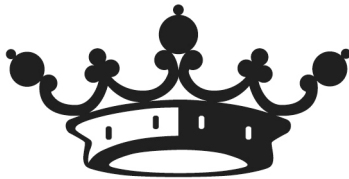


I N S I D E   T H E   M I N D S

# Recent Developments in Food and Drug Law

*Leading Lawyers on Dealing with Increased  
Enforcement, Keeping Up-To-Date with FDA  
Requirements, and Developing Compliance Practices*

2013 EDITION



ASPATORE

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# Food Claims Litigation: Seller Beware

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## Introduction

Within the last several years, the food industry has increasingly become one of the leading targets for class action lawyers. Arguably, the flash point can be traced back to a humble “probiotic” bacterium—*Bifidobacterium lactis* DN-173 010—found in Dannon’s Activia line of yogurts. While Dannon had clinical studies supporting its position and a well-developed marketing program, in 2010 the company found itself agreeing to pay nearly \$45 million to settle claims that it had misled consumers with claims made in connection with the Activia line of products. The Dannon case was certainly not the first case in which a food company found itself defending its marketing claims, but it was arguably the first “big score” for the plaintiffs’ bar.

As this chapter was being prepared, *The New York Times*<sup>1</sup> published an article profiling a number of lawyers who made millions suing the tobacco industry. The article cites twenty-five cases filed by a dozen plaintiffs’ lawyers against some of the largest companies in the food industry. As it and other segments of mass media are beginning to recognize and discuss, the new reality for the food industry is that the Food and Drug Administration (FDA), the US Department of Agriculture’s (USDA’s) Food Safety and Inspection Services (FSIS), and the Federal Trade Commission (FTC) may no longer be the biggest compliance concern—class action litigation has arrived.

A number of factors have led to this point. Significant consideration must be given to changing attitudes and consumer approaches toward food. Consumers are not looking just for food that is affordable and tastes good; rather, the fastest areas of growth in the food industry are products with “enhanced” claims, whether through production (organic, etc.), formulation (addition of omega-3s), or ingredient composition (high-fructose corn syrup). Industry, appropriately and unavoidably, has worked to produce the products its customers want. However, in the process,

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<sup>1</sup> Stephanie Strom, *Lawyers from Suits against Big Tobacco Target Food Makers*, N.Y. TIMES, Aug. 18, 2012, [www.nytimes.com/2012/08/19/business/lawyers-of-big-tobacco-lawsuits-take-aim-at-food-industry.html?\\_r=1](http://www.nytimes.com/2012/08/19/business/lawyers-of-big-tobacco-lawsuits-take-aim-at-food-industry.html?_r=1).

selling a product such as yogurt is no longer as straightforward a proposition as it once might have been.

## The Nature of Natural

There are a number of cases dating back half a dozen or more years, generally involving claims about a product's "naturalness." The "natural" product category was (and remains) a soft target for the plaintiffs' bar, and has provided a wealth of opportunities to explore a new plaintiffs industry.

"Natural" is an amorphous term that has never been defined in regulation by the FDA, the FSIS, or the FTC. Various agencies have attempted to clearly define "natural" over the last twenty years. In the mid-1970s, the FTC proposed to define "natural" foods as "those with no artificial ingredients and only minimal processing." The FTC abandoned this effort in 1983, noting that it would still scrutinize "natural" claims on a case-by-case basis. Ironically, however, the FSIS issued a policy memo on the use of the term "natural" with respect to meat and poultry in 1982 (*see* Appendix D for FSIS Policy Memo 55),<sup>2</sup> largely based on the abandoned FTC definition, which effectively remains the only written "natural" policy for the food industry.<sup>3</sup> Similarly, the FDA attempted to define the term "natural" in 1989; however, it formally abandoned this effort in 1993.<sup>4 5</sup> In the same *Federal Register* notice, the FDA stated that it would "maintain its policy regarding the use of the term 'natural' as meaning that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, an ingredient that would not normally be expected in food."<sup>6</sup>

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<sup>2</sup> USDA, food standards and labeling policy book (2005), [http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling\\_Policy\\_Book\\_082005.pdf](http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf).

<sup>3</sup> In late 2006, citing a need to update and formalize this policy, the FSIS published a notice and request for public comment. The initiative is still pending. 71 Fed. Reg. 70,503 (Dec. 5, 2006) *available at* <http://www.gpo.gov/fdsys/pkg/FR-2006-12-05/pdf/E6-20555.pdf>.

