



CRN

SHAPING THE INDUSTRY
TOGETHER

COUNCIL FOR RESPONSIBLE NUTRITION **2017 ANNUAL REPORT**

FDA

Department of Health and Human Services
Administration

NEWS
NEWS

CRN
SHAPING THE INDUSTRY
TOGETHER



FDA

U.S. Department of
Food and Drug



UNITED STATES

**FEDERAL
TRADE
COMMISSION
BUILDING**

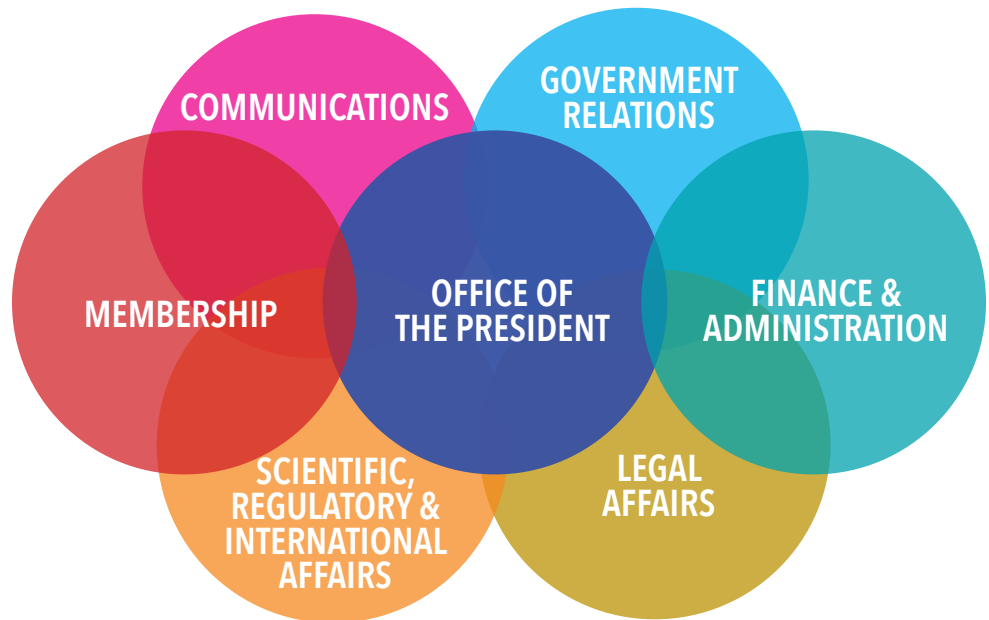
**RESEARCH &
DEVELOPMENT
NEWS**

NEWS

The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food marketers and manufacturers and their ingredient suppliers.

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.

CRN'S DEPARTMENTS WORK TOGETHER TO SERVE OUR MEMBERS



STRATEGIC WORK PLAN 2015 - 2017

Expand 'Responsibility First' initiatives

GOAL: Promote an industry environment in which all companies exhibit responsible behavior and demonstrate a commitment to maintaining consumer confidence in their products and the industry.

Influence government policy on dietary supplements, functional food and other nutritional products

GOAL: Build and maintain a positive regulatory and legislative environment for dietary supplements, functional food and other nutritional products to foster consumer confidence and industry growth.

Foster excellence in nutrition science

GOAL: Foster the development and acceptance of appropriate nutritional science for evaluating the benefits and safety of dietary supplements and functional food.

Positively influence public perception of dietary supplements and functional food

GOAL: Endorse the safety and benefits of dietary supplements and functional food and promote a positive industry image.

Build CRN membership

GOAL: Expand CRN membership to be representative of all aspects of the industry, to enhance the association's voice on behalf of all industry stakeholders, and to generate necessary resources for expanded CRN programming.

CRN is mission-driven, guided by its Board of Directors' expertise and supported by its members. CRN's goals are accomplished through inter-department collaboration and seamless cooperation. This year, we successfully completed a three-year work plan.

The dietary supplement and functional food industry is in great shape: it's robust, resilient and respected. CRN members can pause for some affirmative fist bumps—it's because of your commitment to a strong code of ethics and always raising the bar by putting 'responsibility first' that this industry is thriving. While 2017 has been a year of unpredictability and volatility in some respects for our marketplace, this has been a year of increased stature, sales and strength.

