

FACETS OF SERVICE



*Celebrating 40 years: 1973*  *2013*

**Council for Responsible Nutrition**

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*The Science Behind the Supplements*

2013 ANNUAL REPORT

# Celebrating 40 years: 1973 2013

## 2013 ANNUAL REPORT



Steve Mister  
CRN President & CEO

Forty years ago a small group of companies with vision and conviction established the Council for Responsible Nutrition. And what a 40 years it's been! We've seen dynamic growth for the dietary supplement industry, with entrepreneurs and family businesses joined by pharmaceutical and traditional packaged goods companies entering the market. We've seen bursts of novel products and ingredients that expand the category beyond traditional vitamins, minerals and herbs. We've seen innovation in delivery methods, product packaging and distribution.

Perhaps most importantly, we've seen wider acceptance by the mainstream with more than 150 million Americans—including the majority of healthcare practitioners—taking dietary supplements every year as part of their wellness regimens.

But along with that growth we've seen a divergence of companies on the playing field, and in 2013, we put a stake in the ground that separates the good from the bad, the responsible companies that understand the need for reasonable regulation versus the lawbreakers that seek to rob the bank of goodwill, pushing out products that harm consumers and damage our industry's reputation. It truly is a tale of two industries. CRN members stand unified to protect and promote the growth of responsible firms and to rid the industry of less scrupulous players.

In this annual report, we celebrate CRN's anniversary year efforts to protect a maturing, legitimate industry from outliers who put up roadblocks to our success. Our efforts include fighting back against mischaracterizations of the industry, supporting enforcement actions against bad actors, developing voluntary guidelines that encourage self-regulation—and much more.

As an association, perhaps our greatest accomplishment this year is the growing recognition that CRN is the home for companies that value leadership. We added 32 new members in 2013, many of whom previously would not have thought they would fit in, but now recognize our tent is bigger and broader and welcoming firms, large or small, who believe growth comes from doing the right thing for our consumers. We've felt that recognition in other areas too—the trade press covered our 40<sup>th</sup> anniversary extensively, with large feature stories in at least half a dozen media outlets, culminating in a 2013 "Best of the Industry" award by Nutritional Outlook. With mainstream media, on Capitol Hill, in science and regulatory circles, domestically and internationally, we are, without a doubt, the industry's go-to association.

My thanks to our chairman, John Blair, and to our Executive Committee and Board of Directors who, along with all of you—our valued members—have made 2013 a tremendous success.

### STRATEGIC WORK PLAN 2012 – 2014

#### Experience Sustained Dynamic Membership Growth

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

#### Expand 'Responsibility First' Initiatives

GOAL: Foster 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 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.

#### Foster Excellence in Nutrition Science

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

#### 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.

# 32

## NEW MEMBERS IN 2013

A 15-member task force appointed by CRN's Chair, representing a cross-section of the industry, studied the marketplace, and proposed sweeping changes to CRN's membership structure that recognize categories for branded marketers, contract manufacturers, ingredient suppliers and raw materials distributors. In June, the Board of Directors adopted the task force recommendations and implemented a new dues structure effective in 2014.

### NEW VOTING MEMBERS

Aurora Algae, Inc.  
Barrington Nutritionals  
Delavau, LLC  
Dr. Paul Lohmann, Inc.  
DrVita.com  
Evolva Nutrition, Inc.  
Healthy Directions, LLC  
IFP, Inc. (Innovative Food Processors)  
Metagenics, Inc.  
National Enzyme Company, Inc. (NEC)  
Nature's Sources, LLC  
NutraGenesis LLC  
Pacific Nutritional, Inc.  
Parchem Nutrition Inc.  
Reckitt Benckiser Group plc  
Scientific Living, Inc.  
SIRIO Pharma Co., Ltd.  
STAUBER Ingredients for Innovation  
Stratum Nutrition  
Vititech Nutritional Sciences, Inc.  
Watson Inc.