<sup>4</sup> Food Labeling, 54 Fed. Reg. 32,610 (Aug. 8, 1989).

<sup>5</sup> Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302 (Jan. 6, 1993).

<sup>6</sup> *Id* at 2407.

Accordingly, unlike the term “organic,” which has been defined in the Organic Foods Production Act<sup>7</sup> and its implementing regulations, use of the term “natural” on foodstuffs is subject to loose guidelines and industry colloquialisms, such as the “Grandma’s Kitchen Rule” (i.e., could Grandma have made the food product in her kitchen? If so, its processing procedures probably qualify as natural). Thus, the use of the term is subject to consumer expectations and understanding. This has resulted in lawsuits over the use of the term “natural” in beverages containing high-fructose corn syrup (Snapple), farm-raised salmon that have had food coloring added to them, and the packaging of chicken with salted water.

### **The New Media and Why Twitter Matters**

Celebrity chef Jamie Oliver recently launched a campaign designed, in his view, to make lunch in classrooms across America more healthful. During one of his television appearances, he demonstrated how a product known as lean, finely textured beef was processed.<sup>8</sup> However, his demonstration was accurate only in the same sense that the movie *Abraham Lincoln: Vampire Hunter* was based on historical figures. Nonetheless, a YouTube clip of the show went viral, and after a false start or two, every “mommy blog” in the country was incensed that anyone could feed what Mr. Oliver described as “something not fit for human consumption” to their children.

The Oliver episode, which ultimately resulted in the loss of more than 700 jobs, highlights the relationship between modern communication techniques and the current trend in food-related litigation. The plaintiffs’ bar has developed a much more sophisticated approach, using the same techniques applied in many fields. Networks of websites and blogs on topics such as food safety and labeling create a groundswell of consumer interest, with posts and articles on potential industry targets. For instance, a series of articles on the pollen content of honey inaccurately and

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<sup>7</sup> Organic Foods Production Act (OFPA) of 1990, 7 U.S.C. § 6501 (West 2012).

<sup>8</sup> Lean, finely textured beef was quickly branded as “pink slime” by the blogosphere and media, complete with pictures of a product that was not, in fact, lean, finely textured beef. See Philip M. Boffey, *What If It Weren’t Called Pink Slime?*, N.Y. TIMES, May 12, 2012, <http://www.nytimes.com/2012/05/13/opinion/sunday/what-if-it-werent-called-pink-slime.html>.

misleadingly argued that honey with pollen removed is no longer “honey,” and that the removal of pollen is basically an industry conspiracy to mix imported honey of lesser quality into the American food supply. Of course, pollen increases crystallization in honey, producing a cloudy product that is not preferred by consumers. The website reporting on the honey issue is operated by a plaintiff’s firm specializing in food litigation. The articles were eventually picked up by a host of local and national media outlets, vastly expanding the number of potential plaintiffs.

Similarly, an Internet report on transglutaminase (derisively referred to in the press as “meat glue”), which requires a label declaration when used with meat products, was a recent high-profile example of a blog story that went national. In the case of transglutaminase, an enzyme that has been approved for use by FSIS with mandatory labeling requirements<sup>9</sup> was being improperly used by some restaurants to make fake filet mignons by bonding lower-quality pieces of meat. The story quickly went national, complete with interviews of plaintiffs’ lawyers calling this the next Jamie Oliver/pink slime incident. Of course, the manufacturer was operating in full compliance with the law, as was the meat industry by properly declaring the use of transglutaminase on the labels of products produced in FSIS-inspected plants. However, the emphasis of the multitudes of blog posts was not that a few rogue restaurants were using a legal (and useful) product to commit fraud, but rather that the “food industry” was pulling the wool over consumers’ eyes.

