



**Member
FOCUS**



Council for Responsible Nutrition

The Science Behind the Supplements

2015 ANNUAL REPORT

CHALLENGES & VICTORIES 2015



2015 was a uniquely challenging year for the dietary supplement industry—some have said “game-changing.” But at CRN, we viewed it as “game on”—and we more than met the challenge. The year started with an unprecedented announcement by the New York Attorney General’s office, demanding four major retailers remove several botanical products from their shelves based on DNA barcode test results that most viewed as the wrong test for these products. The year ended with CRN’s Board of Directors taking a first, but important, step toward greater industry transparency, mandating that in 2017 product manufacturers and marketers must submit their product labels to the Office of Dietary Supplements label database as a condition of CRN membership.

And in between those two watershed events, CRN successfully worked to minimize the potential ripple effects from New York to other states; we embarked on a new, three-year strategic work plan; we protected against negative legislation and sensational journalism; and we promoted positive science and public policy that would benefit our industry’s consumers and responsible companies.

Unquestionably, 2015 took us in directions we had not planned. But through it all, we kept our member focus: protecting your business, listening to your concerns, building confidence in your products and giving you opportunities to work collectively to improve the industry. We’re proud of our members and the bold way you are leading the industry forward. Thank you for your trust in us and for your continued commitment to responsibility. Together we can keep the focus on a healthy future!

Steve Mister
President & CEO
Council for Responsible Nutrition

Focused on the
FIGHT

Strategic Work Plan for 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.

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.

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.

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.

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.

Focused on
moving
FORWARD

27 New members in 2015

VOTING MEMBERS:

Bodybuilding.com
Er-Kang Pharmaceutical Co., Ltd.
Ganeden, Inc.
Helios Corp.
Japan Bio Science Laboratory Co., Ltd.
Kappa Bioscience AS
KD Pharma
Lief Labs
Mary Kay, Inc.
MusclePharm Corp.
Natreon, Inc.
NRG Innovations, LLC
Paragon Laboratories
Renew Life Formulas, Inc.
RIBUS
Seppic Inc.
The Honest Company, Inc.

ASSOCIATE MEMBERS:

Bruna Seals
Call & Jensen
NFP Property and Casualty Services
Nicholas Hall & Company
Optum Insight Inc.
Perkins Coie LLP
Polsinelli PC
Qualyst Transporter Solutions, LLC
RNI Consulting
Womble Carlyle Sandridge & Rice, LLP

Focused on
GROWTH

SETTING THE RECORD STRAIGHT IN NY A STRONG RESPONSE

CRN's response to the allegations of the New York Attorney General against the dietary supplement industry was swift and strong. CRN recognized immediately that this was not a one-state or one-size-fits-all issue. And we knew the ramifications would last a good part of the year, and beyond.

CRN RESPONDS TO NY ATTORNEY GENERAL ACTIONS AGAINST HERBAL SUPPLEMENTS | CRN HOME

CONSUMER Q&A:
Herbal Dietary Supplements and Recent Actions by the New York Attorney General

Additional Resources & Materials

- CRN Responds
- What Others Are Saying

New White Paper on DNA Barcode Testing

HERBAL SUPPLEMENT

www.crnusa.org/NYAG

CRN: STANDING UP FOR THE INDUSTRY

The New York Times
New York Attorney General Targets Supplements at Major Retailers

By ANBARAD O'CONNOR
FEBRUARY 2, 2015 12:00 AM

The New York State attorney general's office accused five major retailers on Monday of selling fraudulent and potentially dangerous herbal supplements and demanded that they remove the products from their shelves.

In February, the New York State attorney general's (AG) office launched an attack on the dietary supplement industry, releasing results of DNA barcode tests alleging that herbal supplements sold by four major retailers were misbranded, and demanding the retailers remove the products from the shelves. The Council for Responsible Nutrition (CRN) was the first industry voice to question the AG's specious assertions and continues to push back against this stunt, calling on the AG to demonstrate the same transparency it has demanded of retailers.

Council for Responsible Nutrition
The Science Behind the Supplements

Why DNA Barcode Testing is Not Appropriate for Use on Herbal Extracts

- IT STARTS WITH THE PLANT**
Herbal supplements, also known as botanical supplements, start with plants. If you tested, for example, a ginseng plant right out of the ground using the DNA barcode test method, you would rightly expect to find ginseng DNA.
- THEN COMES THE EXTRACTION**
But many herbal supplements—including those that “failed” the DNA barcode test conducted by the New York Attorney General—go through a manufacturing extraction process where the active ingredients—known as phytochemicals—are separated from the plant cells. The DNA is found in the plant cells.
- WHERE'S THE DNA?**
During this extraction process, DNA can be damaged or left behind. What goes into the finished herbal supplements are the extracts containing the phytochemicals.
- IT'S THE WRONG TEST**
DNA barcode tests are not appropriate tests for finished products made from herbal extractions. In general, DNA barcode tests can identify plant material from unprocessed and properly handled samples from whole plants. Even in whole plant samples, DNA tests are not particularly helpful to determine how much plant material is there, only that it is present.
- THE RIGHT TESTS**
FDA requires that dietary supplement manufacturers adhere to good manufacturing practices—which include meeting product specifications for identity, purity, strength and composition. Manufacturers use appropriate and valid test methods to ensure that the right phytochemicals exist in the final product.

