9, 2019, in Carlsbad, California.

With gratitude,



Steve Mister



**Steve Mister**  
President & CEO  
Council for Responsible Nutrition

## LISTENING TO YOU

CRN followed up on insights learned from a member survey conducted in November 2017 as it shaped additional services and programming. In this report, we'll highlight ways CRN listened to its members and took action. Details of these efforts are also available on CRN's website: [www.crnusa.org/WeHearYou](http://www.crnusa.org/WeHearYou)



The CRN Board of Directors ratified a new three-year strategic plan for the organization for 2018–2020. The plan is the result of nearly a year’s effort by CRN’s committees, Board, Executive Committee and staff. CRN’s work in 2018 fell under the framework of this plan to:

### **Expand self-regulatory initiatives.**

Goal: Promote self-regulatory initiatives that demonstrate an industry-wide commitment to accountability and responsible behavior to maintain and improve consumer confidence.

### **Influence public policy on nutrition and health as it impacts dietary supplements and functional food.**

Goal: Build and maintain a positive legislative, regulatory and commercial environment for nutritional products to foster consumer confidence and industry growth.

### **Foster excellence in nutrition science.**

Goal: Identify and promote best practices in the design, execution, interpretation and acceptance of research that evaluates the benefits and safety of nutritional products and their ingredients.

### **Influence public perception of science-backed nutritional products.**

Goal: Improve the public perception and understanding of the safety and benefits of science-backed nutritional products to promote a positive industry image.

### **Elevate the industry and build association resources through broad membership growth.**

Goal: CRN is widely recognized as a valuable provider of programs and services to all aspects of the industry while generating necessary resources for CRN and industry growth.

## **BROAD MEMBERSHIP GROWTH**

Adding to CRN’s roster of responsible member companies is key to sustaining and growing the association. CRN welcomed these companies into its membership in 2018:

#### **VOTING MEMBERS**

Care/of  
Cypress Ingredients  
DSE Healthcare Solutions, LLC  
International Dehydrated Foods, Inc.  
Inventia Healthcare Ltd.  
Kappa Bioscience  
Kerry Taste & Nutrition  
Lief Organics  
Linden Capital Partners  
Matrixx Initiatives, Inc.  
MeriCal, LLC  
Mito-Q  
NattoPharma USA  
Nelson Bach USA, Ltd.  
Neves Global Resources, LLC  
NuLiv Science USA Inc.  
OMG! Nutrition  
Quincy Bioscience  
Ritual  
Solmic Research USA  
Swisse Wellness  
Wellisen Nutraceuticals

#### **ASSOCIATE MEMBERS**

BakerHostetler, LLP  
Banned Substance Control Group  
Carter Regulatory Group  
M. Vicinanza Consulting, LLC  
Microbac Laboratories, Inc.  
PTM Food Consulting  
RLA Collective, A Ruder Finn Company  
Susan B. Levy Consulting, LLC  
ToxStrategies, Inc.  
Vanteres, Inc.  
Yuyama

**CRN’s mission is to sustain and enhance a climate for our members to responsibly develop, manufacture and market dietary supplements, functional food and their nutritional ingredients.**



# Evolution of the **OWL**

The *Supplement OWL*<sup>®</sup> continued to grow and evolve as more companies uploaded their labels to the industry-wide product registry. Acknowledged as CRN's greatest achievement in its quest to "BE CHANGE" by outgoing board chairman Jim Hyde in his address at the association's annual conference in October, the *Supplement OWL* closed the year with 11,895 labels.

In addition to its ongoing push to boost industry participation, in 2018, CRN expanded efforts to attract retailer attention and augment the information in the registry. CRN launched the Consumer Data Exchange (CDX), allowing for documentation demonstrating compliance/adherence in key areas including: evidence of third-party cGMP audits/inspections; finished product testing/certifications; product attributes, such as non-GMO, gluten-free, allergen-free, halal, kosher, etc.; post-market surveillance statements, such as an adverse event reporting letter of compliance signed by senior regulatory staff; FDA-assigned structure-function claim notification numbers; and more. CRN introduced a pilot program allowing companies to test drive the CDX and provide experience-based feedback to enhance its usability and function.

*Supplement OWL* participation is now a requirement for CRN membership—every member company with finished product labels in the market is in the registry. As Mr. Hyde said, we've secured our position as industry leaders and change-makers.



## INDUSTRY-WIDE GROWTH

As of December 2018:

**11,895 labels submitted**

**9,541 visible** (2,354 under review)

**89 brands**

**5,114 CRN member labels (54%)**

**40 CRN member companies**

**57 CRN member brands (64%)**

## BROAD EXPOSURE

Mentioned in 12 articles and one byline, including:

**The Illegal Ingredients in Your Dietary Supplements**

Wall Street Journal, October 22, 2018

**Harvard study: Avoid Supplements with Higenamine**

USA Today, September 6, 2018

**If We Build It, They Will Come: Supplement Databases for Industry Stakeholders**

Natural Products Insider, October 26, 2018

**The Online Wellness Library (OWL): An American Approach to Transparency and Responsibility**

IADSA Connect, May 2018 edition







**Jim Hyde**  
 Vice President &  
 General Manager,  
 Balchem Corporation,  
 CRN Board Chair,  
 2017-2018



**3 STEPS:**

1. Read and understand the Terms and Conditions for the Supplement OWL. You will need to first register, or log in if you are already registered. More on steps >
2. Learn what product and label to...
3. Determine the best method to...

**10,000+ Labels**  
 As of April 2018, more than 10,000 supplement labels are uploaded to the Supplement OWL.

**SUPPLEMENT OWL**

SEARCH RESULTS: 48 Results

Product Information	Product Name	Product ID	Product Description
Allegri (Menthol) / Cream	OTC/MALACAL CALADOL OTC/MALACAL	100119300	OTC/MALACAL CALADOL OTC/MALACAL
Allegri (Menthol) / Cream	OTC/MALACAL CALADOL OTC/MALACAL	100119300	OTC/MALACAL CALADOL OTC/MALACAL
Allegri (Menthol) / Cream	OTC/MALACAL CALADOL OTC/MALACAL	100119300	OTC/MALACAL CALADOL OTC/MALACAL

**CRN @CRN\_Supplements · Nov 9**  
 Great session at #SSWExpo on two #dietarysupplement databases. CRN's Duffy MacKay shares more information about how the #SupplementOWL is an important resource for the industry. #SSW18



**CRN spoke about the Supplement OWL to key stakeholders, including:**

**Gisele Atkinson**  
**Shopping for Health Webinar**  
 Presented to retail dietitians  
 October 11, 2018

**Gisele Atkinson**  
**CRN Conference Presentation**  
 Presented to industry  
 October 18, 2018

**Duffy MacKay**  
**SupplySide West Presentation**  
 Presented to industry  
 November 9, 2018



# EXPANDING SELF-REGULATORY INITIATIVES

In addition to the major growth of the *Supplement OWL*, CRN expanded other self-regulatory initiatives and supported fellow stakeholder groups' efforts to raise the bar for quality.

## Update of 'Caffeine-containing Dietary Supplement Guidelines'

The association expanded the guidelines to include concentrated liquid forms, as outlined by an FDA guidance released earlier in the year.

## Release of 'Recommended Guidelines for SARMs-Containing Dietary Supplements'

Coinciding with FDA's announcement that products containing Selective Androgen Receptor Modulators (SARMs) do not meet the definition of a dietary supplement, CRN's guidelines urge responsible firms not to distribute or market products containing these ingredients.

## 'Best Practices Guidelines for Probiotics' go into effect

CRN reminded members that the science-based best practices guidelines for the labeling, storing and stability testing of dietary supplements and functional foods containing probiotics, released with the International Probiotics Association (IPA) in 2017, are now fully in effect for CRN members.

## Release of 'SIDI Protocol 3.0'

CRN, leading the Standardized Information on Dietary Ingredients (SIDI™) Work Group, released the SIDI Protocol version 3.0, providing a standardized format for dietary ingredient suppliers to communicate consistent regulatory and quality information on their ingredients and facilities to inquiring manufacturers. The SIDI Work Group is a joint initiative of three dietary supplement industry trade associations—CRN, the Consumer Healthcare Products Association (CHPA) and the United Natural Products Alliance (UNPA)—along with dietary supplement ingredient suppliers and finished product manufacturers, to strengthen the industry's self-regulatory practices. The 3.0 release included press outreach, a bylined article, social media content and on-site promotion at industry events.