The enhanced ability to produce “news,” combined with the explosive speed at which a story moves once it has gone viral, has created a potent new source of litigants. Add in the factor of consumer interest in having healthful, natural, low-calorie/-fat/-sodium, yet delicious, foods that are, of course, safe, environmentally friendly, etc., and we begin to test the limits of food science (and science fiction). It is these evolving consumer

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<sup>9</sup> The FSIS published a direct final rule in 2001 (66 Fed. Reg. 54,912 (Oct. 31, 2001) available at <http://www.gpo.gov/fdsys/pkg/FR-2001-10-31/pdf/01-27264.pdf>) providing conditions under which the transglutaminase enzyme, which the FDA had previously found to be generally recognized as safe, could be used in meat products. The rule, which stated FSIS’s conclusion that transglutaminase was effective in improving the texture by the increasing elasticity and improving cooking yields, set a limit of 65 parts per million (ppm) on the use level and created labeling requirements for any FSIS-inspected product processed with transglutaminase.

expectations, combined with a general lack of understanding of food science, that ultimately set up the basis for food claims litigation. Of course, firms that allow marketing to get ahead of science bear responsibility for this trend as well.

## **The Next Wave of Litigation**

The Dannon case was indicative of a new wave of food claims litigation focusing on health and wellness claims that has been gaining a great deal of traction in the consumer market. While the FTC had pursued a number of companies over the years for various weight loss related claims, as have a number of state attorneys general, private suits of this nature were rare. While the Federal Food, Drug, and Cosmetic Act (FDCA)<sup>10</sup> deems a food product misbranded if its labeling is “false or misleading in any particular,” there is no private right of action under the FDCA. Most complaints regarding labeling claims on food products were previously disputed between companies, via self-regulatory forums such as the Better Business Bureau’s National Advertising Division<sup>11</sup> or via a Lanham Act<sup>12</sup> unfair competition suit.

However, the plaintiffs’ bar soon recognized that the host of state law based consumer protection statutes and business practices laws provided a mechanism to bring claims alleging misleading advertising and labeling claims on food products. Combined with the incomplete preemption afforded food labeling under the FDCA,<sup>13</sup> the landscape for litigation was primed.

It bears notice that the food industry experienced a similar phenomenon more than two decades ago. At that time, nutrition-oriented claims such as “lite,” “lean,” and “low-fat” were proliferating, with limited federal oversight. Into the breach stepped several offices of state attorneys general, who achieved a number of successful verdicts. In response, the

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<sup>10</sup> Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. §301 (West 2012).

<sup>11</sup> Information about the BBB’s NAD, is *available at* <http://www.bbb.org/us/national-advertising-division/>.

<sup>12</sup> Lanham Act, 15 U.S.C. §§1051-1150 (2012).

<sup>13</sup> By statute, preemption is more specific and complete regarding the labeling of meat and poultry products regulated by the FSIS (21 U.S.C. §§ 467(e), 678 (West 2012)).



food industry, led by its largest companies, essentially sued for peace at the federal level. The ultimate result was the Nutrition Labeling and Education Act of 1990.<sup>14</sup> Its implementing regulation mandated the disclosure of the nutrient composite of most prepackaged foods in a prescribed format and established definitions for many nutrient-related claims. In exchange, the industry obtained national standards within this space, effectively cutting off state and local challenges.

At this point, virtually any qualitative feature of a food product must be considered fair game for claims litigation, whether or not a claim is made. Recently, for example, Starbucks was challenged with a class action alleging unfair competition, false advertising, unjust enrichment, fraud, and violation of California's Consumers Legal Remedies Act<sup>15</sup> for not disclosing that it used cochineal extract to color some of its strawberry beverages. Cochineal extract is made from beetles. In fact, cochineal extract is an approved food-coloring ingredient, used for decades in hundreds of food products in the United States. Ironically, for a class of consumers demanding products with "natural" ingredients, cochineal extract fills the bill extremely well.

The Starbucks case<sup>16</sup> points to a number of factors that are unique to restaurants that as a group are not subject to the same labeling rules as packaged consumer foods. The FDCA and the Federal Trade Commission Act (FTCA)<sup>17</sup> have long considered "material" omissions as bases for misbranding. However, the food industry must actively consider when a product that has been labeled in full compliance with the FDCA may still be subject to attack under state law based causes of action. While a product that declares "cochineal extract" on its ingredient list is in compliance with the FDCA in terms of providing the common and usual name of the ingredient, might it still be subject to scrutiny for not using the term "beetle" (juice!) three times on the label?

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<sup>14</sup> Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990).

<sup>15</sup> Consumers Legal Remedies Act, Ca. Civ. Code § 1750 (2009). (This act was held to be preempted by the FDCA by the decision in *Perez v. Nidek Co. Ltd.*, 657 F Supp 2d 1156 (C.D. Cal. 2009).

<sup>16</sup> *Anderson v. Starbucks Corp., et al.*, No. 2:2012-cv-06558 (C.D. Cal. July 30, 2012).

