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THE “NATURAL” AVERSION: THE FDA'S RELUCTANCE TO DEFINE A LEADING FOOD-INDUSTRY MARKETING CLAIM, AND THE PRESSING NEED FOR A WORKABLE RULE

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Visit any local super-market, particularly one such as Whole Foods Market or Trader Joe's, and it is plain to see that consumers are consciously seeking out “natural foods” with many adopting “natural” eating as a way of life. In the past decade, natural foods have transformed from a small “niche market” into a \$22.3 billion industry,¹ and *Mintel's Global New Products Database* reported that “all-natural” was the second most frequently-used claim on new U.S. food products in 2008.² Whole Foods Market, the leader of the emerging pack of grocery stores dedicated to selling only natural and organic products,³ rocketed onto Interbrand Design Forum's list of the top fifty Most Valuable U.S. Retail Brands last year--an impressive feat as the grocery sector ranks “low in terms of consumer loyalty and brand strength.”⁴ Despite playing in a crowded field of nutritional claims targeted toward health-conscious consumers, from low-carbohydrate to organic and antibiotic-free products, “natural” food is the cream of the crop.⁵ “Although much is written about organics,” the Director of Industry Insight at Nielsen stated that “products labeled ‘natural’ generate much higher sales.”⁶

With a multi-billion dollar marketing niche, a dedicated consumer following, and a subcategory of grocery stores selling only natural and organic products quickly ascending up the ranks of corporate prominence, the natural foods industry seems to have everything going for it.⁷ The only thing the industry seems to be lacking is an actual definition of the word “natural” to govern the products it sells. The Food and Drug Administration (FDA) has retained a policy statement governing the use of the term, but has never developed an official rule establishing a definition despite numerous calls to do so. FDA's current policy may protect those who comply from legal action brought by FDA, but the policy statement does not *404 establish a “legal requirement” upon parties flowing from the usage of the term.⁸ This regulatory void has been filled by rival companies, consumer advocates, and plaintiffs' lawyers, wielding state consumer protection statutes to hold companies accountable for “misleading” customers by using the yet-to-be-defined term on their product labels.⁹ “Natural” has become a food industry tug-of-war rope, turning industry representatives like the Sugar Association and Corn Refiners Association into modern-day Montagues and Capulets as each industry fights to protect its own stake in the multi billion-dollar natural food industry.¹⁰ The prices of uncertainty are high; in recent years, class actions against makers of “natural” foods have found their way into federal court, transforming subjective questions like “Is Snapple natural?” into multi-million dollar wagers turning on disparities in state law rather than unified national standards.¹¹

This paper will examine the history of the regulation--or lack thereof--governing the use of the term “natural” and the current agency policies governing the usage of the word. Second, the paper will examine recent lawsuits involving “natural” food claims, federal preemption, and the impact that the Supreme Court's recent preemption cases will have on future claims. Finally, the paper will argue that despite pressing agency concerns, FDA should adopt a rule governing the use of the term “natural.” The paper will conclude by proposing potential models for a rule, which FDA could adopt to define the term once and for all.

I. WHAT IS A “NATURAL?” COMPARING FDA AND USDA APPROACHES TO DEFINING THE TERM

A. The FDA's Approach to “Natural” Claims: A Policy on Ingredients

The lack of a clear FDA rule governing when a product may be described as “natural” has been a source of great confusion and uncertainty within many industries affected by FDA.¹² The first efforts to regulate the use of the term came *405 not from FDA, but from the Federal Trade Commission (FTC) in 1974.¹³ Under its mandate to regulate the use of false and misleading advertising, the FTC considered adopting a rule which would recognize “natural” foods as only those with no artificial ingredients and only minimal processing.¹⁴ Although the organic food industry supported the development of a definition, the prospect of defining the term “natural” for a diverse range of products and policing multiple industries on the use of the word proved too much for the Commission, which officially terminated rulemaking on the matter in 1983 stating:

Quite aside from the significant difficulties that would be posed in enforcing this rule, a fundamental problem exists by virtue of the fact that the context in which “natural” is used determines its meaning. It is unlikely that consumers expect the same thing from a natural apple as they do from natural ice cream We should concentrate our resources on more serious consumer protection problems than addressing whether a claim that “milk is a natural,” is deceptive.¹⁵

In 1978, both the Food Safety and Inspection Service (FSIS)--the public health agency within the U.S. Department of Agriculture (USDA)--and FDA collaborated with the FTC in holding public hearings on matters of mutual concern including whether to formally define the term “natural.” No formal regulation ensued as a result, though both FDA and FSIS embarked on the route to forming policies governing the use of the term.¹⁶ But by 1989, FDA was defining through regulation a number of claims involving nutrient content claims, including such labels as “low calorie,” “reduced calorie,” “sodium free,” and “reduced sodium.”¹⁷ Spurred in part by consumer desire for consistent meanings of claims involving nutritional content, Congress passed the Nutrition Labeling Education Act (NLEA) to amend the Food Drug and Cosmetic Act (FDCA) in order to achieve national uniformity in food labeling by preempting state regulations concerning the labeling of nutritional content, health claims, and standards of identity.¹⁸ The new law gave FDA power to define certain core terms regarding health and nutritional marketing claims, and the law explicitly directed FDA to define some terms such as “light” (or “lite”).¹⁹ “Natural” was not among the terms FDA was required to define. However, in 1991, FDA published an “informal policy”²⁰ in the *Federal Register*, defining “natural” as meaning:

*406 that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there.²¹

Nevertheless, FDA noted that due to the widespread use of the term²² and evidence of consumer confusion, the agency would consider producing a formal definition.²³

True to its word, FDA solicited comments on issues concerning the use of the term “natural” when it proceeded with the rulemaking process to implement the NLEA.²⁴ The comments encompassed widely diverging suggestions ranging from banning the use of the term altogether as misleading, to allowing free use of the term provided it is used in a truthful and non-misleading manner, to harmonizing its definition with that of the USDA with attention to “minimal processing.”²⁵ FDA conceded that if the “term ‘natural’ were adequately defined, the ambiguity in the use of this term, which had resulted in misleading usages, could be abated.”²⁶ Nevertheless, FDA concluded that “none of the comments provided FDA with a specific direction to follow for developing a definition” for the use of the word “natural.”²⁷ Citing “resource limitations and other agency priorities,” FDA announced in the *Federal Register* that it had no intention to pursue rulemaking and it remained committed to its informal policy.²⁸ Again in 2005, Margaret Glavin, the FDA Associate Commissioner for Regulatory Affairs, stated that the agency had no intent to “move away from its current policy.”²⁹

In 2006, FDA received a petition to adopt an official definition for the term “natural.” The petition, filed by the Sugar Association, asked the FDA Commissioner to enact “rules and regulations governing the definition of ‘natural’ before a natural claim can be made on food and beverages regulated by the FDA.”³⁰ The Association specifically asked FDA to base its definition on that adopted by the USDA *Food Standards and Labeling Policy Book*.³¹ Seizing on the definition’s requirement that the *407 product be no more than “minimally processed,” the Sugar Association interpreted the language to require “preservation of the molecular structure inherent in the raw material is an obligatory requirement before a food or beverage ingredient can be labeled as ‘natural.’”³² Quite predictably, although the Sugar Association’s petition never mentioned corn syrup by name, under the strictures of the Sugar Association’s proposed interpretation regarding “minimal processing” of natural foods, high fructose corn syrup could not be considered a natural ingredient.³³

A year later, the Sara Lee Corporation filed a petition requesting that FDA work together with the USDA’s FSIS to create a uniform policy for the use of the term “natural.”³⁴ Strongly advocating that the definition be prescribed by policy rather than regulation, Sara Lee advocated for a uniform definition encompassing the use of natural preservatives.³⁵ In its petition, Sara Lee noted that FDA currently had a written policy governing the term “natural,” but that this definition was not standard across government agencies.³⁶

Despite the petitions from both Sara Lee and the Sugar Association, no new action--either through rulemaking or policy-amendment--was taken by FDA. Rather, in January 2008, FDA representatives announced that FDA intended to leave “natural” formally undefined for the time being as more pressing concerns and limited resources had directed its attentions to other matters.³⁷

Although FDA’s refusal to promulgate an official rule governing the use of the term left substantial confusion remaining as to the proper use of “natural” claims, industry confusion was set ablaze by contradictory statements from FDA officials over the course of the next few months. In April of 2008, Geraldine June, supervisor of the Product Evaluation and Labeling team at FDA’s Office of Nutrition, Labeling and Dietary Supplements, responded to an inquiry from FoodNavigator-USA. com regarding whether high fructose corn syrup could be considered a natural ingredient. June stated that the use of the “synthetic fixing agents in the enzyme preparation, which is then used to produce HFCS, would not be consistent with our (...) policy regarding the use of the term ‘natural.’ Consequently, we would object to the use of the term ‘natural’ on a product containing HFCS.”³⁸ Although the statement attracted considerable attention, the Corn Refiners Association was quick to respond publicly that June’s comments “actually (reflect) only the personal view of that one (FDA) employee who was responding to a reporter’s question,” and her views, did not constitute the official position of the agency.³⁹

*408 FDA backtracked on June’s statement only three months later in July of 2008. In a letter to the Corn Refiners Association, June explained that FDA continued to adhere to its “longstanding policy on the use of the term ‘natural’ means that nothing artificial (including artificial flavors) or synthetic (including all color additives regardless of source) has been added to a food that would not normally be expected to be in the food.”⁴⁰ As such, FDA said it would not restrict the use of the term “natural” except on products with added color and synthetic substances and flavors. Whether HFCS could be considered “natural” depended on the manner in which the corn syrup was made, and products containing HFCS could carry a “natural” label when synthetic fixing agents were not in contact with the product during manufacturing:

[I]t is our understanding that the enzyme used to make HFCS is fixed to a column by the use of a synthetic fixing agent, glutaraldehyde. Any unreacted glutaraldehyde is removed by washing the column prior to the addition of the high dextrose equivalent corn starch hydrolysate, which undergoes enzymatic reaction to produce HFCS. Because the glutaraldehyde does not come into contact with the high dextrose equivalent corn starch hydrolysate, it would not be considered to be included in or added to the HFCS. Therefore, we would not object to the use of the term “natural” on a product containing the HFCS⁴¹

As the process June described was the same process typically used by American HFCS producers, the statement was instantly lauded by many food manufacturers and the Corn Refiners Association.⁴² The Sugar Association retained its prior sentiments. Even before June's statement, it had been “deeply disappointed” with FDA's inaction, and the time had come for FDA to clearly “define ‘natural’ and protect consumers from misleading claims.”⁴³ But misleading or not, FDA has given no indication that it intends to issue a rule to convert its policy into a rule, or to alter its stated policy in any manner.

