

MISSION: RESPONSIBLE

CRN 2012 ANNUAL REPORT



Council for Responsible Nutrition

The Science Behind the Supplements®

CRN'S MISSION:

To sustain and enhance a climate for our members to responsibly develop, manufacture and market dietary supplements and nutritional ingredients.

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THANK YOU FROM CRN'S PRESIDENT & CEO



Steve Mister

It's no secret that CRN takes the "responsible" in our name seriously. An important part of our mission is to develop and execute projects that reflect how sincere our member companies are about following reasonable regulation, supporting strong

science, and doing what is right for consumers.

Our 2012 activities follow that core philosophy and represent the best of what our member companies give back to the dietary supplement industry. Our success in promoting responsibility and protecting those in the industry who walk that path with us is truly a team effort—one that begins with companies that share our vision for a future where dietary supplements are universally accepted as an essential choice for consumers to achieve and maintain good health and wellness.

We hope that you will be proud of what we have accomplished in 2012—and know that we could not have done it without each and every one of our member companies. I'd like to add a special acknowledgment to CRN's Chairman for the past two years—Jim Hamilton—as well as to our Executive Committee and Board of Directors. Remember, the more your company gets involved in CRN's committees and working groups, the more benefit you'll receive from your CRN membership. We value your input and we thank you all for your support of *Mission: Responsible*.

SNAPSHOT: CRN STRATEGIC PLAN 2012 – 2014

I. Expand 'Responsibility First' Initiatives

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

II. Influence Government Policy on Health & Wellness

GOAL: Attain the interest of and recognition by opinion leaders that dietary supplements are a key element for promoting consumer health and wellness policy.

III. Foster Excellence in Nutrition Science

GOAL: Foster the development and acceptance of appropriate research methods for evaluating the benefits and safety of dietary supplements.

IV. Solidify CRN as the Voice of the Industry

GOAL: Maintain CRN's position as the "go to" supplement organization for credible information, analysis, perspective and expertise for targeted stakeholders, and strengthen CRN's voice on behalf of the industry to communicate the benefits of dietary supplements, the actions of responsible industry, and the fact that the dietary supplement industry is regulated.

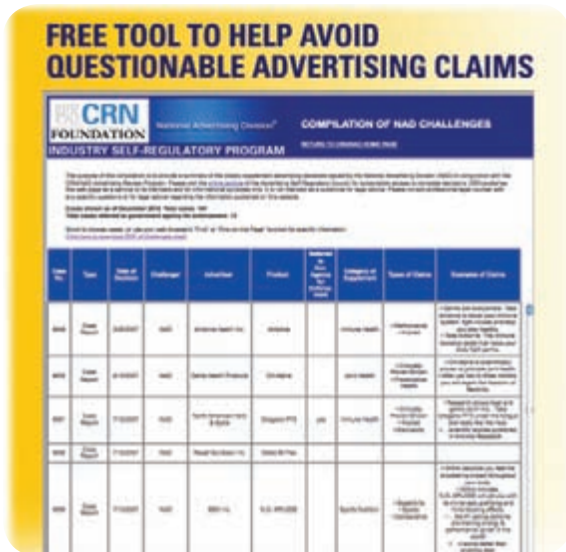
V. Experience Sustained Dynamic Membership Growth

GOAL: Achieve a broad-based CRN membership representative of the industry in order to enhance the association's industry voice and to generate required resources.

RESPONSIBILITY FIRST

Supplement Advertising

- CRN's National Advertising Division (NAD) task force met three times in 2012 and reviewed 27 ads, selecting eight ads for challenges to the NAD—more than half of the ads were referred to FDA for possible enforcement action
- CRN, with VIRGO, held educational webinars for industry on advertising topics: *Doing Business in High-Risk Categories* and *Dietary Supplement Advertising in a Fast Moving World*
- Met with FTC to discuss advertising claims issues
- Partnered with the Food Marketing Institute to remind pharmacists about their legal obligations when making claims for dietary supplements in a retail setting via CRN's "Roadmap for Retailers" free brochure
- Created a tool for industry—a free, searchable compilation of all dietary supplement advertising decisions issued by the NAD since 2007—available on CRN's website: www.crnusa.org/NAD



