# FDA Poised to Spoil a Food Fight, Naturally

*By Gregory D. Cote*

## Note from the Editor:

This article argues that the FDA should define the term "natural" because of the proliferation of litigation over alleged misuse of the term on food and beverage products and the fact that courts are ill-equipped to provide a definition.

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• Leslie Nemo, *How the FDA's New Definition for "Natural" Food Could Affect Your Pantry*, Bon Appetit (Apr. 30, 2018), https://www.bonappetit.com/story/natural-food-definition.

• Baylen Linnekin, *The FDA's Push to Define 'Natural' Food is an Exercise in Futility*, Reason (May 14, 2016), http://reason.com/archives/2016/05/14/the-fdas-push-to-define-natural-food-is.

• Alan Levinovitz, *What Is 'Natural' Food? A Riddle Wrapped In Notions Of Good And Evil*, NPR (May 8, 2016), https://www.npr.org/sections/thesalt/2016/05/08/477057872/what-is-natural-food-a-riddle-wrapped-in-notions-of-good-and-evil.

• Kelsey Albright, *Should the word "natural" be banned from food labels?*, Nat'l Consumers League (July 2014), http://www.nclnet.org/should_the_word_natural_be_banned_from_food_labels.

• Jason Best, *The Case for Banning 'Natural' From Food Labels*, Take Part (May 10, 2016), http://www.takepart.com/article/2016/05/10/natural.

• Alla Katsnelson, *Should the word 'natural' be banned from food marketing? - poll*, The Guardian (July 3, 2014), https://www.theguardian.com/sustainable-business/poll/sustainable-living-communication.

• Urvashi Rangan, *Ban 'Natural' as a Marketing Label on Foods*, N.Y. Times Room for Debate (Nov. 11, 2014), https://www.nytimes.com/roomfordebate/2014/11/10/should-the-fda-regulate-the-use-of-natural-on-food-products-15/ban-natural-as-a-marketing-label-on-foods.

*About the Author:*

*Gregory D. Cote is a partner in McCarter & English's Business Litigation practice group and represents companies in the food and beverage sector in a variety of food-related matters. He also specializes in constitutional and business litigation and has appeared in state and federal courts throughout the country.*

World-renowned chef Thomas Keller once said, "Food should be fun." But for those who make many of the products we eat and drink, there is nothing fun about food and beverage labeling litigation. These lawsuits have scorched federal dockets and reached gluttonous proportions over the last decade—rising from approximately 20 active cases in 2008 to nearly 500 as of this writing. The cases all follow the same standard recipe: a putative class action alleges that the use of certain marketing terms on a product's label or packaging violates a state consumer protection statute because the terms purportedly provide false or misleading information about the product's ingredients or nutritional attributes.

Amid this burgeoning tempest in a teapot, the U.S. Food and Drug Administration (FDA) repeatedly declined to weigh in on the definition of the term "natural," which serves as one of the primary leaveners for these lawsuits. Instead, the agency opted to proffer only an informal guidance on the term.[1] Egged on by what they saw as a gap in the FDA's regulatory oversight, consumer and health advocacy groups filed the initial labeling lawsuits to prune what they described as the "health halo" effect of food and beverage labels.[2] Soon thereafter, plaintiffs' lawyers stuck their fingers in the pie as well and whipped up batches of other claims targeting everything from soup to nuts. Their theories and claims have evolved over the years, and now food and beverage makers are routinely embroiled in litigation over the presence of the word "natural" on their labels, even where the description manifestly describes the products at issue.[3] Moreover,

1 The FDA's guidance interprets 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 the food." Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302 at 2407 (Jan. 6, 1993). The FDA also stated, however, that its guidance did not "address food production methods, such as the use of genetic engineering or other forms of genetic modification, the use of pesticides, or the use of specific animal husbandry practices, nor did it explicitly address food processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation. Furthermore, [the FDA] did not consider whether the term 'natural' should describe any nutritional or other health benefit." Use of the Term "Natural" in the Labeling of Human Food Products, Request for Information and Comments, 80 Fed. Reg. 69905 at 69906 (Nov. 12, 2015); *see also* FDA, "Natural" on Food Labeling, *available at* www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm (last visited April 25, 2018).

2 The phrase "health halo" effect refers to the theory that derivations of the term "natural" (among others) on food and beverage labels contribute to the nation's obesity epidemic by causing consumers to overestimate the nutritional value of the products they purchase and underestimate how much they eat and drink. *See, e.g.*, John Peloza and William Montford, *The health halo: how good PR is misleading shoppers*, The Guardian, March 11, 2015, https://www.theguardian.com/sustainable-business/2015/mar/11/know-what-you-eat-health-halo; John Tierney, *Health Halo Can Hide the Calories*, N.Y. Times, December 1, 2008.

