



# LABELING BEST PRACTICES FOR FOOD COMPANIES & THE FIVE STAGES OF GRIEF

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# THE REGULATORS



- The Food and Drug Administration
- The U.S. Department of Agriculture
- The Federal Trade Commission



# “MISBRANDING” OR MISLABELING OF FOOD



- The FDA, the federal agency charged with overseeing the safety of food, drugs and cosmetics, has promulgated various regulations regarding permissible health claims and other claims on food product labels. The FTC, on the other hand, regulates food advertising.
- The Food, Drug, and Cosmetic Act prohibits “misbranding,” that is, the use of false or misleading information on a label about a food product.
- A determination that labeling is “misleading” considers both what the label says and what it fails to reveal.
- A determination that a food product or dietary supplement is “misbranded” can result in financial and/or criminal penalties.

# FOOD CLAIMS - NUTRIENT CONTENT CLAIMS



- A nutrient content claim is a claim on a food product that directly or by implication characterizes the level of a nutrient in a food product. For example, the FDA regulates the use of the following words on labels:
  - High; Rich In; Excellent Source Of; Good Source Of; Contains; Provides; More; Fortified; Enriched; Added; Extra; Plus; Lean; Extra Lean; High Potency; Modified; Fiber claims; Antioxidant claims

# FOOD CLAIMS - RELATIVE CLAIMS



- A relative claim involves comparing an amount of a nutrient in a food to an amount of a nutrient in an appropriate reference food. For example, the FDA regulates the use of the following relative claims in labeling:
  - Light; Reduced; Added; More; Less; Fewer

# FOOD CLAIMS - HEALTH CLAIMS



- A health claim is any claim made on a label that expressly or by implication characterizes the relationship of any substance to a disease or health-related condition. Health claims must be limited to claims about disease reduction, must meet the “Significant Scientific Agreement” (“SSA”) standard, and must be reviewed and evaluated by the FDA prior to use.
  - For example: “Three grams of soluble fiber from oatmeal daily in a diet low in saturated fat and cholesterol may reduce the risk of heart disease. This cereal has 2 grams per serving.”

# FOOD CLAIMS - QUALIFIED HEALTH CLAIMS



- Qualified health claims must be supported by credible evidence, but the scientific support does not have to be as strong as that required to meet the SSA standard. Qualified health claims must include an appropriate disclaimer, which is set forth in an FDA Letter of Enforcement Discretion.
  - For example: “Consumption of phosphatidylserine may reduce the risk of cognitive dysfunction in the elderly. Very limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of cognitive dysfunction in the elderly. FDA concludes that there is little scientific evidence supporting this claim.”

# FOOD CLAIMS - STRUCTURE/FUNCTION CLAIMS



- Structure/Function claims describe the effect that a nutrient or dietary ingredient has on the structure or a function of the body, but do not make reference to a disease.
  - For example: “Calcium builds strong bones.”
- Structure/function claims may characterize the means by which a nutrient or dietary ingredient acts to maintain a structure or function.
  - For example: “Antioxidants maintain cell integrity.”
- Structure/function claims are not subject to pre-market review and authorization by the FDA.



# THE FTC ACT: RELEVANT SECTIONS



- Section 5 of the FTC Act broadly prohibits “unfair and deceptive acts and practices.”
- Sections 12 and 15 (pertaining to FDA regulated products) prohibit “false advertising,” that is advertising “misleading in a material respect.”

# LABELING BEST PRACTICES



- Keep abreast of the changing landscape of food regulations. Numerous government agencies regulate food labeling. When drafting a label, know and understand the various regulations.
- Do not assume that words on the label mean what you think they mean. A food company should not use words like “natural” or “healthy” on a label unless the company has studied the regulations and caselaw, and knows how courts are interpreting those words.
- Look at the big picture when designing a label. Individual words or phrases may pass muster, but graphics or the combination of words on the label could become a problem.
- Do not oversell the product with puffery, not only on the label but in advertising campaigns.
- Every controversy can be an opportunity. A labeling challenge may be an opportunity to provide a full, positive picture about a product.

# LABELING STRATEGY: THINK STRATEGICALLY ABOUT THE VALUE OF A CLAIM ON A LABEL VS. THE RISK



- What do we expect to gain and what is our basis for believing this?
- What data is the claim based on?
- Can we back it up with scientific data such as the SSA standard?
- How likely are we to be sued?
- What are the consumer complaint/litigation trends for similar claims?
- What would be the damage to the brand (even if we win)?
- If the risk is too high or the benefit is too low, don't be afraid to reject a proposed label claim.
- Don't be enticed by the “But our competitor is doing it” argument.

