ACI
American Conference Institute
Business Information in a Global Context

Council for Responsible Nutrition
The Science Behind the Supplements

American Conference Institute in collaboration with the Council for Responsible Nutrition presents:

EARN CLE CREDITS

ACI's 6th Annual
Legal, Regulatory and Compliance Forum on

Dietary Supplements

A comprehensive guide to the latest developments affecting "products intended to supplement the diet"

June 18–20, 2018 | InterContinental New York Times Square | New York, NY

Distinguished Co-Chairs:

Scott Bass
Partner & Head,
Global Life Sciences
Sidley Austin LLP

Steve Mister
President & CEO
Council for Responsible Nutrition

Keynote Address:

Robert Durkin
Deputy Director
Office of Dietary Supplement Programs, CFSAN
U.S. Food and Drug Administration

Insights From:

GOVERNMENT

U.S. Food & Drug Administration

Federal Trade Commission

CONSUMER AND RETAILER ORGANIZATIONS

Global Retailer and Manufacturer Alliance

National Advertising Division — Advertising Self-Regulatory Council

LEADING MANUFACTURERS

Abbott Nutrition

AdvoCare International, LP

Bayer HealthCare

BodyBuilding.com

Emerson Ecologics

Garden of Life

Herbalife International of America, Inc.

Metagenics, Inc.

Natrol, LLC

Nature's Way Brands

Nutramax Laboratories

Pharmavite, LLC

Pfizer Consumer Healthcare

RB Health

Swanson Health Products

The Clorox Company

The Nature's Bounty Co.

June 18, 2018: Workshop A

Class Action Litigation Boot Camp for Dietary Supplement Industry Stakeholders

June 20, 2018: Workshop B

Claims Substantiation Master Class

Sponsored By

AMIN TALATI UPADHYE

TAP•ROOT
SCIENCE · REGULATORY · STRATEGY

Register
AmericanConference.com/DietarySupplements | 888 224 2480

a C5 Group Company
Business Information in a Global Context

Distinguished Faculty

Co-Chairs

Scott Bass
Partner
Sidley Austin LLP
(New York, NY)

Steve Mister
President & CEO
Council for Responsible Nutrition
(Washington, DC)

Speakers

Rend Al-Mondhiry
Senior Counsel
Amin Talati Upadhye, LLP
(Washington, DC)

Alyse M. Aruch
Corporate Counsel
Pfizer Consumer Healthcare
(Madison, NJ)

Gisele Atkinson
Vice President, Quality & Technical Affairs
Council for Responsible Nutrition
(Washington, DC)

Paul M. Bartkowski
Partner
Adduci, Mastriani & Schaumberg, LLP
(Washington, DC)

Kristen Blanchard
Vice President, External Corporate Affairs
Nutramax Laboratories
(Lancaster, SC)

Travis Borchardt
Vice President of Regulatory Affairs and QC/QA
Nature's Way Brands
(Green Bay, WI)

Jeff Brams
General Counsel and Vice President Product Development, Quality, Regulatory & International
Garden of Life
(Palm Beach Gardens, FL)

Carol R. Brophy
Senior Counsel
Steptoe & Johnson LLP
(San Francisco, CA)

Christine Burdick-Bell
Vice President and General Counsel
Pharmavite, LLC
(Northridge, CA)

Adam Carr
President & CEO
Emerson Ecologics
(Manchester, NH)

Bill Carter
Chief Legal Officer
BodyBuilding.com
(Boise, ID)

Tara Lin Couch, PhD
Senior Director of Dietary Supplements and Tobacco Services
EAS Consulting Group, LLC
(Alexandria, VA)

Kat Dunnigan
Senior Staff Attorney
National Advertising Division
Advertising Self-Regulatory Council
(New York, NY)

Robert Durkin
Deputy Director,
Office of Dietary Supplement Programs
CFSAN
U.S. Food and Drug Administration
(College Park, MD)

Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission
(Washington, DC)

Jeanette Fielding PhD
Head, Global Policy, Government and Stakeholder Affairs
Bayer Consumer Health
(Whippany, NJ)

Gregory W. Fortsch
Senior Legal Counsel for Regulatory Affairs and Privacy Officer
The Nature's Bounty Co.
(Ronkonkoma, NY)

Miriam J. Guggenheim
Partner and Co-Chair,
Food, Drug & Device Practice
Covington & Burling LLP
(Washington, DC)

Martin J. Hahn
Partner
Hogan Lovells US LLP
(Washington, DC)