CRN's NAD microsite with a searchable history of case data

Tainted Products

- CRN continued to dialogue with FDA on solutions for the tainted products issue
- CRN teamed up with CHPA to co-write two bylined articles on the Tainted Dietary Supplement Initiative, appearing in *Convenience Store Petroleum* and *Convenience Store Decisions*



CRN engaged with FDA officials throughout the year—pictured here are CRN Board Chairman Jim Hamilton, FDA's Michael Landa, CRN's Steve Mister and CRN Conference Chair and Chair-Elect John Blair at CRN's annual conference

FSMA

- Conducted industry-wide public service campaign encouraging companies to register their facilities with FDA to comply with the Food Safety Modernization Act (FSMA), including a public service announcement at SupplySide West, a CRN microsite, trade press interviews and collaboration with New Hope/Penton Media on direct email blasts

GMPs

- CRN, with VIRGO, held two educational webinars for industry on good manufacturing practice (GMP) compliance: *Overcoming GMP Challenges* and *Dietary Supplement GMPs: What Can Industry Do Better?*
- CRN President & CEO Steve Mister spoke about GMPs to an audience of retailers at Natural Products Expo; CRN staff incorporated messages encouraging GMP compliance in presentations throughout the year

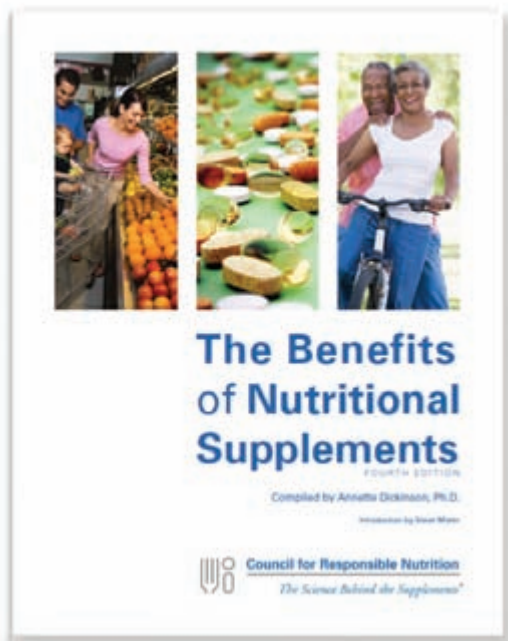
Chicago Tribune

"Any time criminals hijack the reputation of a legitimate industry, it is of great concern. Consumers need to know that this kind of illegal activity is not indicative of the supplement industry. Criminal acts deserve criminal punishments."

CRN's Steve Mister in the *Chicago Tribune* on pharmaceuticals marketed as supplements

Beneficial Products for Consumers

- Published the fourth edition of *The Benefits of Nutritional Supplements*, which assessed the latest scientific research on the health benefits associated with select nutritional supplements, providing members with print editions; made the content available for free on CRN website; distributed copies and a six-page excerpt to key contacts on Capitol Hill



CRN this year released the fourth edition of its comprehensive report, *The Benefits of Nutritional Supplements*

COMMENTS SUBMITTED

- To FDA on synthetic botanical constituents, calling for the reversal of the agency's position
- To U.S. Preventive Services Task Force on Calcium/Vitamin D Draft Recommendations
- To FDA on Adverse Event Reporting and Recordkeeping
- To FDA on Citizen Petition to Require Cautionary Statements on the Label of Dietary Supplements Containing St. John's Wort
- To Codex on the revised draft proposal for a standard for fish oils to be considered by the Codex Committee on Fats and Oils, in collaboration with an informal industry working group

Supplier Qualification

- The CRN-spearheaded Standardized Information on Dietary Ingredients (SIDI) Work Group unveiled a new website and announced a new voluntary guideline, *Dietary Supplement Component Supplier Qualification Guideline*, would be released in January 2013



The SIDI Work Group unveiled a new website in 2012 with improved access and resources for dietary supplement companies

The Washington Post

"...FDA can and does regulate dietary supplements; they are regulated as a category of food and have additional requirements on top of the general food regulations...Marketers are not permitted to skirt the restrictions of either category by dancing between the regulatory lines—and both supplements and conventional foods are held to safety standards. FDA can remove products from the market if it determines they are not safe, regardless of which category they fall in."