## Exposure in the scientific literature

CRN's James Griffiths, Ph.D., co-authored an article published in the journal *Clinical Pharmacology & Therapeutics* examining how the dietary supplement industry drives self-directing initiatives to demonstrate their position as responsible corporate citizens, meeting the needs of the ever-growing body of wellness-seekers.



**“CRN trusts that the dietary supplement industry will adopt these two sets of crucial guidelines into its standard operating procedures. As the marketplace continues to grow and innovate, we lend our full support to FDA’s proactive enforcement efforts to improve consumer safety and industry accountability.”**

—Steve Mister

CRN's press release

*CRN Voluntary Guidelines Reinforce Industry Commitment to Consumer Safety*

**NEW 3.0 RELEASE NOW AVAILABLE**

Learn how the new Standardized Information on Dietary Ingredients (SIDI™) Protocol can help streamline ingredient qualification.

**“Industry Actions to Address Quality Issues for Dietary Supplements, Botanicals, and Other Natural Products”**



## INDUSTRY-WIDE COLLABORATION

CRN hosted industry representatives at its annual conference to discuss their respective programs (pictured above, seated left to right):

**Mark Blumenthal**, founder & executive director, American Botanical Council (ABC), discussed **ABC's Irrevocably Adulterated Ingredients Guidelines**.

**Sudipta Veeramachaneni**, vice president, Research and Development, General Nutrition Centers, gave an update on the **Supplement Safety & Compliance Initiative**.

**Darryl Sullivan**, director, Industry and Regulatory Affairs, Eurofins Food Integrity & Innovation, presented on **AOAC International's** standards development.

**Mike Finamore**, president, Governance Board, Global Retailer and Manufacturer Alliance (GRMA), and CEO, CRN member company Gemini Pharmaceuticals, Inc., discussed the **GRMA Consensus-based NSF/ANSI Standard for Dietary Supplement GMPs**.

## LISTENING TO YOU

CRN heard from its members that they want the association to better address the needs of various sized businesses within the industry, not just large companies. CRN's Membership Committee brought this concern to the attention of the Board and CRN staff with a recommendation for more programs to address the needs of smaller companies and start-ups. One way CRN responded to this was offering a webinar, "Supplement Regulation 101," designed for executives at companies of all sizes seeking a better understanding of the basics.

Learn more: [www.crnusa.org/WeHearYou](http://www.crnusa.org/WeHearYou)



## WEBINAR

### Supplement Regulation 101:

Cross-training in the Basics for the Non-regulatory Industry Executive



Wednesday  
Oct. 10 | 2-4 ET



# We Believe in Supplements: Better Nutrition for *All* Americans

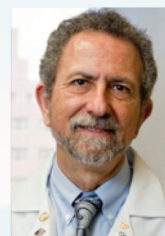
Driven by the conviction that all Americans should have equal access to good nutrition, CRN raised awareness of the value of vitamins and achieved unprecedented levels of support for allowing Supplemental Nutrition Assistance Program (SNAP) recipients to purchase a multivitamin with their program benefits. Working with key contacts on Capitol Hill, CRN saw success in July in the House of Representatives, which passed its version of the 2018 Farm Bill with the bipartisan multivitamin provision as an amendment.

Building on this momentum, CRN's Government Relations team vigorously pursued support in the Senate. CRN met with each member of the Farm Bill Conference Committee to present data on nutritional shortfalls and how multivitamins could fill nutrient gaps and reduce poor nutrition among those with the least access to healthy food.

CRN's Communications team amplified these messages via new and traditional media, both earned and paid. CRN worked with a public affairs firm to place op-eds by Dr. Jeffrey Blumberg, Dr. Tieraona Low Dog, Rep. Mike Rogers (R-AL), and CRN President & CEO Steve Mister that appeared in 23 newspapers across the U.S. CRN also amped up buzz on social media.

**CALL YOUR SENATOR TODAY**  
AND TELL THEM TO FILL THE **#GapInSNAP**  
WITH A MULTIVITAMIN

**GOOD NUTRITION IS NOT A LUXURY.**  
TELL YOUR SENATOR TO FILL THE #GapInSNAP



Texans are overfed,  
but vitamins can help



Women aren't getting  
enough vitamins



The Power of Choice Helps  
Low-Income Alabamans  
Live Healthier



**Council for Responsible Nutrition**  
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Tell Congress to give SNAP recipients the choice to purchase multivitamin-minerals with their benefits. You're just a few clicks away from sending a message to your Senator.

Paid for by Council for R...

CRNUSA.ORG  
**Your message can help reduce hidden hunger** [Learn More](#)  
Contact Congress now.

**Council for Responsible Nutrition**  
Sponsored · Paid for by Council for Responsible... ·

All Americans deserve equal access to good nutrition. Tell Congress to give low-income Americans access to a multivitamin-mineral to address the hidden hunger in their diets. Click here to send a message to your Senator now.

Paid for by Council for ...

crnusa.org  
**Help Stop Nutrition Shortfalls in Low-income...** [LEARN MORE](#)

**POP VOX** National Sentiment

98%   
2%   
171 constituents

Allow Americans on SNAP access to a multivitamin

Input by District

Supporting Opposing



## ...with nutrition and justice for **ALL**



July 4<sup>th</sup> should be a celebration of American values and apple pie—for all. But malnutrition stands in the way.

40% of people from low-income households are deficient in essential nutrients. Currently, the federal Supplemental Nutrition Assistance Program (SNAP) provides aid for low-income families, helping them buy groceries. However, hidden hunger still exists due to lack of access to nutrient-dense foods.

A multivitamin can help reduce nutrient deficiencies by two-thirds.

**One problem: SNAP recipients cannot use their benefits to purchase a multivitamin.**

Doesn't make much sense, does it?

Congress has the opportunity to change that with the final passage of the 2018 Farm Bill—at no additional cost to taxpayers. It's common sense—for less than a dime a day, allow SNAP recipients to access a multivitamin.

**Tell Congress to include multivitamins in SNAP for the benefit of all Americans.**



This is not a question of expanding or shrinking the size of the pie—it's about making the pie as nutritious as possible.

[www.crnusa.org/SNAP](http://www.crnusa.org/SNAP)

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**Council for Responsible Nutrition**  
*The Science Behind the Supplements*

Targeting a key player in the Farm Bill negotiations—ranking member of the Senate Agriculture Committee Sen. Debbie Stabenow (D-MI)—CRN used social media to reach voters and inspire them to call on Congress to fill the #GapInSNAP.

In addition to engaging followers via its Twitter platform, CRN seized the opportunity to launch a Facebook presence. CRN rapidly established a page on the platform and deployed a focused Facebook ad campaign driving constituents to CRN's website to learn more and take action by submitting an electronic letter to their legislator.

Over the July 4 holiday, CRN complemented these efforts with full-page ads in *The Detroit News* and *The Detroit Free Press* calling for "...nutrition and justice for all!" to further engage voters.

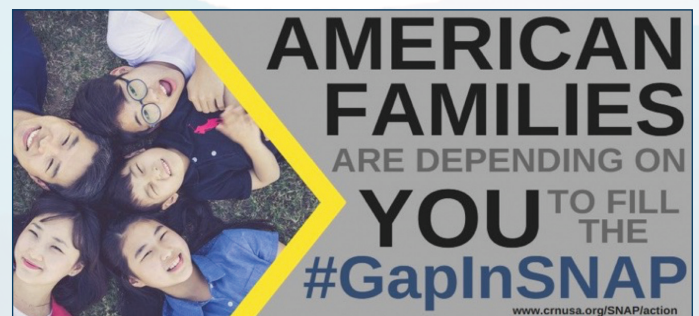


**"Because the data show that low-income America disproportionately is malnourished, this is an issue that is much bigger than the industry and we feel a certain stewardship to continue this effort, because we believe so strongly that the multivitamin offers the potential to close those nutrient gaps."**

—Steve Mister

NutraIngredients

*Farm Bill drops language to allow vitamin, mineral supplement purchase using SNAP*



After exhausting efforts to secure support for identical, stand-alone legislation in the Senate, CRN's Government Relations team encouraged Sen. Orrin Hatch (R-UT) and Sen. Tim Scott (R-SC) to introduce an amendment echoing Rep. Rogers' in the House during the Senate's deliberation. In addition, CRN circulated a letter of support endorsed by more than 50 outside organizations, companies and firms.