**Total Voting Members at year end: 97**

MEMBERSHIP GROWTH

CRN announced a new dues structure, new membership categories, and challenging new initiatives in 2013 that boosted growth this year.

### NEW DUES, better than NEW 'DOs



Celebrating 40 years: 1973 2013  
Council for Responsible Nutrition  
The Science Behind the Supplements®

### NEW ASSOCIATE MEMBERS

ANP Foundation  
(American Nurse Practitioner Foundation)  
Arnold & Porter LLP  
HFL Sport Science, Inc.  
Information Resources, Inc. (IRI)  
Intertek Cantox  
The Law Office of Bayne & Associates  
Loeb & Loeb LLP  
Manatt, Phelps & Phillips, LLP  
Sanford Rose Associates Executive Search  
The Shelton Group Public Relations  
Ullman, Shapiro & Ullman, LLP

**Total Associate Members at year end: 43**

CRN's departments work in concert to achieve the association's goals. This report has highlights arranged by CRN's strategic initiatives, but many stretch across multiple departments and are connected facets of the association's integrative approach.

RESPONSIBILITY FIRST

"All industries are going to have people with criminal problems in their background...It is unfortunately a tale of two industries. There's a mainstream, responsible industry...Then there is this sort of shadow industry, the smaller guys playing around the fringes. The problem is how we distinguish between the two."

**Steve Mister**  
USA Today

# CRN FOUNDATION

The CRN Foundation provided a grant to Frost & Sullivan to conduct an economic analysis of four different chronic diseases and the potential for health care cost savings when U.S. adults, 55 and older, diagnosed with these chronic diseases, use one of eight different dietary supplement regimens.

**FROST & SULLIVAN**

Smart Prevention—Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements

An Economic Case for Promoting Increased Intake of Key Dietary Supplements as a Means to Combat Unsustainable Health Care Cost Growth in the United States

Christopher Shanahan, M.S.  
Robert de Lorme, Ph.D.  
www.frost.com

### Calcium & Vitamin D Dietary Supplements and Osteoporosis

Relative risk reduction: 18.6%

On average, 152,000 osteoporosis-related medical events can be avoided each year through the use of calcium and vitamin D at preventive intake levels.

**1,208,000 Events avoided** between 2013 and 2020 among the target population of U.S. women over 55 with osteoporosis.

Potential savings: \$1.9 billion (annual), \$15.0 billion (cumulative)

Net savings: \$1.5 billion (annual), \$12.2 billion (cumulative)

Savings yet to be realized: \$1.1 billion (annual), \$8.6 billion (cumulative)

16¢ Daily cost

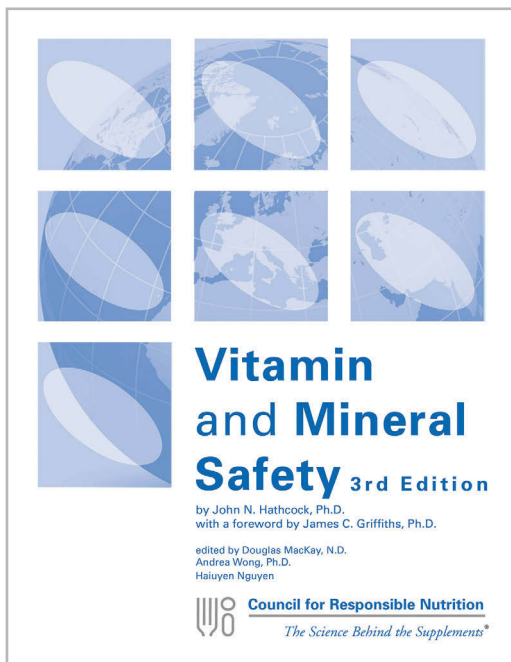
15% Event rate

Preventive Intake Level: 1,000 mg Calcium & 800 IU Vitamin D



“NAD’s...program encourages responsible self-regulation, which increases consumer confidence in the dietary supplement industry...We have a high participation rate, roughly 90 percent.”