CRN's **Steve Mister** in a published letter-to-the-editor following *Washington Post* coverage of FDA reports on energy drinks

INFLUENCING GOVERNMENT POLICY ON HEALTH & WELLNESS

On Capitol Hill

- Mobilized industry opposition to an amendment filed by Sen. Dick Durbin (D-IL) to the FDA Safety and Innovation Act that would have required dietary supplement facilities to register products with FDA, along with a product description, list of ingredients, and copy of the label—the amendment was defeated
- Held 9th annual *Day on the Hill* for CRN members; participants were addressed by several legislators and staff; participants met with 12 members of Congress and 45 different Congressional offices
- Engaged Congressional allies Senators Tom Harkin (D-IA) and Orrin Hatch (R-UT), along with other bipartisan legislators, questioning FDA's anti-DSHEA bias in its New Dietary Ingredient (NDI) Notification Draft Guidance
- Co-hosted three dietary supplement education briefings with the Congressional Dietary Supplement Caucus for Capitol Hill staff
- Circulated a backgrounder on the Hill to clarify inaccuracies in two U.S. Department of Health and Human Services Office of the Inspector General reports
- Continued its Congressional Recess Strategy, encouraging strategic outreach among member companies with a *Recess Handbook*
- Signed onto an open letter to Congress prepared by the American Society of Association Executives Center for Leadership opposing amendments that limit federal employee attendance at conferences
- CRN's Political Action Committee contributed \$18,000 to the campaigns of those in Congress who support the dietary supplement industry, helping educate candidates and elected officials about issues of importance to CRN member companies

AERs

- Developed and distributed backgrounder debunking widely cited unfavorable adverse event reporting (AER) statistic for supplements
- Authored and placed bylines on mischaracterization of AER statistics
- Met with Government Accountability Office to discuss serious adverse event reporting for dietary supplements



NDIs

- Persisted throughout 2012 in calling for FDA's reconsideration of problematic portions of its NDI Draft Guidance, participating in multiple meetings with FDA officials
- Authored article in *Regulatory Toxicology and Pharmacology* calling on FDA to respect the principles of DSHEA and reissue the NDI Draft Guidance; the article was amplified through industry trade press coverage
- Called on FDA to reverse its current position that synthetic constituents of botanicals cannot be dietary ingredients; emphasized that the issue be resolved without having to wait for resolution on other aspects of the NDI Draft Guidance



“It is time for FDA to reconsider its efforts to redistribute the safety burdens allocated by Congress in DSHEA and to recognize that the pre-market paradigm of food additives is not what Congress intended for dietary supplements.”

Steve Mister and John Hathcock, Ph.D.
in *Regulatory Toxicology and Pharmacology*

2012 LEGISLATIVE ACTION

SUPPORTED:

- Designer Anabolic Steroid Control Act
- Family and Retirement Health Investment Act
- Guidance Accountability and Transparency Act

OPPOSED:

- Dietary Supplement Labeling Act

IN THE STATES

Activated CRN Government Relations State Subcommittee (GRSS) to gather and share information on key state legislative interests

Opposed California Genetically Modified Organism (GMO) Labeling Ballot Initiative, Proposition 37

Formed GMO Working Group to explore the policy and procedural implications of GMO labeling for CRN's membership



“CRN was proud to work side by side with our industry champions Sens. Hatch and Harkin. Their continued support for our industry and belief in the basic tenets of DSHEA ensure that consumers have access to safe and beneficial products.”

CRN's Mike Greene in *NutraIngredients.com USA's* coverage of industry's significant victory over an amendment filed by Sen. Dick Durbin (D-IL) to the FDA Safety and Innovation Act (FDA's User Fee bill)



Rep. Diane Black (R-TN) with CRN Chair-Elect John Blair at CRN's *Day on the Hill*



Rep. Tom Coburn (R-OK) with CRN Chair Jim Hamilton at CRN's *Day on the Hill*



CRN worked with Congressional leaders to get the 100th anniversary of the vitamin milestone entered into the *Congressional Record*

