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UNITED STATES FOOD LAW UPDATE: THE FDA FOOD SAFETY MODERNIZATION ACT, OBESITY AND DECEPTIVE LABELING ENFORCEMENT

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The long-awaited enactment of the FDA Food Safety Modernization Act (FSMA),[1] the most significant amendment to the Federal Food, Drug, and Cosmetic Act in several decades, provides the Food and Drug Administration (FDA) with significantly enhanced jurisdiction to close some of the gaps in the domestic food safety system. The enhanced FDA authority, however, will have little impact on the shared governance system at the federal level that involves multiple agencies, as the Act does not address the U.S. General Accounting Office's (GAO) repeated calls for consolidation of the fragmented federal food safety system.[2] Rather, the Act perpetuates the division

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1. Pub. L. No. 111-353, 124 Stat. 3885 (2011). In addition to introducing Senate Bill 510, the Senate version of the Food Safety Modernization Act, Senator Durbin introduced S.654, the Safety Food Act of 2007, in the 110th Congress; S.729, the Safe Food Act of 2005, and S.1534, the Safe and Secure Food Act of 2005 in the 109th Congress; S.2910, the Safe Food Act of 2004, in the 108th Congress; S.1501, the Safe Food Act of 2001, in the 107th Congress; S.1281, the Safe Food Act of 1999, in the 106th Congress; and S.1465, the Safe Food Act of 1997, in the 105th Congress.

2. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-212, FOOD SAFETY: EXPERIENCES OF SEVEN COUNTRIES IN CONSOLIDATING THEIR FOOD SAFETY SYSTEMS 24-25 (2005), *available at* http://www.gao.gov/new.items/d05212.pdf; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-794, FOOD SAFETY: SELECTED COUNTRIES' SYSTEMS CAN OFFER INSIGHTS INTO ENSURING IMPORT SAFETY AND RESPONDING TO FOODBORNE ILLNESS 2 (2008) *available at* http://gao.gov/new/items/d087941.pdf.

of authority between the FDA and the U.S. Department of Agriculture (USDA), as well as the potential for jurisdictional gaps, overlaps and inefficiencies.[3] Part I of this article explores not only the FSMA, but a second piece of federal legislation, the Healthy, Hunger-Free Kids Act of 2010,[4] which *inter alia* provides support for serving locally grown food in the school lunch program. Part II provides a brief update on three ongoing food law issues: the *Pelman v. McDonald's Corp.*[5] obesity litigation and associated local initiatives directed at the fast food restaurant industry, legal challenges to the raw almond pasteurization rule, and an update on the FDA's review of genetically engineered salmon. Part III explores in greater depth a series of public and private enforcement actions directed toward allegedly deceptive labeling.

As in previous editions of this update, necessity dictates that not every legal development is included; rather, the authors limit their analysis to significant changes within the broader context of food production, distribution and retail. The intent behind this series of updates is to provide a starting point for scholars, practitioners, food scientists, and policy-makers devoted to understanding the shaping of food law in modern society. Tracing the development of food law through these updates also builds an important historical context for the overall progression of the discipline and prompts further scholarship on many of these emerging issues.

I. FEDERAL LEGISLATION

A. FDA Food Safety Modernization Act

The FSMA,[6] perhaps the most significant food safety legislation since the 1938 passage of the Federal Food, Drug, and Cosmetic Act (FFDCA), will close some of the gaps in the existing food safety system, while preserving the historical regulatory divide between FDA and USDA for meat and other animal-based products.[7] As described

3. *See generally* Timothy M. Hammonds, *It is Time to Designate a Single Food Safety Agency*, 59 FOOD & DRUG L.J. 427 (2004) (noting inefficiencies and gaps in the current system).

4. Pub. L. No. 111-296, 124 Stat. 3183 (2010).

5. 272 F.R.D. 82 (S.D.N.Y. 2010).

6. Pub. L. No. 111-353, 124 Stat. 3885 (2011).

7. The USDA is responsible for the regulation of meat, poultry and egg products via the 1906 Meat Inspection Act, Pub. L. No. 59-382, 34 Stat. 674 (1906) (current version at 21 U.S.C. § 601 (2006)), the 1957 Poultry Products Inspection Act, Pub. L. No. 85-172, 71 Stat. 441 (1957) (codified at 21 U.S.C. § 451 et. seq.), and

below, this landmark legislation includes several key additions/revisions to the existing food safety framework.

The USDA, with very limited exceptions,[8] has exercised exclusive jurisdiction over farm-level production. The FSMA, however, gives the FDA the ability to mandate food safety measures at the farm level for fruit and vegetable production[9] –an area previously outside FDA's jurisdiction. Specifically, § 105 of the bill directs the FDA, by way of formal rulemaking, to "establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death."[10]

Second, the bill gives the FDA the authority to create a system of hazard analysis and risk-based prevention controls in all food processing facilities–a safety system previously limited to shellfish, juice and low-acid canned foods.[11] Hazard Analysis and Critical Control Points (HACCP), a "prevention-based food-safety system designed to prevent, reduce to acceptable levels, or eliminate the microbial, chemical, and physical hazards associated with food production,"[12] is a proactive approach to food safety long advocated by food safety experts.[13] HACCP places responsibility on the food pro-

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the 1970 Egg Products Inspection Act, Pub. L. No. 91-597, 84 Stat. 1620 (1970) (codified at 21 U.S.C. § 1031 et. seq.), respectively, while the FDA is responsible for most other food products under the Federal Food, Drug, and Cosmetic Act.