David Hilton
Director of R&D
Natrol, LLC
(Chatsworth, CA)

Melissa Hung
Senior Corporate Counsel
The Clorox Company
(Oakland, CA)

Julie L. Hussey
Partner
Perkins Coie LLP

Lori Kalani
Co-Chair; State Attorneys General
Cozen O'Connor
(Washington, DC)

Chi Hee Kim
Senior Director, Global Affairs
Herbalife International of America, Inc.
(Los Angeles, CA)

J. Patricia Kim
General Counsel and Vice President of Regulatory Affairs
Swanson Health Products
(Fargo, ND)

Paul E. Konney
Executive Vice President, General Counsel and Head of Global Regulatory Affairs
Metagenics, Inc.
(Aliso Viejo, CA)

Mark Levine, Esq.
Associate General Counsel
RB Health
(Parsippany, NJ)

Claudia A. Lewis
Partner
Venable LLP
(Washington, DC)

Diane C. McEnroe
Partner
Sidley Austin LLP
(New York, NY)

Lauren Medoff
Senior Counsel
AdvoCare International, LP
(Plano, TX)

Trenton H. Norris
Partner
Arnold & Porter Kaye Scholer LLP
(San Francisco, CA)

Jena Rostorfer, MS, RD
Associate Director, Regulatory
Abbott Nutrition
(Columbus, OH)

Paul D. Rubin
Partner
Debevoise & Plimpton LLP
(Washington, DC)

Risa Schulman, PhD
President
Tap~Root
(Passaic, NJ)

Randy Slikkers, MBA
Executive Director
Global Retailer and Manufacturer Alliance (GRMA)
(Washington, DC)

Thomas J. Sullivan
Partner
Shook, Hardy & Bacon L.L.P.
(Philadelphia, PA)

Marc S. Ullman
Of Counsel
Rivkin Radler LLP
(Uniondale, NY)

Riëtte van Laack, Ph.D.
Director
Hyman, Phelps & McNamara, P.C.
(Washington, DC)

Who You Will Meet:

Dietary Supplement Industry

- In-House Counsel, including generalists and those having responsibility for FDA and FTC compliance and regulatory affairs; Advertising and Promotion; IP, Patents and Trademarks; Licensing and Business Development
- Officers, Directors and Executives for Regulatory Affairs and Business Development

Law Firm Attorneys for the Dietary Supplement Industry whose practices focus on:

- FDA and FTC law
- Advertising and Promotion
- Trademarks, Patents and IP

The dietary supplement industry faces a year of uncertainty and a time of transition in 2018.

Be part of the only forum that will help you navigate the legal and regulatory challenges that lie ahead.

American Conference Institute (ACI) together with the Council for Responsible Nutrition (CRN) invite you to join us at the industry's premier Legal and Regulatory Dietary Supplements Conference.

Dear Colleague:

The news of Orrin Hatch's impending retirement marks the end of an era for the dietary supplements industry. As the industry's most powerful and esteemed advocate leaves the Senate, industry watchers ponder what it will mean for the future of DSHEA as well as the status of pending industry-relevant federal legislation.

Recent and pending appointments at FDA and FTC leave the industry anxious about agency agendas and priorities in the coming years. Dr. Gottlieb's appointment as head of the FDA has begun to affect the regulatory climate for the dietary supplements industry, while pending appointments at FTC may also affect the atmosphere.

Aggressive state AG enforcement activity and an uptick of class action lawsuits continue. In response to these actions, some retailers have instituted new testing requirements for manufacturers as a prerequisite for stocking their products on shelves in an effort to retain consumer confidence. Meanwhile, the *Prevagen* case involving claim substantiation, a petition before the ITC seeking to classify concentrated fish oil as a drug, and the increased usage of CBD hemp oil in supplements add to the current industry intrigue. These high profiled news-worthy events have the industry strengthening its resolve once again, in part through industry self-regulatory measures, such as CRN's Supplement OWL program which is entering its second year.

ACI and CRN have designed this year's agenda to address these challenges while also providing state of the industry updates and opportunities for networking and discussion.

Register today for the industry's premier and most comprehensive legal, regulatory and compliance forum on dietary supplements by calling 1-888-224-2480, or visiting us online.

We hope to see you in New York this June.