HERBAL SUPPLEMENT

Phytochemicals are detected in finished products.

Council for Responsible Nutrition | www.crnusa.org



Working as a team

Led by CRN's President & CEO, the association pulled together an integrated team from its Legal, Communications, Government Relations and Scientific & Regulatory Affairs departments, seamlessly building a multifaceted defense against the New York Attorney General's (NYAG) actions.

- Alerted members ahead of the news breaking in The New York Times
- Issued a press response providing the industry's perspective in first-day stories
- Developed a microsite with consumer-friendly resources, tackling a complex issue, designed to set the record straight
- Spearheaded efforts for an outside scientific expert to develop a white paper on DNA barcode testing
- Hired experts from legal, legislative consulting and public relations firms
- Met with the NYAG office to challenge the test results
- Met with lawmakers in Albany to stop any potential negative legislation resulting from the NYAG actions
- Met with over 40 AGs throughout the country, and had in-depth conversations about the industry and its regulations with 15 AGs in their states
- Represented the industry on a panel presentation at a National Association of Attorneys General Consumer Protection meeting
- Proactively inoculated Congress, FDA and FTC with the industry's perspective on DNA testing
- Worked with Congressional Dietary Supplement Caucus to co-host a lunch briefing on the issue
- Conducted extensive media outreach, resulting in CRN quotes in major outlets such as AP, NBC Nightly News, The Atlantic, The New York Times, NPR, the New York Daily News, the Albany Times Union and more; met personally with a New York Times reporter and editorial board editor
- Published letters-to-the-editor in The Washington Post and The New York Times
- Authored numerous bylined articles in industry trade press outlets
- Kept members updated and involved through ongoing communications and association-wide webinars



**Focused
DEFENSE**

COMPREHENSIVE COMMUNICATIONS

CRN maintained its position as the “voice of the industry” while also expanding its proactive efforts to help foster a more positive image of the industry and dietary supplement usage.



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RECOMMENDED GUIDELINES:
Iodine Quantity in Multivitamin/Mineral Supplements for Pregnancy and Lactation

PURPOSE:

Press Release www.crnusa.org

Council for Responsible Nutrition
The Science Behind the Supplements

For Immediate Release Contact: Nancy Stewart, 202-204-7684

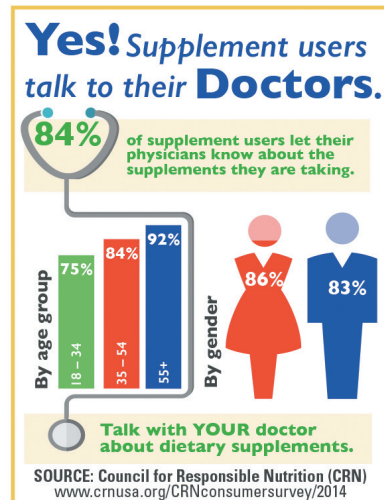
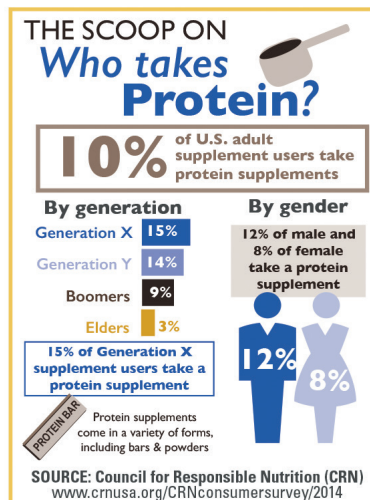
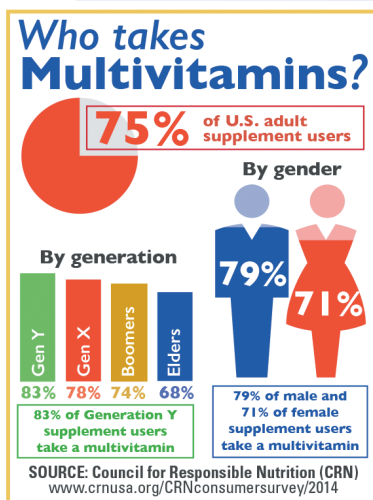
CRN Emphasizes Importance of Iodine this World Thyroid Day —Daily Multivitamin/Mineral Supplement with 150 mcg of Iodine Recommended for Pregnant and Lactating Women—

Washington, D.C., May 25, 2015—As part of efforts to increase awareness of thyroid health on today's 8th Annual World Thyroid Day, the Council for Responsible Nutrition (CRN) joins the American Thyroid Association (ATA) and its sister international thyroid societies in calling attention to the important functions regulated by a healthy thyroid. In particular, CRN is focusing on the role of iodine and its importance for thyroid and overall health, especially for women who are pregnant or lactating.