8. *See* Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation, 74 Fed. Reg. 33,029 (July 9, 2009) (codified at 21 C.F.R. pt. 118) (regulating shell production); *About the Center for Veterinary Medicine*, FDA.GOV, http://www.fda.gov/AboutFDA/CentersOffices/CVM/default.htm (last visited Apr. 1, 2011) (describing role of the Center for Veterinary Medicine with respect to food additives and drugs administered to farmed animals).

9. Food Safety Modernization Act, Pub. L. No. 111-353, § 105, 124 Stat. 3885, 3889-3905 (2011) (to be codified at 21 U.S.C. § 419).

10. 124 Stat. at 3899-3900 (to be codified at 21 U.S.C. § 419(a)(1)(A)).

11. § 103, 124 Stat. at 3899 (to be codified at 21 U.S.C. § 418).

12. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF FRESH-CUT FRUITS AND VEGETABLES (2008), *available at* http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/produceandplanproducts/ucm064458.htm [hereinafter FDA FRESH-CUT PRODUCE GUIDE].

13. *See* Neal D. Fortin, *The Hang Up With HACCP: The Resistance to Translating Food Science into Food Safety Law*, 58 FOOD DRUG L.J. 565, 566 (2003) (outlining HACCP's seven principles and noting that the goal of HACCP is to "prevent food safety problems before they happen"); James Chyau, *Casting a Global Safety Net–A*

ducer to identify critical points in the production process that are susceptible to contamination and implement a written plan to control the identified risks effectively.[14] To that end, § 103 of the FSMA requires food processing, packing, and holding facilities to identify "known or reasonably foreseeable hazards" associated with the facility, including natural toxins (such as *Salmonella* and *E. coli*),[15] implement preventative controls, including at critical control points, to significantly minimize or prevent the identified hazards,[16] and take corrective actions if the preventative controls are found to be ineffective.[17]

Third, the FSMA beefs up the FDA's ability to regulate and inspect the means by which food is introduced into interstate commerce. Specifically, the Act provides authorization for FDA officials to inspect and copy all operational records relating to any article of food that the agency "reasonably believes..will cause serious adverse health consequences or death to humans or animals" from all facilities in the supply chain (with the exception of farms and restaurants).[18] Notwithstanding the previous limitation, during an active investigation of a foodborne illness outbreak, in coordination with state and local food safety agencies, the FDA may request farms to identify potential immediate recipients of any food subject to the investigation.[19] Within the context of a food safety investigation, the FDA now has mandatory recall authority based on a "reasonable probability" that a food is adulterated or misbranded and the exposure or use "will cause serious adverse health consequences" to humans or animals.[20]

In addition to inspection procedures and recall authority, the FSMA authorizes the FDA to develop regulations for the safe transportation of food,[21] thereby encompassing the complete post-farmgate supply chain (with the rather large exception of meat, poultry and egg products falling under exclusive USDA jurisdiction) within the FFDCA.

Framework for Food Safety in the Age of Globalization, 64 FOOD & DRUG L.J. 313, 323 (2009).

14. *See* Fortin, *supra* note 13, at 566.
15. § 103, 124 Stat. at 3889-90 (to be codified at 21 U.S.C. § 418(a)-(b)).
16. § 103, 124 Stat. at 3890 (to be codified at 21 U.S.C. § 418(c)).
17. § 103, 124 Stat. at 3890 (to be codified at 21 U.S.C. § 418(e)).
18. § 101, 124 Stat. at 3886 (to be codified at 21 U.S.C. § 350(c)(a)(2)).
19. § 204(f), 124 Stat. at 3936.
20. § 206, 124 Stat. at 3940 (to be codified at 21 U.S.C. § 423).
21. § 111, 124 Stat. at 3916 (directing development of regulations to implement 21 U.S.C. § 416(b)).

Congress also included a few specific "carve-outs" in the FSMA to protect certain industries—the most notable being the small farm and direct marketing exemption. After intense lobbying by small farm and local food advocates,[22] the Senate passed the Tester-Hagan Amendment to the original bill as a compromise to minimize the financial impact of compliance with many of the new statute's provisions. Specifically, Congress exempted small farms (less than $500,000 in total sales) engaged in direct-farm marketing (so long as 50% of total farm sales were in direct sales to consumers or restaurants in the same state or within a 275-mile radius).[23] Congress also included a similar exemption for these entities from the HACCP requirements.[24]

Finally, § 204 of the FSMA directs the Secretary of Health and Human Services to coordinate with the food industry to develop pilot programs to explore methods to more rapidly and effectively identify foodborne illness outbreaks.[25] The pilot projects must include at least three different types of foods that in the last five years have been subject to significant outbreaks.[26] Likely candidates, based on past history of highly publicized foodborne illness outbreaks, include shell eggs and leafy greens.[27]

B. The Healthy, Hunger-Free Kids Act of 2010

In December 2010, President Obama signed into law a child-nutrition bill that provides for healthier food choices at public schools.[28] In general, the Healthy, Hunger-Free Kids Act of 2010 is aimed at reducing childhood obesity by increasing the nutritional

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22. *See* Bonnie Azab Powell, *Tester Amendment Protecting Local Food Production Now Attached to Food-Safety Bill*, THE GRIST (Nov. 18, 2010) *available at* http://www.grist.org/article/fod-2010-11-18-Tester-amendment-protects-local-food.

