RECENT CHANGES IN FOOD LAW: REGULATORY, LITIGATION AND LEGISLATIVE UPDATES

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In the past few years there have been significant changes and proposed changes in the food law field, including to nutrition labels, menu labels, food label claims (like GMO and natural), and health and nutrient content claims (such as the recent sodium labeling ordinance in New York City). This panel will discuss the myriad changes happening in the realm of food labeling, focusing on how to counsel clients in this changing environment.

1. Nutrition Facts

Summary:

- In July 2016, FDA finalized regulations that update the Nutrition and Supplement Facts panels on foods and dietary supplements. The major changes include:
    - **"Calories from fat"**: The final rule removes the "Calories from fat" declaration from the Nutrition Facts label "because research shows the type of fat is more important than the amount." Further, companies cannot voluntarily declare "calories from fat" on the Nutrition Facts label.
    - **Sugar**: Changes sugar declaration to "Total Sugars," requires disclosure of Added Sugars; establishes a dietary reference value for added sugars (set at less than 10% of daily calories); and requires percent daily value (DV) declaration on the Nutrition Facts label for added sugars.
    - **Nutrient Declarations**: No longer required to declare Vitamins A and C (can voluntary declare these); now required to declare Vitamin D and Potassium; required to declare actual amount (in addition to %) of vitamin D, calcium, iron, and potassium.
    - **Format**: The term "Calories" increased in font size to increase prominence; revised the footnote about 2000 and 2500 calorie diets; requires dual-column labeling for certain containers (those "certain products that are larger than a single serving but that could be consumed in one sitting or multiple sittings").

- **Definitions**: Establishes a definition of dietary fiber (which is important because some substances may or may not fall under that definition) and added sugar (there is at least one type of sweetener that may not fall under the definition of added sugar).

- **Miscellaneous**: Requires records to be kept for declarations of dietary fiber, added sugars, vitamin E, and folate and folic acid, and some other substances; updates definition of "single-serving container"; updates reference amount customarily consumed (RACC); updates serving sizes for some foods.

- The rule took effect on July 26, 2016. Companies with $10 million or more in annual food sales must comply by July 26, 2018, and companies with less than $10 million in annual food sales have an extra year to comply (July 26, 2019).

Resources:

- FDA Summary of Changes to the Nutrition Facts Label, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm.

- Food Labeling: Revision of the Nutrition and Supplement Facts Labels, Final Rule, 81 Fed. Reg. 33742 (May 27, 2016), https://www.regulations.gov/document?D=FDA-2012-N-1210-0875.

- Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Final Rules, 81 Fed. Reg. 34000 (May 27, 2016), https://www.regulations.gov/document?D=FDA-2004-N-0258-0136.

- Food Labeling, 21 C.F.R. pt. 101.

2. Genetically-Engineered Food Labeling

Summary:

- Amendment to the Agricultural Marketing Act of 1946 enacted in July 2016 to require disclosure of bioengineered foods.

- The USDA has two years to establish a nationwide mandatory disclosure standard for bioengineered foods and the procedure for labeling (July 2018).

- The form can be an electronic or digital link, a label on packaging, or a USDA-created symbol.

- Alternative disclosures will be provided for very small packages.

- No labeling required where animals are fed a bioengineered substance.

- The USDA will establish thresholds of amounts of bioengineered food contained in a product before labeling is required.

- Express preemption of state laws requiring labeling.

Resources:

- Congress' GMO-Labeling Law: http://www.agriculture.senate.gov/imo/media/doc/Mandatory%20Labeling%20Bill.pdf.

- Thompson Coburn LLP Food Fight Blog Article: http://www.thompsoncoburn.com/news-and-information/food-fight/blog/16-08-01/what-food-packaging-and-agribusinesses-need-to-know-about-the-first-ever-nationwide-gmo-labeling-law.aspx.

3. "Healthy" Labeling

Summary:

- In March 2015, the FDA sent a warning letter to KIND, LLC (makers of KIND Bar) asserting that certain of KIND's products violated the FDCA. The violation that got the most attention was KIND's implied nutrient content claim that their bars are "healthy."