B. The USDA's Approach: A Focus on Ingredients and Processing

USDA, although ultimately leaving the definition of “natural” to flounder in the realm of policy, appeared to get much closer to establishing a rule governing the use of the term “natural” than FDA. Although neither agency has defined the term “natural,” USDA approaches the subject on the heels of its successful and extensive rulemaking venture governing the use of another popular marketing term: “organic.” The Organic Foods Production Act of 1990 made USDA solely responsible for both *409 defining and regulating product usage of the term “organic.”⁴⁴ In 2000, the agency emerged from a ten-year rulemaking period with a complex set of uniform national standards for the production, marketing, and handling of products bearing the name “organic.”⁴⁵ The extensive details of the regulations are too detailed to be discussed here,⁴⁶ but the USDA's rule-governed system in which producers “opt-in” to organic programs and conform to specifications in order to have their products certified as “organic” has proven successful.⁴⁷ The certification requirement not only dispelled consumer confusion regarding “organic products,”⁴⁸ but it gave birth to a lucrative new market for products bearing the USDA Organic Seal.⁴⁹

Since 1982, USDA has held a relatively consistent and little-changed policy for “natural” claims established in the USDA's well-known memo, Policy Memo 055.⁵⁰ The policy was replaced in 2005 without substantial change,⁵¹ and no formal definition has ever been adopted through rulemaking. But in 2006, Hormel Foods brought a petition before the USDA requesting that the agency undertake rulemaking to define the term natural.⁵² Unlike FDA's response to similar petitions, USDA charged ahead with a notice and comment rulemaking process with the goal of *410 defining the term “natural” in 2006. On Dec. 12, 2006, FSIS held a meeting, open to the public, to solicit comments on the definition of “natural” for the labeling of poultry and meat products.⁵³ USDA was specifically asked to consider defining the terms along four dimensions: The agency specifically sought to determine

(1) whether a definition of “natural” should incorporate a “minimally processed” criterion; (2) the implications and/or conflicts arising from current and new food processing methods and technologies (e.g., high pressure processing, multi-purpose ingredients, and modified atmosphere packaging); (3) consumer research on views, perceptions, and beliefs about the meaning of terms such as “natural,” “minimal processing,” “artificial,” “synthetic,” and “preservatives”; and (4) whether food safety and public health interests outweigh any conflict in a definition of “natural.”⁵⁴

The comments given at the meeting spanned a wide spectrum of subjects and opinions. Some speakers addressed the broader use of the term “natural” as relating to both USDA and FDA-governed products, but many comments addressed concerns applicable only to the USDA's meat and poultry regulation.⁵⁵ As to the more general category, some suggested that the definition of “natural” should take into account consumer expectations, which could be discerned through a USDA study on consumer perceptions. An industry representative proposed a system, under which “natural” claims would mimic the distinctions in “organic” products by attaching different descriptors to various products on the basis of differentiating levels of “naturalness.”⁵⁶

The USDA also challenged whether the “minimally processed” criterion remained viable in an age of advanced food processing technologies diverging widely by food product and industry, and whether multifunctional ingredients could be considered “natural” when used not only for taste, but for preservative or anti-microbial purposes to enhance food safety.⁵⁷ On that issue, industry representatives urged USDA to provide “some definition that will be consistent going forward,” so food-producing companies could determine “what technology to invest in.”⁵⁸ Various *411 groups also proposed that the USDA definition

be developed in “a manner that accounts for FDA and Federal Trade Commission ... policies to promote greater consistency in U.S. federal policy.”⁵⁹

Although the momentum and interest in the topic appeared to be headed toward the creation of an USDA rule defining “natural,” no such rule has emerged. Nevertheless, the burdens facing producers of USDA-regulated products due to this uncertainty are less significant than those faced by producers of FDA-regulated products, as the USDA requires producers to get pre-market approval for labeling.⁶⁰ Additionally, comments relating to the use of the term “natural” as related to USDA-governed finished meat and poultry production processes, as opposed to processing and ingredient standards, did result in the publication of a rule defining the term “naturally raised” for the meat and poultry industries.⁶¹

II. LITIGATION OVER THE USE OF THE TERM “NATURAL” IN FOOD AND BEVERAGE LABELING

A. Suits and Settlements

Despite the lack of any recognized FDA regulation governing the term “natural,” consumer advocacy groups and competitors have used the threat of suit under state law to force food producers to remove the label from their product or change the make-up of their product. Some of these actions have aided compliance with FDA policy. For example, in 2002, the Center for Science in the Public Interest (CSPI) threatened to sue Ben & Jerry's for using the “All-Natural” label when its products contained artificial flavors.⁶² Consequently, Ben & Jerry's dropped the claim from its label. However, other lawsuits have required companies to conform to standards not mandated by FDA's policy. CSPI threatened suit against Cadbury Schweppes (for using the term “natural” to describe 7UP) and sued Kraft (for labeling Capri Sun as natural) when both products contained HFCS. Rather than roll the dice in an uncertain legal climate, both companies chose to remove the word “natural” from their labels before litigation ensued⁶³ even though FDA now has stated that it considers HFCS processed according to regular industry practice to be “natural.” Until a rule is established, it is likely that national food manufacturers will remain under pressure to re-label products in ways that may not conform to any uniform standard. “The Food and Drug Administration has the authority to correct these kinds of deceptive claims on food labels, but despite our many complaints over many years, the agency has rarely acted,” said CSPI executive director Michael F. Jacobson. “So long as the FDA keeps napping, we'll be hauling more and more food companies into court to protect consumers from fraud.”⁶⁴

*412 Kraft and Cadbury Schweppes capitulated in the wake of threatened litigation, but recent federal cases suggest that litigation carries real consequence for those companies that refuse to drop such claims from their labeling. Although the National Advertising Division has relied upon agency policy to determine whether a product's “natural” label is deceptive,⁶⁵ federal courts have shown little inclination to restrain their interpretations when suits are brought under state consumer protection laws. In 2008, the Ninth Circuit found that consumers had alleged sufficient facts to potentially prove that a consumer would be deceived by Gerber's packaged fruit snacks, which were described as being made “with real fruit juice and other all natural ingredients.”⁶⁶ The court found that the label could merit recovery under California's Unfair Competition Law and other statutes not merely because the product contained the corn syrup as opposed to real sugar, but because both corn syrup and sugar were listed as “the two most prominent ingredients.”⁶⁷ This decision suggests that shying away from controversial ingredients like corn syrup would not be sufficient to protect a company from liability, as at least one court considers the term “natural” to be defined not solely by what ingredients a product contains, but by the percentages of certain ingredients within the product.

The ambiguities surrounding “natural”-ness threatened to boil to a \$1 billion head when the Sugar Association filed a lawsuit against McNeil Nutritionals, the maker of the artificial sweetener Splenda, not for actually mislabeling its product as “natural,” but instead for using the slogan “made from sugar so it tastes like sugar.”⁶⁸ Jim Murphy, the Sugar Association's legal representative, stated that McNeil Nutritionals had engaged in “deceptive” behavior because the “whole advertising campaign tries to say that Splenda is natural rather than a chemical compound,” when “[i]t's not natural at all.”⁶⁹ McNeil Nutritionals reached an undisclosed settlement deal with the Sugar Association, but had the litigation proceeded, the lawsuit could have resulted in a \$1 billion judgment--potentially the largest award on record for a false advertising claim.⁷⁰

B. Federal Preemption

Although not deciding the issue of liability for the use of the term “natural” on the merits, recent federal court decisions confirm that producers of FDA-regulated products cannot rely on FDA policy governing the use of the term “natural” to preempt claims of false advertising or consumer fraud brought under state law. Much of the case law governing this issue has been established only within the last two years, and the first cases to address the issue initially pointed to the opposite conclusion. In 2007 and 2008, two federal district courts concluded that federal ***413** law impliedly preempts state tort claims in the field of food or beverage labeling regulation.⁷¹ Field preemption occurs when, although no statute explicitly states Congress’s intention to supplant state law, the state “regulates conduct in a field that Congress intended the federal government to occupy exclusively.”⁷² In *Holk v. Snapple Beverage Corp.*, the District Court of New Jersey held that state law claims against Snapple for its use of the term “natural” were preempted.⁷³ The plaintiff sued Snapple under the New Jersey Consumer Fraud Act⁷⁴ for using the phrase “all natural” to describe its iced teas and juice drinks when those products contained HFCS.⁷⁵ Snapple filed a motion to dismiss the case, claiming that the lawsuit was preempted, both expressly and impliedly, by the FDCA.