"Iodine is a nutrient that is critical for the production of thyroid hormones, and therefore, a deficiency in iodine can lead to thyroid hormone-related and other health problems," said Duffy MacKay, N.D., senior vice president, scientific and regulatory affairs, CRN. "Additionally, pregnant



Focused VOICE OF THE INDUSTRY



A range of stakeholders, audiences



- Promoted data from CRN’s annual Consumer Survey on Dietary Supplements, using media outreach, infographics and press materials, resulting in two USA Today snapshots
- Worked with a boutique PR agency to generate media coverage on positive scientific studies with placements in Prevention, Details, Men’s Fitness, Fox News, AARP magazine, SHAPE, Wine Spectator, local ABC and CBS news affiliates and more
- Convened a record number of CRN executives for the Communications and Media Outreach Committee’s In-person Meeting in New York City, engaged with Anahad O’Connor from The New York Times and reporters from The Atlantic, BuzzFeed and the New York Daily News, as well as speakers on other topics
- Supported outreach to retail executives, reaching a new audience with The Short Report, a topline newsletter just for retailers
- Launched Alliance Building initiative, collaborating with the American Thyroid Association on the importance of iodine for pregnant and lactating women
- Signed on as a sponsor of FoodFluence for January 2016—an invitation-only science symposium for high profile registered dietitians



- Provided a grant to the Academy of Integrative Healthcare Practitioners
- Partnered with Informa Exhibitions on educational webinars for industry and with Skipta for pharmacists and nurse practitioners
- Prepared members for “Vitmania” book and for CBC-TV/PBS-TV programs on the dietary supplement industry
- Continued rapid response program to provide an industry perspective with the press on scientific studies and inaccurate news coverage
- Authored 19 bylined articles for industry publications solidifying CRN as a thought leader

INFLUENCE ON THE HILL

CRN engages in the halls of Congress and throughout the states, educating legislators about the benefits of dietary supplements to their constituents and to their local economies.



1) David Christensen, Bayer, with Rep. Frank Pallone (D-NJ); 2) Rep. Jason Chaffetz (R-UT) with CRN's Mike Greene; 3) Marjorie Fine, Shaklee, with Rep. Mike Pompeo (R-KS) and CRN's Steve Mister; 4) Kate Houston, Cargill, with Sen. Orrin Hatch (R-UT); 5) CRN members with legislators during the association's annual Day on the Hill; 6) John Blair, The Juice Plus+ Company and Tom Tchang, Watson Inc, with Kristi Thompson, from the office of Rep. Renee Ellmers (R-NC)

Shaping policy to protect consumers' interests



Focused on
POLICY
BASED ON SCIENCE

- Met with entire freshman class of 114th Congress
- Coordinated CRN's Day on the Hill, with over 70 participants (a record number), 55 office visits and 8 members of Congress addressing CRN members
- Stopped legislative amendments from Sens. Blumenthal and Durbin that would have negatively and unnecessarily impacted the dietary supplement industry
- Helped grow the bicameral, bipartisan Dietary Supplement Caucus (DSC), reaching a new high membership of 37
- Co-hosted educational lunch briefings for the DSC, featuring speakers such as Tieraona Low Dog, M.D., and Rick Kingston, PharmD.
- Led industry efforts in support of elevating CFSAN's Division of Dietary Supplement Programs to an "Office" at FDA with outreach to Congress and the U.S. Department of Health & Human Services
- Created a CRN committee of DC-based government relations executives holding in-person meetings to address issues related to dietary supplement lobbying
- CRN PAC reached new record levels of receipts and contributions, extending its influence and impact in Washington
- Supported legislation preventing consumer access to pure powdered caffeine in Illinois, New York and Ohio; supported legislation in New Jersey allowing physicians to dispense dietary supplements; vigorously opposed labeling, marketing, direct seller, age restrictions in Florida, Indiana, Massachusetts, New Jersey, New York, and Oklahoma
- Engaged in independent and coalition efforts opposing proposed changes to Prop 65 regulations in California that would increase compliance burdens and confuse consumers



1) Sen. John Boozman (R-AR) with CRN Board Chairman Harvey Kamil, NBTY; 2) CRN members meet with legislators during the association's annual Day on the Hill; 3) Sen. Martin Heinrich (D-NM) speaks to attendees; 4) Rick Kingston, PharmD., speaks at a DSC educational briefing

A COMMITMENT TO SCIENCE

Science is at the center of all CRN does, providing the framework and facts for the association's initiatives.