23. § 105, 124 Stat. at 3903-04 (to be codified at 21 U.S.C. § 419(f) (Exemption for Direct Farm Marketing)).

24. § 103, 124 Stat. at 3892-93 (to be codified at 21 U.S.C. § 418(l) (Modified Requirements for Qualified Facilities)).

25. § 204, 124 Stat. at 3930.

26. § 204, 124 Stat. at 3930.

27. *See* A. Bryan Endres & Nicholas R. Johnson, *Integrating Stakeholder Roles in Food Production, Marketing, and Safety Systems: An Evolving Multi-Jurisdictional Approach*, 26 J. ENVT'L L. & LITIG. (forthcoming 2011) (discussing recent contamination events involving shell eggs and leafy greens).

28. Healthy, Hunger-Free Kids Act of 2010, Pub. L. No. 111-296, 124 Stat. 3183 (2010); Robert Pear, *Child Nutrition Bill Clears Congress*, N.Y. TIMES, Dec. 2, 2010, http://www.nytimes.com/2010/12/03/us/politics/03child.html?scp=1&sq=child%20nutrition%20bill&st=cse.

quality of all foods sold in public schools, including cafeterias and vending machines. To that end, the bill directs the Secretary of Agriculture to update the meal patterns and nutritional standards for the national school lunch program based on recommendations made by the Food and Nutrition Board of the National Research Council of the National Academy of Sciences.[29] Second, it directs each local educational agency participating in the national school lunch program to establish a local school wellness policy that includes "goals for nutrition promotion and education, physical activity, and other school-based activities that promote student wellness."[30] Third, it requires the Secretary to establish national, science-based nutrition standards for all foods sold in schools outside the school meal programs, including those sold in vending machines.[31] Fourth, it requires the Secretary to establish an organic-food pilot program that provides competitive grants to school food authorities in order to improve the nutritional value of school meals.[32]

Finally, the bill contains provisions to improve access to "local foods" in schools. Specifically, current law allows the USDA to offer schools grants for local-foods initiatives, such as buying locally sourced food for cafeterias or establishing school gardens. The 2010 nutrition bill enhances current law: First, it gives the Secretary criteria to use in awarding grants, with priority to schools that make local food available for school lunches.[33] Second, the bill provides five million dollars annually for grants, beginning in 2012.[34] The bill does not define "local food," though it directs the Secretary to consider "regional balance" in awarding grants, including the "equitable treatment of urban, rural, and tribal communities."[35] Accordingly, the 2010 nutrition bill has the potential to benefit children by providing healthier lunches and encouraging the development of local food networks to stimulate economic growth in the community.

In sum, the last half of 2010 represented an unusually active time for federal legislation relating to the food supply. Although the FSMA did not accomplish the complete reform of the food safety system that many hoped for, it did provide significantly enhanced jurisdiction to the FDA to accomplish its increasingly com-

29. § 201, 124 Stat. at 3214.
30. § 204(a), 124 Stat at 3216.
31. § 208, 124 Stat. at 3221-22.
32. § 210, 124 Stat. at 3223.
33. § 243, 124 Stat. at 3236-37.
34. § 243, 124 Stat. at 3238.
35. § 243, 124 Stat. at 3236-37.

plex mission of protecting the nation's multi-sector food supply while offering key exemptions for entrepreneurial, small-scale, direct farm businesses. Likewise, the attention on healthier school lunches, potentially fortified with locally sourced produce, provides another opportunity to develop functioning food networks and support local economies–potential bright spots in an otherwise recessionary economy.

II. OBESITY, ALMONDS & SALMON: THREE LONG-RUNNING FOOD-LAW DISPUTES

A. Obesity Litigation and Local Initiatives Challenging the Fast-Food Industry

Obesity continues to plague the American public. As the incidence of childhood obesity reaches epidemic rates, lifespans for children may be less than their parents.[36] Recognizing this problem, President Obama established a Task Force on Childhood Obesity.[37] Seeking a comprehensive solution to the obesity crisis, the Task Force issued a report outlining strategies to improve nutritious food in schools, ensure access to healthy food at home, and increase physical activity.[38] In addition to the policy changes highlighted by the Task Force, the threat of tort liability from actions such as *Pelman v. McDonald's Corp.*, and restrictive zoning or other regulations on the fast food industry, may provide complementary incentives to change the supply-side of the obesity equation. The following sections discuss recent events in the *Pelman* obesity litigation and local efforts in California targeted at the fast food industry.

