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A Natural Solution: Why Should FDA Define "Natural" Foods?

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A Natural Solution: Why Should FDA Define "Natural" Foods?*

Stephen Gardner, Amanda Howell, and Erika Knudsen

I. INTRODUCTION

This article addresses the current debate surrounding the definition of the word "natural," and recommends that the Food and Drug Administration (FDA) promulgate a formal definition of the word. The authors argue that FDA has a responsibility, as a steward of public health charged with informing and protecting the American consumer, to define the word "natural" and that this definition should be guided by both solid science and consumer understanding, and must be informed by a balanced and inclusive discussion among all stakeholders.

A short trip to any American grocery store will confirm the pervasiveness of "natural" food claims. Products bearing "natural" claims range from cereal to soda to pasta sauces. In 2009, the word "natural" was the *most* frequently used claim on new U.S. food products.[1] As of 2010, "natural" foods constituted roughly a $22.6 billion industry.[2]

Unfortunately for consumers, "natural" is often one of the most deceptive words used on food labels. There is no formal FDA definition of the word[3] or consistent regulation of products that employ it. Nonetheless, studies have shown that consumers assign more meaning to the word "natural" than to "organic," despite the fact that "organic" is clearly defined and strictly regulated by the United States Department of Agriculture (USDA).[4] Consumer confusion surrounding the word "natural" is a concern shared by consumer advocates and businesses alike, who rely on standards and regulations in order to maintain transparency and an even economic playing field.

When consumers see foods marketed and labeled as "natural," not only do they assume this word is regulated, as with organic labeling, but they impart their own understandings onto products, interpreting the word "natural" to mean things like pure, clean, and healthy;[5] free of artificial additives;[6] and very minimally processed.

Recently, Consumer Reports issued a report of a survey it had conducted to determine consumer beliefs and preferences about foods labeled "natural." The conclusion:

> The claim "natural," which is stamped on countless food labels, is widely misunderstood by consumers, according to a new a survey of 1,000 people from the Consumer Reports National Research Center. Nearly 60 percent of people look for the term when they shop for food, probably because they think the products labeled natural are better for them than products without that claim.
>
> About two-thirds believe it means a processed food has no artificial ingredients, pesticides, or genetically modified organisms, and more than 80 percent believe that it should mean those things.[7]

* The authors, Stephen Gardner, Amanda Howell, and Erika Knudsen, are all with the Litigation Project of the Center for Science in the Public Interest (CSPI).

Consumers also may assume that the word "natural" has certain health, ethical, economic, and environmental connotations. For these reasons, consumers are willing to pay more for "natural" products than products that are not labeled as "natural." Companies count on this willingness and profit from it.

Consumers increasingly want to buy products that are better for them and for the earth. This has led to an explosion in the use of the word "natural" on food labels, as the food industry attempts to capitalize on increased consumer interest in more nutritious, less processed, and "greener" foods. Given the lack of definition and regulatory oversight, the word "natural" allows opportunistic companies to take advantage of positive consumer connotations with the word "natural." Unlike the word "organic," which requires specific production methods and procedures, the lack of an FDA definition for "natural" encourages dishonest food companies to use it to mean almost anything they want.[8] Companies indiscriminately slap the word "natural" on food labels in order increase sales, then claim that they are entitled to do so because there is no formal FDA definition of "natural." Because companies take advantage of FDA's silence, consumer deception and confusion are rampant.

In the competitive marketplace, the proliferation of deceptive "natural" claims is a particular problem for the organic industry. The strict requirements for organic certification require time, expense, and conformity to a series of regulations—investments that lose value when consumers cannot tell the difference between "organic" and "natural" claims. Many consumers even think that "natural" is a more regulated word than "organic."[9] Consequently, both consumers and businesses get short-changed.

The magnitude of consumer deception is evidenced in the number of lawsuits involving the word "natural" — according to a recent report, there are now over 200.[10] These lawsuits (brought mostly in California) invoke consumer protection laws. Litigation is a drain on time and resources and is detrimental to courts, consumers, and food companies alike. However, at this time, litigation is the only approach to this deceptive practice. FDA should step in.

USDA has defined "natural,"[11] but the USDA definition doesn't apply to the majority of the food supply — only to meat, poultry, and egg product labeling.[12] Some companies, like Kashi (a division of Kellogg), have also tried to define and create their own standards surrounding the word, but without regulations, self-imposed company standards mean very little and certainly do not protect companies from lawsuits.

The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) vested FDA with the power to "promulgate food definitions and standards of food quality."[13] In 1990, Congress passed the Nutrition and Labeling Education Act (NLEA), which amended the FDCA to require more detailed nutrition labeling.[14] Another purpose of the NLEA was to regulate and prevent inconsistent and poorly defined words used to describe nutrient content and disease-prevention claims. However, the NLEA did not address the term "natural."[15] Despite requests by consumers, companies, and courts, FDA has continued to defer action, repeatedly citing "resource limitations and other agency priorities."[16]

The 2014 Consumer Reports poll is not the only source of existing consumer data. A poll conducted in 2011 by FoodNavigator-USA, showed that two-thirds of respondents want FDA to come up with a more precise definition of "natural," with less than 1% thinking that FDA's existing guidance was adequate.[17] A third poll, conducted by the Sugar Association, found that 83% of consumers want FDA to define "natural."[18] In addition to consumer interest, some members of the food industry have petitioned for a definition of the word,[19] and several courts have deferred to FDA's jurisdiction in the hopes that it would develop a definition.[20] While most stakeholders agree that FDA should develop a uniform and regulated definition of the word "natural," that is as far as consensus goes. Stakeholders diverge at the crux of the issue: *How* should the word be defined?

POLICY RECOMMENDATIONS

FDA should take the following steps regarding the word "natural":

- Resolve to commit the resources necessary to establish a definition for the use of the word that would apply to all foods (including supplements).
- Balance consumer perception and science in establishing the definition.
- Engage in negotiated rulemaking and make sure all stakeholders have a voice in the process.

II. BACKGROUND

In 1974, the Federal Trade Commission (FTC), the federal agency responsible for regulating false and misleading advertising, attempted to define the word "natural" as foods that were minimally processed and free of artificial ingredients,[21] but later decided not to move forward.[22]

In 1991, FDA solicited comments on a potential rule adopting a definition for the word "natural," noting that "use of the word 'natural' on the food label is of *considerable interest to consumers and industry*."[23] However, two years later FDA concluded that "[a]fter reviewing and considering the comments . . . FDA is not undertaking rulemaking to establish a definition for 'natural' at this time."[24] Instead, FDA informally stated that "natural" foods are those that have "nothing artificial or synthetic (including colors regardless of source) included in, or has been added to, the product that would not normally be expected to be there."[25] But not having gone through formal rulemaking procedures, this FDA "natural" policy does not carry the force and effect of law.[26]

This means that the only current FDA definition of "natural" is limited to added colors and flavors in foods.[27] According to FDA, "artificial flavoring means 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."[28] And "natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional."[29] FDA's definition of artificial coloring is much simpler—it "means any 'color additive' as defined in 21 C.F.R. § 70.3(f)."[30]

We don't propose revisiting these ingredient-specific definitions, but instead discuss a global definition that would apply to all foods (including supplements).