INTERNATIONAL INFLUENCE

- Added veteran supplement and safety scientist, Jim Griffiths, Ph.D., as vice president, scientific and international affairs, following the retirement of longtime CRN expert John Hathcock, Ph.D.
- CRN-International (CRN-I) held its third annual scientific symposium *Nutrient Reference Values for Bioactives? New Approaches*—prior to the 34th Session of the Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)
- CRN, as part of an informal working group made up of various industry stakeholders, submitted comments to the first draft of the Codex Standard for Fish Oil
- Sponsored Sidley Austin, LLP, speaker at Vitafoods Europe 2012 to discuss international trade implications of the recently adopted European Union (EU) Health Claims Regulation
- Proceedings of the CRN-I 2011 conference published in the *European Journal of Nutrition*
- Participated in meetings and key activities of the International Alliance of Dietary/Food Supplement Associations (IADSA)
- Attended the 35th session of the Codex Alimentarius Commission in Rome
- Engaged with Department of Commerce and U.S. Trade Representatives on European Food Safety Authority (EFSA) Health Claims regulation and bilateral trade agreement with China



EXCELLENCE IN NUTRITION SCIENCE

Outreach

- CRN staff spoke at numerous conferences, symposia and trade shows on a variety of relevant scientific topics from the safety and benefits of specific ingredients such as vitamin D and calcium, to categories such as probiotics and the multivitamin, as well as the need for a new research paradigm for studying nutrition
- Organized and presented a session at the Institute of Food Technologists (IFT) Wellness Conference titled, *A New Paradigm of Evidence-based Nutrition: Moving Beyond Randomized Controlled Trials*
- The CRN Calcium Working Group held a satellite session as part of the American Society of Nutrition's (ASN) *Controversies in Clinical Nutrition Conference*
- Partnered with the National Osteoporosis Foundation for an educational webinar on the safety and benefits of calcium and vitamin D via a social media platform for pharmacists and nurse practitioners; reached more than 250 healthcare professionals
- Sat on ASN's *Non-traditional Careers in Dietary Bioactives Panel* and chaired a session on *Bioavailability, Bioactivity, and Metabolism of Dietary Bioactives* with more than 125 attendees
- Held *The Workshop: CRN's Day of Science*, a day-long symposium looking at the most timely scientific issues



CRN's Duffy MacKay, N.D., explains current scientific and regulatory issues to his audience



CRN's Taylor C. Wallace, Ph.D., presents Diane Birt, Ph.D., with the Mary Swartz Rose Senior Investigator Award at ASN



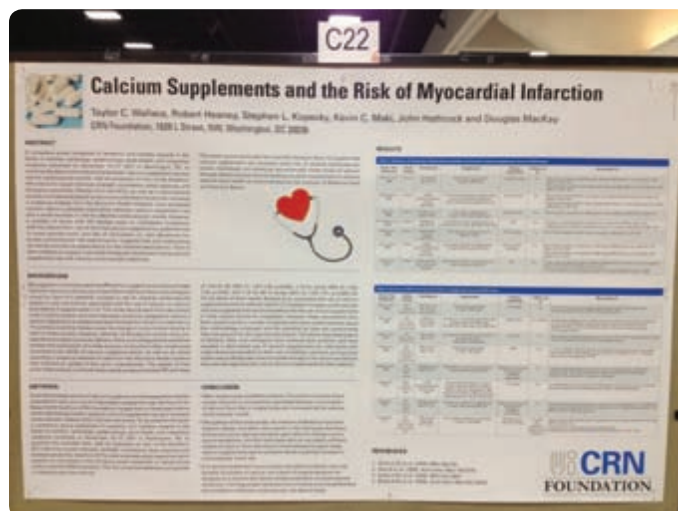
Longtime CRN scientist John Hathcock, Ph.D., retired this year after 17 years with the association



"Vitamins, in combination with other healthy habits, can be a basic and affordable insurance policy for overall wellness.

"No one should expect the multivitamin to wipe out all diseases known to man."