1. Obesity Litigation: Pelman v. McDonald's Corp.

In late October, McDonald's was handed a victory by a New York federal district court, which ruled that a long-running obesity suit against the company, *Pelman v. McDonald's Corp.*, could not pro-

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36. Presidential Memorandum, Establishing a Task Force on Childhood Obesity (Feb. 9, 2010), *available at* http://www.whitehouse.gov/the-press-office/presidential-memorandum-establishing-a-task-force-childhood-obesity.

37. *Id.*

38. WHITE HOUSE TASK FORCE ON CHILDHOOD OBESITY, REPORT TO THE PRESIDENT: SOLVING THE PROBLEM OF CHILDHOOD OBESITY WITHIN A GENERATION (May 2010), *available at* http://www.letsmove.gov/pdf/TaskForce_on_Childhood_Obesity_May2010_FullReport.pdf.

ceed as a class action.[39] In *Pelman*, a group of parents, on behalf of their minor children, claimed that McDonald's, in violation of New York law, engaged in a pattern of deceptive advertising throughout the 1980s and 1990s—including misleading nutritional claims in various media and print outlets—that led the plaintiffs to believe that McDonald's food was "healthy, nutritious ... and/or ... easily part of anyone's healthy daily diet, each and/or all claims being in contradiction to medically and nutritionally established guidelines."[40] The plaintiffs claimed that, as a result of reliance upon the deceptive advertising, they suffered adverse health effects, including obesity, elevated cholesterol levels, increased risk of coronary heart disease, pediatric diabetes, and high blood pressure.[41] The plaintiffs sought to certify a class action under Rule 23(b)(3) of the Federal Rules of Civil Procedure, which allows class certification if questions of law or fact common to the class members predominate over questions that affect only individual members of the class.[42]

The court denied certification, finding that individual issues predominated on three questions central to the litigation: (1) Is there a causal connection between a person's consumption of foods of a certain nutritional makeup and certain health conditions such as obesity? (2) Was McDonald's the primary source of these types of products for each particular plaintiff? (3) Did each plaintiff rely upon McDonald's misrepresentations about its foods when deciding to eat there?[43] Each one of those questions, ruled the court, involved highly particularized inquiries into the eating habits and health of each plaintiff, and the case could therefore not proceed as a class action.[44] The case, originally filed in 2002,[45] continues to move forward as an individual action.

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39. Pelman v. McDonald's Corp., 272 F.R.D. 82, 85 (S.D.N.Y. 2010).

40. *Id.* at 84, 88.

41. *Id.* at 88.

42. *Id.* at 91.

43. *Id.* at 93-95.

44. *Pelman*, 272 F.R.D. at 93 (" '[B]ecause there are so many factors that contribute to obesity and to obesity related illnesses, it is improper to generalize and make assumptions as to causation in any individual.' "); *id.* at 95 (" 'A person's choice to eat at McDonald's and what foods (and how much) he eats may depend on taste, past experience, habit, convenience, location, peer choices, other non-nutritional advertising, and cost' . . . and although '[b]eliefs about nutrition may influence a person's decision in some cases, [it will] not always [be the case].' ").

45. Pelman v. McDonald's Corp., 237 F.Supp.2d 512, 519 (S.D.N.Y. 2003).

2. Local Initiatives to Limit Fast Food Consumption

In addition to the *Pelman* suit, McDonald's and its fast-food brethren have been a popular target of recent legislative efforts aimed at curbing obesity.[46] The last few months have provided little relief. In November, the San Francisco Board of Supervisors overrode a mayoral veto to move forward with its much-publicized prohibition on the inclusion of toys in children's meals that contain unhealthy levels of calories, salt, or fat.[47] A putative class action suit against McDonald's soon followed in San Francisco Superior Court, alleging that the company has engaged in deceptive and unfair marketing practices by using Happy Meal toys as "bait" to stimulate demand for unhealthy food choices.[48]

Things aren't much better for fast-food outlets 400 miles to the south, where the Los Angeles City Council voted in January to permanently ban the construction of any new fast-food restaurants in South Los Angeles, a part of the city that has considerably higher rates of obesity and poverty than other L.A. neighborhoods.[49] The ordinance defines a "fast food restaurant" as "[a]ny establishment which dispenses food for consumption on or off the premises, and which has the following characteristics: a limited menu, items prepared in advance or prepared or heated quickly, no table orders, and food served in disposable wrapping or containers,"[50] but it does not apply to sit-down restaurants that sell equally fatty fare. The City Council estimates that the thirty-square-mile area covered by the moratorium already has nearly 1,000 fast-food restaurants, and that 30% of its residents are obese–twice the rate of wealthier sub-

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46. *See, e.g.*, Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 4205 124 Stat. 119, 573 (2011) (codified at 21 U.S.C. § 343(q)(5)(H) (2006)) (called into question on constitutional grounds by Florida *ex rel.* Bondi v. U.S. Dep't of Health and Human Serv., 2011 WL 723117 (N.D. Fla. Mar. 3, 2011)); Rules of the City of New York, tit. 24 § 81.08 (2007) (banning sale of food containing trans fats in restaurants), *available at* http://24.97.137.100/nyc/rcny/title24_81_08.asp.