Very Truly Yours,

Esther Ro, Esq.
Sr. Legal Analyst & Program Director
American Conference Institute

Steve Mister
President & CEO
Council for Responsible Nutrition

Global Sponsorship Opportunities

With more than 300 conferences in the United States, Europe, Asia Pacific, and Latin America, **American Conference Institute** (**ACI**) provides a diverse portfolio devoted to providing business intelligence to senior decision makers who need to respond to challenges spanning various industries in the US and around the world.

As a member of our sponsorship faculty, your organization will be deemed as a partner. We will work closely with your organization to create the perfect business development solution catered exclusively to the needs of your practice group, business line or corporation.

For more information about this program or our global portfolio of events, please contact:

Michael Balzano
American Conference Institute
Tel: **212-352-3220 x5539**
M.Balzano@AmericanConference.com

Carl Hyland
Council for Responsible Nutrition
Tel: **202-204-7674**
chyland@crnusa.org

Continuing Legal Education Credits

EARN CLE CREDITS

Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education requirements. This course is identified as nontransitional for the purposes of CLE accreditation.

ACI certifies that the activity has been approved for CLE credit by the New York State Continuing Legal Education Board.

ACI certifies that this activity has been approved for CLE credit by the State Bar of California.

You are required to bring your state bar number to complete the appropriate state forms during the conference. CLE credits are processed in 4-8 weeks after a conference is held.

ACI has a dedicated team which processes requests for state approval. Please note that event accreditation varies by state and ACI will make every effort to process your request.

Questions about CLE credits for your state? Visit our online CLE Help Center at www.americanconference.com/CLE

PRE-CONFERENCE WORKSHOP A
Monday, June 18, 2018

2 pm – 5 pm | (Registration begins at 1 pm)

Class Action Litigation Boot Camp for Dietary Supplement Industry Stakeholders: A Guide for Designing Internal Preparedness Protocols, Timelines and Enlisting Outside Counsel

Thomas J. Sullivan
Partner
Shook, Hardy & Bacon L.L.P.
(Philadelphia, PA)

Class action litigation is a harsh reality for the dietary supplement industry. Class action lawsuits filed against dietary supplement companies are growing at an alarming rate and show no sign of slowing down. In today's competitive litigation environment, plaintiffs' firms are always on the prowl for product claims they perceive to be false and misleading. They also ride the coattails of State Attorneys' General and consumer protection agency actions even after these matters have reached resolution.

As such, it is now more imperative than ever for dietary supplement industry stakeholders to thoroughly understand the 'ins and outs' of the class action arena and how they will impact business and economic decisions affecting the company. They must be cognizant of class action litigation timelines and devise protocols for handling these matters internally as well as for the pass off to law firm counsel.

Our workshop leaders will guide you with these challenges and help you develop a thorough class action litigation preparedness plan. Points of discussion will include:

- Ensuring "class action litigation preparedness" – it is no longer a matter of if we are sued, but when we are sued
  - » Establishing document hold and retention policies
  - » Keeping track of government and consumer protection groups' enforcement activity
  - » Predicting when you may be a class action target
  - » Forging strong defense strategies pre-suit
- Understanding the initial process of the class action litigation timeline
  - » Addressing pre-suit demand letters
  - » What to do once the complaint is served
- When to enlist the services of outside counsel
- How to choose your outside counsel
  - » Understanding the in-house counsel-law firm counsel dynamic
- Mastering the art of budgeting, forecasting, and aligning litigation costs to business goals in a class action scenario
- Exploring cost saving options in litigation, including alternate billing, and contingency clauses
- Calculating the costs of litigation and analyzing the benefits of settlement
- Examining cases that are considered "unwinnable", but still continue in the hope of early settlement or dismissal of case

MAIN CONFERENCE DAY ONE
Tuesday, June 19, 2018

7:00 | Registration & Continental Breakfast

8:00

Co-Chairs' Opening Remarks

Scott Bass
Partner & Head, Global Life Sciences
Sidley Austin LLP
(New York, NY)

Steve Mister
President & CEO
Council for Responsible Nutrition
(Washington, DC)

8:15

The Shifting Political and Regulatory Climate of the Dietary Supplement Industry: Reading the Barometers of the Hill and the Administration

Kristen Blanchard
Vice President,
External Corporate Affairs
Nutramax Laboratories
(Lancaster, SC)

Steve Mister
President & CEO
Council for Responsible Nutrition
(Washington, DC)

The dietary supplement industry is in the midst of assessing how recent and pending appointments at FDA and FTC will affect its regulatory climate. The appointment of Dr. Gottlieb as head of the FDA is a barometer for what may be on the regulatory and enforcement horizon. However, the picture is not yet complete, as the wider panorama will not unfold until the speculation surrounding FTC Commissioner appointments clears. Meanwhile, certain Congressional activity also lends to the political intrigue of this emerging new environment.

