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**RADICLE**<sup>™</sup>  
SCIENCE



**clean  
label**  
PROJECT<sup>®</sup>

WEBINAR

# Overkill or Overdue?

## Analyzing the new FTC Health Products Compliance Guidelines

# Meet Your Presenters



**Scott Dicker**

Market Insights Director,  
SPINS  
Moderator



**Martin J. Hahn**

Partner,  
Hogan Lovells



**Dr. Jeff Chen**

Co-founder & CEO,  
Radicale Science



**Pelin Thorogood**

Co-founder & Executive  
Chairwoman,  
Radicale Science



**Jackie Bowen**

Executive Director,  
Clean Label Project

# Top Line VMS Sales

\$ % Change L52 Weeks

NATURAL GROCERY		
-1.2%	-3.5%	+2.4%
Total Channel Sales	Total Units	ARP

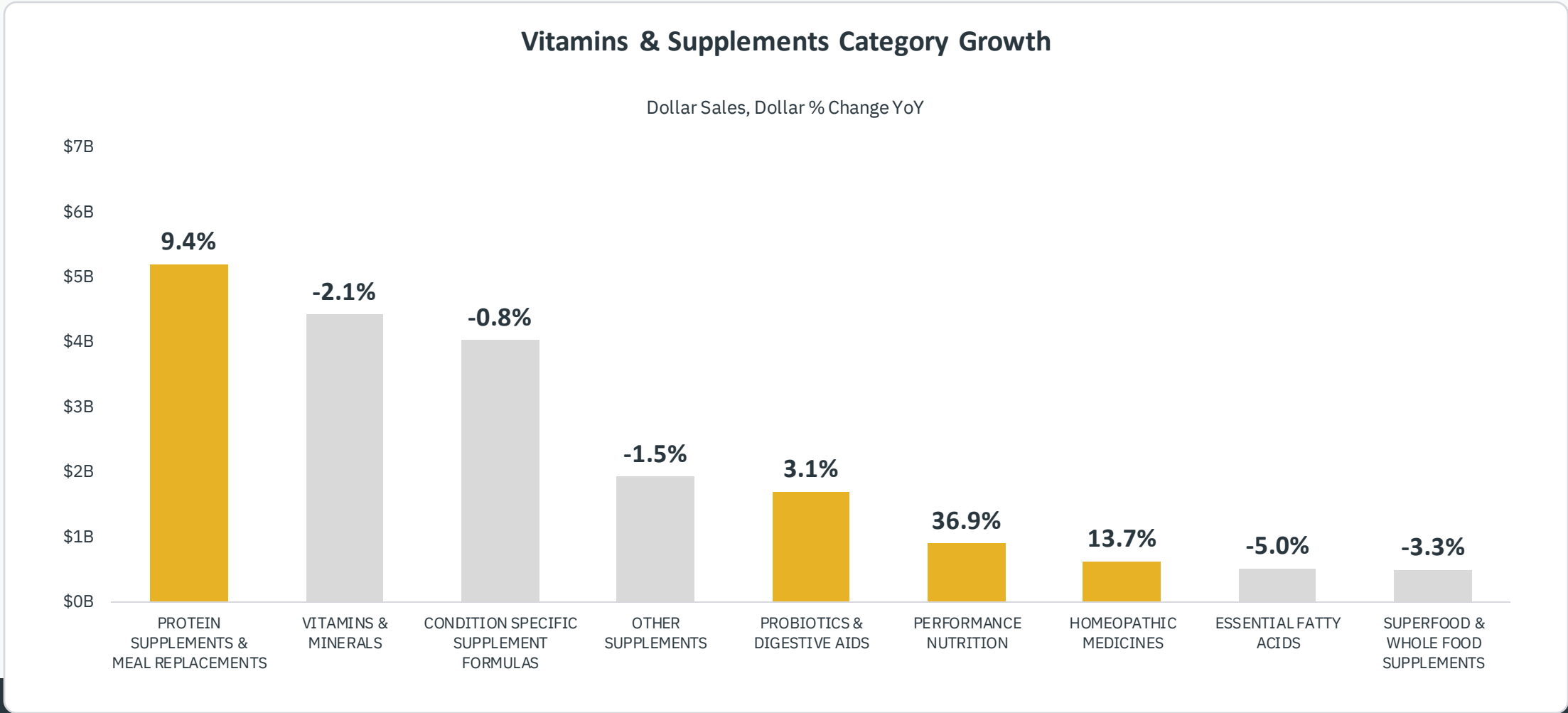
AMAZON		
+0.1%	-5.4%	+5.8%
Total Channel Sales	Total Units	ARP