47. Michael Martinez, *San Francisco Overrides Mayoral Veto, Bans Happy Meals With Toys*, CNN.COM (Nov. 23, 2010), http://articles.cnn.com/2010-11-23/us/california.happy.meals.ban_1_offer-toys-free-toys-veto?_s=PM:US.

48. Amended Class Action Complaint, Parham v. McDonald's Corp., No. CGC-10-506178 (Cal. Super. Ct., San Francisco County Dec. 15, 2010).

49. Jennifer Medina, *In South Los Angeles, New Fast Food Spots Get a 'No, Thanks'*, N.Y. TIMES, Jan. 16, 2011, http://www.nytimes.com/2011/01/16/us/16fastfood.html.

50. Los Angeles City Ordinance No. 180103 (Jul. 11, 2008), *available at* http://clkrep.lacity.org/onlinedocs/2007/07-1658_ord_180103.pdf.

urbs.[51] The Council hopes that the ban will encourage "more sit-down restaurants, produce-filled grocery stores, and takeout meals that center on salad rather than fries."[52] The Los Angeles restrictions are an example of the increasing use of local zoning and other regulatory powers to restrict access to fast food in the name of obesity prevention.[53] As initial empirical studies seem to confirm the link between proximity to fast food restaurants and obesity, more localities may adopt these restrictive measures.[54]

B. Raw Almond Litigation: Challenging the Pasteurization Rule

As first discussed in the spring 2009 edition of the *U.S. Food Law Update*,[55] the USDA, at the behest of the Almond Board of California (Almond Board), instituted a pasteurization requirement for raw almonds produced in the United States–but not imported almonds.[56] The rule mandates the pasteurization of domestically-produced raw almonds with either a steam or chemical treatment.[57] The underlying motivation behind this rule was to preclude the series of *Salmonella* outbreaks in unprocessed, raw almonds that had been plaguing the industry.[58] But rather than saving the industry, the rule has "largely eliminated the domestic raw almond market [but] had no impact on foreign almond producers, who are not sub-

51. Medina, *supra* note 48.

52. *Id.*

53. *See* Paul A. Diller & Samantha Graff, *Regulating Food Retail for Obesity Prevention: How Far can Cities Go*, 39 J.L. MED. & ETHICS 89 (2011); Montrece McNeill Ransom et al., *Pursuing Health Equity: Zoning Codes and Public Health*, 39 J.L. MED. & ETHICS 94 (2011); Allyson C. Spacht, Note, *The Zoning Diet: Using Restrictive Zoning to Shrink American Waistlines*, 85 NOTRE DAME L. REV. 391 (2009).

54. *See* Janet Currie, et al., *The Effect of Fast Food Restaurants on Obesity and Weight Gain*, 2 AM. ECON. J.: ECON. POL'Y 34 (2010); Brennan Davis & Christopher Carpenter, *Proximity of Fast-Food Restaurants to Schools and Adolescent Obesity*, 99 AM. J. PUB. HEALTH 505 (2009); Richard A. Dunn, *Obesity and the Availability of Fast Food: An Institutional Variables Approach* (Mar. 31, 2008), *available at* http://ssrn.com/abstract=989363.

55. A. Bryan Endres, *United States Food Law Update: Pasteurized Almonds and Country of Origin Labeling*, 5 J. FOOD L. & POL'Y 111, 119-21 (2009).

56. Almonds Grown in California; Outgoing Quality Control Requirements, 72 Fed. Reg. 15,021 (Mar. 30, 2007) (codified at 7 C.F.R. § 981.442(b) (2010)). *See also* Koretoff v. Vilsack, 614 F.3d 532, 535 (D.C. Cir. 2010) (noting that the rule exempts imported almonds).

57. 72 Fed. Reg. at 15,022.

58. Endres, *supra* note 55, at 119-20 (describing series of Salmonella outbreaks). *See also* 72 Fed. Reg. at 15,022.

ject to [USDA] regulation and are still permitted to import raw almonds into the United States."[59]

Implemented under the authority of the Agricultural Marketing Agreement Act of 1937 (AMAA),[60] the almond marketing order sought to regulate product safety through the statutory power to place restrictions on quantity, grade, size or quality of an agricultural commodity.[61] This is an increasingly common practice of the USDA—to regulate food safety through the issuance of a marketing order under the jurisdictional hook of "quality" control.[62] Initially passed to benefit producers in their relationship with those further up the food supply chain, the AMAA authorizes the agency to impose requirements on "handlers" for the benefit of the commodity producer.[63] Thus, marketing orders impose processing requirements on "handlers" that in turn are passed down to producers via contract requirements or, as in the case of the almond rule, that impose added costs on the domestic industry not reciprocated on imported products. Furthermore, some technological requirements imposed by marketing orders may have a disproportional impact on smaller-scale producers and handlers due to the underlying voting structure of the AMAA and the respective commodity boards representing producers and handlers.[64]

In September 2008, a coalition of almond producers, processors (i.e., handlers) and producer-retailers challenged the Almond Marketing Order in federal court in the District of Columbia.[65] The plaintiffs alleged that *inter alia* the pasteurization rule exceeded USDA's AMAA-based authority to establish quality control require-

59. *See Koretoff*, 614 F.3d at 535.