This panel will address these developments and provide insights on such matters as:

- Predicting regulatory changes in this time of transition as new leadership positions are assumed within the FDA and FTC
  - » Anticipating how FDA and FTC under new leadership will redefine their positions on safety risk and product claims
  - » Evaluating the probability of future funding for the Office of Dietary Supplements
- Assessing the impact of Dr. Gottlieb's first year at FDA on the dietary supplement industry
  - » Analyzing the significance of the FDA's decision regarding the classification of kratom as a drug as opposed to a supplement
- Status of state and federal legislations/initiatives impacting dietary supplements
  - » Farm Bill/SNAP
  - » FSA
- Update on the future of DSHEA in light of the retirement of its principal author – Senator Orrin Hatch
  - » Educating members of Congress and raising awareness on the Hill to ensure that the importance and value of dietary supplements are firmly entrenched in the minds of regulators and enforcement officials

9:00

FDA Keynote Address

Robert Durkin
Deputy Director, Office of Dietary Supplement Programs, CFSAN
U.S. Food and Drug Administration
(College Park, MD)

9:45 | Morning Coffee Break

10:00

FDA Round Up: Update on FDA Guidances and Rulemaking Activity Impacting the Dietary Supplement Industry

Jeff Brams
General Counsel and Vice President Product Development, Quality, Regulatory & International
Garden of Life
(Palm Beach Gardens, FL)

Miriam J. Guggenheim
Partner and Co-Chair, Food, Drug & Device Practice
Covington & Burling LLP
(Washington, DC)

Jena Rostorfer, MS, RD
Associate Director, Regulatory
Abbott Nutrition
(Columbus, OH)

Revised FDA Draft NDI Guidance

- Exploring the concerns and questions related to the revised FDA draft NDI guidance
- Assessing the impact of the revised draft NDI guidance when it becomes final
- Understanding grandfathered ingredients
- Anticipating a definitive old ingredient list by the FDA and evaluating how that would help the industry
- Distinguishing the significance of naturally-derived from synthetically-derived within the scope of the new guidance

New Supplement Facts and Nutritional Labels

- Decoding the regulations for the new Supplement Facts and Nutrition Facts label
- Understanding the implications of the new guidance issued on March 1, 2018 for dietary fibers
  - » What will FDA consider to be fiber?
  - » How will new fibers be evaluated?
- Deciphering gray areas in the Final Rule relative to reformulations, fiber, and added sugars
- Providing clarity on conversion guidelines involving labeling of Daily Values
- Addressing implementation challenges associated with % Daily Value nutrient intakes with revisions for both label types
- Incorporating Non-GMO law labeling requirements into supplement and nutrition facts label
- Creating best practices for implementation of Rule requirements in view of revised deadlines

Defining "healthy", "natural", and other key terms

- Utilizing key terms in the dietary supplement space including "healthy", "natural", "organic", "non GMO"
  - » What is the FDA's current position on these terms?
- Status of FDA's efforts to define healthy and natural
- Surveying the latest FDA activity related to the federal GMO laws
  - » Understanding the use of these terms and related limitations

11:00

The Evolution of State AG Enforcement Actions and Transparency Requirements: Opportunities for Manufacturer-Retailer Partnership

Rend Al-Mondhiry
Senior Counsel
Amin Talati Upadhye, LLP
(Washington, DC)

Melissa Hung
Senior Corporate Counsel and Director
The Clorox Company
(Oakland, CA)

Lori Kalani
Co-Chair; State Attorneys General
Cozen O'Connor
(Washington, DC)

During the past few years, the dietary supplement industry has been the subject of actions by state Attorneys General regarding the safety and integrity of dietary supplements. The flurry of activity from these officials has led to the creation of new enhanced protocols impacting the dietary supplement industry including various retailer-led initiatives and testing procedures. This session will address the latest AG activity and efforts to self-monitor.

