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

June 8–10, 2021 (EDT) • Virtual Conference

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Vice President & General Counsel
Pharmavite LLC

Tara Falsani
General Counsel, Vice President and Secretary
Nature's Way – Schwabe North America

Fireside Chats with:

Cara Welch
Acting Director, Office of Dietary Supplement Programs
U.S. Food and Drug Administration

Serena Viswanathan
Acting Deputy Director, Bureau of Consumer Protection
U.S. Federal Trade Commission

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- CV Sciences, Inc.
- Emerson Ecologics
- Garden of Life, LLC
- NAD
- Nature's Bounty
- Papa & Barkley
- The Pew Charitable Trusts
- RB
- Unilever

Confirmed Faculty

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

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

Christine Burdick-Bell
Vice President & General Counsel
Pharmavite LLC *(West Hills, CA)*

Tara Falsani
General Counsel, Vice President and Secretary
Nature's Way – Schwabe North America
(Green Bay, WI)

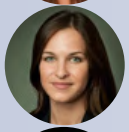
SPEAKERS

Jeffrey B. Brams
General Counsel & Vice President, R&D and Regulatory
Garden of Life, LLC *(Palm Beach Gardens, FL)*

Connor Boyd
Corporate Counsel
Emerson Ecologics *(Manchester, NH)*

Jennifer Boyd
Director, Regulatory Affairs US & International
Atrium Innovations *(Sudbury, MA)*

Kathleen Dunnigan
Senior Attorney
National Advertising Division (NAD)® – BBB National Programs, Inc. *(New York, NY)*

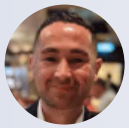


Kathryn Farrara
Associate General Counsel, NA – Marketing
Unilever *(Englewood Cliffs, NJ)*

Gregory W. Fortsch
Associate General Counsel / Privacy Officer
Nature's Bounty *(Ronkonkoma, NY)*

Patricia Kim
Legal Counsel
Papa & Barkley *(Pasadena, CA)*

Douglas "Duffy" MacKay, N.D.
Senior Vice President Scientific & Regulatory Affairs
CV Sciences, Inc. *(San Diego, CA)*



Josue Molina
VP of Quality & Regulatory Affairs
Ancient Nutrition *(West Palm Beach, FL)*

Megan Olsen
Vice President and Associate General Counsel
Council for Responsible Nutrition
(Washington, DC)

Liz Richardson
Director, Health Care Products Project
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Serena Viswanathan
Acting Deputy Director of the Bureau of Consumer Protection
U.S. Federal Trade Commission
(Washington, DC)

Cara Welch
Acting Director, Office of Dietary Supplement Programs
U.S. Food and Drug Administration
(Silver Spring, MD)

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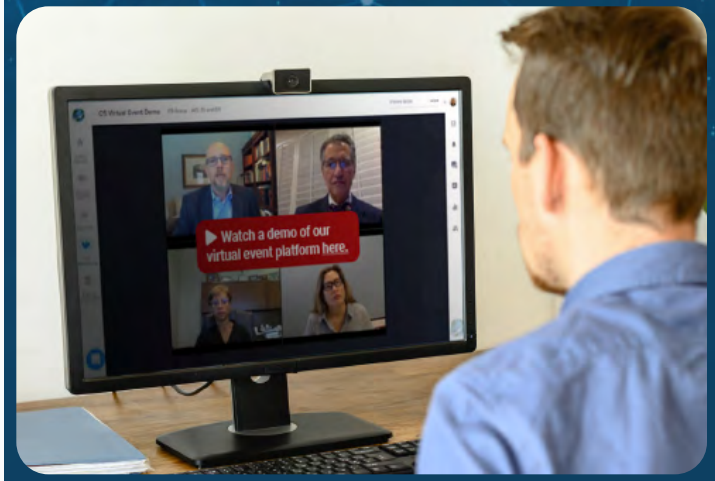

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Tuesday, June 8, 2021 (EDT)

MAIN CONFERENCE DAY 1:
Politics, Policy, FDA, and DSHEA 2.0

11:00

Co-Chairs' Opening Remarks

Steve Mister
President & CEO
Council for Responsible Nutrition

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

11:15

State of the Industry Address

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

The Politics and Policy of Supplements Under the Biden Administration

POLITICS

11:45

Reading the Tea Leaves in the New Washington: Interpreting the Political Signs for What the Dietary Supplement Industry Can Anticipate under the Biden Administration

With every new presidential administration, there are questions as to how new priorities, policies, and political maneuvering may affect the dietary supplement industry. This panel will look at some key factors to watch as the Biden Administration begins to chart its course and will predict what the political future may hold for supplements.