Recognizing that no provision of the FDCA expressly preempted New Jersey’s consumer protection statute as applied to the use of the term “all natural,” the court nevertheless found the plaintiff’s claims to be “impliedly preempted by the detailed and extensive regulatory scheme established by the FDCA and FDA’s implementing regulations.”⁷⁶ Citing FDA’s regulation of the related term “natural flavor,” and FDA’s “obligat[ion] to follow its opinions, including its statements and position on the use of the term ‘natural’” as defined in its published policy statement on the term, the court held that “the FDCA and the FDA regulations so thoroughly occupy the field of the beverage labeling at issue in this case that it would be unreasonable to infer that Congress intended to supplement this area.”⁷⁷ The failure of FDA to define the term “natural” through rulemaking was no impediment to the finding of implied preemption, as the court stated that it would “not determine ‘that which the FDA, with all of its scientific expertise, has yet to determine,’ namely, how the terms ‘natural’ or ‘all natural’ should be defined and whether either may be used on the label of a beverage containing HFCS.”⁷⁸

Notably, the court specified that its opinion did not suggest that “Congress intended to displace all state regulation of foods and beverages.”⁷⁹ It instead identified the preempted “field” as “[d]eterminations regarding what should or should not be permitted on a beverage label.”⁸⁰ The court thus dismissed the complaint, finding that allowing states to impose additional requirements for beverage labeling “would create obstacles to the accomplishment of Congress’s objectives.”⁸¹

Although not relating to the use of the term “natural,” a second case, decided in 2007, swept far more broadly than *Holk* and found that implied federal preemption existed for all food-labeling claims. In *Fraker v. KFC Corp.*, a plaintiff sued ***414** the chicken fast-food giant KFC for violations of California’s Unfair Competition Law, the California False Advertising Law, and other state laws.⁸² The plaintiff’s claim rested on KFC’s advertisements in which the company claimed to use “only the highest quality ingredients” and to provide “the ‘best food,’ and that food can be part of a healthy lifestyle.”⁸³ The court compared FDA’s elaborate regulatory scheme of branding and labeling food products to the complex regulatory scheme governing medical devices under the Medical Devices Act, which the Supreme Court had found to impliedly preempt state law fraud claims. Finding the similarities in the two acts to be conclusive, the district court held that “the FDCA presents a comprehensive regulatory scheme of branding and labeling food products. To overlay the state tort system over the FDCA would significantly increase the burdens on FDA to ensure uniform enforcement of its administrative duties.”⁸⁴ Accordingly, the court held that “to the extent Plaintiff contends that alleged violations of the FDCA and Sherman Law give rise to viable state law claims, such claims are impliedly preempted by the FDCA.”

However, fortunes began to reverse when the Northern District of California reached precisely the opposite conclusion in *Lockwood v. Conagra Foods, Inc.*⁸⁵ In *Lockwood*, a group of plaintiffs filed a putative class action lawsuit under California’s Unfair Competition Law against Conagra Foods for advertising its “Healthy Choice” pasta sauce as “all natural” when the sauce

included high fructose corn syrup. The defendant filed a motion to dismiss, asserting that the claim was expressly and impliedly preempted by the NLEA, and impliedly preempted by a system of comprehensive FDA regulations under the FDCA.⁸⁶ The Court rejected the defendant's preemption claims on both counts in a strongly-worded opinion, reaching a holding contrary to *Holk* not only in terms of its perception of congressional intent, but also in the degree of deference it was willing to show FDA in absence of an actual rule defining the term “natural.”

The Court first addressed the defendant's argument that the preemption provisions of the NLEA to the FDCA expressly preempted the plaintiffs' claim, and found that no such preemption existed. The defendant had relied on section 343-1(a) of the FDCA, which establishes that “no State ... may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce- ... (3) any requirement for the labeling of food of the type required by ... §343(k) of this title that is not identical to the requirement of such Section.”⁸⁷ Section 343(k) deems food to be “misbranded” if it bears or contains “artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact.”⁸⁸ Because the plaintiffs' complaint did not allege that the pasta sauce contained artificial flavoring or other ingredients specified in section 343(k), but instead claimed that “high fructose corn syrup” was not “all natural,” the court found the statute to be inapplicable.⁸⁹ As the express preemption claim under section *415 343(k) regarding the use of the term “natural” was rejected in *Lockwood*, and was not even pleaded by the defendants in *Holk*,⁹⁰ it is reasonable to assume that defendants cannot rely on this provision for an express preemption claim.

The *Lockwood* court's consideration of the defendant's implied preemption claim was colored from the start by the court's presumption against the finding of preemption. It began its analysis ““with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.””⁹¹ Under this presumption, the Court proceeded to discern whether Congress intended to occupy the entire “field of food and beverage labeling.” Instead of confining its analysis to the FDCA, as the *Holt* court had done, the court examined the provisions of the NLEA, which amended the FDCA by adding an express preemption provision which asserts that the NLEA “shall not be construed to preempt any provision of State law unless such provision is expressly preempted under 21 U.S.C. § 343-1(a).”⁹² Section 343-1(a) expressly preempts states from enacting any law not identical to the FDA's food labeling definitions established in section 341, but no definition for “natural” is contained in that section. Rejecting the defendant's argument that its implied preemption argument rested solely on the FDCA misbranding regulations left un-amended by the NLEA, the language from the NLEA caused the court to question why Congress would “explicitly intend not to preempt some state laws on food labeling (those covered by the NLEA amendment to the FDCA), but still intend to occupy the field with respect to food labeling.”⁹³ The court also found that *Holt* and *Faraker* were “neither binding nor persuasive” as the courts in those instances considered only the FDCA regulations governing misbranding, and did not discuss how the FDCA preemption provisions added by the NLEA affected the implied preemption analysis.⁹⁴

Perhaps the greatest disparity from the *Holk* decision came in the Northern District's lack of deference to FDA's policy statement. According to the court, “the fact that [the definition of natural] is a policy means that the FDA treats it as an advisory opinion The policy, however, does not establish a legal requirement.”⁹⁵ The Court found that FDA's subsequent decision not to define the term, despite its awareness of state regulation of the term and a general knowledge that consumers were being misled in some instances, also evidenced “an intent not to occupy the field.”⁹⁶ The Southern District of California arrived at the same conclusion in *Hitt v. Arizona Beverage Co.*, a case involving the use of the term “all-natural” to describe a beverage with HFCS.⁹⁷ Finding no implied preemption could be discerned from FDA's failure to explicitly define the term “natural,” the court noted that ““deliberate agency inaction--an agency decision not to regulate an issue--will not alone preempt state law.””⁹⁸

The Supreme Court has yet to review a case to determine if state regulations of the term “natural” are in fact preempted by federal law, but the Supreme Court's *416 recent preemption cases indicate that the Court would be extremely unlikely to find that such preemption exists, leaving *Holt* and *Fraker* on shaky ground. The much-anticipated decision in *Wyeth v. Levine*,⁹⁹ handed down in early March, offers dim prospects for food and beverage producers hoping to rely on federal preemption to fend off

state law claims. While the Supreme Court's late-2008 decision in *Riegel v. Medtronic* found state tort suits for injuries caused by certain classes of medical devices to be preempted, the holding was one of express preemption resting upon the explicit preemptory language of a separate provision of the FDCA not applicable to food-labeling claims.¹⁰⁰ By contrast, in *Wyeth*, the Supreme Court held that FDA approval of a prescription drug label did not preempt a state lawsuit over Wyeth's alleged failure to provide adequate warnings about the dangers of Phenergan administered via IV push.¹⁰¹ The Supreme Court first rejected Wyeth's argument that because the FDCA required the product to carry an FDA-approved label, and because FDA had approved the label after careful consideration of the language and warnings on the product, it was impossible to comply both with the jury's interpretation of state law requirements and its federal duties where it was possible for Wyeth to “unilaterally strengthen its warning.”¹⁰² The Court additionally rejected Wyeth's secondary preemption claim that permitting juries to engage in their own cost-benefit analysis of drug warning labels would frustrate Congress's purposes in entrusting an “expert agency to make drug labeling decisions that strike a balance between competing objectives.”¹⁰³ Although FDA had expressed in the preamble to its labeling regulations that FDA labeling approval was to be preemptory, the Court held that Congress's failure to include an express preemption provision governing prescription drugs despite its awareness of contrary state tort laws was evidence that “Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.”

In reaching this holding, the Court distinguished *Geier v. American Honda Motor Co.*,¹⁰⁴ a case in which the Supreme Court found implied preemption. However, the Court found that the *Geier* regulatory system involved formal agency rulemaking, but FDA's determination of its preemptory power asserted in *Wyeth* lacked “specific agency regulation bearing the force of law.”¹⁰⁵ The Court left a small window open in its expression that “some state law claims might well frustrate the achievement of congressional objectives,” but no such frustration was present here.¹⁰⁶ Because FDA's policy regarding the use of the term “natural” similarly lacks the power of “force of law,” and it is not governed by an express preemption clause, it is extremely unlikely that the Supreme Court would find FDA's policy statement on the term “natural” to preempt contrary state tort law.