Although both FDA and USDA are tasked with protecting consumer interests by prohibiting false and misleading labeling, to date, only the USDA has broadly addressed the use of "natural" on product labels through a guidance document. That guidance states that the word "natural" may be used on labeling for meat products and poultry products provided that the applicant for such labeling demonstrates that:

> (1) The product does not contain any artificial flavor or flavoring, coloring ingredients, or chemical preservative (as defined in 21 C.F.R. 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 that do not fundamentally alter the raw product or that 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. Relatively severe processes, e.g., solvent extraction, acid hydrolysis, and chemical bleaching, would clearly be considered more than minimal processing.[31]

Although that definition is helpful, it is only applicable to foods within USDA's purview — meat, poultry, and egg products, which is only about 20% of the food supply[32] — leaving the remaining 80% of food products under FDA's jurisdiction without a comprehensive definition of "natural."

Following FDA's 1993 refusal to adopt a comprehensive definition of "natural," companies increasingly began to take advantage of the regulatory vacuum to profit from consumers' increased interest in healthful foods. Companies liberally began to apply "natural" claims to all sorts of products, regardless of whether all ingredients were actually natural or even met FDA's limited guidance about nothing artificial or synthetic in a product's coloring or flavoring.

Not all stakeholders were happy with FDA's inadequate regulation of "natural" claims. For example, in early 2006, the Sugar Association filed a citizen petition with FDA, urging it to adopt the same definition for "natural" as the USDA.[33] CSPI filed a comment in support of the Sugar Association's petition soon after — lending support to the position that FDA should undertake rulemaking to establish specific rules and regulations governing the word "natural," and should ultimately adopt the same definition for "natural" as the USDA.[34] In early 2007, the Oregon Raspberry and Blackberry Commission filed a letter with FDA also supporting the Sugar Association's petition requesting that FDA define "natural."[35]

Sara Lee Corp. also petitioned FDA for a uniform definition for "natural"— specifically supporting a definition that would encompass the use of natural preservatives.[36]

The Corn Refiners Association (CRA) filed its own petition with FDA that opposed any formal definition of "natural," and instead proposed that a definition of the word would be best resolved "in the marketplace and not by regulation"— likely because its products (especially high fructose corn syrup and corn syrup) would be very unlikely to meet any possible definition of "natural."[37]

Following on the results of its survey (discussed above), Consumer Reports has now filed citizen petitions with both FDA and USDA proposing a simple solution — ban the use of the word "natural" in all marketing of foods:

> The ubiquitous "natural" label leads consumers to believe the food they buy does not contain such things as artificial ingredients, GMOs, pesticides, and hormones. Without any oversight or enforcement, food companies can use the "natural" label deceptively on almost any food.

It's time to drop this deceptive label for good. We urge both the FDA and the USDA to make the following changes:

- They should prohibit the use of the "natural" label on food.
- The USDA should issue an interpretive rule prohibiting the "natural" label on meat and poultry by amending the Food Standards and Labeling Policy Book with the following language:
    - The term "natural" is misleading to consumers and may not be used on labeling for meat products and poultry products
- The FDA should the issue the following interpretive rule:
    - The term "natural," or any derivation of the term, such as "naturally grown," "naturally sourced," or "from nature," is vague and misleading and should not be used.
- We believe the FDA and the USDA can and should make these changes based on the regulatory criteria for what constitutes "false and misleading" labeling that both agencies already have.[38]

Although the authors agree that this approach would bring a complete halt to deceptive "natural" marketing, we favor allowing FDA one last chance to do its regulatory job by defining "natural" in a way that stops the current flood of consumer deception but allows companies to use the word honestly.[39]

Recently, the Brookings Institution issued a report by a well-respected academic who had written on these issues before. Law professor Nicole Negowetti studied the issues and concluded:

> The FDA should define misleading terms such as "natural" to achieve uniformity and consistency for consumers and food manufacturers. The issue of whether genetically modified ingredients are "natural" is at the core of many recent food labeling class-action suits. The agency should address the controversial genetically modified organism (GMO) labeling issue to prevent the state-by-state patchwork of laws that is beginning to develop.[40]

Of course, using genetic engineering to modify plants is not the only plant breeding technique used. FDA would also need to consider plants grown from seeds developed through X-ray and chemical mutagenesis and other forms of genetic manipulation.

FDA action is essential because the marketplace has failed to filter out deceptive uses of "natural." Instead, it has incited a race to the bottom through indiscriminate application of the term on product labels. Despite repeated petitions to FDA to clarify the word "natural," FDA has declined to do so and, in at least one situation, FDA's response regarding the meaning of the word "natural" has only served to muddle interpretation of the word even more. In 2008 an FDA staffer told a reporter that HFCS could not be considered natural.[41] However, just a few months later, that same staffer recanted that position in a letter requested by the Corn Refiners Association.[42]

As the Third Circuit noted, the statements of one FDA staffer do not constitute even the most informal guidance from FDA itself.[43]

Even though FDA has not developed any comprehensive guidance or regulations regarding the word "natural," it has enforced its limited "natural" policy in the form of various Warning Letters to companies. In those Warning Letters, FDA prohibited "natural" claims on products containing added colors[44] and preservatives.[45] FDA has said that a product with added color (even if the color is itself natural) can't be called "natural."[46] Similarly, FDA says that when citric acid is used as a preservative in a product, that product cannot be called "natural."[47]

Thus, using an ingredient that may itself be natural can nonetheless prevent a "natural" claim for the product, if the ingredient is used as a preservative or an added color, which consumers do not expect to be an ingredient of a "natural" product.

Nonetheless, FDA's sporadic condemnation of certain uses of "natural" has neither prevented consumer deception nor halted the food industry's indiscriminate use of the term. As a result, industry is facing an increasing number of lawsuits brought by consumers who have been misled into buying supposedly "natural" products that illegally bear the term.

In fact, FDA's limited guidance on natural claims has on occasion frustrated consumer protection lawsuits brought in order to cure consumer deception and to hold food companies accountable for their indiscriminate use of the word "natural," due in large part to the doctrines of federal preemption and primary jurisdiction. A brief overview of those two doctrines is helpful.

A. Preemption

The Supremacy Clause of the Constitution allows federal law to preempt state law.[48] A state law is expressly preempted when a congressional statute or federal agency regulation contains explicit language stating that it supersedes that state law.[49]

There is limited preemption under the FDCA. In 1990, the Nutrition Labeling and Education Act amended the federal Food, Drug & Cosmetic Act to "clarify and to strengthen [FDA's] authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods."[50] Those amendments introduced an express preemption provision[51] that "preempts state requirements about food standards, nutrition labeling, and health claims, and, for the first time, authorizes some health claims for foods."[52]

Courts have applied the preemption doctrine to narrow or strike claims in a number of consumer protection actions alleging deceptive business practices and false advertising.[53]

However, preemption has not been an impediment to "natural" lawsuits. Courts have consistently held that FDA's current policy on "natural" does not preempt consumer protection actions alleging deceptive business practices and false advertising.[54]

B. Primary Jurisdiction

In a limited number of cases, courts have temporarily halted "natural" lawsuits under the doctrine of primary jurisdiction. While both preemption and primary jurisdiction involve interaction between federal and state domains, "[t]he primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint *without prejudice pending the resolution of an issue within the special competence of an administrative agency.*"[55] In other words, "the doctrine is a 'prudential' one, rather than one that indicates that the court lacks jurisdiction."[56] Granting a stay under the primary jurisdiction doctrine only reflects a court's belief that a federal agency may want to resolve an issue currently before the court — it does not indicate that claims based on state law may not go forward due to federal preemption.