- Under current FDA regulations, a food product can only make the "healthy" claim if certain criteria are met with regard to total fat, saturated fat, cholesterol, other nutrients, and sodium. All products wanting to make the claim must be low in fat, saturated fat, cholesterol, and sodium; certain products must contain at least 10% of the recommended daily intake or daily reference value for certain nutrients.

- In December 2015, KIND submitted a citizen petition asking the FDA to reconsider the criteria for use of the "healthy" claim. The citizen petition noted that the 2015 Dietary Guidelines Advisor Committee Report ("DGAC Report") had shifted its focus from the *nutrients* in food to *whole foods*. KIND asked the FDA to bring its thinking and regulations in line with current science and the 2015 DGAC Report.

- "Under FDA's current application of food labeling regulations, whether or not a food can be labeled 'healthy' is based on specific nutrient levels in the food rather than its overall nutrition quality. FDA formulated those regulations more than 20 years ago, when available science *and* federal dietary recommendations focused on limited total fat intake. Today, these regulations still require that the majority of foods featuring a 'healthy' nutrient content claim meet 'low fat' and 'low saturated fat' standards regardless of their nutrient density. This is despite the fact that current science no longer supports those standards." KIND Bar Citizen Petition to FDA, pg. 1.

- KIND asked FDA to do four main things:

    - To revise the regulation for "healthy" claims to allow food producers, when "calculating the total fat or saturated fat levels of a food to determine compliance with the requirements in the 'healthy' claim, [to] exclude the total fat or saturated fat content contributed to the food product by the following foods, provided that such foods are used in their whole form or have been processed in such a way that did not materially degrade their nutritional composition: fruits, vegetables, nuts, seeds, legumes, whole grains, and seafood." KIND Bar Citizen Petition to FDA, pg. 20.

    - To "undertake rulemaking to define 'dietary guidance statement' as a statement in food labeling about the usefulness of a food, or a category of foods, in maintaining healthy dietary practices." KIND Bar Citizen Petition to FDA, pg. 20.

    - To "amend its current nutrient content claim regulations to clarify that claims using the term 'healthy' are nutrient content claims only when such claims characterize the level of a nutrient in a food product; otherwise claims using the term 'healthy' could be regulated as dietary guidance statements." KIND Bar Citizen Petition to FDA, pg. 20.

- To "issue[, as an interim measure while FDA conducts rulemaking,] a guidance document for industry as soon as possible to clarify that a statement about the usefulness of a food, or a category of foods, in maintaining healthy dietary practices is a dietary guidance statement that is not subject to the requirements in FDA's nutrient content claim regulations unless it is an implied nutrient content claim because it is immediately adjacent to an explicit or implicit claim or statement about a nutrient[*]." KIND Bar Citizen Petition to FDA, pg. 20-21. (* This is not how FDA currently defines nutrient content claims. KIND is asking FDA to specify that a "healthy" claim will only be a nutrient content claim if it meets the criteria outlined before the asterisk.)

- In May 2016, the FDA issued a statement explaining its rationale for allowing KIND to continue using the term "healthy" on its labels. The FDA will allow KIND to use the phrase "'healthy and tasty' as part of its corporate philosophy, as opposed to using 'healthy' in the context of a nutrient content claim."

Resources:

- Warning Letter from FDA to Kind, LLC, March 17, 2015, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm440942.htm.

- KIND Bar Citizen Petition to FDA, December 1, 2015, https://s3.amazonaws.com/kind-docs/citizen-petition.pdf.

- KIND, LLC Close Out Letter 4/20/16, April 20, 2016, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm497335.htm.

- Statement on FDA's Actions on Labeling of KIND Products, May 2016, http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm500184.htm.

- Beth Kowitt, *In Reversal, the FDA Says 'Healthy' Can Return to Kind Bar Packaging*, Fortune, May 10, 2016, http://fortune.com/2016/05/10/kind-bar-healthy-fda/.

4. "Natural" Labeling

Summary:

- Recent flood of false advertising cases based on labeling food/pharma product as "natural."

  - ThermoLife Int'l, LLC v. Gaspari Nutrition Inc., No. 14-15180, 2016 WL 1460171, at *1 (9th Cir. Apr. 14, 2016).