- Examine –through history and anecdote– the predicted temperament of this Administration and how it may affect the supplement industry
  - » Pro-regulation, pro-consumer, but also pro-science
  - » Understand how the pandemic has affected the political mindset in supplement policy
- Explore how the new Congressional majority and key committee appointments will affect the industry
  - » House Energy and Commerce and Senate HELP Committee leadership, as well as other committees of jurisdiction
  - » The Dietary Supplement Caucus—bipartisan in a partisan climate
- Anticipate how leadership appointments at FDA and FTC will impact industry regulation and practices
  - » How the FDA Commissioner choice may be a game changer
    - Examining views of acting Commissioner Hamburg on Supplements
  - » Considerations for appointments of FTC Commissioners and Bureau of Consumer Protection Chief
    - Impact of these appointments on industry enforcement and other FTC actions
- Forecast changes in foreign policy
  - » A return to globalism and how this will impact the industry
  - » The new Administration's stance on tariffs
  - » How Biden may approach China and balance American industry with the American consumer

1:00 Break

POLICY

1:15

For the Public Good: Making the Case for Supplement Inclusion in HSAs/FSAs and SNAP/WIC Programs in the Age of COVID-19

- Understand why supplements are not typically eligible for HSA/FSA programs and why supplement purchases are excluded from SNAP/WIC programs
- Examine the inclusion of OTC medicines in HSAs/FSAs in the CARES Act: How did it happen? Why are OTCs different? Could supplements be next?
  - » Research outcomes for zinc, Vitamin C, Vitamin D, etc. in relation to COVID-19—Does this help the case for increased access?
  - » How increased access from HSA/FSA coverage is different than SNAP and WIC accessibility – different populations; different objectives; different opposition
- Assess the prognosis for S. 4463 (bill to classify supplements as necessary medical expenses) in the new Congress
  - » Possible incorporation into ongoing pandemic relief measures?
- Explore how supplements could be included in SNAP and WIC programs
  - » Examine support of the Biden Administration for these inclusion efforts
  - » Understand the debate between filling nutrition gaps and filling empty bellies
  - » Consider industry strategies to educate and supply supplements to individuals in lower income brackets

2:00

1:1 Networking

2:10 Lunch Break

2:45

FDA Fireside Chat

Cara Welch
Acting Director, Office of Dietary Supplement Programs
U.S. Food and Drug Administration

INTERVIEWED BY:

Steve Mister
President & CEO
Council for Responsible Nutrition

3:30 Break

DSHEA 2.0

3:45

From Voluntary to Mandatory: Understanding How Mandatory Product Listings with FDA May be the Cornerstone for DSHEA 2.0

- Analyze how product listings may be the catalyst for DSHEA 2.0
- Examine how the voluntary listing database, the CRN OWL, can be used as a template for mandatory FDA listing
- Explore the arguments for & against mandatory product listing
  - » How concerns over ingredient adulteration, such as one illustrated by the ABC adulterated botanicals project, could be remedied through mandatory listing
  - » How mandatory product listing compliments DSHEA and gives FDA better enforcement tools
  - » Why FDA keeps asking for mandatory product listing
- Envision how a mandatory listing would operate and the obstacles Congress must address
- Assess the likely path to passage: could mandatory listing be incorporated into PDUFA? inserted into CBD legislation, or survive as a "stand alone" bill?