Courts examine four factors when determining if the doctrine of primary jurisdiction applies, including whether there is: "(1) a need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration."[57]

In consumer protection lawsuits relating to food labeling, defendants often argue that a case requires FDA's "expertise" to regulate the issues on which plaintiffs base their claims. However, many courts have held that these types of cases are "far less about science than [they are] about whether a label is misleading,"[58] and "allegations of deceptive labeling do not require the expertise of FDA to be resolved in the courts, as every day courts decide whether conduct is misleading."[59]

As one court noted, "the FDA has signaled a relative lack of interest in devoting its limited resources to what it evidently considers a minor issue, or in establishing some 'uniformity in administration' with regard to the use of 'natural' in food labels. Accordingly, any referral to the FDA would likely prove futile. Thus, the court finds little reason to stay or dismiss the case to allow the FDA the opportunity to take action, even if the other factors are present."[60] Ruling on the same defendant's second attempt to stall the case, the court noted that "Answering the questions of whether the food labeling in question is false or misleading, however, does not require the FDA's expertise . . . ."[61]

Nevertheless, a limited number of courts have stayed cases to allow FDA to weigh in.[62] To date, FDA has not taken a court up on such an invitation, [63] and this litigation tactic appears to be fading in popularity.

FDA's failure, or refusal, to develop a comprehensive definition of "natural" means that courts must decide what "natural" means to consumers on a case-by-case basis. Although courts are certainly capable of deciding whether a specific use of "natural" on a food label is deceptive,[64] it is a far better use of resources (of judges, FDA staff, companies, and consumers alike) to have a clear, uniform, national definition that would stop, or at least stem, the tide of deceptive natural claims and the resultant numbers of lawsuits based on those claims.

III. MAJOR ISSUES IN DISPUTE

A. Should FDA Define "Natural" at All?

FDA has said that because of the complexity of the issue, formal rulemaking would be necessary in order to develop a formal definition of "natural."[65] Although this type of administrative process may demand significant resources and time, the considerable and continued consumer deception inherent in the use of this word demands action.

For instance, the number of "natural" lawsuits illustrates that this is an issue of growing public interest.[66]

The many cases about whether consumers were deceived by products claiming to be "natural" have involved products that contained preservatives,[67] ingredients that have undergone chemical changes in manufacturing, ingredients that were more than minimally processed,[68] ingredients made from crops modified using genetic engineering (GMOs),[69] or a combination of these factors.[70]

The authors conclude (in keeping with the ideas of Professor Negowetti and Consumer Reports) that FDA action is essential, in order to conserve judicial resources and avoid prolonged consumer deception. Clearly, the judicial system is not the best venue to regulate use of the word "natural." However, until FDA or Congress acts, the judicial system will remain the only venue where consumers can address the various depredations of food companies eager to trap consumers into buying a food by labeling it "natural."

At least one federal agency has recognized the value of adopting policies to support a fairer marketplace. The FTC has told FDA that "a consistent and coherent federal policy on food marketing is also important to protect consumers, to avoid conflicting legal standards, and to help stimulate competition to improve products so consumers can improve their diets."[71]

B. How Should FDA Define "Natural"?

FDA has said that it is "difficult for science"[72] to determine what is "natural." FDA is correct—there is a quite a continuum of what *could* be considered "natural" and scientists may, and often do, disagree as to whether a particular ingredient or process is "natural," which does not help to advance the inquiry. A definition subject to significant scientific agreement may be difficult to come by and a definition comprehensible only by scientists is the wrong approach. This is because, consumers may, and often do, have a completely different expectation than that of scientists regarding what a product labeled "natural" *should* contain. According to a recent food labeling survey by the Consumer Reports National Research Center, many consumers feel that the "natural" label on packaged/processed foods *should* mean no pesticides were used (86%), no artificial ingredients were used (86%), no artificial materials were used during processing (87%), and no GMOs were used (85%).[73] Because FDA is tasked with ensuring that labels are not misleading to consumers, FDA must take these expectations into account. Of course, this still does not answer the question of what counts as an "artificial" material or ingredient and what makes GMOs or genetically engineered ingredients different from other types of seed modification. A closer look at the science reveals that it is not as clear-cut as consumers would like it to be.

This section will briefly consider a few ingredients and processes that exemplify the scientific difficulty FDA would face in determining when a product should be able to bear the term "natural," and also suggests how FDA should reconcile the incongruous science around what products and processes *could* be considered "natural" with consumer expectation of what products *may* be labeled "natural."

1. Case Study: High Fructose Corn Syrup

The ingredient **high fructose corn syrup** (HFCS) presents a paradigm of the problem that lies in allowing the food industry to decide when an ingredient, and the process used to create it, *may* be labeled "natural."

To many, HFCS sounds like it comes from corn in the same way sugar comes from sugar cane or sugar beets. In fact, on September 14, 2010, the Corn Refiners Association unsuccessfully petitioned FDA to change the name of HFCS to corn sugar because the organization felt that the name corn sugar more accurately reflected what HFCS is—sugar made from corn (according to the CRA).

The CRA claimed that HFCS and sugar are equivalent by every parameter of relevance to consumers (e.g., that they have approximately the same ratios of fructose and glucose and both are metabolized similarly in the body [something that is also out for scientific debate]).

FDA did not accept the CRA's position, and denied the petition on the grounds that the use of the term "corn sugar" for HFCS would suggest that HFCS is a solid, dried, and crystallized sweetener obtained simply and directly from corn. Instead, HFCS is an aqueous solution sweetener derived from corn after enzymatic hydrolysis of cornstarch, followed by enzymatic conversion of much of the glucose to fructose. Thus, the use of the term "sugar" to describe HFCS, a product that is a syrup, would not accurately identify or describe the basic nature of the food or its characterizing properties.[74]

Scientists from CSPI conclude that — because HFCS is produced by a complex industrial process performed in refineries using centrifuges, hydroclones, ion-exchange columns, backed-bed reactors and other high-tech equipment that ultimately results in a fundamental change in the chemical composition of cornstarch —HFCS cannot be considered "natural." CSPI scientists hold that while the glucose and fructose in HFCS may be identical to naturally occurring glucose and fructose, the fact that chemical bonds are broken and rearranged in their production militates heavily against calling HFCS "natural."