  - Kane v. Chobani, LLC, No. 14-15670, 2016 WL 1161782, at *1 (9th Cir. Mar. 24, 2016).

  - Balser v. Hain Celestial Grp., Inc., 640 F. App'x 694, 695 (9th Cir. 2016).

  - *Ault v. J.M. Smucker Co.*, ––– F.R.D. ––––, 2015 WL 4692454, at *1–2 (S.D.N.Y. Aug. 6, 2015) (considering "All Natural" label on oils).

  - *In re Scotts EZ Seed Litig.*, 304 F.R.D. 397, 403–04 (S.D.N.Y. 2015) (considering efficacy claims on packaging of seed and fertilizer product).

  - *Ebin v. Kangadis Food Inc.*, 297 F.R.D. 561, 564 (S.D.N.Y. 2014) (considering olive oil's "100% Pure" label).

- In re Avon Anti-Aging Skincare Creams & Prod. Mktg. & Sales Practices Litig., No. 13-CV-150 JPO, 2015 WL 5730022, at *4 (S.D.N.Y. Sept. 30, 2015), appeal withdrawn (Nov. 10, 2015).

- Discussing recent case law and FDA guidance on "natural."

- FDA statement:

  - Although the FDA has not engaged in rulemaking to establish a formal definition for the term "natural," we do have a longstanding policy concerning the use of "natural" in human food labeling. The FDA has considered the term "natural" to mean that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food. However, this policy was not intended to address food production methods, such as the use of pesticides, nor did it explicitly address food processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation. The FDA also did not consider whether the term "natural" should describe any nutritional or other health benefit.

  - FDA requested comments on the use of "natural" in food labeling but has not undertaken any rulemaking on use of the term.

Resources:

- FDA website on use of "natural" in food labeling: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm.

5. Health Claims & Disease Claims

Summary:

- Lessons learned from the POM Wonderful litigation on required substantiation of disease related claims in advertisements.

- POM was suggesting a causal relationship between its products and reduced disease risk.

- To make these disease-related claims, POM was required to have two randomized and controlled human clinical trials in order to satisfy Section 5 of the FTC Act and not be considered a deceptive advertisement.

- Lesser standard may apply where no causal link is suggested.

Resources:

- D.C. Cir. Opinion: https://www.ftc.gov/system/files/documents/cases/pom_dc_circuit1_0.pdf.

- Thompson Coburn LLP Food Fight Blog Article on the POM Wonderful case: http://www.thompsoncoburn.com/news-and-information/food-fight/blog/16-07-18/not-so-wonderful-what-the-food-industry-can-learn-from-pom-s-faulty-health-claims.aspx.

- FTC Final Order: https://www.ftc.gov/system/files/documents/cases/160614pomorder.pdf.

6. Federal Menu Labeling

Summary:

- The Patient Protection and Affordable Care Act of 2010 established menu labeling requirements for certain food service establishments across the nation.
- A "covered establishment" is defined as "a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of type of ownership, e.g., individual franchises) and offering for sale substantially the same menu items, as well as a restaurant or similar retail food establishment that is [voluntarily] registered to be covered.."
- At its most basic, covered establishments must:
    - Post calorie information for standard menu items on menus and menu boards;
    - Provide more complete nutrition information to customers upon request; and
    - Include the following succinct statement on the menu boards: "2,000 calories a day is used for general nutrition advice, but calorie needs vary." A different succinct statement is required for menus directed toward children.
- Daily specials, temporary menu items, and test menu items, among a few other items, do not need to be labeled.
- In December 2014, FDA finalized regulations implementing the ACA's menu labeling requirements. In July 2015, FDA extended the compliance deadline by one year to December 1, 2016. However, in December 2015, Congress extended the compliance date again to one-year after publication of the final menu labeling guidance. FDA published its final menu labeling guidance in late April 2016, and FDA will begin enforcing the final rule on May 5, 2017.