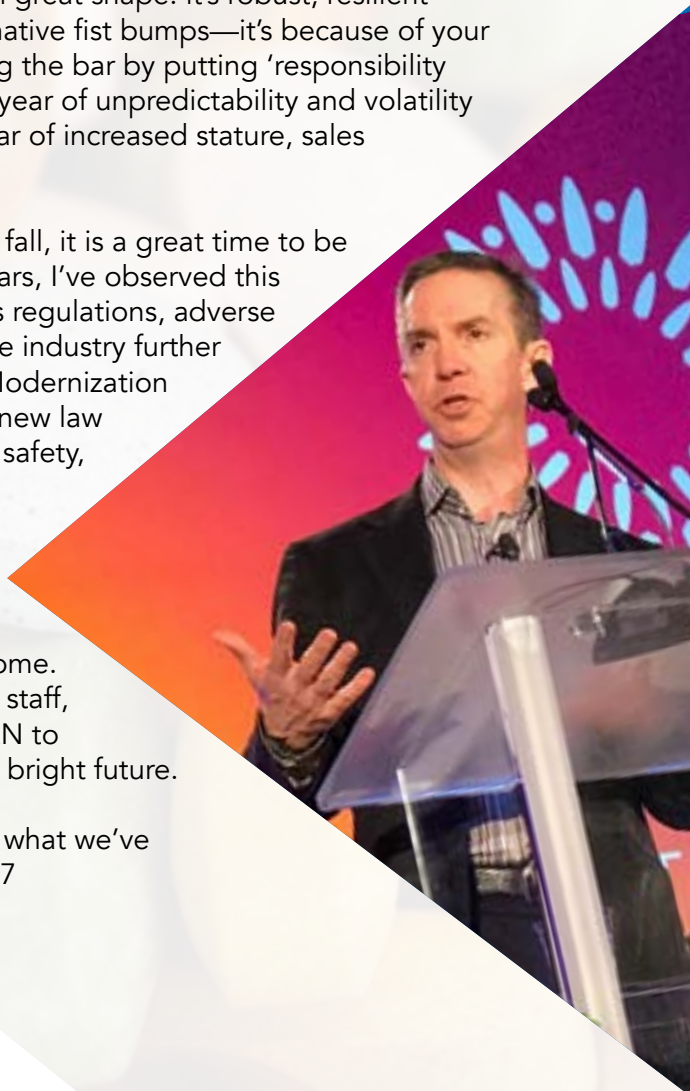
As I observed at CRN's annual conference in Arizona last fall, it is a great time to be in the industry! As the steward of CRN for the past 12 years, I've observed this industry mature under the Good Manufacturing Practices regulations, adverse event reporting, and three sets of Dietary Guidelines. The industry further evolved as CRN worked to help enact the Food Safety Modernization Act, the Designer Anabolic Steroid Control Act, and the new law on GMO labeling. Now companies are more focused on safety, quality, and product integrity than ever before, and CRN continues to lead in self-regulatory initiatives, renewing the NAD Advertising Review Program and launching the Supplement **OWL**.

It's a testament to you, our members, how far we have come. From the collaborative spirit and the synergy of the CRN staff, working across departments, to the trust you place in CRN to influence policy and public perception, we are shaping a bright future.

I invite you to review this report and share in celebrating what we've accomplished together as we shaped the industry in 2017—and to be inspired by what's to come.



Steve Mister
President & CEO
Council for Responsible Nutrition



BUILDING CRN MEMBERSHIP: NEW MEMBERS IN 2017

New Voting Members

Activ Nutritional, LLC
Before Brands, Inc.
Biova, LLC
Brassica Protection Products LLC
Catalent
doTERRA International
Earthrise Nutritionals
Elysium Health
Hermes Pharma
Jigsaw Health LLC
Kaleido
Life Line Foods
Natrol, LLC

NeoCell
Nutrawise
Ortho Molecular Products, Inc.
Personalized Nutrition, LLC
Pharma Tech Industries
Physician's Seal, LLC
Probi USA, Inc. dba Nutraceutix
RoundTable Healthcare Partners
Santa Cruz Nutritionals
Shanghai Freeman
Trident Brands
Vitabiotics

New Associate Members

ACG North America
Debevoise & Plimpton, LLP
Gilbert LLP-Insurance Recovery Law
Kilpatrick Townsend & Stockton
LifeScienceRisk
Michael Schaeffer, LLC
Micro Quality Labs Inc.
Natural Partners, Inc.
Pure Branding Inc.
Q Laboratories
SRO-Bio, LLC
Supplement Safety Solutions, LLC