Not surprisingly, CRA scientists disagree and state, "It is accepted that products derived from natural materials are considered natural. The FDA has concluded that 'natural' flavors include those products derived from processes such as those used in corn refining. Corn syrup, high fructose corn syrup, and crystalline fructose are made from corn, a natural grain product, and are therefore consistent with the definition of natural."[75]

Other scientists, including at least one rogue FDA staffer, have taken the position that whether a man-made ingredient is natural depends on the exact nature of the complex process necessary to create it.[76] In the FDA instance, at the request of the CRA, one staff scientist chose to bypass the regulatory process completely and instead issue a letter that said the question of whether HFCS is "natural" depends not on the process itself (no matter how complicated it might be) but on the type of reagent used in the process. According to this one staff member, if the process uses a chemical, then the resulting HFCS is not natural, but if the process uses an enzyme then the resulting HFCS is natural.

A federal court of appeals rejected this staffer's approach, noting (as discussed above) that the "letter was not issued as part of any formal rulemaking or adjudication and was not subject to notice and comment. Additionally, FDA issued the letter in response to a question from interested parties, rather than doing so in an enforcement action."[77]

2. Plant Breeding Techniques

Ingredients created through various plant breeding techniques offer another example of the difficulty in determining what ingredients should be considered "natural" and the continuum that is created when one starts to consider what *could* be considered "natural" depending on various interpretations of the term.

Plant breeding can be defined as a "means of developing new plant varieties for cultivation and use by humans."[78] Plant breeding includes such various techniques as grafting, hybridization, mutagenesis, and genetic engineering. Plant breeding is a prime example of an area where there has been an evolution of technology that has stretched the scientific spectrum of what *could* be considered "natural" and where there is a stark divergence between science and what consumers think *should* be "natural." In fact, the vehement political and scientific disagreement surrounding certain plant breeding techniques will make FDA's mandate to define "natural" by reconciling science and consumer expectation quite difficult.

Humans have interfered with natural selection by saving seeds and selecting animals to mate for thousands of years. Throughout history farmers, and more recently scientists, have used a variety of techniques to selectively breed closely related plants to create hybrids, superior and novel traits, and more viable crops. Techniques such as grafting (physically joining together two plants to create one plant),[79] hybridization (cross-pollinating two different plant species to create a new plant), mutagenesis (treating seeds with radiation or chemicals to create mutations that result in new plant varieties), and genetic engineering (taking a segment of deoxyribonucleic acid (DNA) from one organism and splicing it into the same or another organism's preexisting DNA to directly select for a new variety)[80] represent a spectrum of human interventions with nature and thus create a spectrum of scientific and consumer interpretation of what could or should be considered "natural."

3. Irradiation

In addition to plant breeding techniques, irradiation of fruits, vegetables, meats, and other foods is another process that begs the question of what should be labeled "natural" and who should decide what products should be included in that definition. Food may be radiated for prevention of foodborne illness, preservation, insect control, delay of sprouting and ripening, and sterilization.[81] There are three sources of radiation approved for use on foods: gamma rays, X-rays, and electron beams.[82] While irradiating food may not be considered "natural," the food itself may remain essentially unaltered.

Although irradiation may have potentially positive public-health benefits, consumer advocacy organizations have repeatedly fought to ensure that irradiated foods are labeled, so that consumers can decide for themselves whether to buy and eat them. As CSPI has previously commented, "In a 1996 poll, *92 percent of consumers* surveyed said they wanted irradiated foods to be labeled. This was true even though respondents were told that irradiation may have some food safety benefits. Irradiation can affect the flavor and texture of food, and can reduce its nutritional value. Consumers have a right to be informed of these effects so that they can make informed choices in the marketplace."[83] CSPI and other consumer advocacy groups continue to oppose efforts to stop labeling foods as irradiated, in order to enable "consumers who are wary of irradiated foods to avoid them, but also allow consumers who want to buy irradiated food to choose to do so. In a 1999 poll commissioned by CSPI and the American Association of Retired Persons (AARP), 88.6 percent of respondents supported labeling of irradiated foods to indicate that they have been irradiated."[84]

Consumer advocacy groups' position on labeling of irradiated foods makes an important point: The debate on "natural" should not be a surrogate for a determination whether a food containing HFCS (or any other ingredient derived from the various processes discussed above) is safe — that is a separate issue.

Historically, FDA has held that when it is not aware of any information showing that foods derived from new methods differ from other foods in any meaningful or uniform way, those methods pose no risk to the consumer and should be treated as "substantially equivalent."[85]

The "substantial equivalence" test determines whether a food should be labeled or treated differently through regulation. However, this does address the concern of many consumers that their food be "natural" as they understand the word. Under the FDCA, a food is misbranded if "its labeling is false or misleading in any particular,"[86] including failure "to reveal facts material . . . with respect to consequences which may result from use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual."[87]

Therefore, in order to determine what products and processes should be included in a legal definition of "natural," FDA needs to consider not only substantial equivalence and the continuum of what scientists themselves consider "natural" but also what a reasonable consumer would consider "material" and would expect from products labeled with the word "natural."

Scientific or legal definitions may sometimes differ from colloquial definitions. However, consumers do not expect terms used in food advertising and labeling to have definitions that are different from what they understand the word to mean.[88] While this can be frustrating for scientists, it is a discrepancy that must be remedied in order to avoid consumer deception. Just as consumers should not be expected to turn over a product and read the ingredients on the back to confirm that representations on the front of the label are not lies,[89] consumers should not have to consult the C.F.R. to determine whether a word on a food label means what they commonly understand it to mean.

In order to avoid misleading labeling and general mistrust of government, FDA must reconcile consumer and scientific understandings of the term "natural." Thus, public debate — perhaps in the context of a rulemaking—is crucial. Acceptance of ingredients, processes, and technologies by consumers "ultimately relies on governing institutions listening and responding to the public, rather than discounting key stakeholders as irrational, scientifically illiterate, or technophobic."[90]

As with HFCS, there have been efforts to circumvent the difficult and often cumbersome regulatory rulemaking process with regard to "natural." In late 2013, the Grocery Manufacturers Association asked FDA to define "natural" claims, but also advised that it planned to file a petition in early 2014 asking FDA to declare that foods with ingredients from genetically engineered crops could be called "natural."[91] Just as the court ruled with regard to the rogue staffer and HFCS, it would be disingenuous for FDA to act at the unilateral request of the industry, without considering the opinions of consumers, scientists, and other stakeholders. Circumventing the process of public debate would only create more division. As key stakeholders, consumers have a right to information, education, and participation.

In short, in order to prevent consumer deception, FDA should solicit consumer understanding of the word "natural" by conducting surveys and requesting comment. Whether products containing ingredients derived from chemical or enzymatic processes, plant breeding techniques such as grafting or genetic engineering, or ingredients that have been subject to irradiation may be labeled as "natural" is a question that can be informed by science but must also consider consumer perceptions and understanding so as not to disenfranchise the public or create mistrust of agency-regulated labeling. Because FDA is required by the FDCA to prevent misleading labeling, it should consider consumer understanding of the word "natural" as well as scientific information.

A definition informed by both science and consumer understanding and expectation would help prevent deception as well as fulfill FDA's mandate to prevent the misbranding of foods.

