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# Class Actions and Overlap with Regulatory Compliance

16<sup>th</sup> Annual Nutrition Law Symposium

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## *Lawsuits Over ‘Misleading’ Food Labels Surge as Groups Cite Lax U.S. Oversight*

A flurry of litigation by advocacy groups seeks to combat what they say is a rise in deceptive marketing by food giants.



Turkeys roam in 20 acres of fields at Gunthorp Farms, an independent family farm in northeast Indiana that has had trouble competing with agricultural giants. Kaiti Sullivan for The New York Times

By Andrew Jacobs

Sept. 7, 2021, 3:00 a.m. ET

“These cases can really have a chilling effect on speech,” Mr. Wasserman said. “And I think that’s damaging not only to the company, but also potentially for consumers, if companies are afraid of giving truthful and accurate information for a fear of being roped into a meritless lawsuit.”

Still, he acknowledged that some of the recent litigation was not entirely outlandish, and said he had become increasingly emphatic in advising clients to avoid words like “natural” or “sustainable” on their labels. The flood of litigation has become so intense that Mr. Wasserman’s firm, Amin Talati Wasserman, recently opened an office in California, which has some of the country’s most stringent consumer protection regulations.

# Class Actions Implicating Regulatory Compliance



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- Rise in cases, especially those implicating FD&C Act compliance
- Even where labeling is compliant, claims may still be misleading
- “Reasonable consumer” standard must be considered



U.S. DEPARTMENT OF AGRICULTURE

# Reasonable Consumer Standard



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## Moore v. Trader Joe's Co., No. 19-16618 (9th Cir. July 15, 2021).

- “100%” in the “100% New Zealand Manuka Honey” label could be read in multiple ways: “100% could be a claim that the product was 100% Manuka honey, that its contents were 100% derived from the Manuka flower, or even that 100% of the honey was from New Zealand.”
- In order to state a claim, plaintiffs must prove "more than a mere possibility that the seller's label might conceivably be misunderstood by some few consumers viewing it in an unreasonable manner. Rather, the reasonable consumer standard requires a ***probability that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled.***"

## The Court reinforced the importance of considering context:

- (1) the impossibility of making a honey that is 100% derived from one floral source;
- (2) the low price of Trader Joe's Manuka Honey; and
- (3) the presence of the “10+” on the label.

# Reasonable Consumer Standard



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**Moore v. Trader Joe's Co., No. 19-16618 (9th Cir. July 15, 2021).**

## **Key Takeaways:**

- Consumers do not interpret labels to mean the impossible;
- Consumers must consider all the information available to them, including context; and
- FDA guidelines can support a “literally true” defense

**“[W]here plaintiffs base deceptive advertising claims on unreasonable or fanciful interpretations of labels or other advertising, dismissal on the pleadings may well be justified.”**

# Nutrient Content Claims



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- Specific regulatory requirements must be met in order to make nutrient content claim;
  - 21 CFR Part 101, Subpart D
  - Are consumers actually deceived?
- “Zero” and “No Added Sugar” claims
  - Challenges where label lacked mandatory disclosure that product is not a low-calorie food
  - No harm, no foul? Context may matter.
- Protein claims
  - Challenges to protein content claims, alleging claims are false and misleading
  - Based on use of nitrogen method grams vs. PDCAAS corrected grams; FDA regs allow both



# Flavor & Color Claims



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- Other Nutrient Claims
  - FDA composite sampling requirements 21 C.F.R. 101.9(g)(2)
  - Pleading v. Proving
- “No artificial flavor”
  - Primary targets: malic acid, citric acid; added for technical function but may still affect flavor
- Vanilla
  - Complaints allege “vanilla” is misleading unless product complies with FDA’s standard of identity
  - Largely unsuccessful



# Flavor & Color Claims

- Fruit flavor claims
  - Variant on Vanilla suits
  - Recent Celsius case gets past pleading stage
- “No artificial colors”
  - CPG Sect. 587.100: regardless of source, added color is “artificial”
  - FDA: “...beet juice, paprika, turmeric, and saffron are not artificial colors per se.”  
38 Fed. Reg. 20718, 20719-20 (Aug. 2, 1973)