Points of discussion will include:

- Update on recent AG activity in the supplement space
  - » Overview of the most active states' enforcement actions
- Examining the potential nexus between new testing requirements for supplement manufacturers and state AG investigations
- Exploring the implications of these new testing requirements for dietary supplement manufacturers
- Reviewing the various authentication programs utilized by retailers and how those compare to the current regulatory requirements for dietary supplements

12:00 | Networking Luncheon

1:15

Update on Self-Regulatory Initiatives in the Dietary Supplement Marketplace

Gisele Atkinson
Vice President,
Quality & Technical Affairs
Council for Responsible Nutrition
(Washington, DC)

Bill Carter
Chief Legal Officer
BodyBuilding.com (Boise, ID)

Randy Slikkers, MBA
Executive Director
Global Retailer and Manufacturer Alliance (GRMA)
(Washington, DC)

The dietary supplement industry recognizes the need for self-regulation as the means to identify bad actors and bolster public confidence. As more ingredients and newer products are presented to consumers, there has never been a more appropriate time to self-police the industry.

With CRN's Supplement OWL, now in its second year, we will get a first-hand glimpse of what the self-regulatory standards and platforms have accomplished and how they have evolved since their inception.

In this session, industry leaders will examine these initiatives and asses their progress.

2:00

Introducing CBD Hemp Oil into the Dietary Supplement Space: Controversies, Legal Concerns and Commerciality

J. Patricia Kim
General Counsel and Vice President of Regulatory Affairs
Swanson Health Products
(Fargo, ND)

Paul D. Rubin
Partner
Debevoise & Plimpton LLP
(Washington, DC)

There is a surge of interest in the use of CBD hemp oil as a dietary ingredient. While these products are derived from hemp, they have none of the hallucinogenic properties associated with cannabis. Why then, are they a point of such contention for the industry?

This panel will explore this controversy.

Points of discussion will include:

- Understanding the use of CBD from hemp in the dietary supplement space
- Examining the medicinal aspects of hemp oil and understanding how CBD poses as an active constituent
- Determining whether hemp can be used legally in the dietary supplement space
  - » Examining the dangers of and obstacles posed by DEA regulations
  - » Predicting the likelihood of enforcement actions
- Survey of various state AG office positions on hemp oil
  - » Anticipating how various state legislatures may or may not react to the use of hemp oil
- Analyzing FDA warning letters on the use of hemp oil

2:45 | Afternoon Refreshment Break

3:00

Exploring New Developments in Claims Substantiation Impacting The Dietary Supplement Arena

Kat Dunnigan
Senior Staff Attorney
National Advertising Division
Advertising Self-Regulatory Council (New York, NY)

Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission
(Washington, DC)

Mark Levine, Esq.
Associate General Counsel
RB Health (Parsippany, NJ)

- Understanding the significance of the *Prevagen case, i.e., FTC et al. v. Quincy Bioscience Holding Co. Inc.* (S.D.N.Y. 2017) and its pending appeal for claim substantiation analysis for dietary supplements
- Exploring how companies review claims internally in order to pass scrutiny at both the FTC and NAD
  - » Comparing and contrasting the differences/similarities of claims review
- Understanding the intersection of FDA into the claims substantiation space for advertising of dietary supplements
- Survey of recent state AG consumer protection activity relative to claim substantiation
- Identifying new enforcement hot spots for claims substantiation
- Revisiting disease vs. structure-function claims in light of recent activity

3:45

Impact of Social Media Influencers and Paid Promoters of Dietary Supplements

Alyse M. Aruch
Corporate Counsel
Pfizer Consumer Healthcare
(Madison, NJ)

Claudia A. Lewis
Partner
Venable LLP (Washington, DC)

Lauren Medoff
Senior Counsel
AdvoCare International, LP
(Plano, TX)

In today's marketing and advertising realm, the risk of promoting products such as supplements are not limited to traditional methods such as television or radio advertising. The industry has moved far from these avenues to include internet advertising, social media posts, bloggers, and YouTube channels. These avenues are vast and their use in the promotion of products can be effective if an influencer or paid promoter makes an impact on consumers. In this session, our speakers will explore the legal limits of marketing and advertising through these new channels in the dietary supplement space.

Points of discussion will include:

- Creating an effective strategy of marketing and advertising in the dietary and nutritional space using social media, the internet, YouTube channels, and other avenues
  - » Understanding consumer trends for dietary supplements in today's climate of instantaneous news
- Exploring the impact of FTC warning letters on influencers and paid promoters in social media
- Understanding the relationship between the supplement company and influencers/promoters who market products but don't mention they are paid to do so

4:30

Case Study on the Future of Fish Oil: Exploring The Consequences of Retroactively Declaring a Dietary Supplement a Drug

Paul M. Bartkowski
Partner
Adduci, Mastriani & Schaumberg, LLP
(Washington, DC)

Christine Burdick-Bell
Vice President and General Counsel
Pharmavite, LLC (Northridge, CA)

A petition to reclassify a dietary supplement as a drug is rare. For example, in 2009, pyridoxamine, a form of vitamin B6, formerly a supplement, was declared a drug through the use of a citizen's petition filed with FDA. Fast forward to 2017, and suddenly refined EPA fish oils – a long accepted dietary supplement – are now the new target for drug classification. However, this time the vehicle of change is not an FDA citizen's petition, but rather an International Trade Commission action.

