



Food Fights in the Courtroom

How Litigation and Consumer Expectations are **Driving Food Labels**

June 5, 2019





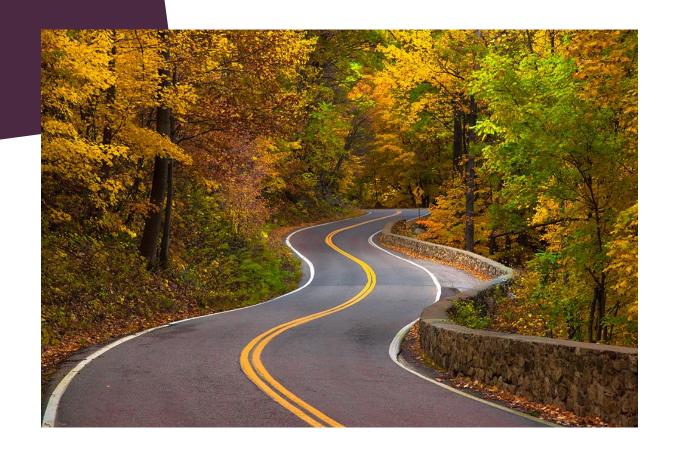
"The brand name [____] is misleading because consumers often associate the word [____] with the color **yellow** ... Consumers also know that **yellow** is the color associated with butter and cream, because of the milk produced by pasture-raised and forage-eating cows. These images reinforce consumers' expectations that the Products will be ice cream, as opposed to the purported light ice cream"

Agenda

- Background
 - Why class action litigation
 - Shift from "natural" to other claims
- Recent Trends in Dairy Food Labeling Litigation
- **Future Predictions**



Background



Food Claims Landscape

- Since ~2012, an explosion of class action lawsuits against the food industry
- Initially, three key areas of focus:
 - 1. Natural claims
 - 2. Alleged labeling violations of Federal Food, Drug, and Cosmetic Act (FFDCA) or similar state laws ("misbranding cases")
 - Technical labeling violations
 - Standard of identity
 - Ingredients
 - 3. Substantiation for health and wellness claims made for foods

Why Class Action Lawsuits

- FFDCA does not have a private right of action
- FDA is not always actively enforcing
- Many states have strong consumer protection laws
 - Allow individuals to sue to enforce
 - Individual consumer represents a "class" of like consumers that could make a similar claim
- Effort to plead in way that purposely avoids federal preemption



"Natural" - Where it Started

- "Informal" FDA definition from 1993
- Nothing artificial or synthetic (including all added colors) and no ingredients that would not normally be expected by the consumer to be in the food
- USDA policy incorporates "minimal processing" requirement
- FDA considering establishing a regulation defining natural
 - Requested comment in December 2015
- March 2018: FDA Commissioner Dr. Scott Gottlieb promises FDA will have more to say on natural "soon"

The "Natural" Landscape

- Hundreds of lawsuits have been filed
- Hundreds, if not thousands, have been "settled" quietly
- Public settlements can range up to \$10 million (many are \$1-3 million)
- Courts have yet to decide key issues such as
 - GE ingredients?
 - What is minimal processing?
 - What is synthetic?
 - What is natural?
 - How should damages be calculated?



If We Want to Avoid "Natural," Can We Say...

- No artificial ingredients
- No artificial flavors, preservatives, or colors
- Real
- Simple
- Healthy
- Wholesome
- Non-GMO
- 555



"No artificial " claims

- "No artificial ingredients"
 - has been challenged as an implied "all natural" claim
- "No artificial flavors"
 - FDA has defined artificial flavor (21 CFR 101.22(a)(1))



- Lawsuits challenging this claim where a product contains malic acid, ascorbic acid, fumeric acid, and others as an ingredient
- "No preservatives"
 - FDA has defined chemical preservative (21 CFR 101.22(a)(5))
 - Lawsuits filed challenging this claim where a product contains citric acid as an ingredient

"No artificial

"No artificial colors"

- FDA takes the view that all colors, regardless of source, are not natural
- FDA regulations define artificial color as any color additive (21 CFR 101.22(a)(4))
- Many companies make a qualified claim: "No artificial colors – added colors from natural sources"





5 Key Trends This Year Relevant to Dairy

- What is "milk"?
 - Skim milk
 - Almond milk, soy milk, etc.
- Sugar-related claims
- "Health halo" cases
- Non-GMO claims
- Natural/ "no artificial ____ "



1. What is "milk"? – focus on "skim milk"

- Under federal standard of identity for "milk," vitamin A and D fortification is optional
- When a food is labeled under the "nutritionally modified standardized food" provision it must be nutritionally equivalent to the standardized food
- Some states define "skim milk" as having added vitamin A
 - Florida Dept. of Agriculture took the view that non-fortified skim milk should be labeled as "imitation" skim milk
 - In 2017, the appeals court ruled it could be called "skim milk"