# Ingredient Permissibility & Product Classification



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- Products are not “dietary supplements” where no NDIN was filed for the ingredient
  - *Rosas v. Hi-Tech Pharmaceuticals*, No. CV 20-00433-DOC-DFM, 202 U.S. Dist. LEXIS 164565 (C.D. Cal. July 29, 2020)
- CBD supplement/food challenges
  - Ex. *Dasilva v. Infinite Product Co.*, No. 2:19-cv-10148 (C.D. Cal. Mar. 3, 2021)
- Cases dismissed, or stayed, on primary jurisdiction grounds
  - Other CBD suits based on failure to meet label content claims proceeding; ex. *Miguel Rodriguez v. Just Brands USA, Inc., et al.*, 2:20-cv-04829 (C.D. Cal. Sept. 24, 2020).

# Structure/Function Claims



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- Allegation that claims such as “support cardiovascular health,” “promote heart health” violate false advertising laws
  - *Dachauer v. NBTY, Inc.*, 913 F.3d 844 (9th Cir. 2019)
  - Struck down on preemption grounds: “*Plaintiff disagrees with the federal statutory scheme for dietary supplements, but we cannot accept his invitation to upend it*”
- More recently, attacks on placement of DSHEA disclaimer
  - Ex. *Barnes v. Iovate Health Sciences U.S.A. Inc.*, No. 5:21-cv-04978 (N.D. Cal. June 28, 2021)
  - Citing non-compliance with 21 CFR 101.93(d)

# Structure/Function Claims



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- *Greenberg v. Target Corp.*, No. 19-16699, 2021 WL 116537 (9th Cir. Jan. 13, 2021)
- Allegation: “helps support healthy hair and skin” claim for biotin supplement misleading, because majority of population obtains enough biotin from diet
- Ninth Circuit affirmed summary judgment in favor of defendant
  - Plaintiff did not dispute biotin supports healthy hair and skin
- Similar to *Dachauer*, plaintiff cannot impose a higher standard on s/f claims
  - “*Simply put, manufacturers may make structure/function claims about a nutrient’s general role on the human body without disclosing whether the product will provide a health benefit to each consumer*”

# Mitigating Risk



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- ✓ Review labeling and marketing materials from the vantage point of the “reasonable consumer”
  - Not merely technical compliance
- ✓ Are all implied claims or messages substantiated?
  - Consider all possible interpretations of the product labeling as a whole
- ✓ Where FDA has not made a final determination, primary jurisdiction and preemption arguments may be useful



## New legislation would reduce toxic heavy metals in baby food

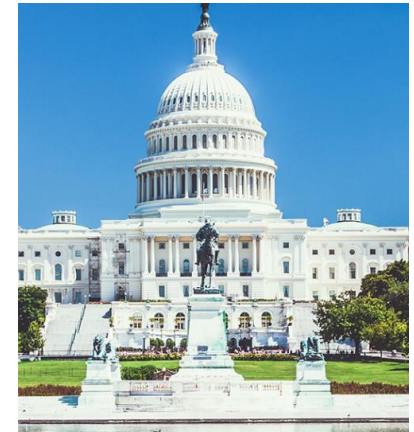
By Sandee LaMotte, CNN

Updated 6:30 PM ET, Thu March 25, 2021



## PALLONE, DELAURO, BLUMENTHAL, WHITEHOUSE, AND MARKEY INTRODUCE FOOD LABELING MODERNIZATION ACT

Aug 4, 2021 | Press Release



# Class Action Trends to Watch



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- Trans-esterified “fish oil” not actually “fish oil”
  - “Irrevocably transformed”
- Geographic origin claims
- Slack Fill Litigation
- Continued focus on “green” claims
  - Sustainability, recycling claims
  - FTC updates to Green Guides?
- More attacks on dietary supplement claims





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# Thank You!

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