Unfortunately, when it came to passage in the Senate, party politics ultimately blocked any changes to SNAP whatsoever in the 115<sup>th</sup> Congress, as Democrats feared opening opportunities for cuts to the program or stricter work requirements. Despite the loss, CRN relished the opportunity to highlight the role of multivitamins for better nutrition to so many receptive audiences.



# INFLUENCING PUBLIC POLICY ON NUTRITION AND HEALTH

CRN's Government Relations team's impact in 2018 extended far beyond advocating for low-income SNAP recipients' access to multivitamins. CRN continued its joint sponsorship of the Congressional Dietary Supplement Caucus, involvement in coalitions and outreach to legislators who shape policy that affects the dietary supplement and functional food industry.

## 2018 achievements at the U.S. federal level include:

### Supporting full funding of FDA's supplement programs

CRN persuaded Senate and House Appropriations Committees to insert report language that instructs FDA to allocate more funds to the agency's Office of Dietary Supplement Programs, in collaboration with the PEW Charitable Trusts.

### Ensuring dietary supplement manufacturers would not bear additional, inappropriate burdens under the Substance Tableting and Encapsulating Enforcement and Registration Act legislation to address the opioid crisis

CRN raised concerns with the members of the Energy and Commerce Committee about provisions that would have effectively made tableting and encapsulating machines themselves controlled substances, subject to U.S. Drug Enforcement Agency (DEA) requirements for registration, record-keeping, security, loss reporting and more; and would have decreed that facilities not otherwise handling any controlled substances now be under Controlled Substances Act and DEA jurisdiction. Because of CRN's efforts, the legislative text was never formally introduced and therefore was not included in the final opioid legislative package.

### Raising awareness about SARMs in products masquerading as dietary supplements

CRN educated legislators about the danger of Selective Androgen Receptor Modulators (SARMs), bolstered by the association's consumer education campaign to warn consumers with support from the U.S. Anti-Doping Agency (USADA). Sen. Orrin Hatch (R-UT) and Sen. Sheldon Whitehouse (D-RI) introduced legislation defining SARMs and giving the Attorney General authority to designate them as Schedule I controlled substances following CRN's outreach. SARMs remain on CRN's radar with plans to usher in new legislation in the 116<sup>th</sup> Congress. See more about CRN's full court press on SARMs on page 20.

**“We do not regulate in a vacuum, and it is important to acknowledge the significant efforts of responsible industry participants to comply with our requirements and set even higher standards for their industry...We applaud the self-regulatory efforts and other voluntary initiatives undertaken by industry, and we intend to continue to maintain a robust dialogue with our stakeholders toward achieving these shared goals...”**

—John Martin, FDA Principal Associate Commissioner for Legislative Affairs, in a letter to Rep. Andy Harris (R-MD) and Rep. Derek Kilmer (D-WA) responding to a Congressional inquiry



## Key 2018 Government Relations achievements in the states and territories:

### Halting registration requirements for dietary supplements in Puerto Rico

CRN championed The Puerto Rico Pharmacy Act (PC 1034), signed into law late in 2018, culminating a two-year effort. The new law acknowledges FDA jurisdiction over nutritional supplements, preempting U.S. companies registered under the FDA Food Safety Modernization Act, and effectively overturns a regulation that would have placed burdensome registration requirements on supplements sold on the island (Regulation 9031).

### Stopping age-restrictive supplement legislation in Massachusetts

CRN actively opposed legislation that would have prohibited the sale of certain dietary supplements to minors and required these products be placed behind retailer and pharmacy counters in the state of Massachusetts. Ongoing since 2017, when CRN testified before the Joint Committee on Public Health (JCPH), CRN's efforts continued in 2018 with regular visits with JCPH members, resulting in the bill being sent to a study and ending any prospect for passage in that legislative session.

### Correcting Arizona State Board of Pharmacy misclassification of select supplements as OTC drugs

CRN worked behind-the-scenes in coalition with other stakeholders to address a mis-applied state regulation that would have allowed the Arizona Board of Pharmacy to reclassify certain dietary supplements as OTC medicines.

### Raising awareness/advocacy for SNAP recipients' need for access to multivitamins in New York

CRN worked with member companies and members of the New York Legislature to pass legislation that would have allowed the New York Department of Disability Services to submit a waiver to the federal government that would allow participants within the SNAP program in the state of New York to purchase a multivitamin with their benefits. The legislation, AB 10697, passed, but Gov. Andrew Cuomo vetoed the measure. Early 2019 update: Following the veto, CRN submitted a rebuttal letter asking for a meeting with the governor's office, correcting multiple misleading and inaccurate statements and reiterating the benefits that a multivitamin would provide SNAP recipients.

### Lobbying the California legislature

CRN convened California-based companies to meet with key state legislators, underscoring the industry's economic impact on the state. The team educated legislators and staff about self-regulatory initiatives to combat bad actors, such as CRN's sponsorship of the National Advertising Division (NAD) program, and the Supplement *OWL*. Also discussed were California AB 2800, on training high school athletic coaches to combat heat illness and concussions, and AB 2632, regulating slack fill in product packaging.



CRN's 'Day in Sacramento' lobbying team visits with California Assembly member Miguel Santiago.



## BRINGING CRN MEMBERS TOGETHER WITH MEMBERS OF CONGRESS, STATE ASSEMBLY

CRN provided its members with opportunities to participate in the legislative process, hosting fly-ins including:

- **Day in Sacramento, May 9**
- **Day on the Hill, June 13**
- **House Hustle** to include multivitamin minerals in SNAP in the House Farm Bill, July
- **Senate Scramble** to include multivitamin minerals in SNAP in the Senate Farm Bill, August

## WORKING IN COALITION

CRN joined two coalitions on key issues of interest:

- **Cannabidiol (CBD)**—CRN successfully supported efforts to protect Hemp Farming Act Senate language in the Farm Bill. See more about CRN's actions on CBD on page 21.
- **Affordable Labeling Act**—CRN joined the Coalition for Accurate Product Labels to address the overarching concern over states inappropriately asserting legislation over labeling and to instead move toward a federal standard. CRN will work with the coalition in 2019 to have the legislation reintroduced.

## SUPPORTING INDUSTRY CHAMPIONS

CRN held two strongly attended fundraising events for:

- **Frank Pallone (D-NJ)**  
Rep. Pallone is a founding member of the Congressional Dietary Supplement Caucus (DSC) and has worked on many issues related to health, wellness, and nutrition. Bonus: He is now Chairman of the House Energy and Commerce Committee for the 116<sup>th</sup> Congress.
- **Mia Love (R-UT)**  
Rep. Love served as the House Republican co-chair of the DSC, with contributions ranging from cosponsoring key legislation, such as the SNAP Vitamin Mineral Improvement Act of 2017, as well as leading the caucus to its highest-ever membership level. CRN was disappointed that Rep. Love lost her bid for re-election in 2018, but is reaching out to newly-elected Rep. Ben McAdams (D-UT), in this key district.



CRN's Steve Mister addresses attendees during the Day on the Hill.



Frank Pallone



Mia Love



Rep. John Faso (R-NY) speaks with team during CRN and AHPA's Day on the Hill.



# INFLUENCING PUBLIC POLICY ON NUTRITION AND HEALTH



Nearly 80 participants flew in for CRN and AHPA's Day on the Hill 2018. This was the second year CRN partnered with AHPA for the annual lobbying effort on Capitol Hill.



CRN's Mike Greene speaks at CRN and AHPA's Day on the Hill.



CRN Government Relations Committee Chair Bethany Davis of FoodState, at the Day on the Hill.

## LISTENING TO YOU

CRN members told us they want CRN to collaborate more with the other trade associations. CRN got the message from its members that there is strength in numbers.