Federal preemption will likely never be achieved so long as FDA refrains from issuing a rule, but the structure is already in place for ensuring such preemption is realized once a rule is made. The claim “natural” would be considered a voluntary “nutrient content claim,” and labels falling within that category are included in 21 U.S.C. § 343(r). Under this statutory provision, a food is considered misbranded if “a claim is made in the label or labeling of the food which expressly or by implication ... characterizes the level of any nutrient” unless “the characterization of the level made in the claim uses terms which are defined in regulations” put forward by FDA.¹⁰⁷ Also, definitions promulgated under section 343(r) are included in the express preemption provision of section 343-1(a), which prohibits states from establishing definitions or requirements for labeling that are not identical to federal regulations. The underpinnings of preemption are clearly in place for a federal rule governing the term “natural”; now, it is up to FDA to make one.

III. THE NEED TO ESTABLISH A WORKABLE DEFINITION FOR “NATURAL” CLAIMS ON FOOD AND BEVERAGE LABELS

As of the writing of this paper, there is no reason to think that consumer or industry calls to formally define the term “natural” have subsided. Whether or not such a definition will exist is ultimately up to FDA, and industry and consumer advocates lack the power to force the agency's hand in court as an agency's refusal to institute rulemaking proceedings is actionable only “in the rarest and most compelling of circumstances.”¹⁰⁸ Therefore, the remainder of this paper will discuss whether or not, in light of current agency concerns, FDA should voluntarily pursue a course of action to formulate an agency rule on the definition of “natural,” and if it does, what form that rule should take.

A. The Compelling Need for Rulemaking

The lack of resolution surrounding the definition of “natural” is creating an atmosphere of inefficiency and uncertainty among food producers, where the only clear winners appear to be the lawyers suing or defending companies for using the term “natural” on their products. As suggested at USDA's meeting regarding the adoption of a new definition, without uniformity, manufacturers are left uncertain about investing in particular processes and ingredients. Without the benefit of an FDA rule and

federal preemption, a food producer is forced to play a guessing game to determine whether a judge will consider its product to be “natural,” with the cost of guessing wrong totaling in the millions for a consumer fraud judgment or a false advertising award.¹⁰⁹ Even where no litigation actually ensues, the potential threat of a devastating lawsuit is forcing companies to undergo the expense of relabeling-- not with the goals of complying with any legitimately created standard, but to suit the standards created by consumer advocacy groups and class action plaintiffs which may not reflect an appropriate balance between industry practice, consumer expectations, and health concerns.¹¹⁰

***418** As a result of these sporadic lawsuits, a patchwork definition for the term “natural” is inevitable: A “natural” fruit snack in Washington may be fraudulently deceiving customers in New Hampshire. This environment of uncertainty seems to be precisely the opposite of what was contemplated in 1906, when necessity first dictated that the federal government regulate food production, as a House Report from the era stated:

the laws and regulations of the different States are diverse, confusing, and often contradictory State boundary lines are unknown in our commerce, except by reason of local regulation and laws, such as State pure food laws. It is desirable, as far as possible, that the commerce between the states be unhindered. One of the hoped for good results of a national law on the subject of pure foods is the bringing about of a uniformity of laws and regulations on the part of the States within their own several boundaries.¹¹¹

It is not only the voices of industry that are clamoring for a final FDA rule governing the use of the term natural. A recent study revealed that 83 percent of consumers would like FDA to define what “natural” means.¹¹² But despite calls for more than two decades to formulate a definition for “natural,” FDA has consistently put forward a number of reasons for choosing not to do so, not the least of which is the FDA's oft-cited lack of agency resources which must be devoted to more pressing priorities. Although FDA's reasons for refusing have merit, the significant inefficiencies and uncertainties that remain in the absence of such a rule outweigh FDA's primary justifications for not putting forward a rule: 1) constraints on agency resources, and 2) the difficulty in issuing a single definition to govern the use of the term for a diverse food and beverage market.

First, the agency's concerns about limited agency resources are both real and significant, as the scarcity of agency resources has become so dire in recent years as to justify hesitation before imposing new regulatory burdens upon the agency. Peter Barton Hutt, former FDA Chief Counsel and current FDA advisor expressed that “Science at the Food and Drug Administration (FDA) today is in a precarious position. In terms of both personnel and the money to support them, the agency is barely hanging on by its fingertips ... FDA has become a paradigmatic example of the ‘hollow government’ syndrome--an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates.”¹¹³ With a budget totaling only \$2 billion, FDA regulates \$1 trillion in products, approximately one quarter out of every dollar spent in the United States. And with the burden of “an ever expanding mission, its budget has shrunk in real terms over the past three decades. The agency's staff has fallen by 1,300 employees, to about 7,800, since 1994.”¹¹⁴

***419** In 2009, the budget deficiency appears to be unresolved, but improving. President Obama signed an omnibus spending bill in March of 2009 giving a \$335 million boost to FDA's previous budget. Although a rulemaking process to define natural would require FDA to expend resources, enforcement costs will be minimal. The FDCA does not grant a private right of action under federal law,¹¹⁵ but the NLEA would allow consumers and consumer advocacy groups to enforce state laws which are identical to the federal definition.¹¹⁶ With uniform state definitions in place, litigation will no longer create a maze of divergent standards and incompatible state regulations. Instead, the energies of consumer advocacy groups and plaintiffs' lawyers will be channeled to ensuring that food manufacturers comply with fair and scientifically sound federal regulations.

Second, as reflected by both the statements of FDA and the enormous discrepancy in views produced in the USDA meeting comments, the term “natural” accommodates no easy one-size-fits-all definition. In fact, FDA has once before issued a rule defining a vague and ambiguous food-marketing term across the spectrum of FDA-regulated food products, and it is a move some suggest FDA has come to regret. In the early 1990s, FDA engaged in rulemaking to define the word “fresh,” a vague term that seemingly straddled the fine line between inactionable puffery and concrete consumer information. FDA regulates

the term “fresh” as used in a brand name, or when it is used as a sensory descriptor when used to refer to a product's texture, flavor, or hue, and also when it is used to connote a lack of processing.¹¹⁷ The term cannot describe food that has been frozen, thermally processed, or chemically processed, or food containing ingredients that have been concentrated or processed.¹¹⁸ But some modifications to the product, such as the use of a refrigerator or certain pesticides or waxes, are permitted.¹¹⁹

While this definition makes sense on its face, the application of the definition to various types of foods has produced absurd results.¹²⁰ For instance, most people would probably consider a loaf of bread pulled straight from a baker's oven to be “fresh.” However, under FDA's definition, if this still-warm loaf contained calcium propionate, a chemical used to inhibit the growth of mold when bread is removed from the packaging, the label may not be applied. Ironically, a loaf with no preservatives left sitting in the window of a bakery for two days could still bear the label. To add more confusion, the loaf coming right from the oven containing the preservative can still be labeled “fresh-baked” bread, but not “fresh,” and be in compliance with FDA regulations.¹²¹

More significantly, the attempt to apply the one-size-fits-all definition to an expansive range of products, including products made from fruits and vegetables, proved to be not only ill-advised but potentially dangerous. By defining the term “fresh” to exclude foods that have been “subjected to any form of thermal processing or any other form of preservation,” a definition which might reasonably improve the quality of items such as snack foods, FDA “encouraged the proliferation of unpasteurized fruit juices in the market” to deleterious results.¹²² In 1996, an E. coli outbreak spread through Washington State, sickening a number of people.¹²³ The culprit was found to be “fresh” apple cider products, particularly those produced by Odwalla, a California beverage producer. Odwalla's “fresh” apple cider was unpasteurized, as consumers were thought to appreciate a theoretical, yet unconfirmed, superiority of taste and vitamin content as compared with pasteurized products.¹²⁴ When the Odwalla apple cider was identified as the source of the outbreak, it was recalled and FDA warned the public not to consume any unpasteurized apple, carrot or vegetable juice products.¹²⁵ Ironically, FDA's exclusion of “thermally processed” foods from the definition of “fresh” forced producers of fresh-squeezed juices to “forego the label ‘fresh’ (and risk losing the product's target market, i.e., health conscious adults) or to forego the safety benefits of pasteurization.”¹²⁶ By making non-pasteurization the attractive marketing alternative, FDA created incentives for less-safe food products with the goal of providing more information to health-conscious consumers. Although FDA has since instituted guidelines requiring apple juice products to be pasteurized,¹²⁷ the Odwalla incident provides a compelling illustration of the safety risks that might accompany an attempt to define “natural” uniformly across a wide variety of consumer products.

Despite the debacle of the “fresh” definition and regulation, continued FDA reluctance to regulate the use of the term “natural” will not necessarily prevent such absurdities and dangers from playing out all over again. In absence of a clear FDA regulation on the topic, lower federal courts, state legislatures, and state courts are free to determine for themselves what “natural” should mean. Lacking the extensive expertise of FDA in making such determinations, there is no reason to believe that a court or state legislature will settle upon a definition that is reasonable and free from adverse consequences. As a uniform rule is clearly desirable for its benefits of certainty and efficiency, the remainder of this paper will examine a few potential formulations of such a rule.

B. Selecting an Appropriate Definition

1. Option One: Transform Current Policies into a Binding Rule

The easiest path to establishing an FDA “rule” governing the term natural may be to simply adopt the current policy as a rule: natural would mean that “nothing artificial or synthetic” has been “included in, or has been added to, a food that *421 would not normally be expected to be in the food.”¹²⁸ Such a definition, though vague, avoids the faults associated with “fresh” by freeing ice cream to go through more processes and include more ingredients than an apple and still remain true to consumer “expectations.” This solution might be the simplest and least controversial, but without more, this definition leaves courts and state legislatures with sufficient discretion in interpretation to enable the litigious sugar and corn syrup industries to continue

fighting the good fight. This option may not be optimal, as the heavy concentration of the litigation on the corn syrup-versus-sugar dispute merits a definition that will bring resolution to this issue.