60. 7 U.S.C. § 608(c) (2006).

61. 72 Fed. Reg. at 15,031.

62. *See* Endres, *supra* note 55, at 122-24 (discussing use of marketing orders to regulate food safety in the almond and leafy greens context and calling into question the appropriateness of this use of statutory power and the potential to shift power away from growers—the intended beneficiary of the AMAA); Endres & Johnson, *supra* note 27 (discussing the leafy greens industry's attempt to enact a national marketing agreement under the AMAA to regulate product safety).

63. *See* Daniel Bensing, *The Promulgation and Implementation of Federal Marketing Orders Regulating Fruit and Vegetable Crops Under the Agricultural Marketing Agreement Act of 1937*, 5 SAN JOAQUIN AGRIC. L. REV. 3, 5 (1995) (citing 7 U.S.C. § 602(2) and Block v. Community Nutrition Inst., 467 U.S. 340 (1984)); Endres & Johnson, *supra* note 27, at 240-57 (discussing legislative history of AMAA and intent to protect growers).

64. *See* CORNUCOPIA INST., FACT SHEET: MANDATORY STERILIZATION OF RAW ALMONDS 3-4, *available at* http://www.cornucopia.org/almond/Almond_Fact_Sheet.pdf.

65. Koretoff v. Vilsack, 601 F.Supp.2d 238 (D.D.C. 2009).

ments.[66] The district court dismissed plaintiffs' claims, holding that the handlers had failed to first pursue an administrative appeal and thereby failed to exhaust their administrative remedies.[67] The court further held that producer-retailers were "handlers" under the AMAA.[68] Accordingly, their claims suffered the same fate as the other handlers.[69] Finally, the court dismissed the growers' claims, holding that growers have no right to judicial review under the AMAA.[70]

On appeal, the D.C. Court of Appeals reversed, in part.[71] Relying on its recent decision in *Ark. Dairy Coop Ass'n v. U.S. Dep't of Agric.*,[72] the court rejected the proposition that because growers had an opportunity to vote in the establishment of the marketing order, they were precluded from later bringing a suit to challenge the allegedly unlawful USDA action.[73] The court noted that the method for calculating the two-thirds of producers needed for approval of the almond order—relying on either the total number of growers or the volume of almonds—readily presents a scenario in which a few large-scale producers could seek USDA approval for a marketing order prejudicial to a large number of small growers.[74] Moreover, the court rejected the government's vicarious representation argument that because the handlers could challenge the order (after exhausting administrative remedies), the statute adequately protected the interests of the growers.[75] As the AMAA regulates handlers for the benefit of growers, there are numerous instances in which the interests of these groups may diverge.[76] Accordingly, the appeals court reversed the trial court's dismissal of the producer-plaintiffs' claims.[77]

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66. *Id.* at 241.
67. *Id.*
68. *Id.* at 243.
69. *Id.*
70. *Koretoff*, 601 F.Supp.2d at 244-45.
71. Koretoff v. Vilsack, 614 F.3d 532, 533 (D.C. Cir. 2010).
72. 573 F.3d 815 (D.C. Cir. 2009).
73. *Koretoff*, 614 F.3d at 538.
74. *Id.* at 539. Although raised within the context of a procedural issue, this is precisely one of the substantive arguments against implementation of the both the almond marketing order and the proposed leafy green marketing agreement. *See* Endres & Johnson, *supra* note 27.
75. *Koretoff*, 614 F.3d at 539-40.
76. *Id.* at 540 (listing examples of potential differences between growers and handlers).
77. *Id.* at 540-41 (reversing dismissal of producers' claims, but affirming on failure to exhaust grounds the claims' of the producer-retailers). A dissenting judge

As this case proceeds into the pre-trial stage and subsequent motion practice, it will be interesting to see if the courts will craft definitive guiding principles on the scope of USDA's authority under the AMAA to promulgate rules with the singular goal of addressing food safety concerns, or if the definition of "quality" under the Act is limited to commodity grading, appearance or other concerns.[78] An expansive reading of the statute would solidify USDA's authority over food safety provisions–an issue of considerable public concern. On the other hand, important governance questions remain as to whether the unique procedural apparatus of the AMAA is the optimal route for food safety rulemaking.[79] But if USDA lacks authority under the AMAA to implement food safety rules at the farm level, which agency has jurisdiction? The recently enacted FSMA provides some authority,[80] but not as comprehensive as some originally envisioned. Accordingly, the almond pasteurization litigation has policy implications that reach far beyond the tree-nut industry and may shape the scope of farm-level food safety initiatives for the foreseeable future.