REGIONAL & INDEPENDENT GROCERY		
+2.6%	-3.5%	+6.3%
Total Channel Sales	Total Units	ARP

CONVENTIONAL MULTIOUTLET (MULO)		
+3.6%	-2.7%	+6.5%
Total Channel Sales	Total Units	ARP

Source: 52 weeks ending 01.01.23 SPINS SNE, RIG, MULO powered by IRI. ClearCut Analytics

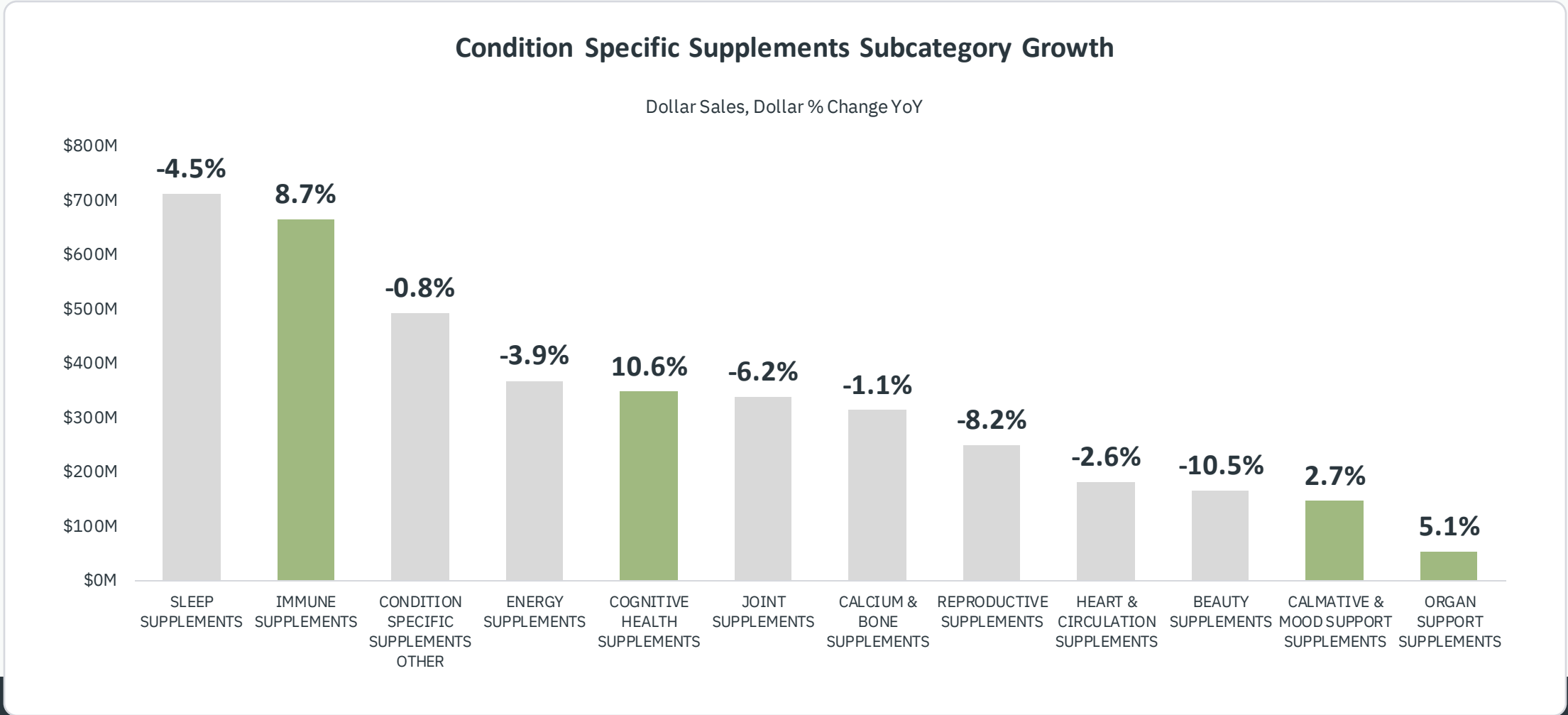
Most categories in Vitamins & Supplements reported a decline but some categories like Performance Nutrition and Protein Supplements saw growth