In June, CRN co-hosted its annual Day on the Hill with AHPA. In May, we co-hosted the Regulatory Summit with AHPA, CHPA, NPA and UNPA. These same groups joined with CRN to introduce and support legislation in the Senate to address SARMs, and coordinated lobbying efforts on the Farm Bill to include multivitamins in SNAP. In addition, CRN collaborates with these groups co-hosting educational briefings with the Congressional Dietary Supplement Caucus (DSC).

We also collaborated on a joint advisory warning consumers about fraudulent products taking advantage of the opioid crisis. The newly revived SIDI Work Group is now a joint initiative of CHPA, CRN and UNPA. Monthly lunches among four of these groups strengthen communication, trust and division of labor among the organizations.

Learn more: [www.crnusa.org/WeHearYou](http://www.crnusa.org/WeHearYou)



CRN's mission to shape policy is not limited to U.S. laws and regulations. CRN engaged with domestic and international organizations involved in global policymaking to sustain and enhance the climate for members to responsibly develop, manufacture and market science-based dietary supplements and nutritional products throughout the world.

Highlights of CRN's work on an international scope include:

## Engagement on key Codex initiatives— including a win on probiotics

CRN engaged domestically with the U.S. Codex Office to foster alignment between industry and the U.S. government in positions that would affect the responsible supplement industry. When it came time for decisionmaking on a troublesome Codex probiotics proposal, CRN's work paid off, with the U.S. and key member countries all in accord with the association's call to table new work on probiotics (see page 16 for more).

## CRN submitted comments to Codex on:

- **Probiotics**
- **Omega-3 long chain fatty acids (DHA+EPA)**
- **Protein supplementation for body-building**

## Submission of comments on international proposals

- Brazilian National Health Surveillance Agency on maximum levels of nutrients, bioactive substances, enzymes and probiotics
- European Food Safety Authority Draft Statement on Genotoxicity Assessment of Chemical Mixtures

## Participation in the International Alliance of Dietary/Food Supplement Associations (IADSA)

- CRN President & CEO Steve Mister was elected vice-chair of IADSA, an international association committed to providing a global platform for the development of policy and regulation related to dietary supplement markets worldwide.
- CRN presented on Regional Evolution of Regulation & Policy and Smart Prevention: Lessons Learned from CRN's Healthcare Cost Savings Study at the IADSA Annual Week.

## Efforts to streamline issuance of Certificates of Free Sale

CRN staff and ITMDC members continued to engage with the U.S. Trade Representative and FDA on streamlining the Certificates of Free Sale (CFS) process. An issue CRN has tracked since 2017, the CFS process is now slated for revision to speed processing and better address acceptability among foreign jurisdictions.

## Opposition to tariffs on Chinese imports

CRN opposed tariffs being imposed on many Chinese-made ingredients imported for supplements. CRN filed comments opposing the tariffs with the U.S. Trade Representative, and worked with the U.S. Chamber of Commerce to convey the negative impacts the tariffs would have on supplement manufacturers and consumers.

## CRN handbook used to protect consumer access to supplements in Sweden

CRN's "Vitamin and Mineral Safety" handbook served as supplemental material in multiple cases in the Swedish administrative court in 2018, according to the Nordic Food Supplement Alliance. The legal arguments put forward combated Swedish municipalities' sales bans on food supplements exceeding non-scientific upper levels for vitamin D, a shortfall nutrient in Sweden.

CRN's handbook and scientific references reinforced legal arguments stating that the country's authorities may not institute restrictions on food supplements deemed to be safe.







CRN's Jim Griffiths, Ph.D., right, with speakers from the 2018 CRN-I symposium.



## CRN-International 2018 symposium and reception

The CRN-International (CRN-I) 2018 event, "Nutrition Interventions for Healthy Ageing Across the Lifespan," surveyed the history of the CRN-I's symposia series and focused specifically on nutrition-related opportunities to improve global public health. More than 60 delegates attended the event. The symposium proceedings are slated for publication in the European Journal of Nutrition, as 2017's proceedings, "Healthy Ageing: the Natural Consequences of Good Nutrition: A Conference Report," pictured, right, were published in the May 2018 edition.



## Educating international regulatory groups

CRN presented to stakeholder groups at our members' request:

**The Evolution and Evaluation of Dietary Supplements – the U.S. Perspective**

*Where Were We?  
Where Are We?  
Where (Might) We Be Going?*

早上好  
胡颖廉

Council for Responsible Nutrition (CRN)  
July 30, 2018 – Professor Yinglian Hu Visit

Council for Responsible Nutrition

Chinese Academy of Governance in the Department of Social and Cultural Studies and China Health Care Association

**THE SCIENCE BEHIND THE SUPPLEMENTS**

社福協  
JHFS  
The Japanese Institute for Health Food Standards

Japanese Institute for Health Food Standards (JIHFS)  
Association for Health Economics Research and Social Insurance and Welfare (ASIW)

Council for Responsible Nutrition

Japanese Institute for Health Food Standards and Association for Health Economics Research and Social Insurance and Welfare

10 years  
Self-regulated organization  
Union of Dietary Food  
Supplements Producers

**DIETARY SUPPLEMENT INDUSTRY AND MODERN SOCIETY: CHALLENGES, SCIENCE, REGULATION**

International Conference dedicated to the 10th anniversary  
Monday, November 26, 2018

Russian Conference on the Dietary Supplement Industry and Modern Society, Challenges, Science and Regulations

## "Healthy ageing: the natural consequences of good nutrition— a conference report"

Published in the European Journal of Nutrition, this paper was co-authored by 10 scientific experts, summarizing presentations made at the 2017 CRN-I Scientific Symposium. The 2018 report is expected to publish in early 2019.



# CRN: The Probiotics Pros

Promoting best practices for probiotics driven by science-based guidelines paid off for CRN, positioning the association as a reliable source for expert commentary to FDA as well as to Codex as these bodies shape policy.

CRN saved the day overseas, leading the charge to send the Argentinian proposal for new work on probiotic foods and supplements back to the drafting table. In coalition with Canada, the European Union, Russia, Malaysia, and several other countries, the U.S. voted to stop the proposal's progression, citing its confusing and obtuse scope—points outlined by CRN in commentary throughout the Codex guidelines development process. In addition, CRN noted the proposal called for an overly restrictive threshold for demonstrating the efficacy of these products to be called probiotics. When Argentina presents a revised proposal to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in 2019, the Committee will make a final decision on whether or not to develop probiotic guidelines. CRN is closely monitoring the proposal's ongoing development.

CRN commended FDA's announcement of its intent to exercise enforcement discretion to allow supplement companies to use colony forming units (CFUs) when declaring the quantity of live microbials on a Supplement Facts label, acknowledging FDA's receptiveness to collaborate with industry to provide consumers with meaningful label information to inform their purchase decisions. However, CRN took issue with the Draft Guidance's statement that the label must also list the quantitative amount by weight. As it is not possible to accurately declare quantity in both weight and CFUs on a consistent basis, listing the weight of probiotic contents does not provide consumers with useful information for comparing probiotic products and making buying decisions, CRN noted in a statement and in follow-up comments.

CRN reminded members that a year had passed since the CRN-International Probiotics Association (IPA) Best Practices Guidelines for Probiotics went into effect, and that companies should review their probiotics products to ensure compliance with the guidelines if they have not done so already.



**“Codex energies need to focus on truly new work and not standards development for micro-segmentation of food categories.”**

—**Jim Griffiths, Ph.D.**

CRN comments on the CCNFSDU proposal for new work on probiotics

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## A rapid response

CRN promptly refuted the conclusion of a review, “Harms Reporting in Randomized Controlled Trials of Interventions Aimed at Modifying Microbiota,” published in the *Annals of Internal Medicine*. The review questioned the safety of probiotics after researchers found that publications of clinical trials on probiotic, prebiotic, or synbiotic usage generally do not adequately report harms data from the studies. According to the researchers, this absence of data calls into question the safety of these products. Although the review made legitimate observations regarding the importance of complete, thorough reporting of trial data, CRN cited the extensive existing literature supporting the safety of probiotic products and reminded consumers of the review's true intent: to assess quantity of data, not the quality of the products.

*See more rapid responses from CRN on page 26.*

## Probiotics Session at ‘The Workshop’

At CRN's annual full-day science symposium, probiotics were a key focus, with three expert speakers comprising a thought-provoking session on the latest research developments.