Resources:

- Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, Final Rule, 79 Fed. Reg. 71156 (Dec. 1, 2014), https://www.gpo.gov/fdsys/pkg/FR-2014-12-01/pdf/2014-27833.pdf.
- Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods – Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11) (April 2016), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm461934.htm.
- Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148 (Mar. 23, 2010), 124 Stat. 119 § 4205.
- 21 U.S.C. § 343(q)(5)(A).
- 21 C.F.R. § 101.11.

7. New York City Sodium Labeling Ordinance

Summary:

- September 2015: the New York City Board of Health passed an ordinance that requires New York City restaurants with 15 or more locations nationwide to identify individual items on their menus that contain 2,300 milligrams (mg) or more of sodium (the daily recommended intake).

- In addition to identifying with a salt-shaker symbol items that meet the sodium-level criteria, covered restaurants must post the following warning (called the "Risk Statement") conspicuously at the point of purchase:

  Warning:  indicates that the sodium (salt) content of this item is higher than the total daily recommended limit (2300 mg). High sodium intake can increase blood pressure and risk of heart disease and stroke.

- A violation of the ordinance results in a $200 fine.

- The regulations were to scheduled take effect on March 1, 2016.

- The National Restaurant Association filed a lawsuit in December 2015 challenging the law on a number of grounds, including that the ordinance is a violation of the First Amendment, that it is preempted by the federal menu labeling law, that the Board of Health's action was ultra vires, among other challenges. Judge Eileen Rakower denied the NRA's request for a stay and a preliminary injunction. A week later, Justice David Friedman heard the NRA's appeal and granted a preliminary injunction of the ordinance pending a hearing on the merits of the NRA's challenge. As of August 2016, the NRA had submitted its brief to the court, but the case had not yet been heard on the merits.

Resources:

- New York City Department of Health and Mental Hygiene Board of Health, Notice of Adoption of Amendments to Article 81 of the New York City Health Code (September 9, 2015), http://www1.nyc.gov/assets/doh/downloads/pdf/notice/2015/noa-repeal-article81.pdf.

- Marc Santora, *Judge Grants Delay of Sodium Warnings for New York City Restaurants*, Feb. 29, 2016, N.Y. Times, http://www.nytimes.com/2016/03/01/nyregion/judge-grants-delay-of-sodium-warnings-for-new-york-city-restaurants.html.

- John Surico, *New York City Can Require Sodium Warnings, Judge Rules*, Feb. 24, 2016, N.Y. Times, http://www.nytimes.com/2016/02/25/nyregion/salt-new-york-city-can-require-sodium-warnings-judge-rules.html.

- Benjamin Mueller & Michael M. Grynbaum, *New York City Health Board Backs Warning on Menu Items With High Salt*, Sept. 9, 2015, N.Y. Times, http://www.nytimes.com/2015/09/10/nyregion/new-york-city-health-board-approves-sodium-warnings-on-menus.html.

8. Organic – Consumer Claims in California

Summary:

- In *Herb Thyme Farms*, the California Supreme Court considered whether the Organic Foods Production Act of 1990 expressly preempted state false advertising and unfair competition claim for intentionally misrepresenting that a product was organic.

- The California Supreme Court held there was no preemption because the Act only displaces state law in two respects:
    - (1) with respect to defining organic production, and
    - (2) with respect to certification of products as organic.
- The Act does not expressly say that it provides the exclusive "sanctions for misuse of the organic label." The civil penalties in the Act for mislabeling are only a floor, not a ceiling.
- Allowing state consumer actions would enhance the Act's goals by deterring mislabeling, enhancing consumer confidence, and encouraging fair competition.
- The Court expressed the significant limitations to its decision, which is confined to cases alleging intentional fraud by a certified entity. In Quesada, there was no dispute as to whether Herb Thyme's certification or procedures under the Act were adequate (distinguishing the Eighth Circuit case *In re Aurora Dairy Corp.*, 621 F.3d 781 (2010)).

Resources:

- Thompson Coburn LLP Food Fight Blog Article on the Herb Thyme case: http://www.thompsoncoburn.com/news-and-information/food-fight/blog/16-05-16/california-s-high-court-federal-law-does-not-preempt-state-claims-for-intentionally-false-organic-labels.aspx.

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