# LABELING - FINAL CONSIDERATIONS



- Have all claims on labels been thoroughly vetted, approved, and determined to be beneficial?
- Has a risk-benefit analysis been done?
- Has everything necessary been done to ensure that allergens not included on a label do not accidentally contaminate a food product?
- Are all labeling claims about the presence of allergens in a food product or a facility accurate and not misleading?

# ALLERGENS OF CONCERN IN THE U.S.



- Milk
- Eggs
- Fish (e.g., bass, flounder, cod)
- Crustacean shellfish (e.g., crab, lobster, shrimp)
- Tree nuts (e.g., almonds, pecans, walnuts)
- Wheat
- Peanuts
- Soybeans  
[See 21 U.S.C. § 321 (qq)]

# FDA RECALLS FOR IMPROPER LABELING AND PRESENCE OF ALLERGENS



- Food products that are improperly labeled are subject to recall by the FDA.
- In one month alone, the FDA recalled 94 food products due to labeling issues, including claiming to be “organic,” and missing or incorrect required information such as ingredients, instructions or expiration dates.
- Allergens contained in a food product but not included on the label could also result in an FDA product recall.
- FDA guidance provides that food allergen advisory statements on labels such as “may contain [allergen]” or “produced in a facility that also uses [allergen]” may not be used as a substitute for adhering to Good Manufacturing Practices, and must be truthful and not misleading.

# CONSUMER FRAUD CLASS ACTIONS CHALLENGING FOOD AND BEVERAGE LABELING - THE CURRENT LANDSCAPE



- In recent years, consumer fraud class actions challenging food and beverage labeling, focusing on claims such as “natural” and “healthy,” have flooded courts nationwide. Plaintiffs’ lawyers have leveraged ambiguous or non-existent federal labeling standards to claim that consumers were misled and paid a premium for products, which, for example, contained processed ingredients that were not “natural.”
- Plaintiffs’ lawyers have been challenging claims on labels about how products are actually made. Alcoholic beverage companies are facing lawsuits for claiming that allegedly mass-produced products were “craft,” “handmade” or “small-batch.” Also, major food chains have been challenged for selling “artisanal” products that are made in allegedly assembly line processes.

# CONSUMER FRAUD CLASS ACTIONS CHALLENGING FOOD AND BEVERAGE LABELING - THE CURRENT LANDSCAPE (CON'T)



- Any food company that uses these production terms exposes itself to legal challenges that it is deceiving the public by suggesting there is something unique and of higher quality about how the company manufactures its goods.
- In the absence of a formalized legal standard, the use of terminology that “puffs” the quality of a product using debatable adjectives – even where there are good reasons to differentiate the product – can expose the company to lawsuits.
- So what should be done? Congress and regulatory agencies should develop clear and precise regulations that spell out the adjectives that companies can use in labeling and advertising, and under what circumstances. Ambiguous or non-existent standards are an invitation for litigation.



# THE FIVE STAGES OF CORPORATE GRIEF WHEN LABELING CLAIMS ARE MADE AGAINST A COMPANY'S PRODUCT THROUGH CLASS ACTIONS OR REGULATORY ENFORCEMENT



- Denial
- Anger
- Bargaining
- Depression
- Acceptance

# DENIAL



- We complied with the FDA's rules and regulations, so we are not liable.
- We hired a doctor or relied on clinical/scientific studies, so we are not liable.
- The FDA and FTC did not comment on the label, so we are not liable.

# DENIAL



- The FDA has issued warning letters declaring that the words “all natural” are not appropriate where the product contains citric acid, calcium chloride, ascorbic acid, or potassium sorbate.
- The FDA has also stated:
  - “Consistent with our policy on the use of the term ‘natural,’ we have stated in the past that the determination on whether an ingredient would qualify for the use of the term ‘natural’ is done on a case-by-case basis. Further, ingredients with the same common or usual name may be formulated in different ways, where a food containing the ingredient formulated one way may qualify for the use of term ‘natural’ and another food containing the ingredient with the same common or usual name, which has been formulated in a different way may not be eligible for the use of the term ‘natural.’”  
*(emphasis added)*

# DENIAL



- All of our competitors are making the same claims
- We have always said it
- It is just puffery
- We are not charging more for the product even though the claim has been made
- Our product is not dangerous
- The consumer did not rely on the statement
- The average person knows the truth

# ANGER



- We will get out of this case without paying any money
- If the lawsuit is frivolous, it will not cost me anything
- We can make this case go away quickly
- They cannot prove that the claim is not true
- We must defend our product no matter what
- This lawsuit is an attack that goes to the heart of our product

# BARGAINING



- Should we negotiate?
- Should we mediate?
- Should we settle?
- Should we agree to change the label?
- Should we pay out money?
- Will we have to make a public statement regarding any settlement or label changes?