3 For example, a lawsuit against Sargento Foods, Inc. alleges that the company's cheese is improperly labeled as "natural" because it is made with milk derived from cows that consumed genetically modified feed and treated with recombinant bovine growth hormone. However, the company's cheese does not contain any unnatural ingredients, and the

some food and beverage makers, presumably looking to carve out their own piece of the pie, have filed labeling lawsuits against their competitors following the U.S. Supreme Court's decision in *POM Wonderful LLC v. Coca-Cola Co*.[4] It's a fine kettle of fish to say the least and a "natural" fit for class litigation.

The problem, in a nutshell, is that the meaning of the term "natural" varies by context in the food and beverage industry—what it means for a bag of chips or a can of ginger ale is different than for a package of cheese, a bottle of vegetable oil, or fresh produce. How food and beverage makers use the term matters as well—the phrase "Made With Natural Ingredients" generally means something different than "100% Natural" or "All Natural." But context is not baked into these cases. Rather, the cases arbitrarily equate the term "natural" with purity and effectively disregard production and processing methods and the functional purpose of some ingredients. The most frequently targeted products are those made with ingredients that are genetically modified or sourced from animals that consume genetically modified feed, ingredients that allegedly contain incidental remnants of processing, and products with incidental additives used for flavoring, color, or other functional purposes.[5]

Both large and small companies—including start-ups and family-owned companies—are targeted in the various types of labeling lawsuits.[6] If not dismissed at the outset, a "natural" lawsuit can put these companies in quite a pickle because they must either settle early or spend a lot of dough to defend it, risking harm to their brand and liability for damages and attorney fees, which can add up to tens of millions of dollars and bankrupt some companies. Litigating also risks establishing an unfavorably subjective judicial definition of "natural" rather than a uniform regulatory definition based on FDA deliberation, experience, and expertise. That is a bitter pill for most companies to swallow, so these cases are usually settled regardless of their merit (or lack thereof). Unfortunately, the settlements do little, if anything, to clarify the meaning of "natural" and are frequently just gravy trains for the plaintiffs' attorneys, who obtain exorbitant fees for themselves, but gather merely crumbs—a nominal cash payment or a coupon or voucher—for the consumers they purport to represent. It's a rotten outcome and leaves both consumers and food and beverage makers with a bad taste in their mouths.[7]

But the FDA is now in the mix and could soon serve up a more appetizing option. After previously declining to define "natural" in the 1990s and subsequently declining the invitation of at least three federal courts to do so in 2013, the FDA announced the opening of a pre-rulemaking request for public comment regarding how it should define the term on November 12, 2015.[8] By the time the comment period closed on May 16, 2016, the FDA received more than 7,600 comments from individuals, consumer and industry groups, and food and beverage makers. Since then, the agency has moved slower than molasses in January and still has not issued a "natural" definition.

The FDA's November 12, 2015 announcement initially led to a dip in the number of new "natural" lawsuit filings and prompted many courts to enter stays in pending cases based on the primary jurisdiction doctrine.[9] But the FDA's silence on the issue since the announcement seems to have induced a slight resurgence of lawsuit filings in 2017 and now, in response to arguments by the so-called Plaintiffs' Food Bar, some courts are beginning to deny new stay requests and to lift stays previously entered. These lawyers argue that the courts are a more expedient and appropriate forum for resolving the "natural" issue because the FDA's extended delay indicates that it either does not intend to define "natural" or has not yet determined whether or how to define the term.

However, the FDA's top banana, Commissioner Scott Gottlieb, M.D., recently made comments that could leave these lawyers with egg on their faces. During his keynote address at the National Food Policy Conference on March 29, 2018,

term "natural" is used to differentiate its cheese from "processed" cheese products. *See generally* Stanton v. Sargento Foods, Inc., C.A. No. 3:17-cv-02281-EDL (N.D. Cal.).

4 573 U.S. ——, 134 S.Ct. 2228 (2014).

5 The food and beverage industry is not the only target of these "natural" lawsuits. They also target personal care products (like toothpaste, cosmetics, baby wipes, and lip balm), household cleaning products (like window cleaner, dishwasher detergent and laundry detergent), furniture polish, and even pet food.

6 *See* Cary Silverman and James Muehlberger, *The Food Court: Trends in Food and Beverage Class Action Litigation*, pp. 15-16, U.S. Chamber Institute for Legal Reform (Feb. 2017) (listing and discussing examples of various labeling lawsuits), *available at* http://www.instituteforlegalreform.com/research/the-food-court-trends-in-food-and-beverage-class-action-litigation.