**Rend Al-Mondhiry**  
NutraIngredients.com



- ◆ Released Recommended Guidelines for Caffeine-Containing Dietary Supplements
  - Member task group developed guidelines for labeling total caffeine content in dietary supplements and consumer advisory language for products containing higher levels of caffeine; CRN member implementation is expected by April 2014
  - Guidelines adopted or used as the foundation by other trade associations for their own guidelines
- ◆ Published online the updated “Vitamin and Mineral Safety” handbook (3rd edition)
- ◆ Teamed with the Enzyme Technical Association (ETA) to publish the Enzyme Dietary Supplement Products Best Practices Guide
- ◆ Continued partnership with the National Advertising Division (NAD) of the Council of Better Business Bureaus
  - 28 case decisions published in 2013
  - Significant increase in monitoring of advertising for dietary supplements increased consumer confidence in the truth and accuracy of advertising claims and encouraged fair competition within the industry
- ◆ Updated Safety Considerations for Dosage Recommendations and Labeling
- ◆ Headed SIDI Work Group’s release of Dietary Supplement Component Supplier Qualification Voluntary Guideline

“GMPs require 100-percent identity testing, and that needs to occur, by whatever methods and technologies are feasible, reliable and acceptable to raw material suppliers, finished goods manufacturers and the regulatory community.”

**Jim Griffiths, Ph.D.**  
Natural Products INSIDER





# INFLUENCE POLICY

## Congressional Record Recognizes CRN's 40<sup>th</sup> Anniversary:

"...CRN has created an environment that allows companies to responsibly develop, manufacture and market dietary supplements and nutritional ingredients that enable consumers to live healthier lives...."

"We will continue our active dialogue with the FDA until each of these [issues we have with the NDI draft guidance] is resolved. But in the meantime, it benefits both the industry and FDA to move forward on the topics where there is agreement. What constitutes an adequate description of the ingredient in an NDI notification is one of those issues where the trade associations and the FDA are likely to agree."

**Steve Mister**

Nutrition Industry Executive Magazine

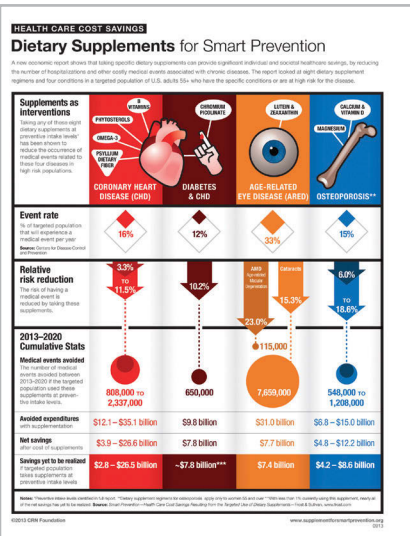
- ◆ Convened CRN members in Washington, D.C., for 10<sup>th</sup> annual Day on the Hill: 60 executive participants, 10 members of Congress, 45 offices
- ◆ Stayed highly engaged with FDA concerning its Draft Guidance on New Dietary Ingredients —Commented on key portions of the draft: definitions of "chemically altered" and supported group comments on identification of NDIs; worked with friends in Congress to reinforce to FDA the importance of a prompt revision; met with agency officials throughout the year
- ◆ Addressed other outstanding issues with FDA —Food Safety Modernization Act (FSMA) implementation; Medical Foods Draft Guidance; Investigational New Drug Final Guidance; Beverage Guidance; Generally Recognized as Safe (GRAS) notifications conflict of interest; Good Manufacturing Practices (GMP) implementation



- ◆ Coordinated bipartisan House of Representatives letter to FDA urging revised NDI notification draft guidance
- ◆ Engaged and educated all 97 member offices of the 113<sup>th</sup> Congress freshman class
- ◆ Monitored legislation on the Dietary Supplement Labeling Act (DSL), Flexible Spending Accounts, labeling of genetically modified organisms (GMOs), energy drinks/caffeine and more
- ◆ Formed Government Relations State Subcommittee to monitor relevant state and local legislative issues and coordinate swift state level lobbying as necessary