CRN's **Andrea Wong, Ph.D.**, (center) with Amy Mackey, Ph.D., director, regulatory affairs, Abbott Nutrition, and William Yan, Ph.D., director, Bureau of Nutritional Sciences Food Directorate, Health Canada led the session, "Probiotics: The Current Regulatory Continuum From Food to Drug," at the RAPS Regulatory Convergence.

**"Probiotics are a hot category and consumer interest is intense...it is unsurprising that the beneficial microorganisms are receiving increased scrutiny from the media and industry critics."**

—**Andrea Wong, Ph.D.**  
 NutraIngredients  
*Probiotics: CRN VP says increased scrutiny is 'not unexpected'; CFU issue needs to be resolved to satisfy scientists, consumers*

## LISTENING TO YOU

Members asked CRN to use its staff—with its depth of knowledge in science, regulatory affairs, international trade, communications and government—to provide more leadership in probiotics. Viewed as fundamental to the growth of both dietary supplements and functional food, probiotics are expected to continue to gain popularity.

CRN took an active leadership role in this emerging market, advocating for the acceptance of CFUs (colony forming units) as the unit of measure for probiotics and will engage with FDA on fine-tuning this measure for its final guidance for industry.

CRN is working to assure probiotics are not negatively impacted internationally, as well. As a member of the International Alliance of Dietary/Food Supplement Associations (IADSA), and an official NGO at Codex, CRN was instrumental in tabling an Argentinian Codex probiotic guidelines proposal that would have set unattainable standards for clinical trials, as noted on the previous page. CRN worked in cooperation with key partners to shape a proposal for new work on harmonized probiotics guidelines.

CRN will continue to support the science and benefits of probiotics, including in our communication with the media, promotion of emerging research and defense of probiotics against inaccurate or unfair news reports. Learn more: [www.crnusa.org/WeHearYou](http://www.crnusa.org/WeHearYou)



# FOSTERING EXCELLENCE IN NUTRITION SCIENCE

CRN's Science team's expertise provided a base for so much of the association's work: the *Supplement OWL*; CRN's efforts to include multivitamin-mineral supplements in SNAP; raising awareness about the dangers of SARMs; and more. In addition to those important contributions, the team's efforts to foster excellence in nutrition science in 2018 included:

## Sponsored ASN Nutrition 2018 satellite sessions

CRN sponsored a SNAP-related session on how dietary supplements can fill nutrient gaps and supported a session as part of the B/24-Pregnancy Coalition focused on influencing the Dietary Guidelines for Americans 2020–2025, both at the American Society of Nutrition (ASN) annual meeting.



## Presented poster on botanical safety evaluation

CRN's Jim Griffiths, Ph.D., presented a poster, "Development of a consensus approach for botanical safety evaluations," at the 57<sup>th</sup> Annual Society of Toxicology (SOT) meeting, outlining a decision tree approach and technical rationale building on discussions at the 2017 European Toxicology Society meeting.

## Published scientific paper on iodine

CRN's Duffy MacKay, N.D., and Andrea Wong, Ph.D., raised awareness of iodine as essential for thyroid hormone production and fetal development. They co-authored a study that aimed to better understand the contribution of top-selling adult multivitamins and prenatal multivitamins to iodine nutrition in the U.S., noting that more effort is needed to ensure adequate iodine content in prenatal vitamins for women who are pregnant, lactating, or planning pregnancy.

## Weighed in on FDA's Nutrition Innovation Strategy

CRN presented oral comments at a public FDA meeting in July, recommending that FDA update the health claims review process, invest in a campaign to educate consumers about the new Nutrition and Supplement Facts labels and modernize regulations to permit innovations to enhance the nutritional quality of foods. CRN also submitted extensive written comments.

### The Workshop: CRN's Day of Science

CRN again hosted a full-day symposium focusing on scientific topics related to dietary supplements and nutritional ingredients—this year with a probiotics segment with three expert speakers in this area alone.

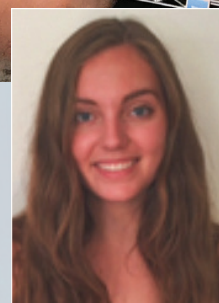
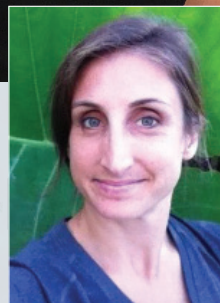
## Additional CRN-submitted comments:

- U.S. Preventive Services Task Force (USPSTF) Draft Research Plan for Vitamin D Deficiency in Adults: Screening
- FDA Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials: Draft Guidance for Industry
- U.S. Trade Representative (USTR) Request for Comments Concerning Proposed Modification of Action Pursuant to Section 301: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation
- U.S. Department of Agriculture (USDA) Proposed Rule: National Bioengineered Food Disclosure Standard
- FDA Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: Draft Guidance for Industry
- USTR Proposed Determination of Action Pursuant to Section 301: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property
- FDA Citizen Petition to allow the use of simple vitamin letter names on both the Nutrition and Supplement Facts labels and Ingredient Declaration lines for vitamins when added for nutritive value only
- USDA Dietary Guidelines for Americans: Request for Comments on Topics and Questions
- FDA Proposed rule to revoke the regulation authorizing the use of health claims on the relationship between soy protein and coronary heart disease
- FDA Pyridoxamine – Citizen Petition from ViGuard Health Inc. that FDA issue a regulation declaring pyridoxamine is no longer an article authorized for investigation as a new drug, and therefore is not excluded from the definition of dietary supplement under 21 U.S.C.
- FDA Review of Existing General Regulatory and Information Collection Requirements





Pictured clockwise from top: CRN's Jim Griffiths, Ph.D., with poster co-author Prof. Corrado Lodovico Galli ERT, at the 57<sup>th</sup> Annual Society of Toxicology (SOT) meeting; CRN's Steve Myster visits a member facility; CRN's Jim Griffiths, Ph.D., and Duffy MacKay, N.D., visit a member facility; Lynn Wojcik, and Jordan Balletto, Masters students, Friedman School of Nutrition Science and Policy, Tufts University, who received educational grants to attend CRN's Day of Science in 2018, part of an ongoing program to develop CRN's network of researcher and nutrition science/policy contacts.





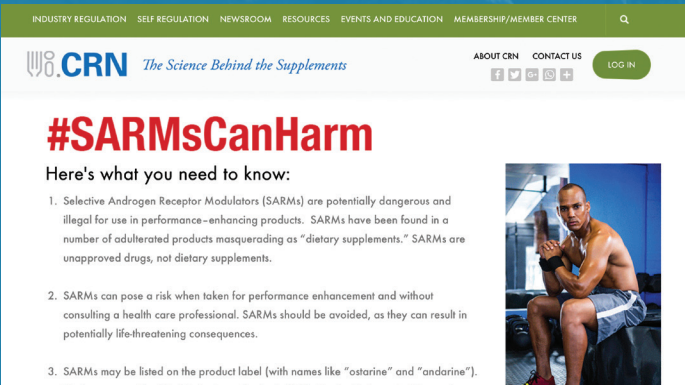
# Working in Concert for Consumer Safety: #SARMsCanHarm Campaign

CRN's Communications team drove a public affairs campaign to warn consumers about the dangers of Selective Androgen Receptor Modulators (SARMs)—unapproved, illegal, and dangerous compounds found in mislabeled performance-enhancing products.

The #SARMsCanHarm messaging educated consumers about ways to identify SARMs and noted there are safe and beneficial sports supplements in the marketplace.

CRN developed a microsite with shareable content for consumers and engaged stakeholders to disseminate the message more broadly. For example, the International Health Racquet Sports Club Association and The Club Spa Fitness Association shared the materials with their members.

CRN's Science and Government Relations teams' expertise complemented these efforts. CRN released Recommended Guidelines for SARMs-Containing Dietary Supplements and SARMs legislation passed in the Senate.



**13,950 unique page views**

**Average time on page: 03:39**

The content got another bump of attention in early 2019 when football players at Clemson University tested positive for ostarine. CRN is working to re-introduce new legislation in the 116<sup>th</sup> Congress, building on its previous progress with Senate legislation in the 115<sup>th</sup>.