C. How Should This Issue Proceed and Who Should Have a Say In the Process?

The authors believe that the only proper way to arrive at a useful definition of "natural" is to consider both science and consumer perceptions. Neither should be ignored. Although FDA will have to draw lines between scientific opinions on "natural" techniques and processes, approaching labeling from the consumer perspective would have several benefits. First, it would define "natural" in terms of the ultimate audience. Second, it would avoid the specter of dueling scientists. Third, importantly, it also would take judges and lawyers out of the equation.

The question of how to define "natural" on a product label must be determined by examining the processes by which an ingredient or product came to the shelf, where that product or process falls on the scientific continuum of things that could be considered "natural," and finally, how that compares to the consumer who has an expectation of what a product labeled with the term "natural" will or won't have in it. While not perfect, these three categories are most likely to address the belief of the average consumer.

Our reasons for suggesting these three categories are: (1) USDA uses the "minimally processed" concept and, while we believe it needs to go further, it is a foundation for stakeholders to build on; (2) FDA, as discussed above, has expressed its own belief that a product with a natural preservative cannot be called natural; and (3) there are many stratifications of techniques and processes that could be interpreted as "natural."

The reasons for the first two prongs are self-evident, and the reason for the third prong is that it recognizes the difference between outright falsity and deception. Consumers are neither scientists nor lawyers, and should not be held to those standards. Consumers may make mistakes when it comes to nutrition science. But that does not permit companies to take advantage of that fact. Companies construct their advertising based on the probable consumer take-away, not on the technical meaning of a word, including consumer misunderstanding of terms, the science behind them, or the technicality of regulatory language.

Take, in another context, the term "made with whole grain." Strictly speaking, if a bread has any amount of whole grain, then it is in fact *made with whole grains*. However, the term can still be deceptive. For example, Sara Lee sold a bread with the mouthful of a name "Soft & Smooth Made With Whole Grain White Bread." In truth, this bread was only 30% whole grain. The Dietary Guidelines for Americans 2010 is to "make half your grains whole."[92] The statement "Made with whole grain" suggests to consumers that the product will impart the health benefits advocated by the Guidelines and that consumers are seeking from a whole grain product. Any consumer wanting to follow that advice by eating this product is doomed to failure — effectively taking one step forward and two steps back. Therefore, although the statement is literally true, it is also significantly deceptive.[93]

Thus, any effort at defining "natural" must examine the science *and* consider consumer perceptions in order to make sure that the perceived benefits of buying a product with a certain term or label is received.

Because FDA has been historically, and very clearly, hesitant (really, unwilling) to proceed with a rulemaking to develop a comprehensive definition of "natural" on its own and because this issue must not be allowed to wither on the vine, one viable choice would be for the various interested parties to come together with the goal of arriving at an agreed-upon definition of natural that could be proffered to FDA as a negotiated rule.

The concept of negotiated rulemaking is embodied in the Administrative Procedures Act.[94] A USDA publication summarizes the general process well:

> Negotiated rulemaking is a consensus-based process through which an agency develops a proposed rule by using a neutral facilitator and a balanced negotiating committee composed of representatives of all interests that the rule will affect, including the rulemaking agency itself. This process gives everyone with a stake a chance to try to reach agreement about the main features of a rule before the agency proposes it in final form.
>
> - The goal of the committee is to reach consensus understood to mean that each interest concurs in the result, unless all members of the committee agree at the outset to a different meaning.
> - Each member agrees to negotiate in good faith.
> - The agency sponsoring the negotiated rulemaking commits, consistent with its legal obligations, to use a consensus agreement from the committee as the basis for, if not the actual text of, a proposed rule.[95]

However, in the case of defining "natural," the authors propose shifting the initial burden from FDA to the interested parties themselves.

The question then becomes, who are these interested parties of whom we speak? It goes without saying that all sides should be represented, but to be more forthcoming, the authors identify at least seven types of stakeholders to come to the table. (This list is not exhaustive in naming possible parties; instead, the specific entities are named for illustrative purposes only.)

1. **Consumer advocacy groups**, such as CSPI, Consumers Union, National Consumers League, and Consumer Federation of America.
2. **Food companies**, such as General Mills, Kraft, PepsiCo, and Kellogg, and Whole Foods.
3. **Industry trade groups**, such as the Grocery Manufacturers Association, the Association of National Advertisers, and the American Association of Advertising Agencies.
4. **Academics** from scientific, legal, business, linguistics, and other disciplines.
5. **Health professional organizations,** such as the Academy for Nutrition and Dietetics, American Heart Association, and Institute of Food Technologists.
6. **State Attorneys General.**
7. **Interested federal agencies**, including FDA, USDA, and FTC.

The important thing is to balance the viewpoints and include all interested parties, as long as they enter into the process with the declared willingness to negotiate in a good faith effort to reach a consensus.

IV. IMPACT OF POLICY RECOMMENDATIONS: HOW WILL THINGS CHANGE?

The motivating factor for the authors' willingness to spend the time on this article is our shared belief that it is a desirable end to have a definition of "natural" that would be meaningful to harried consumers as they pushed their carts through grocery aisles (or the virtual aisles of online stores).

From the industry perspective, the benefit would be twofold. First, for companies making "natural" claims about products that are undeniably natural, capitalism could work — they could compete based on their products and not lose sales to competitors who choose to compete through deception.

Second, for those companies who have gotten sued over "natural" claims, they could save the millions of dollars spent to litigate and settle the lawsuits and focus on selling their products, with a clear guideline for how to market natural products.

V. CONCLUSION

For all these reasons, it is clear that the current approach to controlling marketplace deceptions — hundreds of lawsuits — represents a marketplace inefficiency. Thus, it is incumbent on FDA to work with all interested parties to develop a definition of "natural" that is scientifically sound and that incorporates consumer understandings and knowledge of the word. This could best be achieved by convening all interested parties in an effort to reach consensus, but if that cannot happen in the near term, then FDA must meet its mandate by acting to define the word and put a halt to significant deception of consumers and a tolerance of unfair competition by food companies that take customers from their competitors through those very deceptions.

ENDNOTES

1. Karlene Lukovitz, *"Natural" Claims Most Common on New F&B Products*, MediaPostnews (Jan. 19, 2009), *available at* www.mediapost.com/publications/article/98562/#axzz2YsPn6CWO.

2. Tom Pirovano, Director of Industry Insights, *U.S. Healthy Eating Trends Part 1 Commitment Trumps the Economic Pinch*, Nielsen (Jan. 26, 2010), *available at* www.nielsen.com/us/en/newswire/2010/healthy-eating-trends-pt-1-commitment-trumps-the-economic-pinch.html; *see also "Natural" Beats "Organic" in Food Sales According to Nielsen's Healthy Eating Report*, Nielsen Wire, Jan. 21, 2009, *available at* www.nielsen.com/us/en/newswire/2009/%C3%A2%C2%80%C2%9Cnatural%C3%A2%C2%80%C2%9D-beats-%C3%A2%C2%80%C2%9Corganic%C3%A2%C2%80%C2%9D-in-food-sales-according-to-nielsen%C3%A2%C2%80%C2%99s-healthy-eating-report.html.