CRN's Duffy MacKay, N.D., in the *Wall Street Journal* coverage of the Physicians' Health Study II results

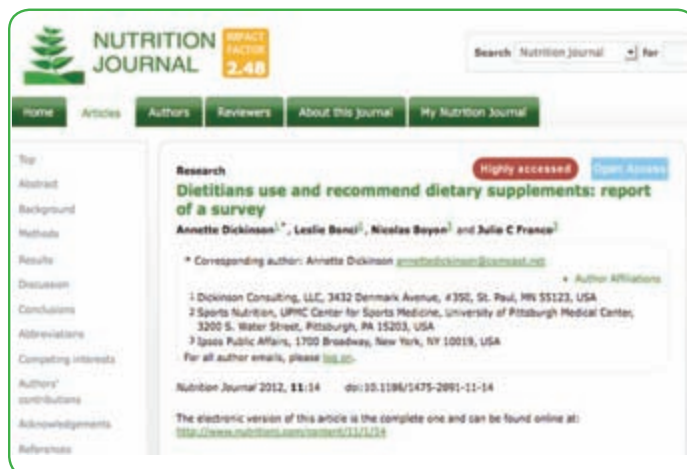


CRN's EB 2012 poster presentation, *Calcium Supplements and Risk of Myocardial Infarction*



“For nearly 40 years, consumers and healthcare professionals have become accustomed to the DV reflecting the highest RDA. There is no question or debate that nutrition labeling should be updated to reflect actual amounts in addition to the %DV and the current science and DRI values.”

CRN’s Taylor C. Wallace, Ph.D., in the *Journal of the American College of Nutrition*, “Dietary Reference Intakes and Nutrition Labeling: Updating the Daily Values for Vitamins and Minerals”



CRN’s article based on *Life...supplemented* study data achieved the journal’s “highly accessed” status with over 5,000 views shortly after publication

PUBLISHED SCIENTIFIC ARTICLES

Soy Isoflavones and Other Constituents

Douglas MacKay, N.D.
Textbook of Natural Medicine, 4th edition

Niacin: Chemical Forms, Bioavailability and Health Benefits

Douglas MacKay, N.D., and John Hathcock, Ph.D.
Nutrition Reviews 2012;70(6): 357-366.

RDA Versus EAR for Nutrition Labeling

Taylor C. Wallace, Ph.D.
Food Technology, January 2012

Re: Dietary Supplement Use is Associated with Higher Intakes of Minerals from Food Sources

Taylor C. Wallace, Ph.D.
American Journal of Clinical Nutrition 2012;95(2): 532-533.

Dietitians Use and Recommend Dietary Supplements: Report of a Survey

Annette Dickinson, Ph.D.; Leslie Bonci; Nicolas Boyon; Julio C. Franco
Nutrition Journal 2012;11:14.

Under The Law, FDA Must Grant Different Standards for New Dietary Ingredients and Food Additives

Steven Mister and John Hathcock, Ph.D.
Regulatory Toxicology and Pharmacology 2012;62(3): 456-458.

Dietary Supplements and Mortality Rate in Older Women

Douglas MacKay, N.D.
Natural Medicine Journal 2011;3:1-3.

Re: Dietary Supplement Use by Children and Adolescents in the United States to Enhance Sport Performance: Results of the National Health Interview Survey

Douglas MacKay, N.D., and Taylor C. Wallace, Ph.D.
Journal of Primary Prevention 2012;33(5-6): 225-226.

Fish Oil and Heart Disease. Nutrient champion hits a scientific speed bump.

Douglas MacKay, N.D.
Natural Medicine Journal, Nov. 2012;4(11).

Review of Supplements Ignores Evidence-Based Nutrition to Promote Tighter Regulation

Steven Mister and John Hathcock, Ph.D.
Journal of Parenteral and Enteral Nutrition 2012;36(3): 265.

Dietary Reference Intakes and Nutrition Labeling: Updating the Daily Values for Vitamins and Minerals

Taylor C. Wallace, Ph.D.
Journal of the American College of Nutrition 2012;31(4): 1-6.

A Review of Calcium Supplements and Cardiovascular Disease Risk

Robert P. Heaney, M.D.; Stephen Kopecky, M.D.; Kevin C. Maki, Ph.D.; John Hathcock, Ph.D.; Douglas MacKay, N.D.; and Taylor C. Wallace, Ph.D.
Advances in Nutrition 2012;3:1-9.