4:30

Seeking Clarity on Drug Preclusion: Understanding Its Applicability, Evaluating Your Options, and Seeking Remedies for Redress

- Understand the scope of the drug preclusion provision under 21 U.S.C. § 321(ff)(3)(B)
  - » It's not just CBD—Explore how the drug preclusion clause can interfere with marketing of other ingredients or stop new ones
- Necessary proof to overcome the preclusion clause's application—Whose job is it anyway?
  - » Determining if the product was marketed as supplement prior to another party seeking its approval as a drug
  - » Determining whether a substance is the same "article" as a substance first approved as a drug
- Examine supplements that have been subject to the preclusion clause arguments in the past and evaluate its effects:
  - » *N-acetyl cysteine* (NAC)
  - » CBD
  - » Pyridoxamine
- Explore how DSHEA 2.0 can offer exclusionary rule redress
- Look at the bigger picture: the effects of drug preclusion on dietary supplement innovation

5:15 Conference Adjourns to Day Two

> "High quality speakers, relevant current content."
>
> Paul Konney
> Executive Vice President, General Counsel
> Metagenics, Inc.

Wednesday, June 9, 2021 (EDT)

DAY 2: WORKSHOP A

9:00 AM – 11 :00 AM

Claims Substantiation Working Group: Mastering the Art of Compliant and Effective Social Media Usage – A Study of Influencers, Reviews, and New Social Media Platforms

Proper claims substantiation is at the heart of effective advertising and promotion of dietary supplements. However, new media have added layers of complexity to an area that was already heavily shaded in gray. The industry must realize that although the media may be new, the standards for substantiating a claim remain the same.

In this working group, we will take a closer look at the use of influencers subsequent to FTC's guidance, consumer reviews, and new forms of social media used to promote our product – all with the goal of determining how to compliantly promote your products, stay out of trouble, and win consumer confidence. Points of discussion, include:

- Adjust your global claims substantiation compliance program to adapt to new social media and regulatory agency guidance
- Protect your products, enhancing creativity through new media, and minimizing your company's exposure to enforcement risk
- Analyze the use of new and emerging social media
  - » TikTok
  - » Instagram Stories
  - » Twitter Fleets
  - » Snapchat
- Review common pitfalls for claim substantiation standards for supplements and related scientific evidence – the standard doesn't change just because you use an influencer
  - » Designing "the right studies" to back up your claim
    - Choosing proper study subjects
    - Evaluating interpretations and extrapolations and post-hoc analyses of study results
  - » Identifying implied claims and their hidden dangers
  - » Staying on the right side of the sometimes fine line between structure/function and health claims
- Learn how the FTC's influencer guidance is affecting influencer use
- Understand the relationship between influencer claims, testimonials, and consumer reviews relative to claims substantiation
- Explore liability for influencer statements and mitigation strategies
  - » Developing strategies for drafting effective influencer contracts
  - » Evaluating protections afforded by disclosures
- From a testimonial or review to a marketing campaign: calibrate the extent to which consumer permission is needed to repurpose reviews
  - » Traditional consumer surveys vs. social media chatter
- Platforms and algorithms: used for good or to suppress negative reviews?
- Gauge how companies are managing expectations relative to influencers and reviews
- Grasp the implications of reviews on Amazon and other third-party websites

> "Topics are timely and important, speakers are well-informed and case studies helpful."
>
> Beth Moore Roberts
> Director of Regulatory Affairs
> MegaFood

Wednesday, June 9, 2021 (EDT)

MAIN CONFERENCE DAY 2
CLAIMS SUBSTANTIATION, ENFORCEMENT, AND CBD

11:15

Co-Chairs' Opening Remarks and Recap of Day 1

Steve Mister
President & CEO
Council for Responsible Nutrition

Christine Burdick-Bell
Vice President & General Counsel
Pharmavite LLC

Focus on Claims Substantiation, Free Speech, and Social Media

11:30 CASE STUDY

May We Speak Freely? Navigating the Fine Line Between Structure/Function and Health Claims in the Pursuit of First Amendment Rights to Lawfully Disseminate Information

The arrival of the global pandemic created new confusion around the legitimate dissemination of information about a supplement under the First Amendment versus making an unsubstantiated disease claim. This panel will use case studies to illustrate how marketers can exercise free speech, educate the public, and not run afoul of the balance between structure/function and disease claims.