If fish oils were declared a drug, the ramifications would be profound. The market share would shift, the disease indicators would expand, and the floodgates would open for other applications seeking to reclassify the status of other supplements.

In this session, our speakers will guide you through the complexities and challenges relative to declaring a supplement a drug in an obscure provision of DSHEA.

Points of discussion will include:

- An analysis of the *Amarin Vascepa* case and the novel use of an ITC petition
- Understanding the wider significance of the *Amarin* case to the fish oil supplement industry
- Exploring the ramifications of Amarin's attempt at the ITC to other dietary supplement products

5:00

Implementing Compliance Controls to Meet New Sophisticated cGMP Standards

Travis Borchardt
Vice President of
Regulatory Affairs and QC/QA
Nature's Way Brands (Green Bay, WI)

Tara Lin Couch, PhD
Senior Director of Dietary
Supplements and Tobacco Services
EAS Consulting Group, LLC
(Alexandria, VA)

- Understanding the FDA's more sophisticated approach to dietary supplement cGMPs
- Petitioning the FDA for an exemption to the 100% identity requirement for ingredient testing and potential for skip lot testing
- Assessing the impact of program alignment under Dr. Gottlieb
- Reassessing cGMPs in the context of cleanliness, safety, and testing for raw materials
- Identifying the right test for the right ingredient within the context of cGMP standards
- Examining the possibility of increased enforcement by FDA in this area
- Comprehending how this potential enforcement ramp up may lead to an uptick in 483 observations

5:45

Conference Adjourns to Day Two

MAIN CONFERENCE DAY TWO
Wednesday, June 20, 2018

7:30| Continental Breakfast

8:00

Co-Chairs' Opening Remarks and Recap of Day One

8:15

Unraveling the Complexities of FSMA Regulation

Martin J. Hahn
Partner
Hogan Lovells US LLP
(Washington, DC)

Riëtte van Laack, Ph.D.
Director
Hyman, Phelps & McNamara, P.C.
(Washington, DC)

- Understanding the latest FDA regulations under FSMA and their impact in the dietary supplement industry
- Determining those parts of FSMA relevant to ingredient suppliers, including exemptions
- Ensuring compliance with Foreign Supplier Verification Program
- Establishing critical control parameters to comply with HARPC
- Preparing for inspection and enforcement activity of FSMA for dietary supplement ingredient suppliers

9:00

Coattail Claims: The Latest Influx of Class Action Litigation Impacting Dietary Supplements

David Hilton
Director of R&D
Natrol, LLC
(Chatsworth, CA)

Julie L. Hussey
Partner
Perkins Coie LLP (San Diego, CA)

Marc S. Ullman
Of Counsel
Rivkin Radler LLP (Uniondale, NY)

- Examining recent class action filings against dietary supplement manufacturers
- Devising strategies to minimize class action exposure and mitigate liability
- Understanding class action litigation in California in light of Prop 65
- Examining the impact of the *BMS* decision on personal jurisdiction and how that impacts class action litigation
- Exploring the link between FTC, NAD, state AG and federal enforcement activity and the plaintiffs' bar
- Examining other popular class action trends impacting supplement makers

10:00 | Morning Coffee Break

10:15

New Challenges of Proposition 65 for the Dietary Supplement Industry

Carol Brophy
Senior Counsel
Steptoe & Johnson LLP
(San Francisco, CA)

Trenton H. Norris
Partner
Arnold & Porter Kaye Scholer LLP
(San Francisco, CA)

- Reviewing the new warning regulations and how they impact dietary supplements
- Updates on affirmative litigation regarding the First Amendment and Labor Code listing process
- Responding to retailer inquiries
- Briefing on status of listings and safe harbors affecting the dietary and nutritional space:
  - » Lead
  - » Glyphosate
  - » Furfuryl alcohol
  - » Bisphenol A
  - » N-Hexane
  - » Coumarin
- Developing protocols and implementation strategies for supplement makers to remain compliant with Prop 65 requirements
- Assessing recent Prop 65 enforcement actions impacting the supplement industry