CRN's Judy Blatman and Holly Vogtman with the Supplement OWL



EXPANDING 'RESPONSIBILITY FIRST' INITIATIVES: THE SUPPLEMENT OWL



**ARE YOUR
COMPANY'S
LABELS IN YET?**

**AT THE END OF 2017:
5,629 labels were visible
in the Supplement OWL**

CRN's Steve Mister
at NBJ Summit

Launched in April 2017, the Supplement **OWL** (Online Wellness Library), the dietary supplement product registry, is being hailed as “a hallmark of industry maturation.” It was all-hands-on-deck for CRN staff leading up to the launch, with Scientific & Regulatory Affairs, Communications, Government Relations, and Legal Affairs working together to ensure a successful flight.

In the months following its launch, the Supplement **OWL** received public support from all of the major trade associations of the dietary supplement industry, as well as from other key stakeholders, such as NSF International and the American Botanical Council.

To boost awareness of the initiative, CRN brought the Supplement **OWL** to life, visiting trade shows with a costumed owl mascot and a falconer displaying a live owl, posing for photos and encouraging #SupplementOWL social media posts.

The Supplement **OWL** rapidly gained momentum within the industry and its stakeholders as more and more companies entered their finished product labels into the registry. In late 2017, CRN established an advisory board to help guide the OWL as it continues to grow.



“As our industry booms, the self-regulatory Supplement **OWL** is just par for the course.”

– Jim Hyde, Chair, CRN Board of Directors, Vice President and General Manager, Balchem Human Nutrition in New Hope Network’s “IDEAXCHANGE”

EXPOSURE & ACCOLADES

In 2017, the Supplement **OWL** was featured in:

- 94 articles published in the trade press, reaching 1.4+ million readers;
- 8 bylined articles by CRN staff and members;
- 14 presentations to lawmakers, industry stakeholders and retailers;
- 6-month ad campaign, garnering 2+ million impressions;
- 5 webinars; and
- Won an American Society of Association Executives (ASAE) award.



CRN ran a six-month ad campaign in industry trade publications (online and print) with several creative flights produced in-house to generate awareness and send stakeholders to the Supplement **OWL** informational website with details on how to submit product labels. The campaign generated over two million impressions.



CRN's Steve Mister with Regan Bailey and CRN's Duffy MacKay

What happens when CRN's Government Relations, Scientific & Regulatory Affairs, and Communications departments join forces with its member company experts in legislative affairs? Progress happens—as CRN made a successful case with House legislators for inclusion of multivitamin/mineral (MVM) supplements in the Supplemental Nutrition Assistance Program (SNAP). Research demonstrates that Americans don't get all the nutrients they need from food alone—and new research underscores that low-income Americans are at greater risk for essential nutrient shortfalls than Americans from higher-income households. In 2017, CRN worked to change that disparity across economic lines.

All Americans need essential nutrients.

SNAP: SCIENCE + POLICY INTERSECT

MAKING THE CASE FOR MVM INCLUSION



Multivitamin/Mineral (MVM) Inclusion in the Supplemental Nutrition Assistance Program (SNAP)
 Prepared by the Council for Responsible Nutrition

New research confirms significant essential nutrient gaps in low-income Americans and the role that a multivitamin/mineral can play to fill nutrient gaps

Abstract
 It is well established that Americans are falling short of key nutrients, but new research shows that low-income Americans are at greater risk for essential nutrient shortfalls than Americans from higher-income households. Dietary supplements, like the multivitamin/mineral (MVM), provide shortfall nutrients and have been shown to help fill nutrient gaps. Including MVMs in SNAP creates no additional program costs, but provides low-income consumers with a choice for better nutrition.


Nutrient shortfalls
 Getting all essential nutrients from food is preferred, but data show that most Americans fall short in key nutrients such as potassium, magnesium, calcium, and vitamins A, D, E, and C.¹ In fact, the 2015-2020 Dietary Guidelines for Americans identified that under-consumption of calcium, potassium, and vitamin D is of public health concern because low intakes are associated with particular health concerns.¹ Additionally, under-consumption of iron in young women, women capable of becoming pregnant, and women who are pregnant is of public health concern.