Points of discussion will include:

- Understanding the impact of a pandemic on claim meaning and increased risk of implied claims
- Exploring immunity support and enhancement: which claims are appropriate and which ones are not?
- Determining when information about legitimate studies, clinical trials, and research can be used in promotional materials
  - » What free speech limitations exist when scientific research is incorporated into promotional materials?
  - » Can marketers communicate this information without getting into trouble with FTC and FDA?
- Identifying First Amendment precedents for protection
  - » *Amarin*
  - » *Pom*
- Avoiding misleading and scientifically unsupported claims about a supplement's ability to treat or prevent coronavirus – or any other sickness or ailment
- Examining ramped-up federal and state enforcement efforts to ensure compliance and measuring the impact of unsubstantiated therapeutic claims in a pandemic
- Analyzing recent NAD/FTC cases relevant to dietary supplements and immunity claims

12:30

And Now a Word from the FTC: A Conversation About Influencers, Reviews, and Other Matters of Social Media and Consumer Focus

Serena Viswanathan
Acting Deputy Director of the Bureau of Consumer Protection
U.S. Federal Trade Commission

INTERVIEWED BY:

Megan Olsen
Vice President and Associate General Counsel
Council for Responsible Nutrition

1:15

1:1 Networking

1:25 Lunch Break

2:30

Keeping the Regulators in Check: A Closer Look at the Future of Federal and State Enforcement and Consumer Protection in the Supplements Space

- Explore possible remedial repercussions of *AMG Capital Management, LLC v. FTC* if the Supreme Court rules against the FTC
- Understand why the supplement industry should be concerned about possible revocation of section 13(b) powers
- Anticipate how State AGs could fill the enforcement void if the Court strips the FTC of its remedial powers under 13(b)
- Gauge whether Congress will act to pass new remedial legislation should the FTC's 13(b) enforcement ability be removed
  - » Analyzing language in the recent Appropriations Bill regarding monetary penalties for false COVID Claims
  - » Exploring potential legislation
  - » Understanding other FTC enforcement authority
- Examine the latest state AG enforcement activity
- Consider how industry cooperation with government authorities can promote consumer confidence

3:30 Break

3:45

The Path Forward for CBD: Exploring the Journey to Legalize Hemp-Derived CBD

- Learn about H.R. 841 – Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act
  - » What became of H.R. 8179 in the last Congress?
  - » What does the legislation actually do?
- Understand the likelihood of FDA actions for CBD in the Biden Administration
  - » Effect of FDA's withdrawal of its *Cannabidiol Enforcement Policy; Draft Guidance for Industry* and release of its notice entitled *"Better Data for a Better Understanding of the Use and Safety Profile of Cannabidiol (CBD) Products"*
- Navigate the dangers of inconsistent state CBD laws in the absence of federal regulation
- Assess the loss of potential revenue streams to industry resulting from this federal and state legal and regulatory conundrum
  - » Weighing the risks of "sitting it out" vs. "going rogue"
- Understand the unspoken connection between finalizing FDA's NDIN draft guidance and creating a legal pathway for CBD
- Consider how an NDI-only pathway for CBD could derail the economic intent of the Farm Bill

4:45 Conference Adjourns to Day 3

Thursday, June 10, 2021 (EDT)

DAY 3: WORKSHOP B

9:00 AM – 11:00 AM

Working Group on International Dietary Supplement Commercialization in a New Political Era

In this session, our speakers will help you devise strategies to ensure cross-border commercial success, while still complying with complex rules and regulations specific to individual countries.

Topics of discussion will include:

- What to Know Before You Go: Devising strategies for successful market entry into foreign countries
- Understanding the dynamic nature of international laws and regulations: Who's changing, harmonizing or increasing their laws?
  - » Focus on Brazil, China, and India and their updated regulatory paradigms
- Assessing the effect of the COVID-19 crisis on international supply chains
- Legal and regulatory resources for "boots on the ground" – how do you find country-specific experts, how can international trade associations like the International Alliance of Dietary/Food Supplement Associations (IADSA) help navigate thorny international regulatory issues?
- A discussion on the role of Codex Alimentarius in international product and ingredient standards
- The importance of developing relationships with U.S. trade contacts (e.g., Department of Commerce and International Trade Administration)

Thursday, June 10, 2021 (EDT)

MAIN CONFERENCE DAY 3
STANDARDS, TRADE, AND LITIGATION

11:15

Co-Chairs' Opening Remarks and Recap of Day 2

Steve Mister
President & CEO
Council for Responsible Nutrition

Tara Falsani
General Counsel, Vice President and Secretary
Nature's Way – Schwabe North America