11:00

Understanding International Dietary Supplement Commercialization in the Current Geo-Political Atmosphere

Jeanette Fielding PhD
Head, Global Policy, Government
and Stakeholder Affairs
Bayer Consumer Health
(New York, NY)

Chi Hee Kim
Senior Director, Global Affairs
Herbalife International of America, Inc. (Los Angeles, CA)

- Appreciating how the future of NAFTA and the reality of Brexit and other populist movements may affect the U.S. supplement industry's trading ability
- Deciphering distinctions between registration, pre-market approval, and post-surveillance review in foreign jurisdictions and understanding how they may be affected by the current political climate
- Highlighting aspects of post-market surveillance that are unique to Asia and Europe
- Exploring how U.S.-Asia trade relations may influence supplement manufacturing in the U.S.
- Understanding the role of domestic retailers vs. suppliers who sell in the international market
- Recognizing the impact of guidance issued by WHO on safety of dietary supplements
- Comprehending the regulatory framework for introducing botanicals as a dietary supplement in international markets
- Examining jurisdictional differences of marketing botanicals as a dietary supplement in the U.S. vs. Europe and Asia
- Ensuring the use of botanicals in dietary supplements are safe and pose no risk to consumers

11:45

Exploring the Risks of the Direct to Physician Supplement Sales Model

Adam Carr
President & CEO
Emerson Ecologics
(Manchester, NH)

Paul E. Konney
Executive Vice President, General Counsel and Head of Global Regulatory Affairs
Metagenics, Inc. (Aliso Viejo, CA)

In today's market, the supplement industry is seeking unique ways to distribute products to consumers through different avenues. One such means is marketing and distributing supplements directly to healthcare practitioners for resale. This channel to market brings unique questions and concerns to a new set of challenges to this industry.

Points of discussion will include:

- Understanding the promotion of supplements to healthcare practitioners
- Analyzing regulations of drugs marketed to healthcare practitioners and how these may have application to the supplement space
- Performing a risk analysis when selling supplements to healthcare practitioners
- Using the healthcare practitioner as a conduit to sell the supplement
- Realizing the associated risk when consumers perceive these supplements "to be better" or "higher level" than supplements sold through traditional retailers

12:30 | Conference Ends

Media Partners

FDA | Law Blog

WholeFoods MARKET

POST CONFERENCE WORKSHOP B
Wednesday, June 20, 2018

2 pm – 5 pm (Registration begins at 1 pm)

Claims Substantiation Master Class

(Luncheon is available for Workshop Attendees beginning at 12:30 pm)

Gregory W. Fortsch
Senior Legal Counsel for Regulatory Affairs and Privacy Officer
The Nature's Bounty Co.
(Ronkonkoma, NY)

Diane C. McEnroe
Partner
Sidley Austin LLP (New York, NY)

Risa Schulman, PhD
President
Tap~Root (Passaic, NJ)

Claims substantiation is the lynchpin in the advertising and promotion of dietary supplements. While dietary supplement makers may take stringent measures to steer clear of disease claims, substantiating structure/function claims may not always be so simple or clearly defined. There is a fine line between making legitimate supported claims and going too far. Enforcement authorities and consumer protection watchdogs look to substantiation to determine if lines have been crossed.

The *Bayer* case and its progeny – most recently – the *Prevagen* case -- have added new layers to the claim substantiation conundrum. To help you meet the challenges of the post-*Bayer* – and now the post-*Prevagen* era – we have designed this interactive workshop to enable you to develop a global claims substantiation compliance program that covers advertising, websites, social media platforms, and other relevant outlets of promotional communication.

- Developing a comprehensive global claims substantiation compliance program
  - » Protecting your products, enhancing creativity and minimizing s your company's exposure to enforcement risk
- Review of claim substantiation standards for supplements and related scientific evidence
- Understanding what is required in the now post-*Prevagen* environment
  - » Examining the thoughts of the FTC, NAD and other enforcement authorities in this regard
- Designing "the right studies" to back up your claim in the post-*Prevagen* world
- Choosing proper study subjects
- Evaluating interpretations and extrapolations and post-hoc analyses of study results
- Identifying implied claims and their hidden dangers
- Review of promotional activities across various media outlets and social media platforms that have raised red flags with government enforcers and consumer watchdogs