Most Americans fall short of these key nutrients

- Calcium*
- Magnesium
- Potassium*
- Vitamin A
- Vitamin C
- Vitamin D*
- Vitamin E

***Under-consumption of calcium, potassium, and vitamin D is of public health concern.**

2015-2020 Dietary Guidelines for Americans



RAISING AWARENESS ON THE HILL

CRN's Government Relations team convened a Congressional Dietary Supplement Caucus (DSC) briefing featuring Regan Bailey, Ph.D., R.D., M.P.H., of Purdue University. Speaking before an audience of more than 60 congressional staffers and guests, Dr. Bailey discussed dietary supplement use and nutrient intakes in U.S. adults, as well as ways to improve nutritional habits and access to products that will help them achieve their health and wellness goals.

MESSAGING ACROSS AMERICA

To help spread the message about nutrient shortfalls, CRN's Steve Mister's op-ed column, "Many Americans Don't Get Enough Nutrients from Food," was published in USA Today and the Detroit News, with a shorter version appearing in 18 smaller community newspapers, reaching a readership of 144 million. The piece was shared 1,280 times on social media and had 98,000 coverage views.

ADVANCING TOWARD OUR GOAL

Low-income Americans are now one step closer to better access to vitamins and minerals. The SNAP Vitamin and Mineral Improvement Act (HR 3841), which allows for the inclusion of MVMs in SNAP, was introduced in September. In a public statement, CRN commended Rep. Mike Rogers (R-AL) and original co-sponsors, Reps. Kyrsten Sinema (D-AZ), Mia Love (R-UT) and Tony Cárdenas (D-CA), for their efforts. CRN is working to introduce similar legislation in the Senate.

"Fortunately, solving America's dietary shortfalls is possible with the help of nutritional supplements like daily multivitamins. They're no substitute for healthy eating, but they're a realistic way to plug the gaps in our diets."

– CRN's Steve Mister



USA
TODAY



Regan Bailey addressing attendees at the DSC educational briefing



Rep. Tony Cárdenas (D-CA) with CRN members

CRN's Ingrid Lebert with Rep. Kyrsten Sinema (D-AZ) and CRN's Steve Mister

INFLUENCING GOVERNMENT POLICY: DAY ON THE HILL AND DAY-TO-DAY



Rep. Markwayne Mullin (R-OK)
meets with Day on the Hill attendees



CRN's Mike Greene addresses Day on the Hill attendees



100+ attendees, 100+ meetings for CRN and AHPA's Day on the Hill 2017

CRN's Government Relations team united many industry voices to demonstrate to lawmakers one collective desire to work together for the good of consumers. CRN embraced opportunities to influence and guide policy pertaining to dietary supplements and functional food, and worked with member companies to make a difference for the industry. Highlights in this area include:

BUILDING ALLIANCES IN INDUSTRY, IN D.C.

- Partnered with the American Herbal Products Association (AHPA) for CRN's 14th annual Day on the Hill. The largest Day on the Hill to date, over 100 representatives from the two associations spent the day conducting face-to-face meetings with more than 100 congressional offices and committee staffers, including 20 members of Congress.
- Engaged the Congressional Dietary Supplement Caucus (DSC) with three well-attended lunch briefings and two Supplement **OWL** demonstrations and welcomed the new DSC co-chair Rep. Mia Love (R-UT). CRN and its member companies encouraged and recruited 11+ new members to join the DSC, resulting in a total bicameral, bipartisan membership of 43.



60 MEETINGS IN 60 DAYS

- Met with 60 freshman members of congress in 60 days to give CRN and its members the opportunity to engage with elected officials, promote positive news, and clarify common misconceptions about the industry. Successfully positioned CRN as the go-to source on the Hill for supplement information.

POLITICAL ACTION COMMITTEE

- CRN PAC held three fundraising events for Sen. Tim Scott (R-SC), Sen. Martin Heinrich (D-NM) and Rep. Tony Cárdenas (D-CA).

IN THE STATES AND BEYOND

CRN actively engaged in key states, as well as in the territory of Puerto Rico. Major actions include:

- **Massachusetts:** Testified against a state age-restriction bill and organized a strong coalition with retailers in opposition.
- **New York:** Halted negative dietary supplement labeling legislation supported by the New York Department of Health.
- **California:** Organized its annual Day in Sacramento to underscore the strong presence of the dietary supplement industry in California, including its positive economic and health impacts. CRN monitored Prop 65 activity as well.
- **Puerto Rico:** Held two educational events to provide more information about dietary supplements and further efforts to stop Administrative Order 346.