3. FDA stands by its informal (and binding only on itself) 1993 guidance that "the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances." Food & Drug Admin. website, Transparency, FDA Basics, www.fda.gov/aboutfda/transparency/basics/ucm214868.htm (last visited July 29, 2014). FDA is merely saying what it will tolerate in the exercise of enforcement discretion. This informal position has had no apparent effect on the burgeoning number of "natural" claims in recent years.

4. *See* 7 C.F.R. § 205.1 *et seq*.

5. National Consumers League, Naturally Misleading: Consumers' Understanding of "Natural" and "Plant-Derived" Labeling Claims 4, *available at* www.nclnet.org/images/PDF/naturalsreport.pdf.

6. National Consumers League, Naturally Misleading: Consumers' Understanding of "Natural" and "Plant-Derived" Labeling Claims 4, *available at* www.nclnet.org/images/PDF/naturalsreport.pdf.

7. Deborah Pike Olsen, *Say No to "Natural" on Food Labels*, ConsumerReports.org, (June 16, 2014), *available at* www.consumerreports.org/cro/news/2014/06/say-no-to-natural-on-food-labels/index.htm.

8. "When I use a word," Humpty Dumpty said, in a rather scornful tone, "it means just what I choose it to mean - neither more nor less." L. Carroll, Through the Looking Glass.

9. Hartman Group, Organic and Natural 2012 Report.

10. Dan Charles, *'Natural' Food Sounds Good But Doesn't Mean Much*, NPR (June 24, 2014), *available at* www.npr.org/blogs/thesalt/2014/06/24/325189610/natural-food-sounds-good-but-doesnt-mean-much.

11. United States Dep't of Agriculture, Food Standards and Labeling Policy Book (Aug. 2005) at 116.

12. USDA website, Food Safety & Inspection Serv., Regulatory Compliance, Labeling Policies, www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Labeling-Policies (last visited July 30, 2014).

13. *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 251 (3d Cir. 2008) (citing 21 U.S.C. §§ 341, 346 (2006)).

14. Pub. L. 101-535.

15. Most likely because "natural" deception had not become the runaway train it now is.

16. 58 Fed. Reg. 2407 (Jan. 6, 1993); Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2,302, 2,397 (Jan. 6, 1993).

17. Elaine Watson, *POLL Results: We Need a Clearer Definition of Natural... and the FDA Should Come Up With It*, FoodNavigator-USA.com (Nov. 7 2011), *available at* www.foodnavigator-usa.com/Regulation/POLL-results-We-need-a-clearer-definition-of-natural-and-the-FDA-should-come-up-with-it.

18. Press Release, Sugar Ass'n, *Sugar Association Disappointed in FDA's Decision Not to Define "Natural"* (Jan. 7, 2008) (The Sugar Association petition to FDA showed that 83% of the 1,000 consumers surveyed said that the government should provide regulations to food manufacturers when making "natural" claims.).

19. Sugar Ass'n Petition to FDA, Citizen Petition re Definition of the term "natural" for making claims on foods and beverages regulated by the Food and Drug Administration, Docket No. 2006P-0094 (Feb. 28, 2006) *available for download at* www.regulations.gov; CSPI Petition to FDA, Petition re: Definition of the term "Natural" for making claims on foods and beverages regulated by the Food and Drug Administration, Docket No. 2006P-0094 (Mar. 13, 2006) *available for download at* www.regulations.gov.

20. *E.g.,* Letter from Linda M. Katz, Director, Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition, to Joseph Kravec re: *Astiana v. Hain Celestial Group, Inc.*, No. C 11-6342 PJH (N.D. Cal. Nov. 19, 2012); Letter from Michael M. Landa, FDA Acting Director, Center for Food Safety and Applied Nutrition, to the Honorable Jerome B. Simandle re: *Coyle v. Hornell Brewing Co., Inc.*, Sept. 16, 2010.

21. 39 Fed. Reg. 39,842 (proposed Nov. 11, 1974); 40 Fed. Reg. 23,086-23,087 (proposed May 28, 1975).

22. Termination of Proposed Trade Regulations; Rule of Food Advertising, 48 Fed. Reg. 23, 270.

23. Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421, 60266 (Nov. 27, 1991) (emphasis added).

24. 58 Fed. Reg. at 2407.

25. Food Labeling: Nutrient Content Claims, General Principles Petitions, Definition of Terms, 56 Fed. Reg. at 60466.

26. 21 C.F.R. § 10.85(d), (e), (j) (1996).

27. 21 C.F.R. § 101.22; Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Foods, 58 Fed. Reg. 2302 (Jan. 6, 1993).

28. 21 C.F.R. § 101.22(a)(1).

29. 21 C.F.R. § 101.22(a)(3).

30. 21 C.F.R. § 101.22(a)(4).

31. United States Dep't of Agriculture, Food Standards and Labeling Policy Book (Aug. 2005) at 116.

32. FDA, USDA, NOAA Statements on Food Safety (2011), *available at* www.fda.gov/newsevents/publichealthfocus/ucm248257.htm

33. Food & Drug Administration, Dockets, Docket No. 2006P-0094, *available for download at* www.regulations.gov.

34. Food & Drug Administration, Dockets, Docket No. 2006P-0094, *available for download at* www.regulations.gov.

35. Food & Drug Administration, Dockets, Docket No. 2006P-0094, *available for download at* www.regulations.gov.

36. Letter from Robert G. Reinhard, Director of Food Safety/Regulatory for the Sarah Lee Corporation to FDA (Apr. 9, 2007), *available at* www.fda.gov/ohrms/dockets/dockets/07p0147/07p-0147-cp00001-02-vol1.pdf.

37. Food & Drug Administration, Dockets, Docket No. 2006P-0094, *available for download at* www.regulations.gov/#!documentDetail;D=FDA-2010-P-0491-0001.

38. Take Action website, Stop Confusing Consumers: Ban the 'Natural' Label, https://takeaction.takepart.com/actions/stop-confusing-consumers-ban-the-natural-label (last visited July 30, 2014).

39. Against the observation that the Consumer Reports approach throws the baby out with the bathwater, the authors note that the magnitude of the fraud, compared to the very limited instances of honest "natural" claims would mean that a total ban would be, at most, throwing out a couple of the baby's fingernails with a swimming pool amount of bathwater.

40. Nicole E. Negowetti, *Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority,* www.brookings.edu/~/media/research/files/papers/2014/06/26-food-labeling-litigation/negowetti_food-labeling-litigation.pdf.

41. Lorrain Heller, *HFCS Is Not "Natural," Says FDA*, FoodNavigator USA (Apr. 2, 2008), *available at* www.foodnavigator-usa.com/Suppliers2/HFCS-is-not-natural-says-FDA.

42. Letter from Geraldine A. June, Supervisor of the Product Evaluation and Labeling Team, Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, to Audrae Erickson, President of the Corn Refiners Association (July 3, 2008), *available at* www.corn.org/wp-content/uploads/2008/07/FDAdecision7-7-08.pdf (last visited Apr. 23, 2014).