<sup>17</sup> Federal Trade Commission Act, 15 U.S.C. §§ 41-58, as amended (2012).

In another instance, while the case was dismissed and remains mostly a reference for derision, the Cap'n Crunch's Crunch Berries<sup>18</sup> case suggests that common sense does not act as a barrier to claims litigation. In that case, PepsiCo was sued for false advertising because the "Crunch Berries" in its cereal do not contain real fruit. However, a similar approach attacking the content (or lack thereof) of a particular ingredient or product attribute certainly presents an opportunity for allegations with an ability to survive a motion to dismiss.

## California Dreamin'

California has become the hotbed of food claims litigation. In addition to creating consumer protection and business practices laws well suited for these types of claims, California is the home of Proposition 65<sup>19,20</sup> and (potentially) the new home of Prop 37<sup>21</sup> (discussed below). While Prop 65 is well known, if not loved, and has been implemented for more than twenty-five years, there appears to be a significant uptick in Prop 65 "bounty hunter" suits aimed at packaged consumer foods for failing to make Prop 65 declarations.

However, Prop 37 is arguably much more troubling and problematic for the food industry. Prop 37, with some limited exceptions, would require declarations on the labels of raw agricultural commodities, as well as processed foods that "may contain" genetically engineered ingredients. Without delving too deeply into the science, this technology has been found

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<sup>18</sup> *Sugawara v. Pepsico Inc.*, No. 2:08-cv-01355, 2009 WL 1439115 at \*1 (E.D. Cal. May 21, 2009).

<sup>19</sup> Safe Drinking Water and Toxic Enforcement Act of 1986, ch. 6.6 Cal. Health & Saf. Code 25249.7 (West 2012).

<sup>20</sup> In November 1986, California voters overwhelmingly approved an initiative to address concerns about human exposures to chemicals in the environment. That initiative, the Safe Drinking Water and Toxic Enforcement Act of 1986, has more commonly been referred to as "Proposition 65." Prop 65 requires the governor of California to publish a list of chemicals "known to the State [of California] to cause cancer or reproductive toxicity." *Id.* The list includes a wide range of chemicals, including dyes, solvents, pesticides, drugs, food additives, and by-products from certain processes, and is updated annually. These chemicals may be naturally occurring or manmade. Some are ingredients of common products, while others are used in specific industrial applications. The law allows private litigants to bring claims on behalf of the state, and a legal industry quickly developed to do just that.

<sup>21</sup> Proposition 37, Mandatory Labeling of Genetically Engineered Food, Cal. Ballot Initiative (Nov.2012).

safe by the FDA, and a review of the scientific literature does not uncover any serious concern in the scientific community (compared to the long-standing use of chemical mutagenesis in the seed industry, which is also safe but falls outside of the recombinant technology domain and has managed to avoid the bad PR that genetic engineering has faced). Yet, under Prop 37, manufacturers will be subject to a potential barrage of litigation over a technology that produces safe foods.

While arguments can be made under “consumer right to know” theories, at what point does a firm’s obligation to explain microbiology and biochemistry to the average consumer cease? In addition to consumers’ often misinformed understanding of food ingredients, firms are responsible for ensuring that the food they produce is safe from food-borne illness and contaminants. The passage of the Food Safety Modernization Act (FSMA)<sup>22</sup> will impose significant requirements in regard to the manufacturing of food, including the need for documented control of potential food safety hazards. These interventions can come in the form of ingredients—such as preservatives—or new and novel technologies—such as bacteriophages used to reduce listeria on vegetables and poultry—or high-pressure pasteurization, which literally squeezes microbiological contaminants to death without adding any ingredients/preservatives to a food product.

## **A New Approach**

For the last thirty-plus years, the food industry, as well as its lawyers, has largely focused on labeling in the context of the FDCA and the FTCA. Compliance, first and foremost, focused on ensuring that products were labeled in accordance with the FDA’s regulations, and that marketing materials complied with the FTC’s laws regarding false advertising.

The food industry must reexamine its approach to labeling and marketing in light of this new wave of claims litigation. Firms must reconsider how they communicate with consumers as part of this process. With the advent of new media, consumers have come to expect a level of transparency and “conversational” communication with the companies from which they buy

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<sup>22</sup> FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011).

products. This new “enlightened” consumer must be considered when labeling and marketing campaigns are being contemplated.