THE VOICE OF THE INDUSTRY

Major Press Coverage

- CRN was consistently quoted as the leading industry voice in consumer press—including ABC, CBS and NBC news programs, the *New York Times*, the *Wall Street Journal*, *WebMD*, *USA Today*, the *Washington Post* and others—as well as industry trade press
- CRN rapidly responded to scientific studies, government reports and investigative reports, providing its members with analysis and providing balance to press coverage

Social Media

- CRN expanded its social media presence, adding @CRN_supplements on Twitter, and partnering with Pharmacist Society and Generation NP to reach pharmacists and nurse practitioners in online social communities and extending its rapid response to blogs and online articles

Live Events

- CRN held its 7th annual Communications and Media Outreach Committee (CMOC) in-person meeting in New York City, an opportunity for CRN members' communications executives to network with each other and gain insights from journalists and other speakers
- *The Conference*, the association's annual symposium for the dietary supplement industry, continued to grow in attendance and stature

23 bylined articles published
55 press releases issued

**Nutraceuticals World
NOW**

"The meaning behind...the AER reports received for dietary supplements is not nearly as bad as some might suggest, and in fact, the number of reports demonstrates the supplement category's strong safety profile."

CRN's **Rend AI-Mondhiry** in a bylined article for *Nutraceuticals World* discussing adverse event reports



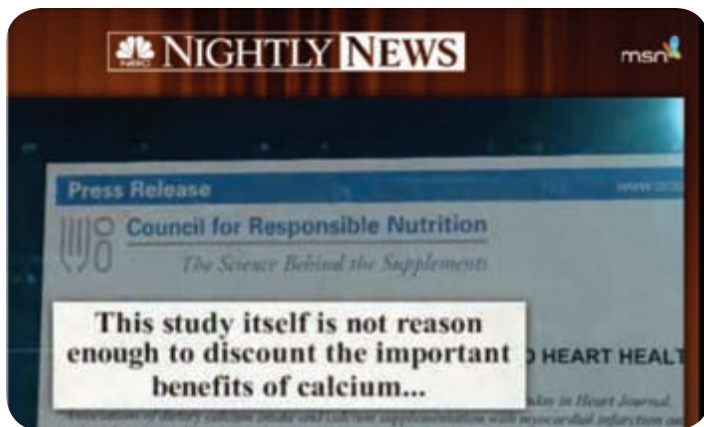
A GANNETT COMPANY

"Americans know they should be eating a diet high in fatty fish... but the reality is that people are simply not doing this. Omega-3 supplements serve as an affordable, convenient and safe way to obtain omega-3 fatty acids and the array of health benefits they offer."

CRN's **Duffy MacKay, N.D.**, in *USA Today's* coverage of a *JAMA* study on omega-3 supplements



Dan Childs, health editor for ABCNews.com with CRN's Judy Blatman at CRN's in-person CMOC meeting



NBC Nightly News noted CRN's statement in its coverage of the *Heart* journal calcium study

BMJ "The proposed guidelines are unreasonably burdensome without providing true extra protection for consumers."

CRN's **Judy Blatman** in the *British Medical Journal's* coverage of a guest commentary in the *New England Journal of Medicine* (NEJM), in which Pieter Cohen, M.D., of Harvard University calls for more stringent regulations for dietary supplements

RAPID RESPONSE HIGHLIGHTS

CRN responded to these 15 major studies or reports in 2012, through press releases, media interviews, or talking points for member companies.

**Assessing Supplement Safety—
The FDA's Controversial Proposal**
New England Journal of Medicine

**Vitamin E decreases bone mass by stimulating
osteoclast fusion**
Natural Medicine

Investigative report on dietary supplements
Dateline NBC

**Efficacy of Omega-3 Fatty Acid Supplements
(Eicosapentaenoic Acid and Docosahexaenoic Acid) in the
Secondary Prevention of Cardiovascular Disease**
Archives of Internal Medicine

**Associations of dietary calcium intake and calcium
supplementation with myocardial infarction and stroke risk
and overall cardiovascular mortality**
Heart

**Vitamin D With or Without Calcium Supplementation for
Prevention of Cancer and Fractures, An Updated
Meta-Analysis**
U.S. Preventive Services Task Force Draft Report

**A Pooled Analysis of Vitamin D Dose Requirements for
Fracture Prevention**
New England Journal of Medicine

Mythbusting sports and exercise products
British Medical Journal

**10 Surprising Dangers of Vitamins & Supplements:
How to Protect Your Family**
Consumer Reports

**Association Between Omega-3 Fatty Acid Supplementation
and Risk of Major Cardiovascular Disease Events**
JAMA

**Effect of Vitamin D3 Supplementation on Upper Respiratory
Tract Infections in Healthy Adults**
JAMA

**Dietary Supplements: Structure/Function Claims Fail to Meet
Federal Requirements and Dietary Supplements: Companies
May be Difficult to Locate in an Emergency**
Office of the Inspector General at the Department of
Health and Human Services Reports