\* % Represents Dollar % Change YoY (vs same time LY)

Source: SPINS Natural Channel, MULO | Department: Vitamins & Supplements  
52 Weeks Ending 01.01.23

Only four subcategories within the Condition Specific Supplements category reported an increase in year-over-year sales



\* % Represents Dollar % Change YoY (vs same time LY)

Source: SPINS Natural Channel, MULO Department: Vitamins & Supplements, Category: Condition Specific  
52 Weeks Ending 01.01.23

# Consumers are shopping label claims when purchasing Supplements

## Labeled Organic

Dollar Share  
**12.5%**

Dol % Growth YoY  
**+8.1%**

+5.3% \$ Share YoY

## Labeled Gluten Free

Dollar Share  
**51.0%**

Dol % Growth YoY  
**+2.1%**

-0.47% \$ Share YoY

## Certified B Corp

Dollar Share  
**7.5%**

Dol % Growth YoY  
**+0.4%**

-4.4% \$ Share YoY

## Certified Non-GMO

Dollar Share  
**12.0%**

Dol % Growth YoY  
**+4.5%**

+0.1% \$ Share YoY

*\*Data represents coded items only not inclusive of Subcategory Not Coded, Private Label Not Coded, Unknown*

Source: SPINS Natural Channel, MULO  
Department: Sports Nutrition Category: Subcategory: Protein & Meal Replacement Powder, Attribute: Label Claims  
52 Weeks Ending 01.01.23

# Advertising 101

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**Martin J. Hahn**

Partner, Hogan Lovells

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# About Hogan Lovells

Area of focus

## Food and Beverages

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From well-established conglomerates to niche startups, we live and breathe (or rather, eat and drink) this space.

The world of food and beverage is an exceptionally complex landscape of legislative concerns and regulatory guardrails. Our Food and Beverage team has honed its know-how alongside some of the most transformational brands in this space for more than 40 years.





# Who regulates claims?

Generally, the FTC has jurisdiction over advertising, which includes:

- ✓ Traditional advertising
- ✓ Online advertising
- ✓ Social media

And the FDA has jurisdiction over the product label and labeling, which can include:

- ✓ the product website, if products can be purchased from the site or if the link is provided on labels
- ✓ Social media

# FDA & FTC: False or Misleading Claims Prohibited

Both the FDA and FTC prohibit false or misleading claims

This means substantiation is required

Must be able to substantiate both express, and reasonably implied claims

Additionally, we need to think about whether a claim might be literally true but could nonetheless be misleading, or could be misleading without certain qualifying/disclosure information

Consult FDA regulations and guidance, FTC guidelines

**Cheat death.**

The antioxidant power of pomegranate juice:



## What percentage of consumers must share an interpretation for it to be “reasonable”?

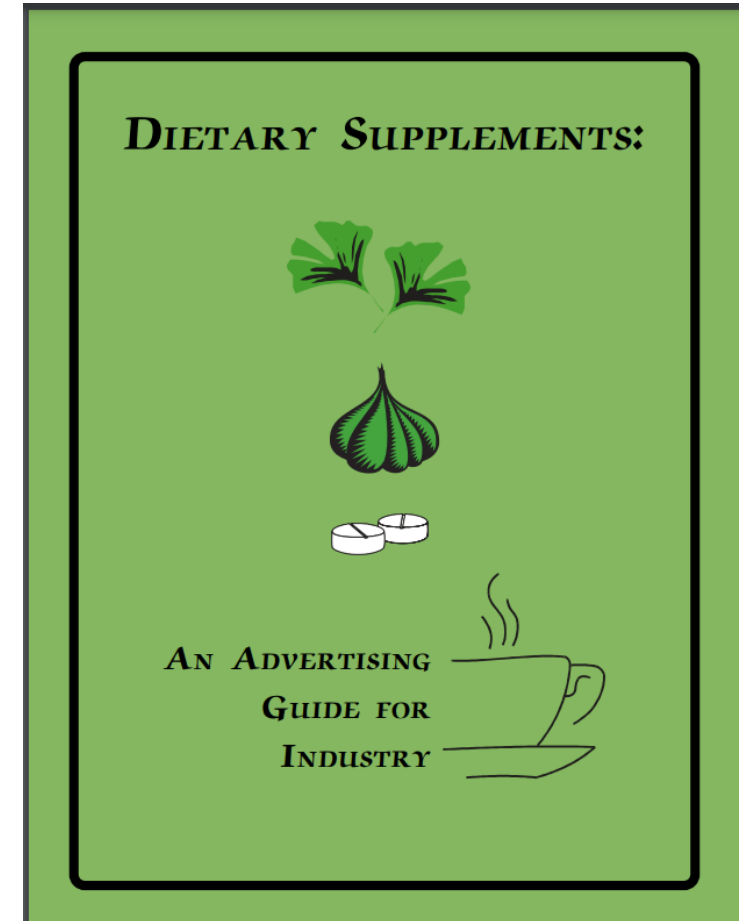
- ☐ 90%
- ☐ 75%
- ☐ 66.6%
- ☐ 51%
- ☒ **10-20%**

Generally, we recommend avoiding a claim when testing shows 15-20% of consumers have an interpretation that cannot be substantiated.

# FTC Guidance on Advertising for Dietary Supplements

- FTC issues guidance in December 2022
- The guidance updates the last guidance issued in 1998
- The updated guidance largely tracks the FTC standard that has been in effect for decades
- FTC clarifies position on traditional use

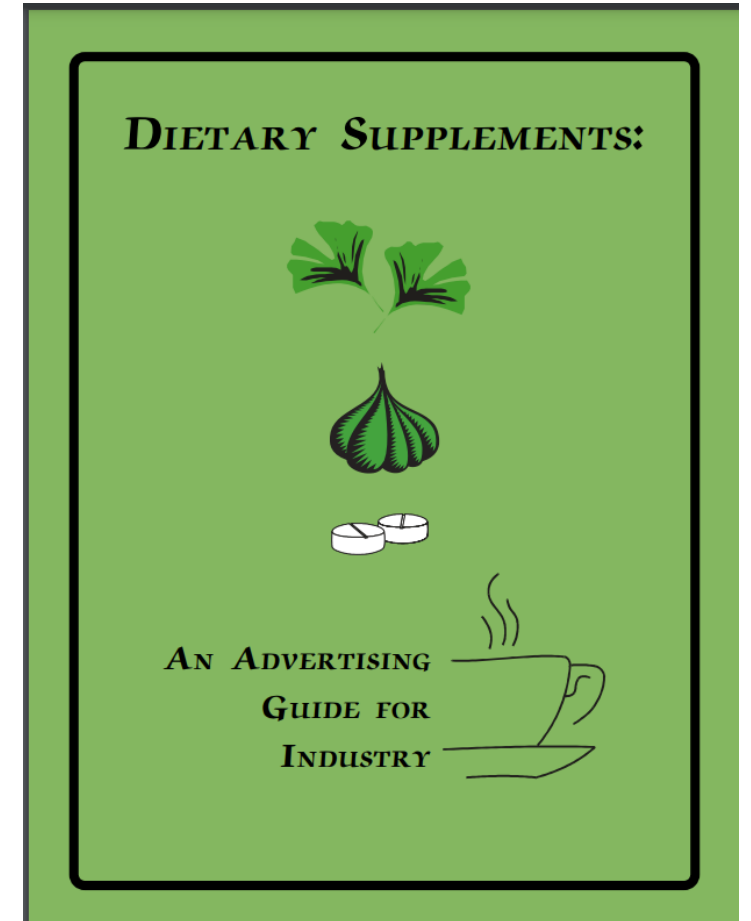
“Claims based on historical or traditional use should be substantiated by confirming scientific evidence, or should be presented in such a way that consumers understand that the sole basis for the claim is a history of use of the product for a particular purpose”