7 Class action settlements that primarily benefit the plaintiffs' lawyers are facing increased scrutiny in the courts as well. Although not a "natural" case, the rejection of the Subway "footlong sub" settlement, which the Seventh Circuit described as a "racket" because it resulted only in fees for the class counsel and provided no meaningful relief for the class members, is perhaps the most notable recent example. *See* In re Subway Footlong Sandwich Mktg. & Sales Practices Litig., 839 F.3d 551, 552, 556-57 (7th Cir. Aug. 25, 2017).

8 *See* Use of the Term "Natural" in the Labeling of Human Food Products, Request for Information and Comments, 80 Fed. Reg. 69905 (Nov. 12, 2015). Relatedly, although the FDA defined the term "healthy" in 1994, the term's use on food and beverage labels has provided ample fodder for litigation as well. However, on September 28, 2016, the FDA recognized that its definition of "healthy" had exceeded its shelf life and opened a pre-rulemaking request for public comment regarding how it should update its definition of that term. *See* Use of the Term "Healthy" in the Labeling of Human Food Products; Request for Information and Comments, 81 Fed. Reg. 66562. The public comment period closed on April 26, 2017. The FDA is still in the process of reviewing the comments and considering how to revise the term's definition.

9 Primary jurisdiction is a discretionary doctrine invoked by courts to stay or dismiss claims that are properly cognizable in court, but involve issues that fall within the specialized competence of an administrative agency. The doctrine furthers uniformity and consistency in the regulation of issues within an agency's purview and promotes better informed legal rulings by enabling courts to defer to and rely on agency expertise regarding technical and policy-related issues. *See* Reiter v. Cooper, 507 U.S. 258, 268–69 (1993); Nader v. Allegheny Airlines, Inc., 426 U.S. 290, 303 (1976); Weinberger v. Bentex Pharm, Inc., 412 U.S. 645, 652-54 (1973); Pejepscot Indus. Park, Inc. v. Me. Cent. R.R. Co., 215 F.3d 195, 205 (1st Cir. 2000).

Commissioner Gottlieb outlined the FDA's new multi-year plan for improving public health and enabling Americans to make better nutritional choices.[10] Per Commissioner Gottlieb, defining "natural" is a key component of the consumer information and labeling initiatives that are part of the FDA's plan. Although he did not offer any definitive information about how or when the agency will define "natural," he confirmed that the agency reviewed all of the comments received in response to the November 12, 2015 announcement and acknowledged that "consumers increasingly want to know what is in the food they eat . . . [and] are trusting in products labeled as 'natural' without clarity around the term."[11] He also noted that "there are wide differences in beliefs regarding what criteria should apply for products termed 'natural,'" but said the agency believes that "the natural claim [on food and beverage labels] must be true and based in science" and promised that it will "have more to say on the issue soon."[12]

These comments echo statements previously attributed to Commissioner Gottlieb in *Wall Street Journal* and *New York Times* articles.[13] All combined, these statements confirm that the FDA continues to ruminate on the "natural" issue and expects its efforts to bear fruit soon. Arguments to the contrary and criticism of the FDA by the Plaintiffs' Food Bar are, therefore, not only half-baked, but self-serving and erroneous.

Some legal commentators have also suggested that recent defense victories indicate that the judiciary is beginning to curtail the "natural" lawsuits notwithstanding the FDA's inaction.[14] Although well-intended and great food for thought, this assertion seems a bit too pie in the sky and should not be taken to indicate that FDA action is not needed. True, some courts have recently dismissed lawsuits concerning products purportedly containing trace amounts of glyphosate as well as suits concerning cooking oil made with bioengineered corn and yogurt made with milk from cows that consumed genetically modified feed. But cases based on the same or very similar allegations were allowed to proceed in other courts, and it is questionable whether the grounds for some of the recent dismissals can withstand appellate scrutiny. Thus, it is best to take such prognostications with a grain of salt because the results in the courts are mostly mixed and lack consistency.

Moreover, these inconsistent rulings demonstrate precisely why judicial deference to the FDA on primary jurisdiction grounds is warranted. Although courts routinely adjudicate consumer protection claims, that alone does not cut the mustard for these cases because they are not about merely alleged consumer confusion. For courts to resolve claims that defendants falsely and deceptively labeled their products "natural," they must first determine whether the defendants used "natural" ingredients and production/processing methods. Such determinations require consideration of complex technical, scientific, and policy issues that lie outside the judicial ken, but squarely within the FDA's expertise, experience, and congressionally delegated regulatory authority.