## BUY SUPPLEMENTS FROM REPUTABLE COMPANIES

Selective Androgen Receptor Modulators (SARMs) may be listed on product labels (with names like "ostarine" and "andarine"). Or they may not be listed in the ingredients at all. SARMs are unapproved drugs, not dietary supplements. That's why it's important to purchase dietary supplements from companies you know and trust—those that don't make drug-like claims.



FOR MORE INFORMATION:  
[www.usada.org/SARMs](http://www.usada.org/SARMs)  
[www.crnusa.org/SARMs](http://www.crnusa.org/SARMs)

**#SARMsCanHarm**

## A RISK FOR CONSUMERS

Selective Androgen Receptor Modulators (SARMs) can pose a risk when taken for performance enhancement and without consulting a health care professional. SARMs should be avoided, as they can result in potentially life-threatening consequences.



FOR MORE INFORMATION:  
[www.usada.org/SARMs](http://www.usada.org/SARMs)  
[www.crnusa.org/SARMs](http://www.crnusa.org/SARMs)

**#SARMsCanHarm**

## SAFETY ALERT: SARMs CAN HARM

### What you need to know

#### 1. SARMs CAN BE DANGEROUS AND ARE ILLEGAL IN SUPPLEMENTS

Selective Androgen Receptor Modulators (SARMs) are potentially dangerous and are illegal for use in performance-enhancing products. SARMs have been found in a number of adulterated products masquerading as "dietary supplements." SARMs are unapproved drugs, not dietary supplements.

#### 2. A RISK FOR CONSUMERS

SARMs can pose a risk when taken for performance enhancement and without consulting a health care professional. SARMs should be avoided, as they can result in potentially life-threatening consequences.

#### 3. BUY SUPPLEMENTS FROM REPUTABLE COMPANIES

SARMs may be listed on the product label (with names like "ostarine" and "andarine"). Or they may not be listed in the ingredients at all. That's why it's important to purchase dietary supplements from companies you know and trust—those that don't make drug-like claims.

#### 4. A HEALTHY ROLE FOR SAFE SUPPLEMENTS

Sports nutrition dietary supplements can play a beneficial role in your workout routine. But keep this in mind: dietary supplements are not intended to have the same immediate or dramatic effects that you would expect from taking a drug. Labels that sound too good to be true, probably are.



FOR MORE INFORMATION:

[www.usada.org/SARMs](http://www.usada.org/SARMs)

[www.crnusa.org/SARMs](http://www.crnusa.org/SARMs)

BROUGHT TO YOU BY:

Council for Responsible Nutrition  
 The Science Behind the Supplements



# Science & Responsibility: Walking the Talk on CBD

CRN remained committed to its science-based, responsible approach as it participated in the cannabidiol (CBD) conversation. CRN commissioned a legal analysis, prepared by Covington & Burling, LLP, that highlighted several obstacles inhibiting the legal marketing of CBD in dietary supplements—passage of the Hemp Farming Act notwithstanding.

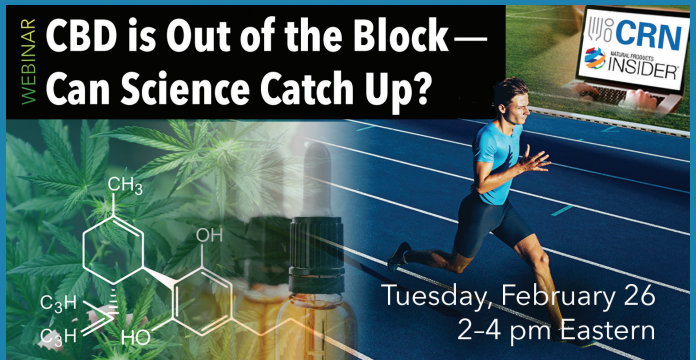
The association's Board of Directors formed a task force as CRN expressed support for the 2018 Hemp Farming Act, which passed, and then advised on options for working with FDA to re-evaluate CBD's legal status as a dietary ingredient.

CRN hosted a frank discussion at its annual conference, featuring a range of views on key scientific and regulatory aspects of the hot ingredient—"For Adults Only: What You Need to Know About CBD,"—with Miriam Guggenheim, Covington & Burling, LLP; Anthony Almada, Council for Science & Innovation of Cannabis and Cannabinoids; and Stuart Tomc, CV Sciences, Inc.

CRN also co-hosted an educational briefing on Capitol Hill with Ms. Guggenheim and Mr. Tomc as expert presenters—"Legal, Regulatory Considerations for Cannabidiol (CBD): Current & Future."

CRN encouraged FDA leadership to issue a statement on CBD contemporaneously with the signing of the Farm Bill (with the Hemp Farming Act as part of it), reiterating the agency's authority to regulate products containing cannabis or cannabis-derived compounds and noting that under the Federal Food, Drug, and Cosmetic Act, it remains unlawful to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as dietary supplements, or as ingredients in dietary supplements, regardless of whether the substances are hemp-derived.

CRN ended the year asking FDA to create a legal pathway to market for hemp-derived CBD. CRN is presenting a webinar in early 2019, "CBD is Out of the Block—Can Science Catch Up," and is pursuing discussions with FDA.





# CRN: 'Friend of the Court,' Advocate for Industry

CRN's Legal Committee filed several amicus curiae briefs in 2018. CRN defended the First Amendment and helped ensure the protections of the Dietary Supplement Health and Education Act of 1994 (DSHEA), responding to an uptick in litigation affecting dietary supplement companies this past year.

## CRN 2018 filings include:

### Amarin v. ITC

CRN continued to combat misguided legal action from Amarin, a prescription drug company trying to restrict the importation of esterified, omega-3, EPA fish oil as a dietary supplement. Through advocacy with the U.S. International Trade Commission (ITC)—the agency through which Amarin has pursued its actions—and an amicus brief before the U.S. Court of Appeals for the Federal Circuit, CRN has argued that Amarin's efforts are not consistent with the law and could harm consumers by limiting their access to beneficial omega-3 products, while seeking to obtain a monopoly for its drug product. Amarin filed an appeal with the Federal Circuit after the ITC declined to open an investigation into Amarin's allegations that the esterified fish oil products could not be imported as dietary supplements. CRN's amicus brief urged the appellate court to uphold ITC's determination that the agency did not have jurisdiction over Amarin's claims because FDA has exclusive authority to determine whether an ingredient can be included in a dietary supplement. CRN argued that allowing other agencies to usurp FDA's authority would undercut its singular ability to interpret and properly enforce DSHEA. The case is still pending.

### Washington v. Living Essentials

CRN filed an amicus brief in Living Essentials' appeal in a Washington state case brought by the Washington Attorney General, pushing back on a court's determination that dietary supplement advertising claims must be supported by "clearly established" scientific evidence—a standard that goes well beyond what is allowed by law. CRN objected to such a high burden and insisted that a charge for false advertising must be based on more than a dispute about the methodology employed in the scientific study that serves as the substantiation. (CRN previously submitted briefs for a Living Essentials false advertising case in Oregon, brought by the Oregon attorney general.)

### FTC v. Quincy Bioscience

CRN's involvement in FTC v. Quincy Bioscience boldly illustrated why amicus briefs are so important, not only to those involved in the case, but the industry as a whole. While the defendant had to focus on addressing FTC challenges to specific advertising claims and the science supporting those claims, CRN's brief addressed broader issues affecting the industry by exposing the Federal Trade Commission's (FTC) efforts to impose inappropriate drug-level standards for substantiation of dietary supplement claims that disregarded DSHEA, agency guidance and decades of agency precedent.

### Korolshteyn v. Costco

CRN came to the aid of supplement marketers whose marketing claims for ginkgo were challenged as false and misleading in Korolshteyn v. Costco (and Sonner v. Nature's Way in 2017) in the U.S. Court of Appeals for the Ninth Circuit. CRN's brief addressed the appropriate legal standard for private litigants in false advertising cases—that by law private plaintiffs must offer facts to prove claims false and merely arguing that an advertiser's substantiation is weak or equivocal is insufficient to bring a case. (CRN previously submitted a related brief in 2017.)