C. GENETICALLY ENGINEERED SALMON: ONE STEP CLOSER TO THE DINNER PLATE?

The FDA has moved a step closer to approving the marketplace's first genetically modified food[81]–a salmon engineered to grow more quickly than its natural-born counterparts–but still isn't sure how the fish should be labeled. In early September, the FDA

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would have voted to uphold the district court's ruling that producers do not have standing to challenge marketing orders and agreements. *See id.* at 541-44 (Henderson, J., dissenting in part).

78. *See* Endres & Johnson, *supra* note 27, at 202-15; 274-91 (discussing definition and application of the term quality under the AMAA).

79. *See id.* at 292-300; 371-375.

80. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011). The Act provides authority for FDA to mandate food safety measures at the farm level for fruit and vegetable production. Section 105, 124 Stat. 3899-3901 (to be codified at 21 U.S.C. § 419). But this would not include almonds (tree nuts) or other specialty crops. The FSMA also authorizes implementation of Hazard Analysis and Critical Control Points (HACCP) in all food processing facilities, which conceivably could apply to almond processing similar to the current requirement on handlers under the almond marketing order. *See* § 103, 124 Stat. 3889 (to be codified at 21 U.S.C. § 418).

81. For a good background on the broad regulatory issues surrounding transgenic fish, see Rekha K. Rao, *Mutating Nemo: Assessing the Environmental Risks and Proposing the Regulation of the Transgenic Glofish*, 57 ADMIN. L. REV. 903 (2005).

concluded that food from AquAdvantage salmon "is as safe as food from conventional Atlantic salmon" and that there is a "reasonable certainty of no harm from consumption of food from this animal."[82] The sentiment that the fish is safe to eat also appeared to prevail at a series of hearings before the FDA's Veterinary Medicine Advisory Committee in late September,[83] though the Committee refrained from offering a consensus view on whether the fish should be approved, and instead recommended that the government conduct further studies on the fish.[84] As of this writing, however, the FDA is still unsure about whether to require a label on the fish indicating genetically modified status—something that would conflict with its longstanding policy that eschews labeling of plant-derived genetically engineered food products based solely on the process by which the food is produced, and would reverse an earlier statement embedded in its Draft Guidance for Industry on the regulation of genetically engineered animals.[85] Nonetheless, with substantial public support for labeling (at least based on the public comments submitted to the agency),[86] a change in labeling policy (at least with respect to animals) is not inconceivable.

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82. VETERINARY MED. ADVISORY COMM., FOOD AND DRUG ADMIN. CTR. FOR VETERINARY MED., BRIEFING PACKET: AQUADVANTAGE SALMON 70 (2010), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf.

83. Documents for the Committee meeting—including background on the scientific issues associated with genetically-modified salmon—are available at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm201810.htm.

84. Andrew Zajac, *No Agreement Imminent on Salmon Labeling*, L.A. TIMES (Sept. 22, 2010), http://articles.latimes.com/2010/sep/22/nation/la-na-salmon-fda-20100922.

85. Andrew Zajac et. al., *Panel Tackles Salmon Engineering; One Member Says FDA Will Likely OK Genetically Modified Fish, But Not Soon*, CHICAGO TRIBUNE, Sept. 21, 2010. *See* FDA, *Statement of Policy: Foods Derived from New Plant Varieties*, 57 Fed. Reg. 22984 (May 29, 1992). FDA, *Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering*, 66 Fed. Reg. 4239, 4839-41 (Jan. 18, 2001). *See* CTR. FOR VETERINARY MED., FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY, REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS 14 (Jan. 15 2009), *available at* http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf. For a more thorough discussion of the regulation of genetically engineered animals, see Margie Alsbrook, *What's the Rush? An Examination of the FDA's Push to Introduce Genetically Engineered and Cloned Animal Products into the Food Supply*, 13 DRAKE J. AGRIC. L. 457, 469-73 (2008).

86. *See* FDA Docket Number FDA-2010 -N-0385, at http://www.regulations.gov/#!searchResults;dct=PR;rpp=10;po=0;s=FDA-2010-N-0385 (listing

III. CRACKING-DOWN ON DECEPTIVE FOOD LABELS: PRIVATE AND PUBLIC ENFORCEMENT ACTIONS

As food manufacturers continue to attempt to differentiate their products in order to attract a more label-savvy consumer with increasingly specialized and targeted labeling claims, the risk of crossing the line into misbranding under the FFDCA or unlawful deception under any one of the numerous state consumer protection statutes correspondingly increases. The inevitable result is a proliferation of private and public claims against the food industry for deceptive labeling. In an effort to provide additional guidance, the government has also stepped in (albeit in a limited role) to clarify or revise labeling rules for specific products. The following discussion highlights some of the litigation, the pushback against the government, the development of agency rules to specify labeling claims for other products, and an effort by a collection of food-industry leaders to revise front-of-package labeling of nutrition information.