**"I've always known that dietary supplements have benefits. Most people know that. But by [Frost & Sullivan] doing this report we've shown that dietary supplements can reduce health care costs as well. This information is new and it's fresh and it's interesting to see how it has been received."**

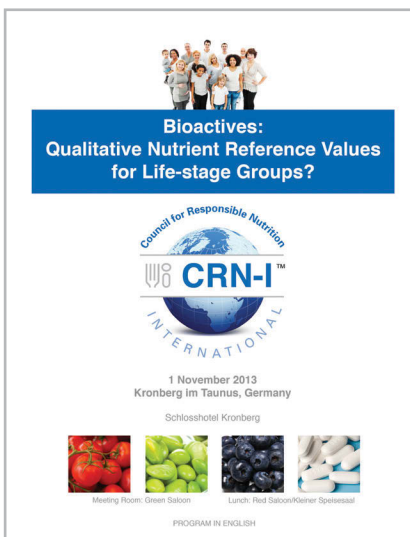
**Mike Greene**  
NutraIngredients.com



- ◆ Led efforts with the Congressional Dietary Supplement Caucus, coordinating briefings for legislators and staff, including a presentation on findings from the Frost & Sullivan report, "Smart Prevention—Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements"
- ◆ Engaged with FTC—*Worked cooperatively with FTC to support its mission to protect consumers from false and misleading advertising*  
—*Filed amicus brief for POM Wonderful case, disagreeing with FTC's approach to evaluating consumers' understanding of claims and the departure from its traditional analysis of claims and substantiation*



- ◆ Published Op-Ed on regulation in USA Today, the "Opposing View" to the publication's call for increased oversight of dietary supplements
- ◆ Engaged in Dietary Guidelines for Americans 2015 process  
—*Met with key officials from Health and Human Services, U.S. Department of Agriculture, National Institutes of Health; produced new research on the role of dietary supplements to help Americans reach nutrition sufficiency*



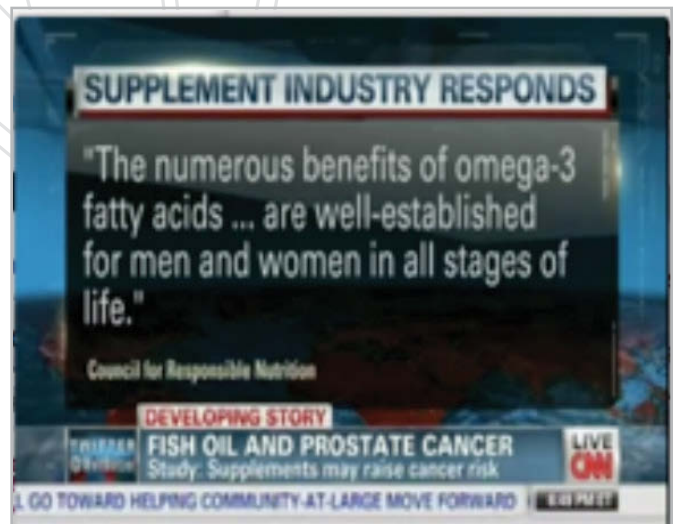
- ◆ Stayed abreast of proposed reforms to California's Proposition 65 (Prop 65) to curb lawsuit abuse, improve warning system—*Submitted comments to Office of Environmental Health Hazard Assessment (OEHHA) and administration; participated in OEHHA workshops, stakeholder forums*
- ◆ CRN PAC held two well-attended fundraisers: for Sen. Lamar Alexander (R-TN), ranking member of the Senate Health, Education, Labor and Pensions (HELP) Committee; and for Rep. Jason Chaffetz (R-UT)
- ◆ Participated in International Alliance of Dietary/Food Supplement Associations (IADSA) activities
- ◆ Monitored Codex issues through CRN International Trade and Market Development Committee (ITMDC)
- ◆ CRN-International (CRN-I) held its fourth annual symposium, *Bioactives: Qualitative Nutrient Reference Values for Life-stage Groups*