A rule adopting the current USDA policy might still the rattling sabers of the sugar and corn syrup industries, but it has other disadvantages. Factoring “minimal processing” into the definition of “natural” would enable FDA to make determinations on such matters like HFCS, and it would also have the added benefit of creating uniformity between the USDA and FDA. However, this path seems inadvisable considering that the USDA, in soliciting comments on whether to continue to include processing in its policy definition, is having great difficulty determining whether to discourage the use of safety-increasing processes by precluding them from being applied to “natural” products. FDA’s adoption of such a policy could increase the risk of devolving into another “fresh” conundrum because such processes as pasteurization and preservation would need to be considered. FDA should steer clear of this pitfall by rejecting any inclusion of “minimal processing” language in its definition. FDA would be better served by transforming its own policy statement into a rule, and then modifying the definition with language explicitly stating that processing shall have no bearing on whether a product may bear the name “natural.”

2. Option Two: Make Separate Ingredient or Processing Standards for “Natural” Claims by Food Category

As the CEO of the Sugar Association suggested, “This is the appropriate time [for the FDA] to clearly define ‘natural’ After all, FDA has established regulatory guidelines for the term ‘healthy,’ why can’t the same be done for natural?”¹²⁹ Although such a challenge is easier said than done, the success of the agency in defining “healthy”¹³⁰ suggests that FDA could come up with appropriate differentiated standards by type of food to reflect the fact that consumers do not expect “the same thing from a natural apple as they do from natural ice cream.”¹³¹ FDA’s experience with making categorized determinations for the “healthy”-ness of various types of foods illustrates that such an undertaking with regard to natural products is not infeasible.

After a notice and comment period, FDA created a rule with detailed criteria for the use of the word “healthy” as applied to various types of foods. FDA’s requirements were finalized in a chart, which set individualized limits for various types of food regarding the quantities of fat, saturated fat and cholesterol which could *422 be contained therein and nevertheless allow the product to be labeled as healthy.¹³² Specifically, the regulation provides separate levels for categories such as a) raw fruits or vegetables, b) single-ingredient or mixture of canned fruits and vegetables, c) enriched-cereal grain products or d) raw, single-ingredient seafood or game meat, e) other meal products or main dishes, and f) other foods not specifically listed.¹³³ These might not be the precise distinctions FDA would desire to make with respect to determining the “naturalness” of a food, but a glance at these categories reveals a few obvious areas for differentiation. One would expect an enriched cereal grain to involve more ingredients and more processing than a raw fruit or vegetable; thus it would make sense to provide separate standards for these food types to determine whether “natural” was an appropriate descriptor of that food. Although formulating categories and prescribing different standards may prove contentious among food industry players, FDA’s success in defining “healthy” counsels that a term not lending itself to a one-size-fits-all application should not be forced to inflexibly cover all products in the same manner. It makes sense for “natural” to take on a different meaning when applied to the diversity of foods and beverages occupying American grocery store shelves.

3. Option Three: Determine “Natural” Foods by Listing and Excluding “Unnatural” Ingredients or Processes

In the wake of FDA’s inaction, natural foods retailers such as Whole Foods have determined what products to carry by creating their own lists of ingredients which they consider to be “unnatural” and refusing to stock products containing those ingredients.¹³⁴ Such an approach could be advisable, as FDA already has experience in making these types of ingredient-specific determinations for “natural” flavors. For example, FDA limits what flavors may be added to a “natural” product. “Artificial flavors” may not be included, and an “artificial flavor” is defined as “any substance, the function of which is to impart flavor which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof.”¹³⁵ “Natural flavors” are allowed, and may consist of “essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from” the list in section 101.22(a)

(1).¹³⁶ In the same manner, FDA could attempt to define an “artificial process” by requiring food labels to indicate whether food products had undergone such processes.

Whole Foods uses a list-based model which expounds upon the current FDA policy of screening out ingredients not normally ... “expected”¹³⁷ to be in the food by reviewing each ingredient and asking the following question: “Is this something *423 that our shoppers would expect to find in a natural food?”¹³⁸ “[S]traightforward” unnatural ingredients like artificial flavors and preservatives are banned, while naturally derived preservatives like citric acid are permitted.¹³⁹ But not all ingredients are so clear-cut. Whole Foods prohibits L-cysteine, a natural amino acid, because it “allows bakers to cut corners and replace traditional kneading ... with an additive.”¹⁴⁰ For a separate class of questionably-natural ingredients, Whole Foods requires that the quantity of the ingredient to be limited to conform to what a consumer would naturally expect to be in the product. Whole Foods also places “additional requirements” on the labeling of foods containing these ingredients, ensuring that “customers know what they’re getting.” This practice is compatible with a strategy suggested in the USDA comments: “natural” labeling would adopt the same tiered status as organic labeling, with some foods bearing the distinctions of “100% natural,” “natural,” or “made from natural ingredients” based upon the quantity of specific ingredients within the product.¹⁴¹

Although this formulation would increase clarity and minimize discretion in interpretation, a list-based definition would certainly be fraught with objections from warring industries striving to keep their ingredients or processes off the non-natural list. Additionally, there appears to be little certainty, even within the food industry, regarding what ingredients and processes are natural. In 2008, the Institute for Food Technology conducted a webcast survey to determine what processes and ingredients were considered natural. Although some processes were uniformly considered natural (drying-91 percent and steaming plant material-90 percent), a considerable number of processes obtained decidedly mixed results (microbiological processes-67 percent, enzymatic process-59 percent, extraction by ethanol and/or water-55 percent).¹⁴² This pattern repeated in questions regarding what ingredients could be considered “natural.”¹⁴³ With such contention within the industry, any attempt to define the term through the exclusion of particular ingredients or processes could stall and end in another failed effort to define the term.

IV. CONCLUSION

In summary, although FDA’s reluctance to define the term “natural” in rule form is both non-unique and understandable, the \$22.3 billion natural foods industry is simply too large to rest on such uncertain grounds. FDA has repeatedly suggested that the current regime creates significant room for consumer deception, and it is clear that forcing national food manufacturers to fit their labels to the expectations of numerous different states and consumer-protection special-interest groups will only complicate the matter further. For these reasons, it is critical that FDA enact some type of rule to create uniformity and dispel confusion. To the potential detriment of consumer health,¹⁴⁴ what is considered “natural” currently fluctuates with consumer expectations and desires. Those expectations are powerful, as evidenced by recent changes to the Snapple beverages. Snapple, after its victorious defense in *Holk*, announced in February 2009 that the company would exchange HFCS *424 for sugar in its iced-tea beverages, and the change would accompany a bottle and label redesign geared at better suiting the expectations of Snapple consumers.¹⁴⁵ However, market-driven decisions will not be sufficient to guard against lawsuits by competitors and watchdog groups with differing ideas of what constitutes a “natural” product. For these reasons, FDA should respond to consumer demand for a definition of the term “natural” with a rule that will be sensitive to consumer expectations while appropriately reflecting health concerns as determined by the expert agency. It must also provide sufficient clarity for food producers to invest in appropriate ingredients or processes without fear of being subject to unpredictable lawsuits. Such a “natural” solution, for both consumers and food manufacturers, would be refreshing indeed.

Footnotes

^{a1} Ms. Farris is a law clerk for Judge Jennifer Walker Elrod, United States Court of Appeals for the Fifth Circuit. She was awarded first place for this paper in the 2009 H. Thomas Austern Memorial Writing Awards Short Paper Competition.