CRN's Andrea Wong and Duffy MacKay with conference speakers Stephen Schmitz, Rick Kingston and Michael Fraser, experts on the poison control center data panel at The Conference

Science is at the heart of everything CRN does. You won't find any labs or test tubes at CRN's office, but the scientific expertise and depth of analysis are very real. CRN's Scientific & Regulatory Affairs team maintains working relationships with key stakeholders. Through these relationships, CRN and its members collaborated on evidence-based initiatives and engaged in the regulatory process to support the association's mission.



CRN's Steve Mister, FDA's Stephen Ostroff and CRN Board Chair Jim Hyde



CRN's Steve Mister on a panel at the Office of Dietary Supplements Practicum

FOSTERING & FURTHERING: EXCELLENCE IN NUTRITION SCIENCE



Participants in the personalized nutrition panel at CRN Day of Science: Ahmed El-Sohemy, Susan Hazels Mitmesser and Chris D'Adamo

KEEPING UP WITH THE NDIs

CRN actively participated in the regulatory process on New Dietary Ingredient (NDI) notifications:

- Submitted comments to FDA on the development of a pre-DSHEA list of dietary ingredients as the “reasonable path forward” for the industry.
- Presented CRN’s perspectives on a pre-DSHEA ingredient list at FDA’s public meeting.
- Conducted a webinar for members and industry with Natural Products INSIDER following the meeting.

“More than 170 million Americans take dietary supplements each year, and the responsible industry is invested in bringing safe and quality products to meet this demand.”

– CRN Statement on CNN, ‘Calls to Poison Centers About Supplements Up 50%, Especially Among Kids’

ADDITIONAL COMMENTS ON CRITICAL ISSUES

CRN filed written comments on:

- FDA’s definition of dietary fiber on labeling.
- Use of the term “Healthy” in the labeling of human food products.
- FDA Draft Guidance setting new standards for infant formula structure/function claims substantiation; co-signed a letter with the Grocery Manufacturers Association (GMA) and the Infant Nutrition Council of America (INCA).
- FDA Draft Guidance on “Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates.”
- A citizen petition to FDA from the International Probiotics Association (IPA), requesting enforcement discretion on the use of colony-forming unit (CFUs) probiotic product labels (CRN partnered with IPA to release probiotics best practice guidelines, which went into effect January 2017).
- A petition to FDA for a qualified health claim for magnesium and reduced risk of high blood pressure.
- U.S. Department of Health and Human Services strategic plan for 2018–2022.

SCIENCE-BASED RESPONSES

Provided science-based analysis to support CRN responses to studies and reports, such as:

- Statement emphasizing creatine’s strong safety record in response to a Pediatrics article, “Dietary Supplements and Young Teens: Misinformation and Access Provided by Retailers.”
- Letter-to-the-editor published in Thyroid on iodine content of prenatal multivitamins in the U.S.
- Letter-to-the-editor published in Journal of Medical Toxicology in response to study on reports to poison control centers related to dietary supplements.
- Statement on Selective Androgen Receptor Modulators (SARMs).

ENGAGEMENT IN KEY GROUPS

- Global Retailer and Manufacturer Alliance (GRMA): Worked on development of a standard for dietary supplement GMP audits.
- Dietary Supplement Quality Collaborative (DSQC): Worked with other stakeholders to raise the bar on dietary supplement quality.
- AOAC International: Worked on developing standard methods for more dietary ingredients.
- Regulatory Affairs Professionals Society (RAPS): Co-edited and published a bylined article—“Regulatory Focus” October publication.



CRN's delegation at the July Codex Alimentarius Commission meeting in Geneva: Mark LeDoux, Natural Alternatives International, CRN's Jim Griffiths, and Harvey Kamil, The Nature's Bounty Co.

SCIENCE ACROSS THE GLOBE: INTERNATIONAL AFFAIRS

The 2017 CRN-International Scientific Symposium—Healthy Aging: The Natural Consequences of Good Nutrition—drew 50 registrants from 21 countries, the best turnout in the eight-year history of the event. This year, CRN-I added a follow-up event to recap the previous day's symposium, providing another opportunity to reach attendees of the Codex CCFNSDU meeting.