Focused on
TRANSPARENCY



INTERNATIONAL IMPACT

- Published proceedings from the 2014 CRN-I Scientific Symposium in the European Journal of Nutrition
- Submitted comments to broad-ranging government bodies including:
 - Taiwan—GMO labeling
 - Japan—use of NAC (N-Acetyl Cysteine) in supplements
 - Canada—upper limits for selenium supplements
 - India—developing food and nutritional regulations
 - European Food Safety Authority—caffeine and Nutrient Reference Value (NRV) for magnesium
 - Codex Committee on Nutrition and Foods for Special Dietary Uses—vitamin and mineral NRVs and omega-3 fatty acids DHA/EPA as an NRV for cardiovascular health

Focused on
GLOBAL STANDARDS



- Annual CRN-I Scientific Symposium provided scientific dialogue on Codex-relevant activities and topics, set a new record for regulatory delegation attendance

Science and responsibility go hand in hand

- Created a Transparency Working Group to evaluate possibilities for a dietary supplement product registry and develop a recommended course of action to the CRN Board; announced implementation of the first step in CRN's long term strategy for improving industry accountability by mandating CRN members submit all product labels to the Office of Dietary Supplements (ODS) label database
- Submitted comments to ODS on its dietary supplement label database with suggestions on improving its usefulness and efficiency
- Developed guidelines for the labeling and formulation of melatonin-containing dietary supplements for sleep support
- Developed guidelines on iodine in multivitamin/mineral supplements for pregnancy and lactation
- Increased engagement in standards-setting processes with the U.S. Pharmacopeial Convention for soft-gel rupture and dissolution, beta carotene, and calcium pantothenate monographs
- Engaged in the public process for development of the Dietary Guidelines for Americans, resulting in favorable inclusions of dietary supplements and no negative mentions



- Completed a consumer survey and published results in the peer-reviewed Nutrition Journal, "Consumer attitudes about the role of multivitamins and other dietary supplements"
- Published articles in Natural Medicine Journal on the importance of iodine supplementation for pregnant and lactating women and on FDA's proposed changes to nutrition and supplement labeling
- Submitted comprehensive comments to FDA regarding the Redbook
- Supported efforts to update magnesium dietary reference intakes (DRIs) sponsoring a workshop sponsorship and funding a health claim application with FDA for reduced risk of hypertension
- Presented scientific posters at Experimental Biology meeting

Safety Evaluation of the Dietary Ingredient Melatonin #1395
 Andrea W. Wong Council for Responsible Nutrition, Washington, DC

INTRODUCTION: Although known and marketed as a dietary supplement for a long time, melatonin is a relatively new dietary supplement. The Dietary Supplement ODS label database was created to ensure that all dietary supplements are properly labeled and that consumers have access to accurate information about the ingredients in their supplements.

OBJECTIVE: A literature search was conducted to identify the safety profile of melatonin, including its pharmacology, metabolism, and toxicity. The search was limited to English literature published between 1990 and 2010.

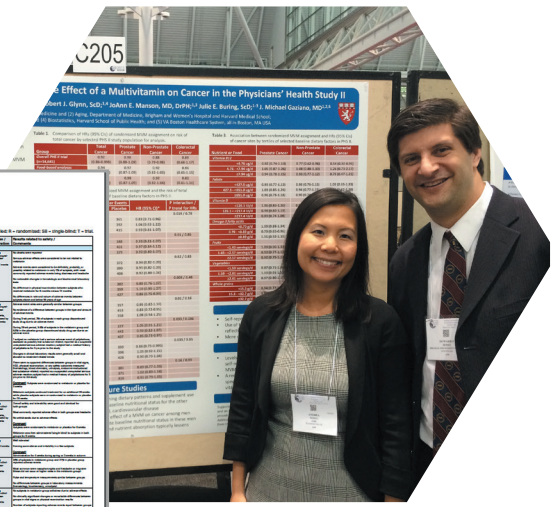
RESULTS: The search identified 100 articles. The most relevant articles were reviewed and summarized. The results of the search are presented in the following table:

Author	Year	Title	Summary
Wong et al.	2010	Safety Evaluation of the Dietary Ingredient Melatonin	Comprehensive safety evaluation of melatonin, including pharmacology, metabolism, and toxicity.
...

CONCLUSION: Melatonin is a safe and effective dietary supplement. It is recommended that melatonin-containing dietary supplements be properly labeled and that consumers be educated about its safe use.

Chemical Structure: CC(=O)Nc1ccc2c(c1)ncn2

References: Wong AW, et al. Safety Evaluation of the Dietary Ingredient Melatonin. *Natural Medicine Journal*. 2010;16(1):1-10.



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