Nor are courts well-suited for establishing a uniform nationwide definition of "natural" for food and beverage labeling purposes. Rather, they are functionally equipped to resolve discrete cases, based only on the evidence and arguments presented by the parties to each case. Adjudicating the meaning of "natural" on a case-by-case and product-by-product basis in nearly 500 separate lawsuits is a costly and slow process and will almost assuredly produce discordant and subjective rulings that impose a patchwork of labeling standards and requirements that vary by jurisdiction. These rulings may also conflict with the definition Commissioner Gottlieb said is forthcoming from the FDA, which risks improperly elevating enforcement of state consumer protection statutes above the FDA's authority to establish food labeling laws.

Congress bestowed on the FDA the discretion and authority to establish labeling standards and determine whether and how to define "natural" for food and beverage labeling purposes.[15] If rendered independent of FDA input, judicial determinations as to whether products are properly categorized as "natural" intrude upon the FDA's discretion and authority, undercut its expertise, potentially inhibit the uniformity of its regulatory and labeling regime, and potentially burden food and beverage makers by subjecting them to conflicting labeling standards.[16] This is exactly what the primary jurisdiction doctrine is designed to prevent.

In fairness to the FDA and its seemingly slow-roasted approach to the task, defining "natural" is no piece of cake. The diversity of opinions in the comments received by the FDA makes defining "natural" a hard nut to crack. Technological advances in how ingredients are grown, harvested, and processed add even more complexity to the task. Plus, the agency's plate is already full with implementing the Food Safety Modernization Act as well

10 The speech, entitled Reducing the Burden of Chronic Disease, indicated that the FDA intends to build upon, not roll back, certain aspects of the Obama administration's healthy eating agenda, contrary to concerns expressed about the Trump administration's anti-regulatory agenda by health and nutrition advocates. The text of the speech is available on the FDA's website at www.fda.gov/NewsEvents/Speeches/ucm603057.htm.

11 *Id.*

12 *Id.*

13 *See* Heather Haddon, *FDA Commissioner Wants Closer Look at Health Claims on Packaging*, Wall St. J., October 10, 2017, https://www.wsj.com/articles/fda-commissioner-wants-closer-look-at-health-claims-on-packaging-1507673335; Julie Creswell, *Is It 'Natural'? Consumers, and Lawyers, Want to Know*, N.Y. Times, February 16, 2018, https://www.nytimes.com/2018/02/16/business/natural-food-products.html.

14 *See* Charles Sipos and Mica Simpson, *"Natural" Litigation and Rising Judicial Skepticism*, Nat'l L. J., November 28, 2017, https://www.law.com/nationallawjournal/sites/nationallawjournal/2017/11/28/natural-litigation-and-rising-judicial-skepticism/.

15 *See* 21 U.S.C. § 343.

16 Several courts have rejected similar arguments seeking dismissal based on the related doctrine of implied preemption because the FDA has not yet taken regulatory action regarding use of "natural" that is entitled to preemptive effect. *See* Holk v. Snapple Beverage Corp., 575 F.3d 329, 339-42 (2009); *see also* Garcia v. Kashi Co., 43 F. Supp. 3d 1359, 1373-74 (S.D. Fla. 2014); In re Frito-Lay N. Am. All Nat. Litig., No. 12-MD-2413, 2013 WL 4647512 at *10 (E.D.N.Y. Aug. 29, 2013). Thus, courts should instead invoke the primary jurisdiction doctrine pending FDA's anticipated action, which is likely to have preemptive effect and provide clarifying guidance for resolving the "natural" lawsuits.

as the new requirements for the Nutrition Facts panel and menu labeling—not to mention navigating a change in presidential administrations. That the FDA is still chewing on the issue is understandable given the circumstances.

Although promises—like eggshells and pie crusts—are made to be broken, the FDA finally appears poised to provide clarity regarding use of the term "natural" on food and beverage labels. In light of Commissioner Gottlieb's consistent and repeated messaging, food and beverage makers that are defending "natural" lawsuits should promptly request stays on primary jurisdiction grounds. The courts should grant such requests and stay all pending "natural" lawsuits to avoid inconsistent outcomes and conserve judicial and litigant resources until the conclusion of the FDA's proceedings. However, given the ongoing risk of litigation and the inconsistent manner in which the courts have managed the "natural" lawsuits thus far, food and beverage makers not presently defending a "natural" lawsuit should consult with counsel to assess their potential exposure and take appropriate mitigation measures to avoid getting burned by one of these lawsuits.