# Traditional Use

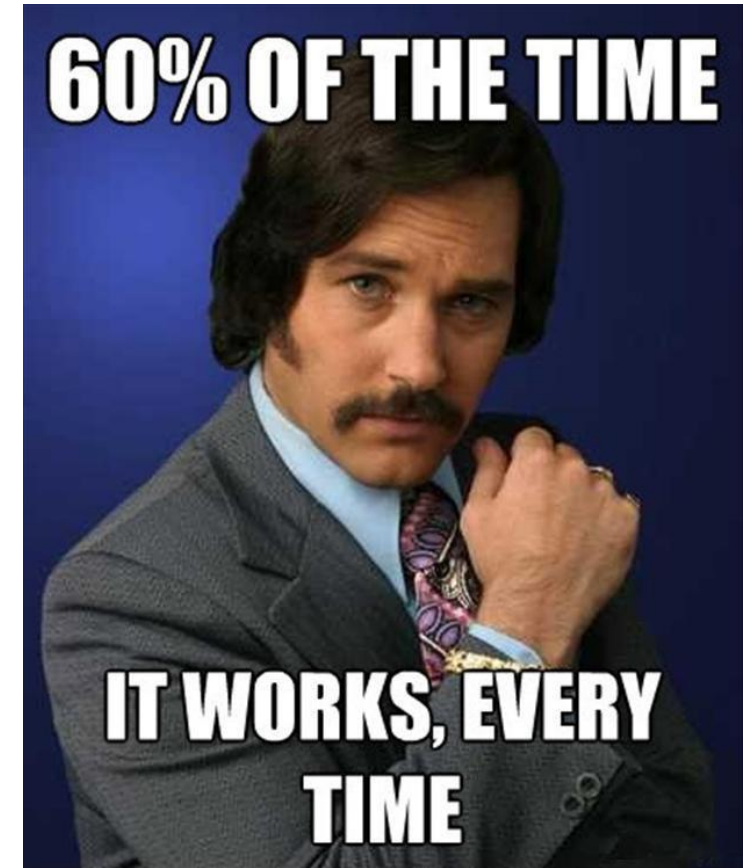
“The advertiser should make sure that the product it is marketing is consistent with the product as traditionally administered. If there are significant differences between the traditional use product and the marketed product, in the form of administration, the formulation of ingredients, or the dose, a traditional use claim may not be appropriate.”

Example: A supplement manufacturer markets a capsule containing a concentrated extract of a botanical product that has been used in its raw form in China to brew teas for increasing energy. The advertisement clearly conveys that the energy benefit is based on traditional use and has not been confirmed by scientific research. The ad may still be deceptive, however, because the concentrated extract is not consistent with the traditional use of the botanical in raw form to brew teas and may produce a significantly different effect.



# Disclosures

- Is a claim truthful but nevertheless potentially misleading?
- Does the claim omit a material fact – or a fact that is important to help consumers properly understand the claim or put it into context?
- **An inherently misleading statement cannot be cured through a disclaimer!**
  - Stated differently, a disclaimer can't contradict the claim
- FTC has provided guidance on placement and prominence, but generally, the closer the disclosure appears to the claim, the more effective



# What type of substantiation is needed?

- Advertisers must have substantiation for all claims that the ad conveys to reasonable consumers – express and implied – before making the claim
- Reasonable basis standard
- Structure-function and other health-related claims require a high level of substantiation

- “Competent and Reliable Scientific Evidence”
  - “Tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results”
  - FTC expects companies to support health-related claims with high quality, randomized, controlled human clinical trials (RCTs)”

# FTC's Guidance on Clinical Trials Needed for Claims



**Dr. Jeff Chen MD/MBA**

Co-Founder/CEO,

Radicle Science

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History's first Proof-as-a-Service company, enabling supplements to easily **prove their true effects** beyond placebo





“

**Randomized, controlled human clinical trials (RCTs) are...the type of substantiation...[required] for health benefit claims.**

**Marketers should ensure that...any health-related claim complies with these [scientific] principles”**

2022 FTC Health Products  
Compliance Guidance

## To substantiate health claims, need high-quality trials with:

### 1. Control Group

Necessary to establish causality.