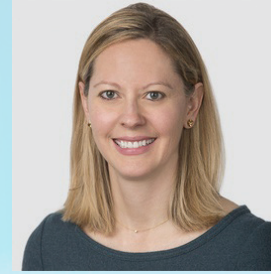
**"We know that courts listen to what CRN has to say. In some cases, the judges have even quoted from CRN's briefs in their legal opinions. By developing these legal arguments, CRN is making legal precedent and changing the environment—not just for the companies involved in these cases, but for the entire dietary supplement and functional food industry."**

—Steve Mister  
bylined article in  
Natural Products INSIDER  
*In court, it's good to have friends*

**While most of these cases are still awaiting decisions, they demonstrated that the robust defense of the supplement industry features a new tool: amicus briefs.**



Megan Olsen joined CRN early in 2018 as Assistant General Counsel, continuing the association's work with its Legal Committee and playing a key role in several initiatives including: development of CRN's "Recommended Guidelines for SARMs-Containing Dietary Supplements"; formation of the Cannabidiol (CBD) Task Force; co-hosting the Annual Legal, Regulatory and Compliance Forum on Dietary Supplements with the American Conference Institute; and representing CRN as a speaker at several professional meetings and conferences throughout the year.



## In addition, CRN's efforts included:

### Still 'Standing up for Truth in Advertising,' with an upgraded NAD database

CRN re-invigorated its program with the National Advertising Division (NAD), funded through the CRN Foundation, following a late-2017 commitment to support the program through 2020. The program enables review of dietary supplement advertisements to help ensure they are truthful and non-misleading, and has earned praise from FTC. In 2018, the online database of NAD challenges got an update, making it easier to navigate and more useful: [www.crnusa.org/NAD](http://www.crnusa.org/NAD)

### Ever diligent on Prop 65

CRN monitored relevant developments in California related to Proposition 65 (Prop 65) and supported initiatives to ensure requirements aren't unduly burdensome. CRN supported California Chamber of Commerce comments on proposed amendments to how exposure levels are calculated for substances considered reproductive toxicants, and comments that opposed the listing of overly broad categories of substances that could be used in dietary supplements. CRN also supported measures to establish safe harbor levels for substances that may be used in dietary supplement manufacturing.

### An eye on intentional overages

CRN held a webinar, "Intentional Ingredient Overages: Legal Concerns, Regulatory Considerations, and Best Practices to Ensure Products Contain Declared Values Throughout Shelf-Life," following attention from consumer products testing services, plaintiffs' attorneys and the media. CRN convened experts, including an FDA representative, to help companies better understand regulatory and marketing considerations and best practices to ensure consumer safety and confidence.



**SupplySide WEST**

## Responding to State Legislators & Attorneys General

### State Attorneys General Outreach

CRN continued to engage with state attorneys general (AGs) on dietary supplement issues. In addition to optimizing opportunities to reach AGs through attendance at key meetings of the National Association of Attorneys General (NAAG) and the Conference of Western Attorneys General (CWAG) Annual Meeting, CRN accompanied Wisconsin AG Brad Schimel and his staff on a tour of a local dietary supplement manufacturing facility operated by a CRN member.



# INFLUENCE PUBLIC PERCEPTION OF SCIENCE-BACKED NUTRITIONAL PRODUCTS

CRN's Communications team gave visibility and a voice to the association's many initiatives. As shown in previous pages highlighting CRN's full court press to bring Supplemental Nutrition Assistance Program (SNAP) recipients better access to good nutrition, the #SARMsCanHarm campaign, and more, CRN developed high-quality content to spread the word about the safety and benefits of dietary supplements.

## Here are some additional Communications highlights in 2018:

### CRN Consumer Survey on Dietary Supplements

The CRN Consumer Survey on Dietary Supplements serves as the leading resource for statistics on usage of and confidence in dietary supplements. CRN has conducted the survey with Ipsos Public Affairs annually since 2000. CRN uses the data for content such as social media posts and it is widely cited in reporting on dietary supplements. See a sample of graphics from the survey, right.

### Alliance-building with trusted nutrition thought leaders

CRN sponsored and attended Shopping for Health, an invitation-only event held in Asheville, NC, for RDs, nutritionists, and consumer advisors at supermarket and retail chains, including Whole Foods, Jewel-Osco, Giant, Kroger, and more. CRN's Duffy MacKay, N.D., facilitated the session "Science Behind the Supplements: Advising Consumers with Credibility," discussing regulation, best practices, and self-regulatory initiatives such as the *Supplement OWL* and sharing data from CRN's Consumer Survey on Dietary Supplements.

Additionally, Dr. MacKay with CRN's Andrea Wong, Ph.D., and Gisele Atkinson, participated in a Shopping for Health webinar viewed by over 80 supermarket dietitians. Dr. MacKay and Dr. Wong discussed recent science behind popular supplements such as the multivitamin, omega-3s, probiotics, and vitamin D. Ms. Atkinson presented on the *Supplement OWL* and its role as a helpful tool for retailers.

**Shopping for Health**  
Supermarket Dietitian Resources

**OPTIMIZING YOUR SUPPLEMENT AISLE: ADVISING SHOPPERS WITH SCIENCE AND CREDIBILITY**

**CRN PRESENTERS**

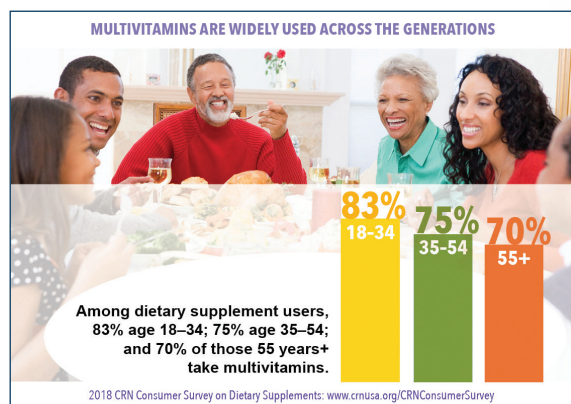
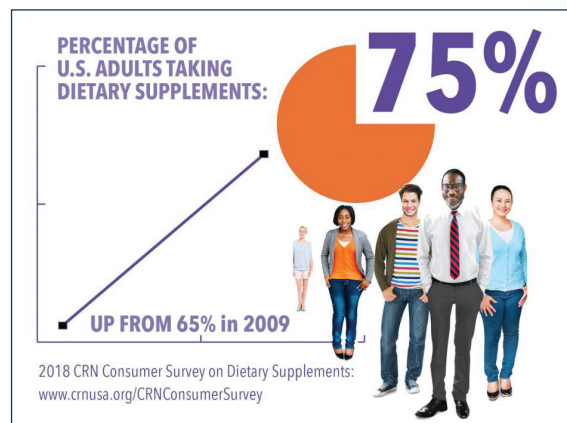
- Duffy MacKay, N.D., senior vice president, scientific & regulatory affairs, Council for Responsible Nutrition
- Andrea Wong, vice president, scientific & regulatory affairs, Council for Responsible Nutrition
- Gisele Atkinson, vice president, quality & technical affairs, Council for Responsible Nutrition

Kim Kirchherr @KimKirchherr · Jul 30  
Knowing the right questions to ask can help more easily navigate the supplement aisle @CRN\_Supplements Duffy MacKay #sth2018 #sponsoredtravel

**INGREDIENT SAFETY CONT...**

When being pitched on a novel product or ingredient inquire about the regulatory status of the ingredient - New (ND); Old (OD); A food ingredient (GRAS or Food Additive)?

Regulations at a Glance	
Ingredient	Regulation
GRAS	21 CFR 170.30
Food Additive	21 CFR 171.1
New Dietary Ingredient (NDI)	21 CFR 101.91
Old Dietary Ingredient (ODI)	21 CFR 101.92



### BRIAN ON BOARD

CRN hired veteran communications strategist Brian Wommack as Senior Vice President of Communications. As noted by President & CEO, Steve Mister, Brian brings a uniquely diverse background as a public affairs counselor, a lobbyist, and a lawyer and his in-depth communications experience working with a variety of industries and entities, including trade associations and government agencies, gives CRN a new competitive edge.





# Amplifying messages about the benefits of dietary supplement

CRN executed two timely influencer marketing campaigns—**#MyWeekSupplemented** and **#MyYearSupplemented**—with agency Clever.