# EXCELLENCE IN SCIENCE

- ◆ Generated peer-reviewed science to fill data gaps for Dietary Guidelines for Americans 2015 recommendations
- ◆ Promoted “evidence-based” nutrition—*Emphasized in comments, press quotes and other venues that clinical trial design and interpretation must consider that supplements are not drugs*
- ◆ U.S. Preventive Services Task Force (USPSTF) report on multivitamins recognizes unique challenges of supplement research
- ◆ Provided scientific underpinnings for CRN rapid responses to negative journal studies as well as government reports such as the USPSTF reports on multivitamins and vitamin D and calcium
- ◆ Calcium Working Group actively shared the science reinforcing the safety and benefits of calcium
  - Developed session at Institute of Food Technologists (IFT) Conference on calcium safety
  - Held webinars for healthcare practitioners offering continuing education credits through partnership with the National Osteoporosis Foundation
  - Partnered with the American Nurse Practitioner Foundation on educational campaign
- ◆ Engaged with Harvard researchers for further analysis of Physicians’ Health Study II data
- ◆ Participated in meetings of the Society of Toxicology (SOT), Toxicology Forum, Institute of Food Technologists (IFT), and the American Society of Nutrition (ASN) Experimental Biology (EB) meeting

“...We believe the paucity of clinical trial evidence should not be misinterpreted as a lack of benefit for the multivitamin...We know for sure that multivitamins can fill nutrient gaps, and as so many people are not even reaching the recommended dietary allowances for many nutrients, that’s reason enough to add an affordable and convenient multivitamin to their diets.”

**Duffy MacKay**  
HealthDay News





# Comments

- ◆ **Dietary Guidelines for Americans 2015**—on nutrient topic areas and separately on the committee’s 2010 Report on Future Research Needs Related to Multivitamins
- ◆ **USPSTF: Draft Recommendation Statement on Vitamin, Mineral, and Multivitamin Supplements for the Primary Prevention of Cardiovascular Disease and Cancer**
- ◆ **FDA: NDI Draft Guidance Draft on definition of “chemically altered”** (by Steptoe & Johnson LLP)
- ◆ **FDA: NDI Draft Guidance on Identification of NDIs** (joint comments)
- ◆ **FDA: Initiating a Risk Assessment for Establishing Food Allergen Thresholds** (joint comments)
- ◆ **USDA: National Organic Program**—on expiration of items on national list
- ◆ **FDA: Draft Guidance on Medical Foods**
- ◆ **FDA: Current GMP and HARPC Proposed Rule**
- ◆ **USDA: National School Lunch/Breakfast Program Nutrition Standards** (and later on interim final rule)

## Gaining Traction:

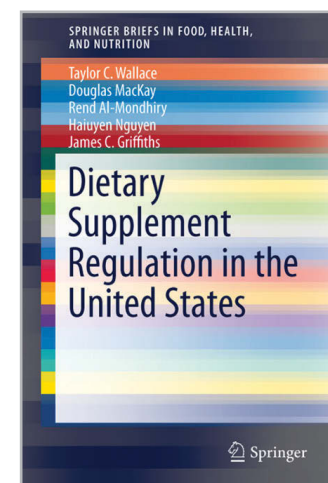
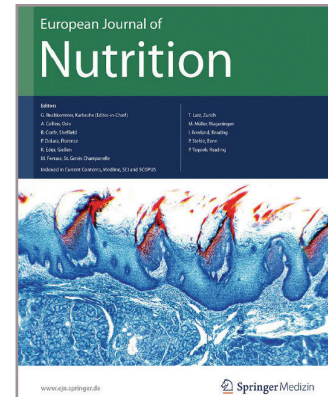
2013 USPSTF report on vitamins and chronic disease recognized the limitations of studying nutrients like drugs—“This is a review of trials, a study design used primarily to evaluate drug therapy. This design might not be ideally suited to evaluating nutrients.”