Hotel Information

Hotel:
InterContinental Times Square New York

Address:
300 W. 44th Street New York, NY 10036

Online:
AmericanConference.com/DietarySupplements/Venue

Telephone:
1-866-875-1978

American Conference Institute is pleased to offer our delegates a limited number of hotel rooms at a preferential rate. To book a room at the discounted rate please contact the hotel directly and mention "ACI's Dietary Supplements" or you can book a room online using the reservation link provided below and click "Book": Reservations: 1-866-875-1978 or visit AmericanConference.com/dietary-supplements/#event-venue-info

3 Ways to Register

ONLINE:
AmericanConference.com/DietarySupplements

EMAIL:
CustomerService@AmericanConference.com

PHONE:
1-888-224-2480

Registration Information

Conference Code: 669L18-NYC

Registration Type	Register & Pay by May 25, 2018	Register & Pay after May 25, 2018
ELITEPASS* Conference and Both Workshops	$3295	$3495
Conference and Workshop A☐ or B☐	$2695	$2895
Conference Only	$2095	$2295
All program participants will receive an online link to access the conference materials as part of their registration fee.		
Please reserve ___ additional copies of the Conference Materials at $199 per copy.		

Bringing a Team?	
3 - 4	10% Conference Discount
5 - 6	15% Conference Discount
7	20% Conference Discount
8 or more	Call 888-224-2480

Special Discount

ACI offers financial scholarships for government employees, judges, law students, non-profit entities and others. For more information, please email or call customer service.

Terms and Conditions

Payment Policy

Payment must be received in full by the program date to ensure admittance. All discounts will be applied to the Program Only fee (excluding add-ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to 3 or more individuals employed by the same organization, who register at the same time.

Delegate Substitutions and Cancellations

You must notify us by email at least 48 hrs. in advance of the conference if you wish to send a substitute participant. If you are unable to find a substitute, please notify us in writing no later than 10 days prior to the conference date and a credit voucher will be issued to you for the full amount paid, redeemable against any other ACI conference in the next 12 months. Delegates may not "share" a pass between multiple attendees without prior authorization.

All cancelled conference registrations will be subject to a cancellation fee of $350 and applicable taxes. Any product extensions (inclusive of workshops, receptions, masterclasses, etc.) will be subject to a cancellation fee of $50 and applicable taxes.

If you prefer, you may request a refund of fees paid less the applicable cancellation fee. No credits or refunds will be given for cancellations received within 10 days of the conference start date. No liability is assumed by American Conference Institute for changes in program date, content, speakers or venue. American Conference Institute reserves the right to cancel any conference it deems necessary and will, in such event, make a full refund of any registration fee, but will not be responsible for airfare, hotel or other costs incurred by registrants.

ACI's 6th Annual Legal, Regulatory and Compliance Forum on

Dietary Supplements

A comprehensive guide to the latest developments affecting "products intended to supplement the diet"

June 18–20, 2018
InterContinental New York Times Square
New York, NY

American Conference Institute
45 West 25th Street, 11th Floor
New York, NY 10010

Attention Mailroom
If undeliverable to addressee, please forward to:
General Counsel; Dietary Supplements Counsel; Director, Dietary Supplements Regulatory

Update your Contact Information
If you would like us to change any of your details, please email **Data@AmericanConference.com**
And reference the conference code on the brochure.

REGISTRATION CODE

S10-669-669L18.S

Can be recycled

ACI American Conference Institute
Business Information in a Global Context

Council for Responsible Nutrition
The Science Behind the Supplements

American Conference Institute in collaboration with the Council for Responsible Nutrition presents:

ACI's 6th Annual
Legal, Regulatory and Compliance Forum on

Dietary Supplements

A comprehensive guide to the latest developments affecting "products intended to supplement the diet"

June 18–20, 2018
InterContinental New York Times Square, New York, NY

ACI in collaboration with CRN is pleased to present this 6th forum on dietary supplements. Join preeminent counsel and regulatory/ compliance executives representing the dietary supplement industry as they share their insights and help you:

ASSESS the shifting political and regulatory climate of the dietary supplement industry

DECIPHER FDA guidances and rulemaking activity impacting the dietary supplement industry

EVALUATE the evolution of state AG enforcement actions

EXAMINE new retailer testing requirements

EXPLORE the potential for CBD hemp oil in dietary supplements

PREPARE for the new era of claims substantiation in the wake of *Prevagen*

ADDRESS the consequences of reclassifying a dietary supplement as a drug