**#MyWeekSupplemented** tapped 15 hand-selected bloggers to create original content chronicling a typical week of their lives and how they incorporate dietary supplements into their daily routine.

## #MyWeekSupplemented

**18.4 million social impressions** (number of times content could be viewed, based on sum of followers and audience of bloggers)

**12,200 social engagements** (total number of retweets, shares, likes, comments, saves, and clicks)

The **#MyYearSupplemented** campaign featured supplement-using influencers who work with children, communicating the importance of wellness and self-care throughout the school year. Focusing on dietary supplements as part of a healthy lifestyle, 15 participating influencers published content on social media and their personal blogs.

## #MyYearSupplemented

**13.4 million impressions**

**Several thousand social media engagements**

The campaigns yielded relevant content that will be repurposed in 2019.



# LISTENING TO YOU

CRN members told staff to be more proactive promoting the benefits of dietary supplements to consumers. They called upon CRN to do more to promote positive studies as well as defending the industry from negative research.

In 2018, CRN amplified its messages about the wellness benefits of dietary supplements by partnering with influencers to deliver authentic content to consumer audiences via blogs and social media as described on this page. CRN even authored a bylined article highlighting its work reaching consumers via influencers, "Two Things Companies Need to Know When Working With Influencers," in Natural Products INSIDER.

CRN also sponsored and spoke at "Shopping for Health," making the case for dietary supplement use with influential retail dietitians.

In addition, CRN worked with a boutique PR firm to disseminate news about positive science on dietary supplements and nutritional ingredients—see highlights on page 27.

Learn more: [www.crnusa.org/WeHearYou](http://www.crnusa.org/WeHearYou)



# Rapid responses to supplement studies and more

## Building credibility, in alignment with FDA for consumer safety

CRN swiftly declared support of FDA's guidance on highly concentrated caffeine in supplements. NBC Nightly News, USA TODAY, WSB-TV 2 Atlanta, and several other outlets included CRN's statement cautioning consumers about pure powered caffeine.

Separately, on social media CRN supported FDA Commissioner Dr. Scott Gottlieb's announcement of agency-wide action protecting consumers from outlier claims that certain dietary supplements could prevent sunburn or protect against skin cancer. CRN expressed support for FDA's efforts on Twitter and LinkedIn, and was retweeted by Dr. Gottlieb himself.

## Feting folic acid

CRN praised the results of a new study published in JAMA that reinforced the critical need for folic acid supplementation in women of childbearing age—especially those taking antiepileptic drugs (AEDs). The study found the risk of autistic traits in children exposed to AEDs in utero may be mitigated by periconceptional folic acid supplementation and folate status. In a statement, CRN affirmed folic acid's proven track record of reducing neural tube birth defects in babies and promoting the health and wellbeing of future children, and encouraged women to “discuss candidly both their medication and supplement regimens with their doctors or other healthcare practitioners.”

## Omega-3 does defend against disease

CRN issued a press statement addressing the results of a new meta-analysis published in JAMA that questioned the benefits of omega-3 fatty acids in heart disease outcomes. CRN advised that the meta-analysis did not demonstrate the dramatic results one would expect from a drug intervention, but noted the results identified the potential benefit on a lesser scale, stating “Even though these results are not statistically significant, they come close, thereby validating nutritional interventions, such as omega-3 fatty acids, as having subtle, but important, effects.”

CRN also responded to a paper published in the Cochrane Database of Systematic Reviews, “Omega-3 Fatty Acids for the Primary and Secondary Prevention of Cardiovascular Disease,” criticizing the authors' broad conclusions.

## Caring for consumers: Alerts and advice

CRN released a public service announcement (PSA) in response to an article published in JAMA that drew attention to unapproved pharmaceutical ingredients identified by FDA in 776 dietary supplements between 2006 and 2017. CRN's PSA offered three guidelines for consumer safety and also pointed to one-dozen additional tips.

On another issue, CRN teamed up with the other major trade associations to issue a consumer warning about the dangers of phenibut, a substance illegally marketed in products fraudulently labeled as dietary supplements.



**“..Do not purchase products with outrageous names sold by unknown or unfamiliar brands and companies...”**

## A taxing proposition

CRN addressed the results of a Preventive Medicine study, “Could a Tax on Unhealthy Products Sold for Weight Loss Reduce Consumer Use? A Novel Estimation of Potential Taxation Effects.” CRN said the authors' recommendation was “unsupported by the facts and the study's own outcome that consumer purchasing behavior for these products is relatively inelastic.”

## A responsible, regulated industry

CRN alerted members to a piece by Pieter Cohen, M.D., published in JAMA Internal Medicine calling the industry under-regulated and apathetic. CRN provided an analysis of the piece and developed talking points for members to use in media responses.

## VITAL news about vitamin D and more

CRN responded to results of the highly anticipated VITAL study, noting positive secondary findings that reaffirm the safety and benefit of vitamin D and omega-3 fatty acids. CRN alerted members and distributed detailed summaries of the study and its key findings.

CRN also alerted members to a positive study published in the Journal of the National Cancer Institute, “Circulating Vitamin D and Colorectal Cancer Risk: An International Pooling Project of 17 Cohorts.” The study found vitamin D supplementation correlated with a statistically significant, substantially lower colorectal cancer risk. The study received positive media coverage in major U.S. outlets including The Washington Post, NBC News, and NPR.

These are just *some* examples of CRN's rapid responses.



# INFLUENCE PUBLIC PERCEPTION OF SCIENCE-BACKED NUTRITIONAL PRODUCTS

## Science-based supplement coverage

CRN collaborated with a boutique public relations firm to generate science-based positive stories about dietary supplements and nutritional ingredients. Among some of the many results were:

- **Turmeric** Improves Memory and Reduces Brain Plaque, Time for Wellness
- **Melatonin** May Promote Healthy Aging, Sleep Review
- **Omega Fatty Acid** Supplementation in Toddlers Born Preterm Shows Promising Results, Health News Digest
- Consumption of **Turmeric** Compound Might Improve Memory, Agribusiness Intelligence
- **Omega Fatty Acid Supplementation** Could Benefit Toddlers Born Preterm, Nutraceuticals World
- **Curcumin's** Cognitive Benefits Look Convincing, Medscape
- **Omegas** May Reduce ASD in Preterm Toddlers, Farmington Patch
- **Vitamin D3** May Benefit Heart Surgery Patients, HealthDay
- 23 **Vitamin D** Benefits That Can Save Your Life, Reader's Digest
- **Omega 3s and GLA** Found to Help Ease Symptoms of Autism in Toddlers Born Pre-term, Natural News
- **Folic acid** Supplements Can Reduce the Risk of Stroke by 73% in Hypertensive Patients, Natural News

## A strong body of bylines

CRN authored several bylined articles throughout 2018 on industry topics, including:

- **In a New Year of Promise, the Fight for ODSF Support Continues** Mike Greene, New Hope
- **The Healthcare Practitioner Channel: Connecting Industry and Medical Professionals** Duffy MacKay, Natural Products INSIDER
- **Five Ways to Play Fair in Sports Nutrition** Duffy MacKay, Natural Products INSIDER
- **Your Trade Association is Not a Luxury; It's an Extension of Your Company** Steve Mister, NutraIngredients
- **24 Years After DSHEA, Industry Still Lacks ODI Clarity** Duffy MacKay, Nutraceuticals World
- **#SARMSCanHarm, but Industry Fights Back** Steve Mister, Natural Products INSIDER
- **Will CBD Become a Shakespearean tragedy?** Steve Mister, Nutrition Industry Executive

## BY THE NUMBERS

**16 bylines**  
**44 science-based articles**  
**50 press releases**



## CRN's BEST-KEPT SECRET

CRN's Communications team again held a successful in-person gathering in New York City to hear from top communications experts on the latest trends and innovations. If you didn't attend, be sure to check out our 2019 agenda and join us in the 'The Big Apple' for a can't-miss event—**May 21 and 22** this year: [www.crnusa.org/CMOC-19](http://www.crnusa.org/CMOC-19)

## VIDEO HIGHLIGHTS

In 2018, CRN added video clips to its website to enhance its messages about nutrient shortfalls, supplement regulation, CRN's Voluntary Guidelines and more.





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