# Publications

- ◆ **Nutravigilance: Principles and Practices to Enhance Adverse Event Reporting in the Dietary Supplement and Natural Products Industry**  
*International Journal of Food Science and Nutrition*
- ◆ **Multivitamin/Mineral Supplement Contribution to Micronutrient Intakes in the United States, 2007–2010**  
*Journal of the American College of Nutrition*
- ◆ **Calcium and Vitamin D Disparities are Related to Gender, Age, Race, Household Income Level, and Weight Classification but not Vegetarian Status in the United States: Analysis of the NHANES 2001–2008 Dataset**  
*Journal of the American College of Nutrition*
- ◆ **Systematic Review of Multivitamin-Multimineral Use and Cardiovascular Disease, and Cancer Incidence and Total Mortality**  
*Journal of the American College of Nutrition*  
(CRN commissioned)

- ◆ **Do Fatty Acids Really Increase the Risk of Prostate Cancer? Evaluating the Results of the Recent Report From the SELECT Trial**  
*Natural Medicine Journal*
- ◆ **Fish Oil and Heart Disease**  
*Natural Medicine Journal*
- ◆ **Nutrient Reference Values for Bioactives: New Approaches Needed? A Conference Report**  
*European Journal of Nutrition*
- ◆ **Correcting the Record on Dietary Supplement Regulation**  
*JAMA letter-to-the-editor*
- ◆ **Dietary Supplement Regulation in the United States**  
*Springer Brief*



# VOICE OF THE INDUSTRY

- ◆ More than 250 quotes/mentions in industry trade press and more than 70 quotes/mentions in consumer press, including major outlets such as the New York Times, the Washington Post, HealthDay News, the Wall Street Journal, USA Today, NBC News, ABC News, CBS News, CNN, WebMD, NPR and more
- ◆ Issued 59 press releases, placed 14 bylined articles and one USA Today op-ed
- ◆ Responded to continuous media coverage of "Do You Believe in Magic: The Sense and Nonsense of Alternative Medicine," by Paul Offit, M.D., and the related clampdown on supplement use at Children's Hospital of Philadelphia
- ◆ Worked with USA Today to provide the responsible industry's perspective to its investigative reports
- ◆ Letters-to-the-editor/online comments published in the New York Times, Dallas Morning News, Forbes and others
- ◆ Rapidly responded to studies in scientific journals such as Annals of Internal Medicine, British Medical Journal, JAMA and The Lancet, as well as to reports from the U.S. Preventive Services Task Force, General Accountability Office, Consumer Reports, and The Dr. Oz Show
- ◆ Expanded CRN social media reach to include Google+, Vine and YouTube, adding to our existing presence on Facebook (Life...supplemented), Twitter, Generation NP and Pharmacist Society



"It's important that whatever we do defines a responsible industry...And so we work on initiatives that put us front and center with the media, [making] us a respected voice in the scientific community, on Capitol Hill and in the international arena."

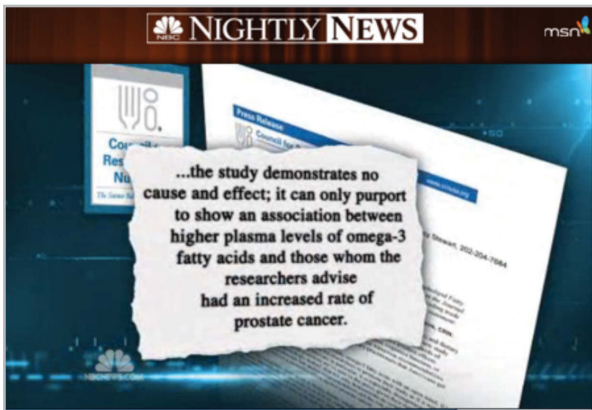
**Judy Blatman**  
Drug Store News

- ◆ Conducted CRN Consumer Survey on Dietary Supplements and released data showing that the vast majority of U.S. adults stand confident in the safety, quality and effectiveness of dietary supplements