43. "The letter was not issued as part of any formal rulemaking or adjudication and was not subject to notice and comment. Additionally, the FDA issued the letter in response to a question from interested parties, rather than doing so in an enforcement action" *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 342 (3d Cir. 2009).

44. *See* FDA Warning Letter to Fresh Made Inc., Oct. 16, 2007, *available at* www.fda.gov/iceci/enforcementactions/warningletters/2007/ucm076542.htm (stating that the company's cheese products are misbranded because some products contained turmeric and annatto, which are natural colors. "Although turmeric, annatto, and other color additives not subject to certification need not be declared by name, 21 CFR 101.22(k)(2) requires that they be declared as, e.g., 'artificial color' or 'color added".

45. *E.g.*, FDA Warning Letter to Alexia Foods Potatoes and Mushrooms, Nov. 16, 2011, *available at* www.fda.gov/iceci/enforcementactions/warningletters/2011/ucm281118.htm (stating that "FDA considers the use of the term "natural" on a food label to be truthful and non-misleading when 'nothing artificial or synthetic . . . has been included in, or has been added to, a food that would not normally be expected to be in the food."); FDA Warning Letter to Bagels Forever, Inc., July 22, 2011, *available at* www.fda.gov/iceci/enforcementactions/warningletters/2011/ucm265756.htm.

46. *See* FDA Warning Letter to Fresh Made Inc., Oct. 16, 2007, *available at* www.fda.gov/iceci/enforcementactions/warningletters/2007/ucm076542.htm (stating that the company's cheese products are misbranded because some products contained turmeric and annatto, which are natural colors. "Although turmeric, annatto, and other color additives not subject to certification need not be declared by name, 21 CFR 101.22(k)(2) requires that they be declared as, e.g., 'artificial color' or 'color added'".

47. *See* FDA Warning Letter to Fresh Made Inc., Oct. 16, 2007, *available at* www.fda.gov/iceci/enforcementactions/warningletters/2007/ucm076542.htm (stating that the company's cheese products are misbranded because some products contained turmeric and annatto, which are natural colors. "Although turmeric, annatto, and other color additives not subject to certification need not be declared by name, 21 CFR 101.22(k)(2) requires that they be declared as, e.g., 'artificial color' or 'color added'".

48. U.S. Const. Art. VI, cl. 2. *See, e.g.*, *Fidelity Fed. Sav. & Loan Ass'n v. De la Cuesta*, 458 U.S. 141, 152-153 (1982).

49. *Fidelity Fed. Sav. & Loan Ass'n v. De la Cuesta*, 458 U.S. 141, 153 (1982).

50. *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1030 (N.D. Cal. 2009) (citing *Nat'l Council for Improved Health v. Shalala*, 122 F.3d 878, 880 (10th Cir. 1997) (quoting H.R. Rep. No. 101-538, at 7) (1990)).

51. 21 U.S.C. § 343-1(a) ("preemption section").

52. FDA website, What We Do, History, Significant Dates in U.S. Food and Drug Law History, www.fda.gov/aboutfda/whatwedo/history/milestones/ucm128305.htm (last visited July 8, 2013).

53. *See, e.g.*, *Jones v. ConAgra Foods, Inc.*, 912 F. Supp. 2d 889 (N.D. Cal. 2012) (denying motion to stay under the primary jurisdiction doctrine); *Krzykwa v. Campbell Soup Co.*, No. 12-cv-62058-WPD (denying motion to stay under the primary jurisdiction doctrine); *Janney v. General Mills*, 944 F. Supp. 2d 806 (N.D. Cal. 2013) (holding that primary jurisdiction doctrine did not require that FDA, rather than the court, determine the issue of whether the products were natural). *But see Van Atta v. General Mills, Inc.*, No. 12-cv-02815-MSK-MJW (D. Colo. July 18, 2013) (granting stay under the doctrine of primary jurisdiction for FDA to define natural).

54. *E.g.*, *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 340 (3d Cir. 2009); *Jones v. ConAgra Foods, Inc.*, 912 F. Supp. 2d 889 (N.D. Cal. 2012).

55. *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008) (emphasis added).

56. *Id.* at 1115.

57. *Delacruz v. Cytosport, Inc.*, C 11-3532 CW, 2012 WL 2563857 (N.D. Cal. June 28, 2012) (internal citations omitted).

58. *Jones v. ConAgra Foods, Inc.*, C 12-01633 CRB, 2012 WL 6569393 (N.D. Cal. Dec. 17, 2012).

59. *Id.* citing *Syntek Semiconductor,* 307 F.3d 775, 781; *Lockwood v. Conagra Foods, Inc.,* 597 F.Supp.2d 1028, 1035 (N.D. Cal. 2009); *Reid v. Johnson & Johnson,* No. 11CV1310 L BLM, 2012 WL 4108114, at *11 (S.D. Cal. Sept.18, 2012); *Delacruz v. Cytosport*, No. 11-3532, 2012 WL 2563857, at *10 (N.D. Cal. June 28, 2012).

60. *Janney v. General Mills*, 944 F. Supp. 2d 806, 815 (N.D. Cal. 2013).

61. *Janney v. General Mills*, Case No. 3:12-cv-03919-WHO (N.D. CA, October 10, 2013).

62. *E.g.*, *Cox v. Gruma Corp.*, No. 12-CV-6502 YGR, 2013 WL 3828800 (N.D. Cal. July 11, 2013); *Van Atta v. General Mills, Inc.*, No. 12-cv-02815-MSK-MJW (D. Colo. July 18, 2013); *Astiana v. Hain Celestial Group, Inc.*, 905 F. Supp. 2d 1013 (N.D. Cal. 2012); *Coyle v. Hornell Brewing Co., Inc.*, No. 08-2797 (JBS-JS), 2010 WL 2539386 (N.D. Cal. Sept. 22, 2011).

63. *See, e.g.,* Letter from Michael M. Landa, FDA Acting Director, Center for Food Safety and Applied Nutrition, to the Honorable Jerome B. Simandle re: *Coyle v. Hornell Brewing Co., Inc.*, Sept. 16, 2010; *Coyle v. Hornell Brewing Co., Inc.*, Civ. No. 08-2797(JBS), Order Lifting Stay (Doc. 119) (Sept. 23, 2010).

64. *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d, 1111, 1124 (N.D. Cal. 2010) (Plaintiffs advanced a "relatively straightforward claim: they assert that defendant has violated FDA regulations and marketed a product that could mislead a reasonable consumer. This is a question courts are well-equipped to handle.").

65. Letter from Linda M. Katz, Director, Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition, to Joseph Kravec re: *Astiana v. Hain Celestial Group, Inc.*, No. C 11-6342 PJH (N.D. Cal. Nov. 19, 2012).

66. Asby Jones, "Is Your Dinner 'All Natural?'" The Wall Street Journal, Sept. 20, 2011; Elaine Watson, "PopChips agrees $2.4m 'all-natural' lawsuit settlement; settlements also likely in Kashi and Bear Naked cases," FoodNavigator-USA (Feb. 26, 2014), www.foodnavigator-usa.com/Regulation/PopChips-agrees-2.4m-all-natural-lawsuit-settlement-settlements-also-likely-in-Kashi-and-Bear-Naked-cases.