PUBLISH, PRESENT AND PERSUADE

- Published the proceedings from the 2016 CRN-I symposium—Optimal Nutrition and the Ever-Changing Dietary Landscape—in the European Journal of Nutrition. Industry trade press widely covered the paper and CRN disseminated its abstract, translated into nine languages, to Codex CCFNSDU delegates.
- International Carotenoids Symposium in Lucerne—played a key role in organization and sponsorship, gave introductory remarks, and co-authored poster presented at meeting and published in the European Journal of Nutrition.



- European Society of Toxicology (SOT) in Bratislava —attended and developed a poster for 2018 SOT meeting follow-up presentation and publication.
- Israeli nutrition labeling—CRN comments yielded industry-recommended changes.
- Certificate of free sale—engaged CRN members and U.S. regulatory officials in efforts to modify the current regulations to ease the export of U.S.- manufactured dietary supplements globally.
- Promoted science-based establishment of Codex Nutrient Reference Values for vitamins and omega-3 fatty acids in published industry trade press articles.
- Published five scientific journal articles related to international affairs in 2017.

LEGAL AFFAIRS, FOR THE WIN

FIXING A FISHY SITUATION

CRN played a key role in a victory for the dietary supplement industry—the International Trade Commission (ITC) decision not to pursue a complaint filed by biopharmaceutical company Amarin which would have detrimentally impacted consumer access to omega-3 supplements. CRN submitted a public interest statement and non-institution letter to ITC and also engaged allies on Capitol Hill and FDA to weigh in on this matter, resulting in ITC's decision. CRN is monitoring Amarin's ongoing efforts to appeal the decision and will proactively respond as needed.



CASE IN POINT

CRN submitted an amicus brief to support a motion for summary judgment in *Korolshteyn v. Costco Wholesale Corp.*, a case involving alleged false statements for a ginkgo biloba supplement. Although amicus briefs at the district level are somewhat rare and often not given much weight when filed, in this particular case the court credited CRN's arguments to allow the brief, and CRN's involvement was key to the positive outcome of this case.



CRN/NAD INITIATIVE LIVES ON

The CRN Board approved a three-year renewal of the CRN/National Advertising Division (NAD) Dietary Supplement Advertising Review initiative, funded by the CRN Foundation (CRNF).

The initiative, heralded by the Federal Trade Commission as a demonstration of "...just how impactful self-regulation can be," achieved the following milestones in 2017:

- CRNF has provided grants to NAD totaling more than \$2.8 million since the program's inception in 2006.
- NAD has issued more than 300 decisions evaluating dietary supplement advertising.



AGs LOVE THE OWL

CRN hosted a breakout session for state Attorneys General (AG) staff, including California, New Mexico, Wisconsin, North Dakota, Arkansas and Hawaii, who attended the Conference of Western Attorneys General (CWAG) annual meeting. At the event, AG staff learned about the dietary supplement industry's latest self-regulatory initiatives to promote transparency and accountability and had a chance to try the Supplement **OWL** for themselves with live demos of the registry.



CMOC17

crnusa.org



CRN's Judy Blatman speaks at the annual CRN Communications and Media Outreach Committee (CMOC) meeting in New York City

POSITIVELY INFLUENCING PUBLIC PERCEPTION OF DIETARY SUPPLEMENTS AND FUNCTIONAL FOOD



MICRO IS MAJOR: RETHINKING INFLUENCING

CAT LINCOLN
CEO

CLEVER

CRN's Nancy Weindruch introduces a speaker at the annual CRN CMOC meeting

USA SNAPSHOTS®

76%

of Americans take dietary supplements, up 5 percentage points from 2016.



SOURCE Council for Responsible Nutrition survey of 2,001 adults

WHO TAKES DIETARY SUPPLEMENTS?



CRN's Communications team publicly amplified the work of the association, in concert with subject experts from other departments. The team voiced science-based endorsements—and defenses—of the safety and benefits of supplements and functional food to promote a positive industry image.

Key accomplishments and activities in 2017 include:

RAPID RESPONSE

- Responded to 16 studies/reports on a range of topics, including: supplement exposures reported to U.S. Poison Control Centers (Journal of Medical Toxicology); liver injury from supplements (Hepatology); memory supplements (U.S. GAO report); and more.

