

Morgan Lewis

When Natural Isn't Good for You: Managing Food Safety, Litigation & Regulatory Risk

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Global Food Forums
2013 Clean Label Conference

www.morganlewis.com



CLEAN LABEL CONFERENCE

www.GlobalFoodForums.com/CleanLabel

Question: What is “Clean” Labeling?

- Answer: No “clean definition.” In part, a response to misunderstanding or lack of knowledge regarding food science and safety



- Industry should not encourage the use of “clean” label nomenclature – nothing dirty about labels
- But – clear pressure on industry from consumers and advocacy groups

What Is a “Clean Label”?

- No “big” words - can the consumer pronounce it?
 - Ingredients (although, there are exceptions if the ingredient is “hip” and sounds natural, e.g. “acai,” pronunciation gets a pass)
 - Additives, preservatives, colors (to some extent)
 - Flavors can get a bit of a pass here
 - Where processing techniques are indicated, back to the old “could grandma make it in the kitchen” question



What Is a “Clean Label”?

- It is a subjective term, influenced by consumer knowledge or lack thereof
- Example – xanthan gum
- Xanthan gum is the product of fermentation of sugars (glucose, sucrose, lactose, etc.)
- Depending on production technique, being marketed as an “all natural” ingredient
- Nonetheless, there has been some level of reformulation to remove xanthan gum, because it “sounds artificial”
 - Don’t tell folks who need “gluten-free” products about this



So What Else Does the Consumer Want?

- Price – however, there is some overlap with the market paying premium prices for organic and “natural”
- Taste
- Texture
- Health/healthy
- Shelf life
- “Minimal” processing
- SAFETY



Brass Tacks

- Labels still need to comply with FDA and FSIS requirements
- Ingredients
 - Still required to use the common and usual name of ingredients unless a regulation provides for a different term
 - *“Sugar” is still “sugar” on the ingredients list, not “Andalusian summer’s breeze sugar”*
 - *“Corn syrup” is not an acceptable synonym for HFCS*
 - *“Modified” and other new ingredients – “milk protein”*

Ingredient Labeling Exemptions Remain Limited

- Processing aids and certain incidental additives
 - Incidental additives and processing aids are present at “insignificant levels” AND have no function or technical effect in the finished product
 - An incidental additive is usually present because it is an ingredient of another ingredient, or a processing aid added to a food for its technical or functional effect in the processing
 - “Insignificant” – not defined, clearest example in regulations is sulfites, considered to be incidental only if present at less than 10 ppm

Flavors

- “Spices”
- “Flavor”
- “Natural flavor”
- “Artificial flavor”
- “Flavor Flav”



Overlap with Natural and Organic

- There is a “natural” overlap with “organic” products here
- OFPA and Organic rules will generally get you to a similar place – but not necessarily - the “National List” currently allows (in certain processed organics):
 - Ammonium bicarbonate
 - Calcium hydroxide
 - Potassium carbonate
 - Tetrasodium pyrophosphate
 - And . . . xanthan gum (identified as a “synthetic”)



Overlap with Natural and Organic

- USDA and FDA Policies for Natural
 - Nothing artificial or synthetic (including all color additives regardless of source and flavors) has been included in or added to a food that would not normally be expected to be in the food
 - Processing taken into account – minimal processing – think “Grandma’s kitchen”

Issues and Concerns

- SAFETY
 - Clearly, this is the #1 concern
 - Formulation/process changes that affect shelf life, stability, need to be validated and reviewed in the context of final labeling
 - Preservatives – what effective alternatives are available – HPP, etc.
 - See recent recalls of Greek Yogurt

Issues and Concerns

- Formulation
 - Can the product be reformulated and still maintain the taste and texture expected by consumers
 - For example – some past attempts at low-sodium soups did not resonate with consumers



Issues and Concerns

- Labels must still be truthful and accurate
 - Cannot be “false or misleading in any particular”
 - Omission of material fact(s) can be misleading
 - Does reformulation negate or alter other claims on your label?
 - Nutrition information/claims
 - Health claims