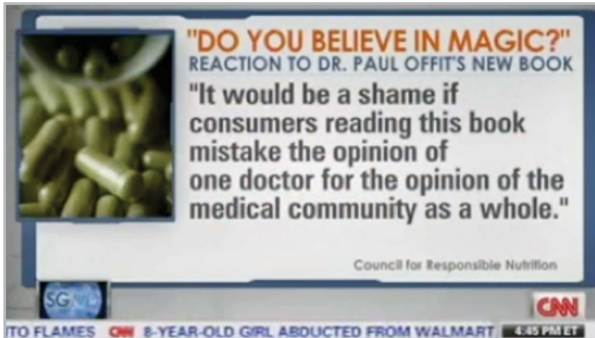
*Weight Watchers Magazine*

- ◆ Held annual in-person Communications and Media Outreach Committee meeting in New York, with record attendance and high-profile speakers
- ◆ Hosted educational webinars with VIRGO
- ◆ Presented *The Conference*, CRN's annual symposium for the dietary supplement industry, and *The Workshop*, CRN's day of science, to a record number of attendees in Park City, Utah
- ◆ Generated full feature stories on CRN's 40<sup>th</sup> anniversary in Drug Store News, Natural Products INSIDER, Nutraceuticals World, NutraIngredients, Nutritional Outlook and "The Tan Sheet"



“150 million Americans safely use supplements—such as multivitamins, herbs and protein powders—with few reported adverse events.”

**Steve Mister**  
USA Today



**'A TALE OF TWO INDUSTRIES'**  
USA TODAY's ongoing investigation has shown that consumers of tainted diet supplements have paid dearly in some cases, suffering side effects ranging from severe bleeding to dangerous effects on diabetes



“We know that consumers are not getting recommended nutrients that they need every day. With their hectic lifestyles and diets, they simply need to fill in those nutrient gaps...and multivitamins do that.”

**Steve Mister**  
CBS Evening News with Scott Pelley

## Bylines and Op-Eds

- ◆ **Do Synthetic Botanicals Have You Worried?** Duffy MacKay, N.D., *Nutraceuticals World*
- ◆ **The Complexity of the Inflammation Claim** Duffy MacKay, N.D., *Natural Products INSIDER*
- ◆ **In Life and Diets: Nothing is Perfect** Judy Blatman, *NutraIngredients.com*
- ◆ **The Great Caffeine Debate** Duffy MacKay, N.D., *Nutraceuticals World*
- ◆ **Groundhog Day at the Capitol** Mike Greene, *Nutraceuticals World*
- ◆ **Silencing the Critics With a Dose of Research** Steve Mister, *NutraIngredients.com*
- ◆ **Caffeine Controversy Percolates, CRN Stimulates a Label Change** Steve Mister, *Natural Products INSIDER*
- ◆ **Increased Scrutiny of Dietary Ingredients for Safety** Jim Griffiths, Ph.D., *Natural Products INSIDER*
- ◆ **Enough is Enough: Multivitamins Are An Excellent Source of Nutrients to Fill in the Gaps We Miss In Our Less-Than-Perfect Diets** Steve Mister, *Nutraceuticals World*
- ◆ **Searching for a Standard for Fish Oil** Jim Griffiths, Ph.D., *SupplySide Insights*
- ◆ **The Best and the Worst of the Supplement Industry** Steve Mister, *Functional Ingredients*
- ◆ **2013: The Year FDA Got Serious** Steve Mister, *Natural Products INSIDER*
- ◆ **A Whale of a Fish Story for Omega-3s** Steve Mister, *NutraIngredients.com*
- ◆ **ObamaCare and Dietary Supplements** Steve Mister, *Natural Products INSIDER*
- ◆ **Dietary Supplements Regulated Enough: Opposing View** Steve Mister, *USA Today, Op-Ed*



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