# DEPRESSION



- Changing our label is admitting defeat
- If we settle, we will attract more plaintiffs, more lawsuits and more regulatory scrutiny
- Settling will cost too much money

# ACCEPTANCE



- We either settle or we fight
- We either change the label or keep it the same
- This must be decided on a case-by-case basis





# TRENDS IN FOOD LABELING CLASS ACTION LITIGATION



- Glyphosate
  - A herbicide used in the harvesting of wheat and oats.
  - About two years ago the anti-pesticide non-profit Environmental Working Group (“EWG”) published an article claiming to have detected trace amounts of glyphosate in several popular oat-based breakfast cereals.
    - The glyphosate levels were in the billionths, and were well below the levels that the EPA and FDA permit in oats.
    - EWG’s report nevertheless spawned a group of class actions against Quaker Oats, Kellogg’s, Bob’s Red Mill and General Mills, whose cereals were identified in the EWG report.
    - These lawsuits alleged that the companies should be required to disclose the presence of trace amounts of glyphosate, even though there was no federal requirement to do so.
    - These lawsuits, and lawsuits involving glyphosate in other food products, have not been successful.

# TRENDS IN FOOD LABELING CLASS ACTIONS - GLYPHOSATE CLAIMS



- The EPA’s “Proposed Interim Registration Review” Decision on Glyphosate (April 23, 2019)
  - Glyphosate is a herbicide registered for use in a wide variety of both agricultural and non-agricultural settings. (p. 4)
  - The EPA indicated that some commenters had pointed to the use of glyphosate as a “pre-harvest desiccant [drying agent] for wheat as a source of glyphosate residues in cereal products.” (p. 9)
  - The EPA responded that “wheat desiccant use was considered in the agency’s dietary risk assessment; EPA assumed maximum legal residues in wheat and other cereal grains. Taking exposures from those residues into consideration in its most recent human health risk assessment, EPA’s estimation of risk from aggregate exposure to glyphosate, even including residues from pre-harvest desiccant use on wheat, is below the agency’s level of concern.” (p. 10) (*emphasis added*)

# TRENDS IN FOOD LABELING CLASS ACTIONS - GLYPHOSATE CLAIMS (CON'T)



- *In Re General Mills Glyphosate Litigation*, 2017 WL 2983877 at \*5 (U.S.D.C., D. Minn., Jul. 12, 2017) class action dismissed because “[i]t is implausible that a reasonable consumer would believe that a product labelled as having one ingredient—oats—that is ‘100% Natural’ could not contain a trace amount of glyphosate that is far below the amount permitted [by the FDA] for organic products.”)
- *Gibson v. The Quaker Oats Company*, 2017 WL 3508724 at \*3-4 (N.D. Ill., Aug. 8, 2017)(dismissing complaint in class action which had alleged that “the use of the slogans ‘Natural,’ ‘100% Natural,’ ‘100% Natural Whole Grain,’ ‘Heart Healthy’ or ‘part of a heart healthy diet’ are deceptive because Quaker Oats contain trace amounts of glyphosate.”)

# TRENDS IN FOOD LABELING CLASS ACTIONS - GLYPHOSATE CLAIMS (CON'T)



- *Axon v. Citrus World, Inc.*, 354 F. Supp. 3d 170, 183 (E.D.N.Y., Dec. 10, 2018) (following *General Mills*, and concluding that “it is not plausible to allege that a reasonable consumer would interpret the brand label ‘Florida’s Natural’ as meaning that the product contains no traces of glyphosate.)
- *Parks v. Ainsworth Pet Nutrition, LLC*, 377 F. Supp. 3d 241, 248 (S.D.N.Y., April 18, 2019) (dismissing plaintiff’s claims and holding that “[t]he presence of negligible amounts of glyphosate in a dog food product that do[es] not have, harmful, ‘toxic,’ or ‘carcinogenic’ effects is not likely to affect consumers’ decisions in purchasing the product and is thus not material.”)