11:30

In Search of a Uniform Standard: Understanding the Legal and Regulatory Implications of Inconsistent Retailer Third-Party Testing Programs and Quality Standards

Several years ago, in response to actions by a NY AG that questioned the quality of dietary supplements, retailers started policing their supplement aisles by imposing their own standards and 3rd party testing requirements on supplement products sold in their stores and on their websites. More have followed suit with the largest online retailer being the latest to put its own standards into place. Unfortunately, many of these retailer programs contain duplicative or inconsistent testing requirements, leaving manufacturers to comply with only by government guidelines, but also by a patchwork of other testing requirements. Topics of discussion will include:

- How to assess best practices for manufacturer compliance with third party testing with CVS, Amazon, and other retailers
- Understand the controversy surrounding Amazon's testing requirements
  - » Fallout from one company's own testing program of its competitors purchased through Amazon
  - » The mystique of ISO 17025 lab accreditation
- Explore the supplement industry's efforts to harmonize testing standards
- Understand metrics available to industry to demonstrate compliance with federal dietary supplement requirements to retailers
- Explore GRMA and SSCI efforts to harmonize GMP audit standards
- Examine legal consequences for products that do not meet individual retailer standards and are removed from shelves
- Safeguard manufacturers from fraudulent or counterfeit products sold through Internet sales

12:30

Sustainability and Ethical Business Practices: Lessons for Industry to Ensure the Integrity of the Supply Chain and Winning Consumer Confidence through Transparency

- Reconciling ingredient sourcing and supply chain practices with consumer demand for ethical sourcing and environmentally conscious business practices
- Incorporating safeguards to ensure ethical sourcing and compliance with labor law and human rights measures
- Understanding the new scope of green claims and how this ties into environmental policy changes under Biden
- Examining how sustainability encompasses every area of supplement manufacture from ingredient sourcing to processing to packaging to transportation to factory design

1:30 Break

1:45

Imports, Exports, and Certificates of Free Sale: A Guidebook to Help Supplement Manufacturers Navigate A New Era of Globalism

- Examining the status of tariffs and treaties under the Biden Administration will impact the dietary supplement industry
- Exploring the extent to which tariffs on raw material and ingredient imports, and exports of finished goods to other countries, such as China, will continue
- Understanding the role of a certificate of free sale to the compliant export of dietary supplements
- Working with FDA, state regulators, and trade associations to ensure proper issuance of a certificate of free sale that gets recognized by your destination country
- Appreciating the importance of adhering to the laws of the imported and exported country to ensure products are exported without roadblocks

2:30

1:1 Networking

2:40 Lunch Break

3:30

Focus on California: A Study in Golden State Specific Reforms, Initiatives, and Litigation and Their Impact on the Supplements Industry

California has some of the strictest regulations on consumer goods in the nation—and that includes dietary supplements. This panel will explore some of the most recent issues vexing the industry from the Golden State.

- Examine the impact of the California Privacy Act one year after it went into effect
  - » Assess how it has changed industry marketing practices and outreach
- Calibrate the potential effects from the re-introduction of California's single use plastic law and steps to take to prepare if it's adopted
- Explore new Prop 65 developments
  - » Understand the significance of changes to the short form warning
  - » Potential Prop 65 warnings for THC in CBD products – when is a trace amount, truly a trace amount?