FDA & FTC Enforcement

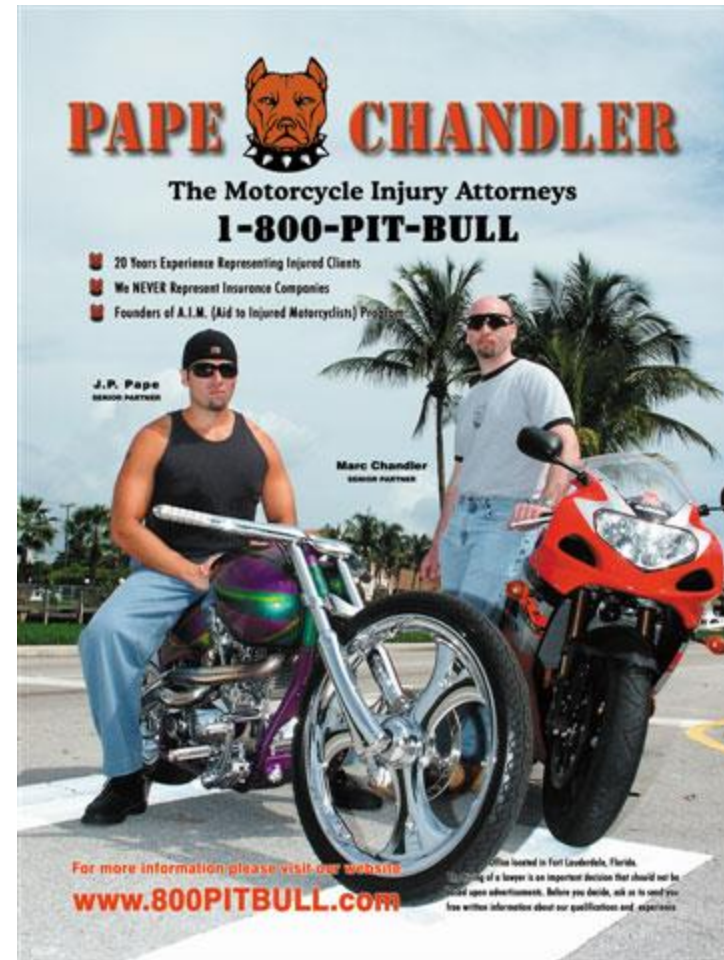
- FDA
 - Big emphasis on “Front of Package” claims
 - Food products claiming to treat or mitigate diseases;
 - Misleading “healthy” claims; etc.
- FTC
 - Increased scrutiny of foods
 - Associate Director for Advertising Practices has said:
 - *“Health-related claims are becoming more prevalent in food advertising – so we are giving increased scrutiny to food advertising”*
 - *“Claims such as boost the immune system, assist with memory and brain function, boost metabolism, protect the heart, etc.”*
 - *“We have concerns with disease prevention or treatment claims not approved by FDA”*

Additives Are Under Attack

- Pew Charitable Trusts (now at NRDC) – Food Additives Initiative
 - One paper published, several in the pipeline
 - Aggressive media campaign
- CSPI “Food Additives Mobile App”
 - CARMEL COLORING - “But not so fast: Much of what goes by this innocent-sounding name is made with ammonia, or sulfites, or both.”
 - *“Shopping was easy when most food came from farms. Now, factory-made foods have made chemical additives a significant part of our diet.”*
- BTW – shopping was EASY when “most” food came from farms? Really? Dust Bowl anyone? Bueller?

Food Litigation

- The *%@! lawyers
- Plaintiffs' bar is aggressively going after the food industry
- Big Food is the new Big Tobacco
 - the same lawyers who went after tobacco now have their sights set on food
- All the issues we've discussed are potential targets – omissions, ingredient names, processing – plaintiffs are using “consumer fraud” statutes to pursue labeling that “misleads” consumers



Food Litigation

- FDA is picking its labeling battles as a result of strained resources
- FDA has said “Natural” claims are a lower priority than e.g. food safety issues
- As a result, a gap has been created by FDA’s inaction on developing a definition of “Natural”
- Plaintiffs’ claims bar is filling that gap

Food Litigation

- “Natural” claims first targeted high-fructose corn syrup, artificial preservatives, products processed with unnatural ingredients, and now GMO ingredients.
- Products targeted vary – chips, ice cream, yogurt, almond milk, canned tomato products
- Class actions alleging:
 - Violation of state consumer protection laws
 - Fraud and misrepresentation
 - Breach of express and implied warranties
 - Unjust enrichment