# TRENDS IN FOOD LABELING CLASS ACTIONS - GEOGRAPHIC FOOD CLAIMS



- Kona Beer
  - In June 2019 the court in *Broomfield v. Craft Brew Alliance, Inc., et al.*, Case No. 5:17-cv-01027 (N.D. Cal. 2019), approved a settlement expected to cost up to \$4.7 million to resolve claims that the Kona Brewing Co. had deceived consumers into believing that its beer was brewed only in Hawaii.
  - The plaintiffs alleged that Kona's labels, which depicted traditional Hawaiian images, (hula dancers, surfers, the Kilauea volcano) bore names such as "Longboard Island Lager" and "Big Wave Golden Ale," and invited consumers to "visit our brewery and pubs whenever you are in Hawaii," falsely gave consumers the impression that the beer was brewed only in Hawaii. In fact, Kona beer sold in the continental U.S. is brewed in New Hampshire, Tennessee, Oregon and Washington state.
  - Following the district court's class certification, a settlement agreement was reached pursuant to which Kona agreed to pay claimants specified amounts for each pack of Kona beer purchased, and to change its product labels to indicate where each beer was brewed.

# TRENDS IN FOOD LABELING CLASS ACTIONS - GEOGRAPHIC FOOD CLAIMS (CON'T)



## ■ Cascadian Farms

- Also in June 2019, the court in *Reed v. General Mills, Inc.*, 2019 WL 2475706 at \* 4 (W.D. Wash., June 13, 2019) held that the plaintiffs had stated a claim that the defendants had misled them into believing that 81 different Cascadian Farms frozen fruit and vegetable products were produced at the same small Washington farm. In fact, most of the produce came from large-scale farms around the world.
- To prove their claims, plaintiffs noted the brand name (Cascadian Farms) as well as a picturesque, rural Skagit Valley, Washington emblem on the label inviting consumers to “visit our home farm.” (*Id.* at \*\* 4-5)
- In denying defendants’ motion to dismiss, the court held that a reasonable consumer relying on the labels could reasonably conclude that all or substantially all of the ingredients in the products came from a small idyllic farm in Washington. (*Id.* at \* 5)

# TRENDS IN FOOD LABELING CLASS ACTIONS - GEOGRAPHIC FOOD CLAIMS (CON'T)



- These geographic cases demonstrate the potentially high costs to a food company if label images and statements give consumers the false impression that products originate in a specific place when they don't.
- This issue needs to be carefully considered when evaluating geographic labeling and marketing decisions.

# WHAT ARE THE FDA/USDA DOING REGARDING LABELING ISSUES?



- Warning letter to Curaleaf, Inc. on July 22, 2019, from the FDA's Center for Drug Evaluation and Research
  - Curaleaf is the largest cannabis company in the U.S. by revenue, and sells CBD<sup>1</sup> lotions, patches and “vape pens.” The FDA reviewed Curaleaf’s website and found that certain of Curaleaf’s CBD products were “unapproved new drugs” and were also “misbranded.”
  - The FDA expressed concern about claims on Curaleaf’s website that CBD has “properties that counteract the growth of [and/or] spread of cancer,” and is capable of “killing human breast cancer cells.” Other posts flagged by the FDA claimed that CBD was an “effective treatment” for Alzheimer’s and Parkinson’s diseases.
  - In a July 26<sup>th</sup> press release, Curaleaf indicated that, upon receiving the FDA’s letter, the company “immediately began an extensive review of its website and social media platforms to remove all statements that [the] FDA identified as non-compliant.”
  - Following the FDA’s announcement, Curaleaf shares fell by as much as 13% before recovering in afternoon trading to close down 7%.

<sup>1</sup> As noted in a Feb. 26, 2018 article on [healthline.com](https://www.healthline.com):

Cannabidiol is a popular natural remedy used for many common ailments. Better known as CBD, it is one of over 100 chemical compounds known as cannabinoids found in the cannabis or marijuana plant...Tetrahydrocannabinol (THC) is the main psychoactive cannabinoid found in cannabis, and causes the sensation of getting “high” that’s often associated with marijuana. However, unlike THC, CBD is not psychoactive. This quality makes CBD an appealing option for those who are looking for relief from pain and other symptoms without the mind-altering effects of marijuana or certain pharmaceutical drugs.