67. *Colucci v. ZonePerfect Nutrition Co.*, (non-natural ingredients ascorbic acid, calcium pantothenate, calcium phosphates, glycerine, potassium carbonate, etc.); *Brazil v. Dole Food, Inc.*, 935 F. Supp. 2d 947 (N.D. Cal. 2013).

68. *E.g.*, *Astiana v. Dreyer's Grand Ice Cream, Inc.*, No. C-11-2910 EMC, 2012 WL 2990766 (N.D. Cal. July 20, 2012) (non-natural due to alkalizing agent); *Holk v. Snapple Beverage Corp.*, 575 F.3d 329 (3d Cir. 2009) (HFCS); *Lockwood v. ConAgra Foods, Inc.*, 597 F. Supp. 2d 1028 (N.D. Cal. 2009) (pasta sauce containing HFCS); *Janney v. General Mills, Inc.*, No. 12-cv-3919-WHO (N.D. Cal. 2013).

69. *In re ConAgra Foods, Inc.*, No. CV-11-05379, 2013 WL 4259476 (C.D. Cal. Aug. 12, 2013) (Wesson cooking oils containing GMOs); *Krzykwa v. Campbell Soup Co.*, No. 12-cv-62058, 2013 WL 2319330 (S.D. Fla. May 28, 2013); *In re Frito-Lay North America, Inc. All Natural Litig.*, 908 F. Supp. 2d 1379 (E.D.N.Y. 2013); *Parker v. J.M. Smucker Co.*, No. C 12-0690 SC, 2013 WL 4516156 (N.D. Cal. Aug. 13, 2013) (Crisco oils containing GMOs); *Cox v. Gruma Corp.*, No. 12-cv-6502-Y GR, 2013 3828800 (N.D. Cal. July 11, 2013).

70. *Anderson v. Jamba Juice Co.*, 888 F. Supp. 2d 1000 (N.D. Cal. 2012) (smoothie kits containing non-natural ascorbic acid, steviol glycosides, xanthan gum, citric acid).

71. Press Release, Federal Trade Commission, *FTC Chairman Steiger Discusses Food Advertising: Announces Staff Comments to FDA on Proposed Food Label Regs, in Remarks Before Advertising Agencies* (Feb. 25, 1992), *available for download at* www.fda.gov/ohrms/dockets/dockets/07p0147/07p-0147-cp00001-toc.htm. The FTC did not expressly address "natural" claims. In 1992, "natural" claims had not yet become the pox on consumer rights they now are.

72. FDA Basics, *What is the Meaning of "Natural" on the Label of Food?*, www.fda.gov/aboutfda/transparency/basics/ucm214868.htm (last visited Feb. 12, 2014) ("From a food science perspective, it is difficult to define a food product that is 'natural.'").

73. Consumer Reports National Research Center National Survey Report Food Labels Survey 2014 Nationally-Representative Phone Survey.

74. FDA Response to Petition from Corn Refiners Association to Authorize "Corn Sugar" as an Alternate Common or Usual Name for High Fructose Corn Syrup (HFCS) (May 30, 2012) *available at* www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/ucm305226.htm.

75. Corn Refiners Association *Position Statements* www.corn.org/wp-content/uploads/2009/12/CornSweetenerNatural.pdf (last visited June 23, 2014).

76. Lorrain Heller, *HFCS Is Not "Natural," Says FDA*, FoodNavigator USA (Apr. 2, 2008), *available at* www.foodnavigator-usa.com/Suppliers2/HFCS-is-not-natural-says-FDA.

77. *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 342 (3d Cir. 2009).

78. F.J. Novak et al., *Plant Breeding: Induced Mutation Technology for Crop Improvement*, 4 Int'l Atomic Energy Agency Bulletin 25 (1992).

79. There are a number of different types of grafts, including cleft grafting, bark grafting, side-veneer grafting, splice grafting, whip and tongue grafting, saddle grafting, bridge grafting,

and inarch grafting. See North Carolina State University, Grafting and Budding Nursery Crop Plants, for a detailed illustration of each process. *Available at* www.ces.ncsu.edu/depts/hort/hil/grafting.html.

80. David Alan Nauheim, *Food Labeling and the Consumer's Right to Know: Give the People What They Want*, 4 Liberty U.L. Rev. 97, 102 (2009).

81. FDA, Food Facts, Food Irradiation: What you Need to Know (June 2011), *available at* www.fda.gov/downloads/Food/IngredientsPackagingLabeling/UCM262295.pdf (last visited May 7, 2014).

82. FDA, Food Facts, Food Irradiation: What you Need to Know (June 2011), *available at* www.fda.gov/downloads/Food/IngredientsPackagingLabeling/UCM262295.pdf (last visited May 7, 2014).

83. CSPI Reports, Oppose Weakening the Labeling Requirements for Irradiated Food, www.cspinet.org/reports/irrad-fs.htm (last visited July 30, 2014).

84. CSPI Letter to U.S. Dep't of Agriculture Re: Request for Comment on Irradiation as a Processing Aid (Oct. 8, 2008), *available at* http://cspinet.org/new/pdf/fsis_e-beam_irradiation__oct_2008.pdf.

85. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984-01 (May 29, 1992) (Notice by Food & Drug Administration, HHS).

86. FDCA § 403(a)(1).

87. FDCA § 201(n).

88. A recently published law review article suggesting that GMO ingredients be considered "natural" asserted that — while the author's recommendation to include GMO ingredients in a "legal" definition of "natural" was based neither on factual scientific evidence or consumer expectation — "there is often a difference between a lay definition and a legal definition, and 'natural' is no different."

89. *Williams v. Gerber Products Co.*, 552 F.3d 934 (2008) ("We disagree with the district court that reasonable consumers should be expected to look beyond misleading representations on the front of the box to discover the truth from the ingredient list in small print on the side of the box.").

90. Brian Dick et al., *Atomic Gardens: Public Perceptions and Public Policy*, Life Science Foundation Magazine (Spring 2012) www.lifesciencesfoundation.org/magazine-Atomic_Gardens.html#sthash.U6AznygC.dpuf (last visited May 7, 2014).

91. Jenny Hopkinson, "GMA urges FDA action on 'natural' labels—Farm bill principals to meet this morning," Politico (Dec. 13, 2013), www.politico.com/morningagriculture/1213/

morningagriculture12488.html. As of the date of this article, this promised action by GMA has not materialized.

92. U.S. Dep't of Agriculture, U.S. Dep't of Health & Human Services, Dietary Guidelines for Americans 2010, at xi, 30, 34, 36, *available at* www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm.

93. CSPI's Litigation Project obtained a settlement wherein Sara Lee agreed to disclose clearly that the product only had 30% whole grains. http://cspinet.org/new/pdf/sara_lee_settlement-letter-072108.pdf.

94. 5 U.S.C. § 565.

95. What is Negotiated Rulemaking? *Available at* www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089434 (last visited Sept. 23, 2014).

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