**Multivitamins in the Prevention of Cancer in Men:
The Physicians' Health Study II Randomized Controlled Trial**
JAMA

**Mortality Rates Across 25-Hydroxyvitamin D (25[OH]D)
Levels among Adults with and without Estimated Glomerular
Filtration Rate <60 ml/min/1.73 m2: The Third National Health
and Nutrition Examination Survey**
PLOS ONE

**Multivitamins in the Prevention of Cardiovascular Disease
in Men: The Physicians' Health Study II
Randomized Controlled Trial**
JAMA

Life...supplemented.™

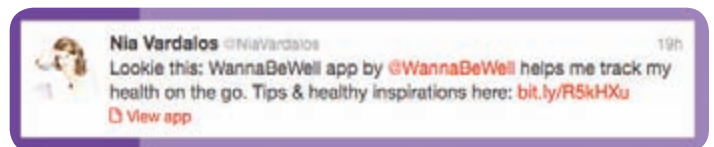
Year Five of Consumer Campaign

- *Life...supplemented* WannaBeWell free mobile app for the iPhone launched, noted in major online press including the *Saturday Evening Post* and *SELF*, as well as industry trade press and various niche blogs
- Academy Award-nominated actress and screenwriter Nia Vardalos teamed with *Life...supplemented* as spokesperson for a media tour
- *The Supplemental* blog launched, offering consumers fresh perspectives on the three pillars of health (healthy diet + supplements + regular exercise), and driving more than 16,655 visitors to the blog, garnering 260+ comments from users praising the expert bloggers and their topics
- Distributed WannaBeWell app advertorial in Hungry Girl online newsletter to 1.2 million subscribers, and a link to the app was posted on the Hungry Girl Facebook page (Hungry Girl Facebook page has 608,213 Likes)
- Two-month “mommy blog” tour featured 60 bloggers, through a partnership with *Mom Central*, furthered awareness of the mobile app and encouraged downloads by key demographic
- Supported Vitamin Angels with \$15,000 in donations, linked to downloads of the WannaBeWell mobile app

 **13,249 Likes**

 **1,706 Followers**

**5,353 downloads
of the new WannaBeWell
mobile app**



Actress Nia Vardalos and CRN's Duffy MacKay participated in 24 broadcast interviews and successfully conveyed the *Life...supplemented* key messages during the multimedia tour on such programs as the syndicated *Daily Buzz*

FamilyCircle
Where Family Comes First™

“Seventy-nine percent of physicians recommend vitamins to their patients for bone, joint, heart and overall health according to a survey funded by the Council for Responsible Nutrition.”

From a four-page feature in *Family Circle*



The Washington Post

“As a scientist who recommends vitamin D to his 91-year-old grandmother, I strongly disagree with this draft recommendation... If [consumers are] not getting enough from their diet, then supplementing with vitamin D and calcium is appropriate.”

CRN's Taylor C. Wallace, Ph.D., in the *Washington Post* health blog's coverage of a USPSTF report

DYNAMIC MEMBERSHIP GROWTH

NEW CRN MEMBERS IN 2012

Voting Members

AdvoCare International, L.P.
AeroDesigns, Inc.
Cepharm Inc.
Chr. Hansen Inc.
Cyvex Nutrition Inc.
FoodState, Inc.
Gencor Nutrients, Inc.
Ingredients by Nature
InterHealth Nutraceuticals Inc.
Nature's Gifts International Inc.
Neptune Technologies & Bioresources Inc.
OmniActive Health Technologies, Ltd.
POM Wonderful, Inc.
The Procter & Gamble Company
Sensient Pharmaceutical Coating Systems
Thompson Brands, LLC

Associate Members

Aegis Sciences Inc.
Akin Gump Strauss Hauer & Feld, LLP
Alkemists Laboratories, Inc.
Biofortis Inc.
dicentra Inc.
Greenberg Traurig, LLP
Natural Marketing Institute (NMI)
Ropes & Gray LLP

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