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**“All Natural” Class Action Litigation:  
An Overview of the Regulatory Regime and  
Developing Case Law**

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Quarterly Food Industry Web Conference Series

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# Overview of “Natural” Claims

- Consumers value “natural” claims
- US FDA has not established formal definition
- USDA has ongoing rulemaking but also has not established formal definition
- Each have informal policy/guidance however.
- Recently seeing significant class action suits for natural and all-natural claims.
- Courts may be forced to fill in gaps where Agencies have been unwilling/unable.

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## Consumers Value “Natural”

- Despite lack of regulatory definition, consumers clearly value and seek “natural” foods and ingredients.
  - US retail sales of natural and organic foods rose nearly \$39B in 2010, an increase of 9% over previous year and 63% higher than 5 years earlier according to market research publisher Packaged Facts.
  - Continued growth is predicted - 103% between 2010-2015 to \$79B.

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## Consumers Value “Natural”

- Example: Frito Lay
  - Beginning of 2011 Frito Lay announced half of its products will be made with “all natural ingredients” including Lays Potato Chips, Tostitos tortilla chips and SunChips.
  - (No good deed goes unpunished?)
    - In December 2011 Frito Lay was sued over natural claims for its Tostitos and SunChips products.

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## FDA and “Natural”

- FDA has not established a formal definition through the rulemaking process.
  - In 1993 preamble on nutrient content claims FDA offered an informal policy: natural means “nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food.”
  - Except as to “flavors” and “colors,” however, FDA has not defined or issued guidance regarding the terms “synthetic” or “artificial”.
    - Thus, products with added color, synthetic or artificial substances, or artificial flavors cannot be called natural.

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## FDA and “Natural” - History

- In Feb. 2006, the Sugar Association requested that FDA undertake rulemaking to establish definition.
  - In Aug. 2006, FDA provided an interim response saying it was unable to reach a decision on the petition, citing “competing agency priorities and the limited availability of resources”.
  - To date it has not issued a substantive response.

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## FDA and “Natural” - History

- In July 2008, in response to a meeting between FDA and the Corn Refiners Association on whether the term natural can be used to describe HFCS
  - Geraldine June, Supervisor of FDA’s Product Evaluation and Labeling Team on the Food Labeling and Standards Staff issued a letter
  - Stating FDA would not object to term natural whereby enzymes are fixed to a column by the use of a synthetic fixing agent called glutaraldehyde, so long as the agent does not come into contact with the high dextrose equivalent corn starch hydrolysate.
- However, both the courts as well as FDA have called this letter “non-binding.”

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## FDA and “Natural” - History

- In June 2010, several natural litigation cases were stayed while the Judges requested an administrative determination from FDA as to whether HFCS qualified as a natural ingredient. (*Holk v. Snapple* and *Coyle v. Hornell Brewing Co.*)
- In September 2010, FDA responded to this request making four points:
  - 1. Resolving the issue whether HFCS is “natural” would require opening a rulemaking process which would likely take two or three years to complete.
  - 2. “Priority food safety matters” are currently occupying the resources FDA has available for public proceedings on food matters.

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## FDA and “Natural” - History

- In September 2010, FDA responded to this request making four points:
  - 3. Consumers currently receive some “protection in the absence of a definition of natural” because FDA requires that all ingredients be declared on the food’s label and thus here, consumers will know from the label if a product contains HFCS.
  - 4. The most relevant statement of the Agency’s views is the preamble language in the 1993 rulemaking. The Geraldine June letter is deemed to be a “informal communication and does not provide a binding agency interpretation.....”
- Based on this response and FDA’s current focus and priority on FSMA issues, it appears no rulemaking on “natural” will be forthcoming in the future.

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## FDA Enforcement of “Natural” Claims

- In the past, FDA enforcement of natural claims has been limited. Between 2001 and 2011 only 3 warning letters citing “natural” claims.
  - 8/16/01 – Oak Tree Farm Dairy, Inc.: Oaktree All Natural Lemonade cited for “All Natural” claim when it contained potassium sorbate. Iced tea also cited for containing citric acid.
    - Also contained other labeling violations (color additive not declared, citric acid not declared).
    - See <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2001/ucm178712.htm>

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## FDA Enforcement of “Natural” Claims

- 8/29/01 -- Hirzel Canning Co.- Canned chopped tomato products had labels bearing the claim "All NATURAL," but listed calcium chloride and citric acid as product ingredients. FDA stated that the addition of these ingredients "preclude the use of the term 'natural' to describe this product."
  - Number of other labeling violations noted (“Fresh-Packed claim, “healthy” claim, “sodium free” claim).
  - <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2001/ucm178343.htm>
- 8/13/09 -- Ninth St. Management, Inc. -- Cheese ravioli and lobster ravioli products had labels that stated "All Natural Ingredients," but then listed some synthetic substances in the products' ingredients. This led FDA to issue a Warning Letter. (Warning Letter did not specify what the synthetic ingredients were.)
  - Other labeling violations noted (HACCP, ingredient statement).
  - <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm179558.htm>