Food Litigation

- Claims allege that plaintiff would not have bought the product if did not display “All Natural” on the label
- Damages alleged from higher prices paid for premium natural products
- Non-GMO cases – Some courts dismissed because plaintiffs did not plead reliance on “Natural” label, as other ingredients are also required to be on label
- Identifying ingredient as GMO is not required on the label, so this reliance issue is not present for plaintiffs

Food Litigation

- Sample of products at issue in GMO litigation:
 - Cereals
 - Chips
 - Crackers
 - Soups
 - Rapeseed/canola and soy oils
- Ingredients
 - Corn
 - Soy

Food Litigation

- Popular jurisdictions:
 - Northern District of California
 - Central District of California
 - Eastern District of New York
 - District of New Jersey
 - Southern District of Florida

Food Litigation

- Defenses in play:
 - Preemption under NLEA
 - Failure to state a claim for fraud or misrepresentation under *Iqbal* and *Twombly*, Rule 9(b)
 - Primary jurisdiction of FDA
 - Not suitable for class action because claims are too individualized, lack predominance
 - Lack of standing

Food Litigation

- Preemption rulings:
 - For products containing meat, courts are finding preemption as a result of USDA and FSIS label approvals
 - Generally finding no preemption under FDCA and NLEA
 - *No express preemption in FDCA or NLEA*
 - *No implied preemption as FDA deferred taking regulatory action and therefore does not intend to occupy the field*

Food Litigation

- FDA's primary jurisdiction
 - Some courts finding FDA's primary jurisdiction implicated and clearly not comfortable defining “natural”
 - *Coyle v. Hornell Brewing Co.*, D.N.J., - In 2010, certified to FDA for an administrative determination of whether HFCS qualifies as a “natural” ingredient. FDA declined to provide guidance.
 - *Cox v. Gruma Corp.*, N.D. Cal. – Referring to FDA determination of whether GMO ingredients are natural and staying case for six months

Food Litigation

- *Barnes v. Campbell Soup Co.*, N.D. Cal. – Staying case six months for referral to FDA because otherwise the court would risk “undermining, through private litigation, the FDA’s considered judgments.”
- *Van Atta v. General Mills, Inc.*, D. Colo., - R&R to stay case pending FDA determination sought by Cox v. Gruma court.
- **Some courts are ruling primary jurisdiction is not applicable**
 - *Krzykwa v. Campbell Soup, Co.*, S.D. Fla. – Court found primary jurisdiction doctrine did not apply, because FDA consistently refuses to rule on the meaning of the word “natural.”

Food Litigation

- Class action claims:
 - Inconsistent rulings on whether plaintiff claims are too individualized for class treatment
 - *Vitaminwater* case – Class certification denied as to monetary damages, class proceeding as to injunctive relief only
 - *Moro v. Barbara's Bakery* – Denying preliminary injunction to enjoin label because monetary damages provide sufficient relief.

Food Litigation

- Settlements
 - 2012 – *Ben & Jerry's* case (alkalized cocoa) – \$5,000,000
 - 2012 – *Breyers* case (same) – \$2,500,000
 - 2013 – *Trammell v. Barbara's Bakery* (GMO) – \$4,000,000 and removal of natural and artificial claims on labels and packaging on foods containing GMOs or artificial ingredients
 - 2013 – *Pappas v. Naked Juice Co.* (GMO) – \$9,000,000 and changes to labels

Food Industry - Multiple Silos

Research and Development

Food Safety / Manufacturing / Processing

Legal and Regulatory

Policy and Government Affairs

Advertising, Marketing & Communications

Corporate and Commercial

Conclusions

- There is some need to respond to consumer demand
- Reformulation requires a holistic review
 - Safety
 - Shelf life
 - Product attributes
 - Related label claims
- Regulatory requirements must still be met
- Consider plaintiffs' lawyers and misleading claims/omissions
- Don't feed the clean-label trolls
- Meld Silos
- Education of consumers

Presenter



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- Tony Pavel is a Partner at Morgan, Lewis & Bockius LLP, whose practice centers on food law.
- Mr. Pavel is the past Chair of the Institute of Food Technologists' Food Laws and Regulations Division.
- During Mr. Pavel's undergraduate and legal studies, he worked for a food HACCP consulting business.

THANK YOU!