- 1 NIELSEN, HEALTHY EATING REPORT FOR 2008 (2009); *see generally* Kosher Organics, The Demand for Kosher, Natural, and Organic Products, [http:// www.kosherorganics.com/articles_the_demand_for_kosher_products.htm](http://www.kosherorganics.com/articles_the_demand_for_kosher_products.htm) (last visited Apr. 20, 2009).
- 2 Sarah Hills, *Kosher Leads Top Ten Claims for New Products*, FOOD NAVIGATOR-USA, Dec. 11, 2008, <http://www.foodnavigator-usa.com/Financial-Industry/Kosher-leads-top-ten-claims-for-new-products>. This was an increase from 2007, when “all natural” was the third leading term. *See Corn Sweetener not “Natural,” TUFTS UNIV. HEALTH & NUTRITION LETTER*, (Tufts Univ.) Jun. 1, 2008 at 3.
- 3 *See* Whole Foods Market, *About Whole Foods Market*, [http:// www.wholefoodsmarket.com/company-/index.php](http://www.wholefoodsmarket.com/company-/index.php) (last visited Apr. 19, 2009).
- 4 *Interbrand Design Forum Ranks the Most Valuable U. S. Retail Brands; Walmart is Top Retailer, Followed by Best Buy and Home Depot*, BIOTECH WEEK, Jan. 28, 2009 (“Whole Foods Market ... is perceived to provide the highest quality food offering in the industry [and] delivers on its promise of an unmatched variety of organic and natural foods.”).
- 5 “Natural” foods accounted for 22.3 billion dollars in sales in 2008, dwarfing sales of organic foods (4.9 billion), “carb conscious” foods (2 billion), and “hormone/antibiotic-free” foods (2.4 billion). NIELSEN, *supra* note 1.
- 6 “Natural” Beats “Organic” in Food Sales According to Nielsen’s Healthy Eating Report, NIELSEN WIRE, Jan. 21, 2009, <http://blog.nielsen.com/nielsenwire/consumernatural-beats-organic-in-foodsales-according-to-nielsen-s-healthy-eating-report/>.
- 7 *See id.*
- 8 21 C.F.R. § 10.85(j) (2008).
- 9 *See infra* discussion Part III.
- 10 Susan Salisbury, *It’s only ‘Natural’--Or Is It?*, PALM BEACH POST, Jan. 14, 2008, at 1F (“But in comments to the FDA about the sugar industry petition [to define the term natural] the corn refiners’ group argued that the petition was a transparent attempt by the Sugar Association to shift food labeling policies to favor sucrose over other sweeteners such as HFCS, and to increase the market share of sucrose.”). The sugar industry and the corn syrup industry have also sponsored competing scientific studies on whether corn syrup has worse health consequences for the body than sugar, particularly in terms of obesity. Recent studies suggest the two are relatively equivalent. *Compare* George A Bray et al., *Consumption of High Fructose Corn Syrup May Play Role in Obesity Epidemic*, 79 AM. J. OF CLINICAL NUTRITION 537, Apr. 2004 with AM. MED. ASS’N COUNCIL ON SCI. & PUB. HEALTH, REPORT 3, THE HEALTH EFFECTS OF HIGH FRUCTOSE CORN SYRUP, A-08 (June 2008) (“Because the composition of HFCS and sucrose are so similar ... it appears unlikely that HFCS contributes more to obesity or other conditions than sucrose.”). Although the merits of such scientific claims are outside the scope of this paper, it is sufficient here to note that the debate over high fructose corn syrup’s “natural” properties has been an animating force behind litigation over the term.
- 11 Michael A. Watkins, *Snapple’s “Natural” Claim May Turn Sour*, July 6, 2007, STAR-LEDGER (New Jersey); *see also* [Holk v. Snapple Bev. Corp.](#), 574 F. Supp. 2d 447 (D.N.J. 2008).
- 12 As to whether consumer confusion from the use of the term exists, FDA has issued confusing statements. *Compare* Letter from Raymond E. Newberry, Acting Director, Division of Regulatory Guidance, FDA to Clinton K. Davies, Ph.D., Director of Quality Assurance, National Sea Products, Inc. (Sept. 29, 1988) (explaining that FDA “has consistently discouraged the use of such term [natural] because its meaning is ambiguous and may unjustifiably imply to consumers that foods labeled as natural are inherently superior to other foods especially in nutrient content, quality, and safety”) with Salisbury, *supra* note 10 (“We have not been hearing from consumer groups on [the need to define “natural”].’ A spokesman for FDA said. ‘We don’t have any evidence that people are confused.’”) This confusion is not unique to the food industry. For a discussion of the greater uncertainties concerning the use of the term “natural” as applied to cosmetic products, see Paul M. Hyman & Samina N. Rodriguez, *Regulation of Labeling and Advertising Claims*, in COSMETIC REGULATION IN A COMPETITIVE ENVIRONMENT 43, 46-48 (Norman F. Estrin & James M. Akerson eds., 2000).
- 13 Proposed Trade Regulation Rule, 39 Fed. Reg. 39,842 (Nov. 11, 1974); Proposed Trade Regulation Rule, 40 Fed. Reg. 23,086 (May 28, 1975).

- 14 Termination of Proposed Trade Regulation; Rule on Food Advertising, 48 Fed. Reg. 23,270 (May 24, 1983).
- 15 *Id.*
- 16 Food Labeling; Tentative Positions of Agencies, 44 Fed. Reg. 75,990, 76,012 (Dec. 21, 1979).
- 17 F. Edward Scarbrough, *Perspectives on Nutrition Labeling and Education Act*, in NUTRIENT LABELING HANDBOOK, 47 (Ralph Shapiro, ed., 1995). At that time, FDA was also considering proposed regulations governing terms like “reduced cholesterol” and “cholesterol free.” *Id.*
- 18 The purpose of the legislation was to heighten FDA’s control governing the labeling of food nutritional content, and to define set situations when specific claims could be made regarding the nutritional content of a food. *See* H.R. Rep. No. 101-538 at 7 (1990).
- 19 Scarbrough, *supra* note 17.
- 20 Food Labeling; Nutrient Content Claims, General Principles Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (Nov. 27, 1991). Policy statements, though lacking the power to bind parties with force of law, are not without significant affect. FDA cannot punish parties who label their products in accordance with the policy. 21 C.F.R. §10.85(e) (2008). Likewise, an agency is obliged to follow its determinations regarding the use of the term “until [they are] amended or revoked.” *Id.* FDA is also free to take action against manufacturers whose product labels violate the policy. 58 Fed. Reg. 2,302 (Jan. 6, 1993).
- 21 Food Labeling; Nutrient Content Claims General Principles, Petitions, Definition of Terms, 56 Fed. Reg. at 60,466. This policy includes a distinction between natural artificial flavors as outlined in 21 C.F.R. §101.22.
- 22 *See, e.g.*, Claudia D. O’Donnell, *Bypassing the NLEA - Nutrition and Education Labeling Act - Foods for Health*, PREPARED FOODS, Apr. 15, 1993 (noting a 485 percent increase in new products with “all natural” claims between 1988 and 1992).
- 23 Food Labeling; Nutrient Content Claims General Principles, Petitions, Definition of Terms, 56 Fed. Reg. at 60,466.
- 24 Food Labeling; Nutrient Content Claims General Principles, Petitions, Definition of Terms, 58 Fed. Reg. at 2,407. Notably, when FDA commenced this process, there was some expectation by consumers that “natural” would be defined before the process’s end. *See* Marion Burros, *Eating Well; FDA Plans to Take Fantasy Out of Food Labels*, N.Y. TIMES, Sept. 18, 1991 at C1 (implying that the use of the term “natural” on a juice product containing only 10 percent juice would be an example of product mislabeling which David A. Kessler, the FDA Commissioner, would seek to rectify in creating “rules to carry out the 1990 Nutrition Education Labeling Act”).
- 25 58 Fed. Reg. 2,407 (Jan. 6, 1993).
- 26 *Id.*
- 27 *See id.*
- 28 *Id.*
- 29 Letter from Margaret Glavin, FDA Assoc. Comm’r for Reg. Affairs, to Antonio Zamoja (Dec. 12, 2005).
- 30 Sugar Association, Citizen Petition re Definition of the term “Natural” for making claims on foods and beverages regulated by FDA (Feb. 28, 2006), http://www.cspinet.org/new/pdf/sugar_fda_petition.pdf.
- 31 *See id.* at 4-7; *see also* U.S. DEP’T. OF AGRICULTURE, FOOD SAFETY AND INSPECTION SERV., “NATURAL CLAIMS” IN FOOD STANDARDS AND LABELING POLICY BOOK (revised Nov./Dec. 2006) (defining a product as “natural” when “(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.”).
- 32 *See* Sugar Association, *supra* note 30, at 5.
- 33 *Id.* at 5-7.
- 34 Sara Lee Corp., Citizen Petition Requesting FDA to Develop Requirements for the Use of the Term “Natural” Consistent with the USDA’s FSIS (Apr. 9, 2007), *available at* <http://www.fda.gov/ohrms/dockets/dockets/07p0147/07p-0147-cp00001-toc.htm>. Unlike

in the case of the Sugar Association petition, Sarah Lee was not motivated by the desire to exclude corn syrup from consideration as a “natural” ingredient. *Id.*

35 Letter of Robert G. Reinhard, Director of Food Safety/Regulatory for the Sarah Lee Corporation to FDA, (Apr. 9, 2007), available at <http://www.fda.gov/ohrms/dockets/dockets/07p0147/07p-0147-cp00001-01-voll.pdf>.

36 See Sara Lee Corp., *supra* note 34, at 11.

37 Lorraine Heller, ‘Natural’ Will Remain Undefined, Says FDA, Jan. 4, 2008, FOOD NAVIGATOR-USA, <http://www.foodnavigator-usa.com/Financial-Industry/Natural-will-remain-undefined-says-FDA> (noting that, in an interview with the publication, “Geraldine June from FDA’s Food Labeling and Standards department said the agency had not put the ‘natural’ issue on its priority list because there is not enough evidence that the current situation means consumers are being misled.”).

38 Lorraine Heller, *FDA Comments on HFCS Spark Industry Opposition*, FOOD NAVIGATOR-USA, Apr. 3, 2008, <http://www.foodnavigator-usa.com/Legislation/FDA-comments-on-HFCS-spark-industryopposition>; see also Tufts Univ., *supra* note 2.

39 Heller, *supra* note 38 (emphasis removed).

40 Letter from Geraldine A. June, Supervisor of the Product Evaluation and Labeling Team, FDA, Dep’t of Health and Human Servs. (HHS), to Audrae Erickson, President of the Corn Refiners Ass’n, (Jul. 3, 2008).

41 *Id.* FDA noted that the HFCS would not be “natural” if a synthetic substance or fixing agent was included in the product, or if the acids used to obtain the hydrolysate did not fit within the FDA’s definition of “natural.” *Id.*

42 *Corn Refiners Welcome FDA Clarification*; WAREHOUSES FROZEN FOOD DIGEST, Oct. 1, 2008 at 25 (citing Corn Refiners Association president Audrae Erickson as stating that “[u]pon careful review of the manufacturing process for High Fructose Corn Syrup, the FDA found that HFCS can be labeled natural.”)

43 Jane Hoback, *FDA Refuses to Define Natural*, NATURAL FOODS MERCHANDISER, Jan. 22, 2008, at 9 (noting that the Sugar Association’s President and CEO expressed that the Sugar Association was “deeply disappointed” in FDA’s reversal).

44 7 U.S.C. § 6501 (2008).