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## FDA Enforcement of “Natural” Claims

- But in 2011 FDA issued four Warning Letters cited natural claims.
- 3/11/11 -- Shemshad Food Products, Inc. -- Lime Juice Natural product cited for natural claim because product had sodium benzoate 1% (chemical preservative).
  - Other labeling violations noted (GMP/processing, allergen labeling and unapproved drug claims.)
  - <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm247908.htm>

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## FDA Enforcement of “Natural” Claims

- 7/22/11 – [Wisconsin Bagel Company] -- blueberry bagel products deemed misbranded because label used the term "All Natural," when they were manufactured with infused wild dry blueberries that contain potassium sorbate (chemical preservative). Label also made the claim "No Preservatives."
  - Other labeling violations noted (GMP).
  - <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm265756.htm>
- 9/28/11 -- Lebanese Arak, Corp. -- "Sadaf Natural Lemon Juice" cited for natural claim because product had sodium benzoate and sodium bisulfite (chemical preservatives).
  - Other labeling violations noted (HACCP/GMP).
  - <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm274047.htm>

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## FDA Enforcement of “Natural” Claims

- Most significantly, in November 2011, FDA issued a Warning Letter to Alexia Foods for Roasted Red Potatoes & Baby Portabella Mushrooms solely for making an “All Natural” Claim.
  - FDA noted the product contained “disodium dihydrogen pyrophosphate, which is a synthetic chemical preservative”.
  - No other allegations noted.
  - See <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm281118.htm>
- Although no warning letters have yet been issued in 2012, just last week (4/3/2012) FDA issued an import alert against an Israeli “berry juice”, citing, among other things, a natural claim when it contained “sulfur dioxide” (product also failed to bear % juice declaration).
- Thus, it appears FDA has increased enforcement, or at a minimum is more willing to review and cite such claims. Also significantly, plaintiffs attorneys are citing these warning letters in complaints.

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## USDA and “Natural”

- FSIS Policy on Natural contained in *Standards and Labeling Policy Book*
  - Established in 1982: provides that a “natural” claim may be used in the labeling of meat and poultry products provided:
    - (1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR 101.22), or any other artificial or synthetic ingredient; and
    - (2) the product and its ingredients are not more than minimally processed.
      - Minimal processing can include: smoking, roasting, freezing, drying and fermenting as well as separation like grinding meat, separating eggs and pressing fruit.
      - Does not include: solvent extraction, acid hydrolysis, chemical bleaching.

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## USDA and “Natural”

- If more than minimally processed can be labeled as All Natural if “ingredient would not significantly change the character of the product to the point that it could no longer be considered a natural product.”
  - Must be qualified in label: All Natural except dextrose, modified food starch, etc.
- In September 2009, FSIS issued an ANPRM concerning use of the term “natural” in labeling for meat and poultry products.
  - The ANPRM is a continuation of USDA’s December 2006 request for comments on “natural” claims
    - After considering the comments it initially received on “natural” claims, FSIS found that the comments demonstrate there is a lack of consensus as to the general or common understanding of what the claim “natural” means to the industry and the public and also on the approach that FSIS should take to address the issue.
- Nothing further since 2009.

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## Alleged Ingredients

- Although some of the ingredients cited by FDA may seem straightforward as not being “natural”, many ingredients which have not formerly been questioned are appearing in lawsuit complaints.
- These include:
  - Cocoa processed with alkali
  - Maltodextrin
  - Chicory root fiber/inulin
  - GMO derived foods including soy and corn products
- Much of focus has shifted to not simply the ingredients but HOW they have been made. Plaintiff attorneys taking a very narrow view and applying regulations of other agencies and even standards companies have affirmatively stated.

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## Regulatory Summary

- Neither FDA nor USDA appear willing to invest resources in rulemaking on “natural”
- In the absence of regulatory guidance, the courts may be forced on a case by case basis to weigh in on these issues
- Litigation in this area is increasing and plaintiff attorneys are becoming more savvy and looking for quick settlements with companies with large pockets.

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## Consumer Class Actions

- Small potential damages for each individual consumer
- Potential exposure dramatically increased by aggregating individual claims
- Special rules apply for when you can certify a class

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## Why Is This Area So Hot Now?

- The (virtual) death of the preemption defense for now
- *Holk v. Snapple Beverage Corp.*, 575 F.3d 329 (3d Cir. 2009)
  - Claimed Snapple falsely labeled beverages as “all natural,” but they contained HFCS
  - District court dismissed as impliedly preempted by FDA regulations governing “natural flavors” and the labeling of juices
  - Third Circuit reversed – no “clear and manifest” intention to preempt state warranty and consumer protection laws governing beverage labeling
- Several other courts have joined in rejecting similar preemption arguments

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## Why so hot, cont.