### 2. Double Blinding

Necessary to reduce “expectancy” bias

### 3. Randomization

Necessary to reduce “selection” bias

### 4. Statistically Significant Results

Unlikely due to error/  
random chance = matters  
to a scientist

### 5. Clinically Meaningful Results

Palpable/noticeable and improves  
daily life = matters to an individual

### 6. Prespecified Analysis/Protocol

Prevent post-hoc analysis  
 (“p-hacking”)

### 7. Relevance

The study population should  
 “reflect the characteristics of the  
 population targeted by the ad”

# Diversity and Generalizability of Clinical Trial Data



**Pelin Thorogood**

Co-Founder/Exec Chair,  
Radicle Science  
[Pelin@radiclescience.com](mailto:Pelin@radiclescience.com)

# New Guidance Promises Change

“

**Study populations should “reflect the characteristics of the population targeted by the ad” ...**

**“Advertisers shouldn’t rely on research based on a specific test population for claims targeting the general population.”**



2022 FTC Health Products  
Compliance Guidance

# Demographic Disparities in Clinical Trials

Participants in clinical trials should represent [those] that will use the products to reduce biases, promote social justice and health equity, and produce more innovative science (FDA)  
Yet....

Most participants in traditional trials [are Caucasian men in metropolitan areas](#)

< 20% of drugs had data regarding Black patients (Memorial Sloan Kettering Cancer Center)

Women, minorities, and rural populations still under-represented

- White men represent < 30% of the U.S demographics.
- Non-white ~40% of US population, though represent 2% - 16% clinical trial population.

# Clinical Trial Diversity is Key to Health Equity

People of different ages, races, and ethnicities may react differently to certain medical products

The lack of diversity in clinical trials...costs billions of dollars a year in early deaths and poor health (National Academies of Science, Engineering and Medicine).

A majority of drugs recalled had greater health risks for women (U.S. Government Accountability Office)

# Clean Label Project

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**Jackie Bowen**

Executive Director,  
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# About Clean Label Project

A national non-profit with the mission to bring truth and transparency to consumer product labeling.

We believe that sometimes what's NOT on a label is what matters most.

Food safety attention has largely been focused on short term acute exposure to food-borne pathogens like salmonella, e.coli, and listeria.

The long-term threat of cancers and reproductive disorders linked to industrial and environmental contaminant exposure have largely gone unnoticed, untested, and therefore unregulated in food and consumer products, until now.

Clean Label Project uses actual retail sampling and testing to establish evidence-based benchmarks on the levels of contaminants in America's best-selling food and consumer products.

Together, we are changing the definition of food and consumer product safety in America.

# Current State

There is a growing divide between consumers and government on the definition of “quality” and “safety”.

## What’s driving the divide?



*“Growing frustration with corporate apathy and government inaction has led to a shift in consumer purchasing behavior to support businesses that are proactively solving for nutritional and environmental issues.”*



Pew Research Center

FEATURE | JUNE 6, 2022

*“The percentage of Americans that say they trust the government in Washington to do what is right:*

- “Just about always” (2%)*
- “Most of the time” (19%)*
- Trust in the government has declined since last year, when 24% said they could trust the government at least most of the time*

**S&P Global**

Market Intelligence






*US leaders plead for trust while... Americans confidence dwindling*

- Trust in the US federal government has steadily declined since the 1960s*
- In the past decade, trust has been on an exponential decline*
- Consumers are looking elsewhere to make decisions for themselves and their family*

**GatesNotes** THE BLOG OF BILL GATES

*Even the world’s most famous optimist, Bill Gates, fears that in 2022, “decreased trust in institutions might be the biggest obstacle standing in our way.” ....misinformation makes people suspicious...”*

## 5 Tips for Restoring Consumer Trust and Complying with the FTC Guidance

-  Use data to know customer wants and expectations to help inform product claim strategy
-  Make evidence backed claims central to your marketing strategy
-  Establish brand and product value propositions that align with consumer expectations
-  Commit to transparency
-  Remember, compliance with federal law is table stakes



# Thank you!

Questions? Please reach out to [sdicker@spins.com](mailto:sdicker@spins.com)  
or visit our website: [spins.com](http://spins.com)

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