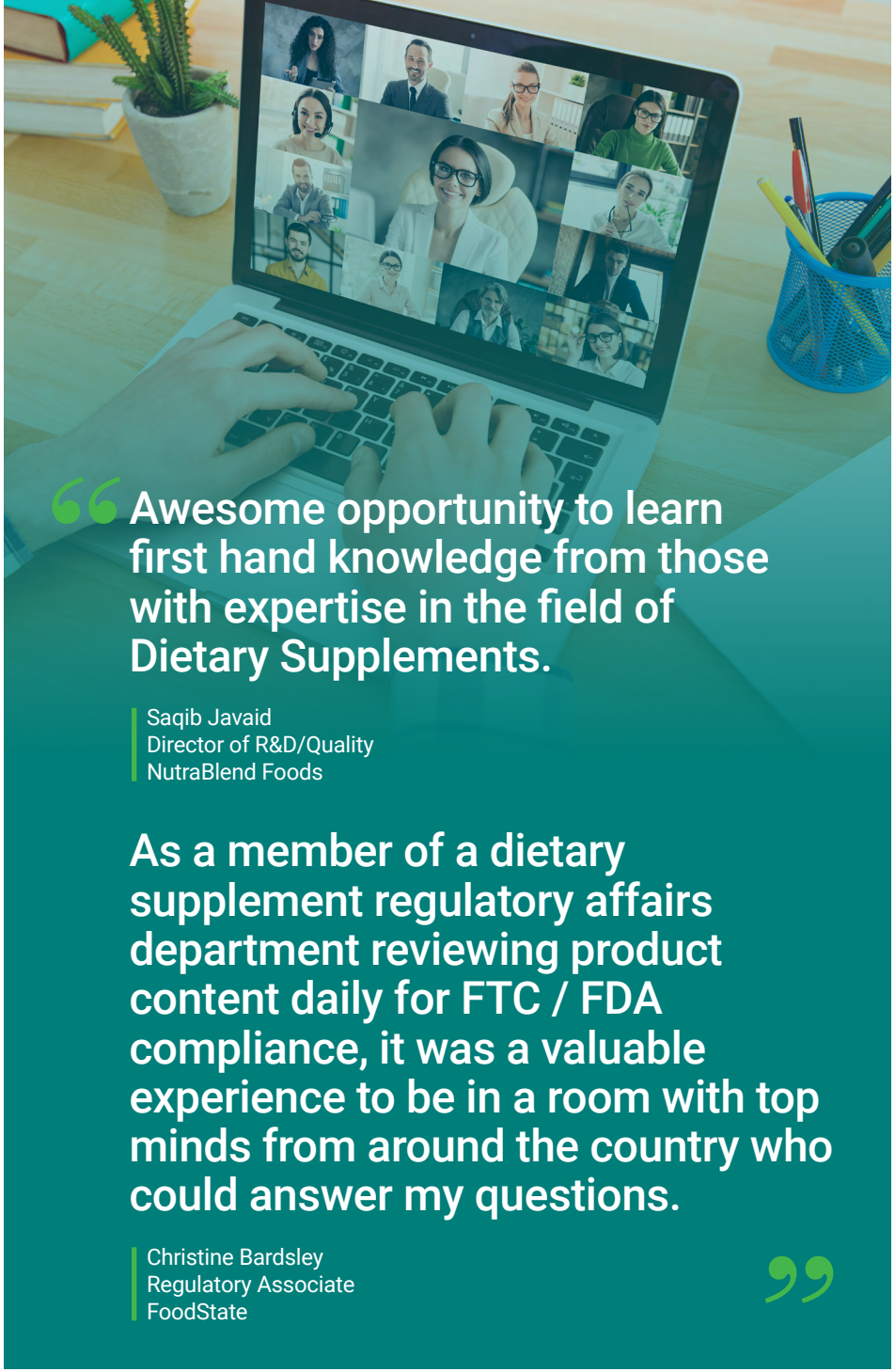
4:15

Complexities of the New Class Actions Landscape: Novel Causes of Action and Strong Defenses

The plaintiffs' bar never seems to run out of new and novel theories in class action laws suits against the industry. However, some recent decisions may give plaintiffs' counsel reason to pause.

- Examine the recent success of primary jurisdiction and preemption defenses
- Analyze the 9th Circuit's unique preemption application in Greenberg v. Target Corp.
  - » Court says that structure/function claims under FDC&A trump California consumer protection statutes
- Conduct class action risk assessments for some of the more unique plaintiff's theories:
  - » Nutrient content claims
  - » Calorie labeling of macronutrients
  - » Vegan claims
  - » Pure and natural claims
  - » Quality claims
  - » Trace amounts of heavy metals—How low can you go?
- Can RICO statutes be the newest tool to fight plaintiffs' attorneys actions?

5:15 Conference Adjourns



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Saqib Javaid
Director of R&D/Quality
NutraBlend Foods

"As a member of a dietary supplement regulatory affairs department reviewing product content daily for FTC / FDA compliance, it was a valuable experience to be in a room with top minds from around the country who could answer my questions."

Christine Bardsley
Regulatory Associate
FoodState

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