It behooves the food industry to look back at its product lines and markets with a fresh perspective; namely, “If I did not know anything about food science, safety, or regulation, are there any statements present on (or absent from) my product labels that could mislead me?” Obviously, this is a fairly extreme starting point, but the evidence suggests that it is warranted. The next question firms should be asking is, “Is there anything on our label that, while fully compliant with FDA requirements, might be considered obfuscation by an unsophisticated consumer?”

Second, a general review of product labeling and marketing for compliance with the FDCA, FTCA, and Federal Meat Inspection Act (FMIA)/Poultry Products Inspection Act (PPIA)<sup>23</sup> should be undertaken. While newer products tend to bear more of the “enhanced” claims discussed above, less obvious claims (for example, cane/corn sugar--type claims on products) that have been in the market for extended periods can carry greater liability due to the extended time for sales to consumers.

Mass food claims litigation can still be considered a fairly young body of law. Accordingly, it will be important to closely monitor the progress (or lack thereof) of recent cases in this area to further identify the areas of legal exposure. There remain a number of issues that will need to be addressed by the courts—including the possibility that the FDCA’s preemption of food labeling may be further refined in the coming years, although the likelihood of this is quite remote.

## **Conclusion**

As this discussion indicates, today’s food industry is on a collision course with an increasingly energetic plaintiffs’ bar. Through its collective marketing efforts, the food industry continues to respond to consumer signals by relying heavily on the use of terms such as “natural” that elude precise definition. But it is this imprecision that, in at least some circumstances, may allow a given litigant to successfully maintain that the issue as to whether such a claim is or is not misleading is best left for

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<sup>23</sup> Federal Meat Inspection Act of 1906, 21 U.S.C.A. §§ 601-95 (West 2012); *Poultry Products Inspection Act* of 1957 (as amended), 21 U.S.C.A. §§ 451-72 (West 2012).

evaluation by a jury. And, as distinct from past controversies involving nutrition-related claims, no meaningful relief at the federal level can reasonably be anticipated. As a consequence, companies that are not inclined to “roll the dice” in this fashion first need to become fully aware of this new reality. Second, they need to evaluate the relevant risks intelligently, obtain the right types of internal and external support, and develop an effective plan to reduce them to an acceptable level. Third, firms must adapt to the interactive and high-speed nature of social media and decentralized blog news to be able to respond and present their messages to their customers.

## **Key Takeaways**

- Advise food industry clients to reexamine their approaches to labeling and marketing in light of the new wave of claims litigation. Firms must reconsider how they communicate with consumers, and whether anything on their product labels might be considered obfuscation by an unsophisticated consumer. A risk/benefit approach is useful here. Companies need to carefully assess both the practical utility of the claim and the related potential exposure.
- Substantiation efforts, with related documentation for claims that companies ultimately choose to make, need to be enhanced significantly. For claims that are inherently subjective or subject to different interpretations, this may be easier said than done, but this reality should not preclude the effort. For claims based on clinical data, it is critical that the strength of the data is assessed and disclaimed appropriately. It is even more important that liberties are not taken in the translation of clinical findings into marketing and label claims.
- Review your clients’ product labeling and marketing strategies for compliance with the FDCA, FTCA, and FMIA/PPIA.
- Closely monitor both recent and future cases in this area to further identify areas of legal exposure for your clients.
- Closely monitor blogs and other social media to see what issues are being driven by the plaintiffs’ bar and other key actors.

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Mr. Pavel also assists clients with novel food and color additive petitions, food packaging and labeling, Food Contact Notifications and secondary food additives (packaging, processing aids), food safety compliance, hazard analysis and critical control points (HACCPs), sanitation standard operating procedures (SSOPs), good manufacturing practices (GMPs), and generally recognized as safe (GRAS) self-affirmations and notifications. Additional areas of his work include the National Organic Program, recall and market withdrawal strategies, import detentions, seizures, and alleged food tampering.

Mr. Pavel is a past chair of the Institute of Food Technologists Food Laws and Regulations Division. During his undergraduate and legal studies, he worked for a food HACCP consulting business.

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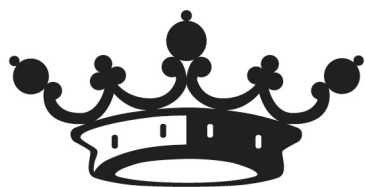
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