45 See National Organic Program, 65 Fed. Reg. 80,548 (Dec. 21, 2000).

46 For a summary overview of the relevant requirements and regulations pertaining to the USDA National Organic Program, see FOOD MARKETING INST., SUMMARY: THE USDA NATIONAL ORGANIC PROGRAM REQUIREMENTS FOR FOOD RETAILERS AND DISTRIBUTION CENTERS (2002).

47 The National Organic Program regulations are codified at 7 C.F.R. § 205.

48 See, e.g., FOOD MARKETING INST., FMI BACKGROUNDER: NATURAL AND ORGANIC FOODS 2 (June 2007), available at http://www.fmi.org/media/bg/natural_organic_foods.pdf (“Before the NOP was finalized, the term organic was defined by disparate state, regional and private standards, generating confusion and making it difficult to gauge just how organic an item was. The launch of the NOP with the USDA Organic seal ... designed to make it easy for consumers to identify organic foods received widespread media attention.”).

49 Two-thirds of American shoppers now buy organic products at least on occasion. FOOD MARKETING INST., FMI BACKGROUNDER: NATURAL AND ORGANIC FOODS 3 (Sept. 2008), available at http://www.fmi.org/docs/media/bg/natural_organic_foods.pdf#search=%22natural%22. In addition “U.S. retail sales of natural and organic foods and drink reached \$28.2 billion in 2006, up from \$23.0 billion the previous year—a 14.1 percent increase.” FOOD MARKETING INST., *supra* note 48, at 2. In 2007, that number shot up to \$31.0 billion dollars. FOOD MARKETING INST., FMI BACKGROUNDER: NATURAL AND ORGANIC FOODS 2 (Sept. 2008).

50 The FSIS policy memo contained a decision tree posing the following two questions: “(1) Does the product contain an artificial flavor/flavoring, a coloring ingredient, a chemical preservative, or any other synthetic or artificial ingredient? (If yes, then the product is not natural). (2) Are the product and its ingredients only minimally processed? (If yes, then the product is natural).” Carolyn Fisher & Ricardo Carvajal, *What is Natural?*, FOOD TECH., Nov. 2008 at 24, 25.

- 51 See LABELING POLICY BOOK, *supra* note 31. The Policy Book defined “natural” as meaning (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 may include: (a) those traditional processes used to make food edible or to preserve it or to make it safe for human consumption, e.g., smoking, roasting, freezing, drying, and fermenting, or (b) those physical processes which do not fundamentally alter the raw product and/or which only separate a whole, intact food into component parts, e.g., grinding meat, separating eggs into albumen and yolk, and pressing fruits to produce juices.
- Id.* The Policy Book contains additional directives on the use of the term “natural,” requiring the label to be “accompanied by a brief statement explaining what is meant by the term,” and providing additional guidance regarding what forms of processing are too “severe” to be considered minimal. *Id.* Although the August 2005 edition provided that sugar, sodium lactate, and natural flavors from oleoresins are acceptable in “natural” foods, the use of sodium, lactate is now considered on a case-by-case basis. See *id.*
- 52 See Hormel Foods, Petition for the Issuance of a Rule Regarding Natural Label Claims (Oct. 9, 2006), available at http://www.fsis.usda.gov/regulations_&_policies/Petition_Natural_Label_Claims/index.asp.
- 53 Product Labeling: Definition of the Term “Natural,” 71 Fed. Reg. 70,503 (Dec. 5, 2006).
- 54 Covington & Burling, Food & Drug E-Alert, FSIS Holds Public Meeting on the Definition of the Term “Natural,” (Dec. 14, 2006).
- 55 The dispute over whether a product should be defined as “natural” based on the ingredients in the product, or alternatively, based on the manner in which the product was produced (including the substances fed to meat producing animals, the living conditions of the animals, and other related concerns) was of great significance. Product Labeling: Definition of the Term “Natural” Public Meeting (Dec. 12, 2006, 9 a.m.), transcript available at http://www.fsis.usda.gov/pdf/natural_claims_transcripts.pdf [hereinafter Transcript]. The latter concern gave rise to a new regulation governing “naturally raised” labeling claims. See *infra* note 61.
- 56 See Transcript at 91 (statement of Tim Sontag, representing Wixom, Inc., a spice, seasoning, and flavoring manufacturer). Under USDA regulations, products labeled “100 percent organic” contain only organic ingredients and may display the USDA Organic Seal; products labeled “organic” contain at least 95 percent organic materials and may display the seal; products labeled “Made with organic ingredients” contain 70-95 percent organic ingredients and may list up to three of such ingredients; and products with less than seventy percent organic ingredients may only use the term “organic” to label individual organic ingredients, see U.S. DEPT OF AGRICULTURE, AGRICULTURAL MARKETING SERV., ORGANIC LABELING AND MARKETING INFORMATION, 1-2 (Apr. 2008), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3004446>.
- 57 Transcript, *supra* note 55, at 25-26.
- 58 See *id.* at 54-55 (“Consumers see pasteurization as all natural. Is high-pressure pasteurization all natural? It fundamentally alters the product[A]ir radiation is not obviously not accepted as all natural by consumers but to begin really investing, we’re talking capital expenditure here, you know, we’re in a quandary where to go.” (statement of Deborah O’Donnell, product developer for Kayem Foods.))
- 59 Covington & Burling, *supra* note 54, at 4.
- 60 Fisher & Carvajal, *supra* note 50, at 29-30.
- 61 United States Standards for Livestock and Meat Marketing Claims, Naturally Raised Claim for Livestock and the Meat and Meat Products Derived From Such Livestock, 74 Fed Reg. 3,541 (Jan. 21, 2009). In all, the proposed rule garnered more than 44,000 comments.
- 62 Press Release, CSPI, *Ben & Jerry’s Fudging the Truth, Says CSPI: Nothing Natural About Artificial Flavors* (July 30, 2002). However, this threatened suit was not totally in line with FDA policy as it also challenged the use of corn syrup and corn syrup solids as unnatural. See *id.*
- 63 Laura Crowley, *HFCS is natural, says FDA in a Letter*, FOOD NAVIGATOR-USA, Jul. 8, 2008, <http://www.foodnavigator-usa.com/Financial-Industry/HFCS-is-natural-says-FDA-in-a-letter>; see Press Release, CSPI, 7UP Drops “All Natural” Claim (Jan. 12, 2007); Press Release, CSPI, Kraft is Sued for Calling Capri Sun Drink “All Natural” (Jan. 8, 2007).

- 64 *Consumer Group Sues Whole Foods Market*, CONSUMERAFFAIRS.COM, May 3, 2005, http://www.consumeraffairs.com/news04/2005/cspi_food_suits.html (discussing various misleading food claims).
- 65 The National Advertising Division offers a dispute resolution service which reviews advertisements for truthfulness and accuracy. In many cases, the “NAD has referenced or relied upon federal definitions and policies to inform its decisions” although the ultimate determination of truthfulness depends upon the evaluation of “the entire advertisement instead of the meaning of the words or phrases standing alone.” Covington & Burling, *supra* note 54, at 4 (citing NAD Case No. 4289, Sanderson Farms Chicken (Mar. 8, 2005); NAD Case No. 3499, Procter & Gamble (Olean Fat Substitute) (Oct. 1, 1998); NAD Case No. 4442, Swiss Research, Inc. (Shugr Sweetener) (Jan. 20, 2006)).
- 66 *Williams v. Gerber Products Co.*, 523 F.3d 934 (9th Cir. 2008).
- 67 *Id.* at 937.
- 68 *See Sugar Ass’n v. McNeil Nutritionals*, No. CV 04-1077DSF (C.D. Cal. 2008).
- 69 Tresa Baldas, *Artificial Sweetener Draws Volley of Very Sour Lawsuits*, Nat’l L.J., Apr. 4, 2005 (quoting Jim Murphy of Squire, Sanders & Dempsey).
- 70 *See Jaime Jofre, Splenda Lawsuit Seeks \$1 Billion from Johnson & Johnson*, <http://www.lawyersandsettlements.com/articles/01598/splenda-lawsuit.html>.
- 71 *Holk v. Snapple Beverage Corp.*, 574 F. Supp. 2d 447 (D.N.J. 2008); *Fraker v. KFC Corp.*, No. 06-CV-01284-JM(WMC), 2007 WL 1296571 (S.D. Cal. Apr. 30, 2007) (holding more broadly that the FDCA impliedly preempts liability for the branding and labeling of all food products).
- 72 *English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990) (also noting that preemption is implied “where an Act of Congress ‘touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on that subject.’” (citation omitted)).
- 73 574 F. Supp. 2d 447 (D.N.J. 2008).
- 74 Specifically, the plaintiff alleged that the use of the phrase “All Natural” to describe its products constituted unjust enrichment and breach of express and implied warranties under the New Jersey Consumer Fraud Act. *See id.* at 449.
- 75 *Id.* Corn syrup could not be considered “all natural,” according to the plaintiff, as “the molecules in HFCS do not originate from natural sources, but instead are created through ‘enzymatically catalyzed chemical reactions in factories.’” *Id.* (quoting Amend. Compl., at ¶ 33).
- 76 *Id.* at 454.
- 77 *Id.* at 455.
- 78 *Id.* (citing *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990)).
- 79 *Id.* at 456, n.4.
- 80 *Id.* at 455 (noting that such preemption was warranted as such determinations were “clearly within the expertise of the FDA, which has already expended tremendous resources and time considering this ‘field’ and its impact on public health and safety.”).
- 81 *Id.* at 456.
- 82 No. 06-CV-01284-JM, 2007 WL 1296571 (S.D. Cal. Apr. 30 2007).
- 83 *Id.* at *1.
- 84 *Id.* at *4.
- 85 597 F. Supp. 2d 1028 (N.D. Cal. 2009).