# WHAT ARE THE FDA/USDA DOING REGARDING LABELING ISSUES? (CON'T)



- Bioengineered Foods (“BE”)
  - On Dec. 21, 2018, the U.S. Dept. of Agriculture issued its long-awaited final rule (Federal Register, Vol. 83, No. 245 at 65814-65876) which established the requirements for disclosing BE foods, which, according to the USDA’s website, are “those that contain detectable genetic material that has been modified through certain lab techniques and cannot be created through conventional breeding or found in nature.”
  - Pursuant to this rule, the label of a BE food must include a disclosure indicating that the food is a BE food or contains a BE ingredient. Failure to provide an adequate BE disclosure is prohibited, and will subject the product to a recall.
  - Certain foods are either exempt or excluded from the mandatory BE disclosure, however.
    - Mandatory disclosure is limited to foods subject to the labeling requirements of the Food, Drug and Cosmetic Act, and to certain foods subject to labeling under the Federal Meat Inspection Act.

# THE TREND TOWARDS CRIMINAL PROSECUTIONS OF INDIVIDUALS AND COMPANIES FOR FOOD PRODUCT VIOLATIONS



- The Department of Justice, with the strong support of the FDA, focused several years ago on criminal prosecutions of food company owners and executives, and the companies themselves, for food safety violations.
  - Thus, unlike before, when criminal prosecutions for FDA food safety violations were rare, food industry officials were facing the threat of imprisonment for such violations, not simply civil monetary penalties or injunctive relief.
- Virtually all of the criminal cases brought thus far have involved egregious violations involving unsanitary plant conditions and widespread food-borne illnesses and/or deaths.
  - Jensen Farms case, cantaloupes adulterated with Listeria (Sept. 2013)
  - Quality Egg case, adulteration of eggs with salmonella, and misbranding, for mislabeling expiration dates (May 2014)
  - Oasis Brands case, distribution of cheese products contaminated with Listeria (November 2016 sentencing)

# THE TREND TOWARDS CRIMINAL PROSECUTIONS OF INDIVIDUALS AND COMPANIES FOR FOOD PRODUCT VIOLATIONS (CON'T)



- The Peanut Corporation of America (“PCA”) Case (September 2014)
  - While almost all cases have involved misdemeanor criminal charges, in the PCA case the food company’s executives were charged with, and convicted of, felonies.
  - The charges resulted from a nationwide salmonella outbreak in 2008-09 that killed nine people and sickened hundreds.
  - In September 2015, PCA’s President, 61-year-old Stewart Parnell, received a sentence of 28 years (federal officials had sought a life sentence). Stewart’s brother Michael, a plant supervisor, received 20 years, and Mary Wilkerson, a QC manager convicted of obstruction of justice, received 5 years.
  - These are eye popping sentences.

# THE TREND TOWARDS CRIMINAL PROSECUTIONS OF INDIVIDUALS AND COMPANIES FOR FOOD PRODUCT VIOLATIONS (CON'T)



- Recently, several felony cases have been brought by the Department of Justice against individuals and companies for misbranding or mislabeling food products.
  - Two Long Island companies and their owners were recently indicted and charged with falsely labeling squid as octopus. (*United States v. Anchor Frozen Foods, et al.*, E.D.N.Y., 9/26/18)
  - Vice President for Marketing & Operations of seafood company pled guilty to, among other charges, falsely labeling millions of dollars worth of foreign crab meat as “Product of USA.” (*U.S. v. Michael Casey*, E.D. Va., 7/18/19)
  - Owner and operator of seafood company pled guilty to falsely labeling millions of dollars worth of foreign crab meat as domestic blue crab labeled “Product of USA.” (*U.S. v. Phillip Carawan*, E.D.N.C., 8/13/19)

# THE TREND TOWARDS CRIMINAL PROSECUTIONS OF INDIVIDUALS AND COMPANIES FOR FOOD PRODUCT VIOLATIONS (CON'T)



- Co-owners of wholesale meat company in Brooklyn, NY charged with using counterfeit U.S. Department of Agriculture stamps to misbrand USDA “Choice” beef as higher quality USDA “Prime” beef. (*U.S. v. Howard Mora & Alan Buxbaum*, E.D.N.Y., 9/24/19)
- This isn't what your company does, right? Your company is well respected and law-abiding, and would never engage in such practices.
- But what if careless mislabeling of allergens or of expiration dates on a food product results in injuries or even deaths to consumers?
  - Therefore, even your company needs to be extremely careful, and follow labeling and production best practices.

# TAKEAWAYS



- Identify your company's priorities
- Preventive medicine is key
  - Assess legal and regulatory requirements for product labels
  - Assess emerging labeling issues and threats
  - Evaluate labeling risks vs. rewards
  - Fix any labeling problems
  - Is your company engaging in labeling best practices?



# LABELING BEST PRACTICES FOR FOOD COMPANIES & THE FIVE STAGES OF GRIEF

THANK YOU

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