PROACTIVE MESSAGING

- Placed flagship statistic from CRN's Consumer Survey on Dietary Supplements as a USA SNAPSHOT on the front page of the Life section of USA TODAY—the 2016 stat appeared in January 2017 and the 2017 stat (shown left) appeared in December.
- Further promoted results from its 2016 Consumer Survey and fielded 2017's survey, releasing initial results at The Conference.
- Issued 72 press releases and published 20 bylined articles in trade publications.
- New CRN website won an Academy of Interactive & Visual Arts "Communicator Award."
- Commissioned blogger tour featuring 25 influencers publishing personal blog posts on the benefits of living #LifeSupplemented—reaching 8,020,599 followers.

ALLIANCE BUILDING

- Sponsored/presented at the invitation-only FoodFluence meeting for the second consecutive year, reaching 30 high-profile registered dietitians (RDs); resulted in publicity in the Miami Herald, Boston Globe, New York Daily News and more.
- Sponsored/presented at invitation-only Shopping for Health event for 20+ select RDs/nutritionists/advisors at supermarket and retail chains. CRN spoke about regulation, trustworthy resources and survey data.



EXPANDED POSITIVE PUBLICITY

- CRN continued its partnership with boutique PR firm Wyatt Communications to help generate positive publicity for dietary supplements.

2017 results include:

- 96 stories published—75 online, 21 in print, via outlets such as those shown above—garnering more than 4 million impressions online alone.
- 41 positive scientific studies promoted.

PROTECTING CONSUMERS & RESPONSIBLE INDUSTRY

- Issued statements on hot-button topics, including a warning about Selective Androgen Receptor Modulators (SARMs), working with the U.S. Anti-Doping Agency (USADA), and an alert emphasizing that supplements may not make claims to treat opioid addiction.



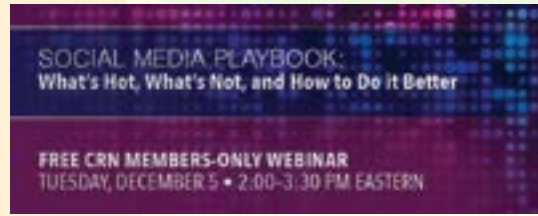
MEMBER EDUCATION & EVENTS— BROUGHT TO YOU BY THE CRN STAFF

CRN's educational opportunities and events were more plentiful than ever in 2017, with in-person meetings added to the calendar as well as increased webinar offerings.

WEBINARS



You want experts? CRN shares experts. Working with Natural Products INSIDER, CRN produced four popular webinars in 2017. Then, CRN added three more webinars for our members—and only our members—at no cost. The more we all know, the better we can shape our industry.



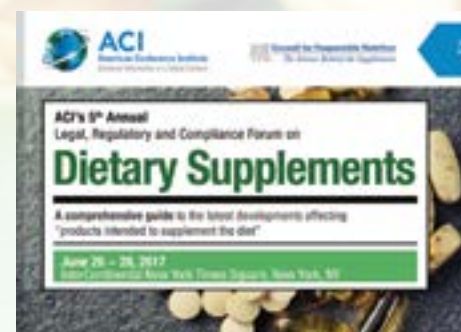
TWITTER CHAT

CRN hosted a Twitter chat to discuss the significance of supplement-specific GMPs and the importance of increasing compliance across the industry. Tweeters used the hashtag #GMPsTurn10 to reach an impressive 29,860 accounts, resulting in 247,810 impressions.



IN-PERSON MEETINGS

There's nothing like in-person networking. In 2017, CRN provided ample opportunities for members to interact with each other—and with potential members, with regulators, with scientists—all with a commitment to building a better, stronger, safer, science-based industry for our consumers. How many of these meetings did you attend?



CRN's Carl Hyland and Andrea Wong with champion boxers Larry Holmes and Gerry Cooney. Photo courtesy of Polyphenolics at SupplySide West.

CRN punched up our membership efforts this year, thanks to a new and engaged Membership Committee. CRN sought to broaden our membership to represent voices from all segments of the responsible industry. CRN added 37 new member companies in 2017—and here's a fun fact: we've boosted our representation of products sold exclusively in the natural channel.

Thanks to all of you who participated in our first—but not our last—CRN Member Survey. We've learned a lot about serving you better.

SupplySide West. Expo East. NBJ Summit. CRN was there. Presenting, listening, influencing. In short, shaping our industry together.

CRN STAFF: WORKING TOGETHER FOR YOU

Visit www.crnusa.org/staff for CRN team contact information and explore www.crnusa.org to stay up to date on what CRN is doing for our member companies throughout the year.

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