86 *Id.* at 1029-30.

87 21 U.S.C. § 343-1(a)(3).

88 21 U.S.C. § 343(k).

89 *Lockwood*, 597 F. Supp. 2d at 1031. The Court also rejected a claim of express preemption based on [section 343-1\(a\)\(2\)](#) which prohibits states from establishing a labeling of food that is required by [section 343\(c\)](#), unless it is identical to the federal requirement deeming a food to be misbranded if it is an imitation of another food but is not identified as such. The court also rejected this argument, as plaintiffs were not claiming the pasta sauce to be an imitation. *Id.*

90 *Holk v. Snapple Beverage Corp.*, 574 F. Supp. 2d 447, 453 (D.N.J. 2008) (noting that although an express preemption claim had been raised and rejected as to a separate issue concerning the appropriate labeling of the actual juices contained within a juice beverage, no express preemption claim was raised regarding the use of the term “all natural”).

91 *Lockwood*, 597 F. Supp. 2d at 1030 (quoting *Altria v. Good*, 129 S. Ct. 538, 543 (2008)).

92 NLEA, Pub. L. No. 101-535, § 6(c)(1).

93 *Lockwood*, 597 F. Supp. 2d at 1032.

94 *Id.* at 1034.

95 *Id.* at 1033 (citing 21 C.F.R. § 10.85(j)).

96 *Id.* 1033-34.

97 No. 08cv809, WQH, 2009 WL 449190 (S.D. Cal. Feb. 4, 2009).

98 *Id.* at *3 (quoting *Fenner v. Tr.-Union Seafoods, LLC*, 539 F.3d 237 (3d Cir. 2008)).

99 129 S. Ct. 1187 (2009).

100 128 S. Ct. 999 (2008). *Riegel* was considered by many to be an easier case, as the Medical Devices Amendments, codified at 21 U.S.C. § 360k(a), clearly state that states may not “establish or continue in effect ... any requirement ... which is different from, or in addition to, any requirement applicable under [federal law] to the device.”

101 *Wyeth*, 129 S. Ct. 1187.

102 *Id.* at 1199. Even though *Wyeth* would have had to submit a new label with even stronger warnings for FDA review following the original label’s approval with no guarantee FDA would have approved such a label, the Court found that it was not “impossible” for FDA to adhere to both the state and federal law.

103 *Id.*

104 *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000).

105 *Wyeth*, 129 S.Ct. at 1203.

106 *Id.* at 1204.

107 21 U.S.C. § 343(r).

108 *See, e.g., WWHT, Inc. v. FCC*, 656 F.2d 807, 818 (D.C. Cir. 1981).

109 *See Fisher & Carvajal, supra* note 50, at 31 (“[I]n absence of a regulation or guidance from FDA that addresses the issue, manufacturers are likely to continue to make their own decisions case-by-case, and to take their chances with competitors, consumer watchdogs, and plaintiffs lawyers.”).

- 110 Press Release, Inst. of Food Tech., *Conflicting Messages May Put Consumers at Risk* (June 26, 2006) (noting that due to the perception that less-processed foods are “natural” and better for consumers, customers are putting themselves at risk by seeking out raw foods, and food producers are responding to the trend by producing raw foods; a food safety expert at the University of California, Davis stated that “Now, without cooking, things that were not a problem before are turning up.”)
- 111 H.R. Rep. No. 59-2118, at 5-6 (1906), cited in *Hearing on H.R. 3200 Food Amendments and the Animal Drug Availability Act of 1996 Before the Subcomm. on Health & the Environment of the H. Comm. on Energy & Com.*, 103rd Cong. (1996) (statement of Peter Barton Hutt, representing the Grocery Manufacturers Association of America and the Cosmetic, Toiletry, and Fragrance Association).
- 112 “A 2006 survey conducted by Harris Interactive found consumers believe FDA should provide official definition for making a natural claim. In a petition submitted to FDA ... the Sugar Association showed that 83% of the 1000 surveyed said the government should provide regulations to food manufacturers when making ‘natural’ claims.” Press Release, Sugar Ass’n., *Sugar Association Disappointed in FDA’s Decision Not to Define ‘Natural’* (Jan. 7, 2008).
- 113 *FDA Oversight: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. (statement of Peter Barton Hutt). Hutt also recommended that the FDA budget be doubled. *Id.*; see also *FDA SCIENCE AND MISSION AT RISK: A REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY PREPARED FOR THE FDA SCIENCE BOARD* (2007).
- 114 Arthur Allen, *Consumers’ Right to Sue Weakening, Upcoming Case Could Bar Public From Taking Drug Cases to Court*, THE WASHINGTON INDEPENDENT, Mar. 21, 2008, available at <http://washington-independent.com/1921/consumers-right-to-sue-weakening>.
- 115 The FDCA provides that, in general, “proceedings for the enforcement, or to restrain violations, of the [FDCA] shall be by and in the name of the United States.” 21 U.S.C. § 337(a).
- 116 See 21 U.S.C. §§ 337(b), 343(k), 343-1(a)(3).
- 117 21 C.F.R. § 101.95.
- 118 See 21 C.F.R. § 101.95(a). However, a food may nevertheless make a claim of “fresh”-ness as to particular ingredients, rather than the food as a whole, in circumstances where such a claim would not be misleading. *Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms*, 58 Fed. Reg. 2,302, 2,405 (Jan. 6, 1993).
- 119 21 C.F.R. §101.95(c)(2).
- 120 See James L. Vetter, *Labeling and Regulatory Requirements*, in RONALD E. HEBEDA & HENRY F. ZOBEL, *BAKED GOOD FRESHNESS: FOOD SCIENCE AND TECHNOLOGY* 269-72 (1996) (describing FDA’s adoption of a definition for “fresh” food products).
- 121 Cindy Skrzycki, *FDA’s Fresh Stand on Rule Baffles Bakers*, WASH. POST, Oct. 15, 2002.
- 122 Chryssa V. Deliganis, *Death by Apple Juice: The Problem of Foodborne Illness, the Regulatory Response, and Further Suggestions for Reform*, 53 FOOD & DRUG L.J. 681, 711 (1998); Christopher Drew & Pam Belleick, *Threat Can Hide Behind Freshness*, N.Y. TIMES, Jan. 5, 1998, at A1. Note, however, that FDA regulations allow the use of the terra “fresh” when it is not being used to convince the consumer that the food is unprocessed, such as references to “fresh milk” which are governed by section 403(a) of the FDCA which requires that the term not be used in a manner that is misleading.
- 123 Deliganis, *supra* note 122, at 690. The sickness was found to be caused by 0157, a “particularly virulent” strain of E. coli. *Id.*
- 124 See *id.*
- 125 *Id.* at 691-692.
- 126 *Id.* at 711 (citing National Advisory Committee on Microbiological Criteria for Foods, *Fresh Produce Subcommittee Meeting Transcript*, Vol. I at 62 (Dec. 16-17, 1996) (statement of Dr. Edward Scarbrough, Director, Office of Food Labeling, Center for Food Safety and Applied Nutrition (CFSAN)).

- 127 1997 Food Code Updates Food Safety Guidelines, FDA Talk Paper (June 11, 1997).
- 128 [Food Labeling Claims: Nutrient Content Claims, General Principles, Petitions Definition of Terms](#), 58 Fed. Reg. 2,302, 2,407 (Jan. 6, 1993)
- 129 Press Release, Sugar Ass'n, Sugar Association Disappointed in FDA's Decision Not to Define 'Natural,' (Jan. 7, 2008).
- 130 [21 C.F.R § 101.65](#) (identifying the term “healthy” as an implied nutrient content claim under section 403(r) of the FDCA.)
- 131 Termination of Proposed Trade Regulation; Rule on [Food Advertising](#), 48 Fed. Reg. 23, 270 (May 24, 1983).
- 132 [21 C.F.R § 101.65\(d\)\(2\)\(i\)](#).
- 133 *Id.*
- 134 Joe Dickson, “*Natural Means ... What?*,” WHOLE STORY, Mar. 20, 2009, <http://blog.wholefoodsmarket.com/2009/03/natural-meanswhat/> (“One of the most simple and effective tools we give our team members is a list of ingredients, each marked acceptable or unacceptable. The list covers most of the food ingredients on the market and represents significant research into where it's from, how it's made, and what our stance is.”)
- 135 [21 C.F.R. § 101.22\(a\)\(1\)](#).
- 136 [21 C.F.R. § 101.22\(a\)\(3\)](#).
- 137 [Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms](#), 56 Fed. Reg. 60,421, 60,466-67 (Nov. 27, 1991)
- 138 Dickson, *supra* note 134.
- 139 *Id.*
- 140 *Id.*
- 141 *See supra* note 55.
- 142 Fisher & Carvajal, *supra* note 50, at 28, T.1.
- 143 Compare citric acid (85 percent of respondents approved ingredient as natural) with caramel color (47 percent), cellulose gum (48 percent), and enzyme-modified cheese (45 percent). *Id.*
- 144 *See supra* note 110.
- 145 Kim Severson, *Sugar is Back on Product Labels, This Time as a Selling Point*, N.Y. TIMES, Mar. 21, 2009, at A1; Jennifer 8 Lee, *Reading the Tea Leaves, Snapple Refreshes Itself*, CITY ROOM, N.Y. TIMES BLOG (Feb. 19, 2009, 1:45 p.m.), <http://cityroom.blogs.nytimes.com/2009/02/19/reading-the-tea-leavessnapple-refreshes-itself>.