1. What is "milk"? – focus on "skim milk"

- April 2018: Maryland creamery sues FDA on First Amendment grounds, arguing they should not be required to label skim milk without added vitamins as "imitation milk" when sold interstate
- July 2018 Letter from FDA's Susan Mayne to the creamery offered alternative names:
 - Non-fortified skim milk, 0% DV vitamins A & D
 - Non-fortified non-fat milk, 0% DV vitamins A & D
 - Skim milk, 0% DV vitamins A & D
 - Non-fat milk, 0% DV vitamins A & D
- FDA says it has no plans to require imitation labeling and has been unable to identify a single instance in which FDA too misbranding enforcement action related to additive-free skim milk
- April 2019: Court rejects FDA's motion to dismiss



1. What is "milk"? – focus on plant-based milks

- "Soy milk," "almond milk, "coconut milk," etc.
- Initial cases focused on compliance with the standard of identity for milk
 - 2013 case held "almond milk" or "soy milk" are the common or usual names and federal preemption applies
 - "it is simply implausible that a reasonable consumer would mistake a product like soymilk or almond milk from dairy milk from a cow"
 - Other courts dismissed similar cases, finding no reasonable consumer would be misled



1. What is "milk"? – focus on plant-based milks

- More recent cases focus on plant-based milk as "nutritionally inferior" to dairy milk while failing to be labeled as "imitation milk"
 - One court dismissed such a case
 - "By using the term almond milk, even the least sophisticated consumer would know instantly the type of product they are purchasing. If the consumer is concerned about the nutritious qualities of the product, they can read the nutrition label."
 - Other courts have issued a stay on primary jurisdiction grounds, finding that whether almond milk should be labeled as an "imitation food" is within FDA's authority and expertise



2. Sugar-related claims

- Focus on "no added sugar" claims
 - Technical compliance with the regulation
 - "Not a low calorie food. See nutrition information for calorie and sugar content"
 - Presence of juice concentrates, including those for color/not used for sweetening
 - Does the food substitute for one that normally contains added sugars?
- New focus in demand letters: "o g sugars" icons
 - Presented as part of standardized Facts Up Front display
 - "Not a low calorie food..." disclosure
 - Cheese products with "o g sugar" icon



3. "Health halo" cases

- "wholesome" claims examples of challenges:
 - Sugar levels
 - Saturated fat levels
 - Glyphosate residues
 - **PHOs**
 - Doesn't qualify as "healthy"
 - Refined white flour



3. "Health halo" cases – focus on added sugars

- FDA established a DRV of 50 g for added sugars (~10% of daily calories)
- Lawsuits claim products with high amounts of added sugar are deceptively labeled with claims that are inconsistent with "dangers of excessive added sugar" consumption
 - "Healthy"
 - "Whole grain"
 - "Fiber"
 - "Wholesome"
 - "Nutritious"
 - "No high fructose corn syrup"
- Target foods with more than 5% of calories from added sugars
- Allege violations of additional regulations (e.g., health claim and nutrient content claim regulations)
- August 2018 one of the primary cases passed the class certification stage



4. "Non-GMO" or "GMO free"

- No regulatory definition of these claims
- New federal legislation says certified organic products may bear a "non-GMO" claim
- A food that is not subject to the mandatory BE disclosure does not automatically qualify as "non-GMO"



- Wide variety of interpretations
 - "Free" could be viewed as meaning no detectable levels
 - Are cheese or yogurt "non-GMO" if it is made from milk from a cow that consumed GE feed?

4. "Non-GMO" or "GMO free"

- Lawsuits filed in 2015 over non-GMO claims made by restaurant chain
 - BE corn syrup used in carbonated beverages
 - Meat and dairy products derived from animals that consumed BE feed
 - At least 5 similar lawsuits filed
- More recently, lawsuits filed in 2018 over "No GMO ingredients" claim on coffee-creamers and frozen meals
 - Suit focuses on dairy from cows fed BE feed; cites Non-GMO Project criteria
 - Also focuses on alleged implied representation that products were certified by an independent third party
 - Case is pending



5. "Natural"/"No artificial..."

- "No artificial"
 - Multiple cases pending over "no preservatives" and "no artificial flavors" claims
 - Focus on organic acids
- "Natural Cheese"
 - Cases pending against multiple companies
 - Some cases stayed pending FDA action on "natural"
 - IDFA-supported legislation introduced last June to define "natural cheese"
 - Passed Senate by a voice vote
 - Reintroduced in May 2019
 - Would help distinguish between "natural cheese" and "process cheese"



Where are the class action lawyers going?

Will follow consumer interest!

- Labeling of plant-based products
 - New state laws
 - Anticipated action from FDA
- "No added sugar" claims and implied claims that a product is healthful when it contains added sugars
 - New NFP requirement for added sugars declaration
- "Real" (fruit, cheese, cocoa etc.) claims and "Made with" Claims
- Protein claims
- "No preservatives," "no artificial _____", etc.



Role of consumers

- Consumer understanding
- Role of consumer research
 - Plant-based beverages
 - "Potassium salt"
- Pressure on FDA to define certain terms



Role of consumers











Discussion



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