- Some new focus by FDA (discussed earlier)
- More focus in advertising on “natural” products
- Copy cat cases
  - No longer a focus simply on health concerns
- Belief in looser standards for pleading class actions, primarily in California
  - *In re Tobacco II Cases*, 46 Cal. 4<sup>th</sup> 298 (Cal. 2009) (standing under Prop. 64)
  - *Kwikset Corp. v. Superior Court*, 51 Cal. 4<sup>th</sup> 310 (2011) (“Made in USA” claims)

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## Relevant State Law Theories

- Misrepresentation or fraud
- State Consumer Protection Acts
  - Broader than common law fraud or negligence
- Warranty claims
- Unjust enrichment

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## Types of Products Involved

- Beverages – Snapple; Tropicana (HFCS)
- Cooking Oils/Corn Chips – genetically modified organisms (“GMO”)
- Cereals and Bars – Kashi; *Chacanaca v. The Quaker Oats Co.*
- Pasta Sauce – *Lockwood v. ConAgra*
- Butter – *Rosen v. Unilever* (partially hydrogenated oil)
- Cookies – *Larsen v. Trader Joes Co.*, (N.D. Cal. 2011)
- Skinny Girl Margarita Mix (preservatives)

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## Health Claims

- Slightly different than “all natural” claims, but related
  - Activia Dannon Yogurt (digestive benefits)
  - *Turek v. General Mills* (7th Cir. 2011) (negative impact or lack of benefit of non-natural ingredients)

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## What are the issues/defenses?

- 1) Challenges to the sufficiency of the claims
- 2) Challenges to class certification
- 3) Challenges to the merits

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## 1. Sufficiency of the Claims

- Pleading standards of *Iqbal* and *Twombly*
  - No reliance on legal conclusions/plausibility standard
    - Did plaintiff adequately allege causation or reliance
    - Did plaintiff adequately allege any injury-in-fact or damage (i.e., that they paid a premium)
      - *Wright v. General Mills* (S.D. Cal. 2009)
      - *Weiner v. Snapple Bev. Corp.* (S.D. N.Y. 2011) (granting summary judgment based on lack of evidence of purchase price or premium paid)
      - *Carrea v. Dreyer's Grand Ice Cream, Inc.* (9th Cir. 2012) (no reasonable consumer test)

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## Sufficiency of the claims, cont.

- Fed. R. of Civ. P. 9(b) –
  - Must plead fraud with particularity
  - Typically applies to “all natural” claims under state consumer protection acts
    - Key often is that claim, regardless of name, is grounded in fraud
  - What was the alleged misrepresentation, identify the who, what, where, and how of the transaction

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## 2. Challenges to Class Certification

- Primary argument is a lack of predominance
  - Must prove causation and/or reliance –
    - Many courts have held that reliance is not a necessary element under particular state consumer protection acts
    - However, the prevailing view is that causation is a required element and in consumer cases that requires a showing of individual reliance
    - Heavily contested by plaintiffs’ counsel, particularly in California
    - These issues often prevent class certification

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## Challenges to Class Certification, cont.

- Adequacy or Commonality
  - *Coyle v. Hornell Brewing Co.*, 2011 WL 2147218 (D. N.J. May 26, 2011) (plaintiff claimed that she bought Snapple multiple times without knowing about HFCS, despite signing a retainer agreement for suit seven months earlier)
- Damages – Can be individualized and thus preclude certification (but not if they are subject to a simple formula for recovery)

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- Choice of Law Issues –
  - If multiple state laws apply, subtle differences in these laws create predominance hurdles
  - Nationwide class actions are difficult to certify absent application of a single state's laws

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### 3. Challenges to the Merits

- Challenging damages
- Challenging whether ingredients are natural (for example, maybe they were only processed)
- Harm to health not provable
- Contesting lack of health benefit

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### What should you do?

- Act before it is too late
  - Check your ingredients
  - Check your suppliers
    - Verification requirements or certifications
    - Do you have an indemnification agreement that covers these situations?
  - Check your labels and advertising
  - Do not just look at your advertising for the product in question --
    - As with the Kashi allegations – ask yourself whether your products measure up to your own broader advertising campaign

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## What should you do, cont.

- Switch ingredients if necessary and feasible
  - Is there a substitute?
  - What is the cost?
  - Is it worth it to use the ingredient in question given the potential cost of litigation and negative publicity?
  - If not, can you change the label or advertising slightly (more disclosure may be better and may not negatively impact business)

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## If it's too late, as always, consult experienced counsel.

- Class actions have a life of their own
- Discovery, briefing, the types of arguments you may want to make, all can be very different in a class action
- Work with counsel early to develop a strategy to avoid excessive litigation fees, costs and exposure

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## Questions?

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