A. Deceptive and False Advertising Litigation

1. Government Enforcement

a. FTC takes action against acai berry marketers

In August, an Illinois federal district court, at the request of the Federal Trade Commission, granted a temporary injunction against online marketers of acai berry weight-loss products that promised rapid weight loss and protection against colon cancer.[87] Anyone who has used the Internet in the last three or four years has probably seen the shrill advertisements along these lines: "WARNING: AcaiPure is fast weight loss that works. It was not created for those people who only want to lose a few measly pounds..USE WITH CAUTION! Major weight loss in short periods of time may occur."[88]

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396 public submissions in response for the FDA's request for comments regarding labeling requirements for genetically engineered salmon).

87. Press Release, Fed. Trade Comm'n, Court Orders Marketers of Acai Berry Weight-Loss Pills and "Colon Cleansers" to Stop Deceptive Advertising and Unfair Billing Practices (Aug. 16, 2010), *available at* http://www.ftc.gov/opa/2010/08/acaicolon.shtm [hereinafter FTC Press Release].

88. Complaint at 12, Fed. Trade Comm'n v. Central Coast Neutraceuticals, Inc., No. 10-cv-4931 (N.D. Ill. Aug. 5, 2010), *available at* http://www.ftc.gov/os/caselist/1023028/100816centralcoastcmpt.pdf.

The acai berry, which is harvested from palm trees in Central and South America, was virtually unknown in the United States until 2001, when the company Sambazon Inc. began touting its antioxidant properties.[89] Bolstered by positive endorsements from celebrity doctors (most notably "Oprah Winfrey Show" experts Dr. Mehmet Oz and Dr. Nicholas Perricone), sales of acai berry supplement products surged from $435,000 in 2005 to $13.5 million in 2007.[90] Today, acai berry products can be found in mainstream retail outlets such as Whole Foods and Jamba Juice.[91]

The health benefits of the berry, however, are uncertain at best. Though it generally is recognized as an antioxidant that can inhibit key enzymes in the body, few medical studies assessing the berry's efficacy as a weight-loss product exist.[92] In any case, there is little or no evidence backing some of the most outrageous claims made by certain Internet marketers about acai berry products, including claims that the effectiveness of such supplements were backed by "ironclad, double-blind, placebo-controlled weight loss studies from the medical establishment."[93] It is precisely claims like these that led to the FTC's complaint, which charges five different companies, operated primarily by just two individuals, with multiple violations of § 5(a) and § 12(a) of the FTC Act, which generally prohibit deceptive acts or practices and the distribution of false advertising of food, drug, or cosmetic products. The FTC estimates that approximately one million people have been scammed out of more than thirty million dollars as a result of the companies' false and deceptive advertising campaigns.[94]

Before elaborating further on the FTC's claims, it is worth briefly explaining the jurisdictional overlap between the FDA and the FTC on the issue of false advertising and deceptive business practices. Both the FDA and the FTC are empowered to take enforcement action against companies that engage in deceptive marketing of food and food products. The basic difference between the two agencies is that the FDA polices *labeling*—including health claims

89. Susan Donaldson James, *'Superfood' Acai May Not be Worth Price*, ABC NEWS (Dec. 12, 2008), http://abcnews.go.com/Health/Diet/story?id=6434350&page=1.

90. *Id.*

91. *Id.*

92. A professor at Texas A&M University who conducted one of the few human trials on acai berry told ABC News that while the berry could potentially offer health benefits, "[most weight loss] claims that I am aware of are not validated at all." *Id.*

93. *Id.* at 12.

94. FTC Press Release, *supra* note 87.

made on labels—whereas the FTC polices *advertising*.[95] This regulatory distinction is long-standing: federal regulation of advertising began with the Federal Trade Commission Act of 1914, which created the Federal Trade Commission.[96] The crux of the FTC Act's consumer protection provisions is § 5(a), which provides that "unfair or deceptive acts or practices in or affecting commerce..are..declared unlawful."[97] The FTC's power initially was limited, however, to enforcement actions in which there was evidence of injury to a *competitor* rather than the public at large.[98] That changed with the passage of the Wheeler-Lea Amendment of 1938, which amended the FTC Act to designate the FTC as the agency charged with the regulation and enforcement of the advertising of food, drugs, and cosmetics.[99] The Amendments also removed the requirement of proof of injury to competition; a showing of injury to the public at large is now sufficient to trigger FTC action for false advertising of food products.[100]

The FTC uses a three-pronged test to determine whether an advertisement is deceptive: (1) There must be "a representation, omission or practice that is likely to mislead the consumer;" (2) deception is analyzed from the perspective of the "reasonable consumer," not subjectively; and (3) the deception must be "material"—that is, the consumer must have relied detrimentally on the representation, omission, or practice.[101] The FTC Act defines an "unfair" act or practice as one that "causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition."[102]

It is clear that the FTC has the authority to regulate advertising on the Internet, though that authority may overlap with the authority of the FDA to regulate labeling. The Supreme Court long ago

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95. *See generally* Chelsea M. Childs, Note, *Federal Regulation of the "Smart Choices" Program: Subjecting Front-of-Package Nutrition Labeling Schemes to Concurrent Regulation by the FDA and the FTC*, 90 B.U. L. REV. 2403, 2406-11 (2010) (describing FDA and FTC jurisdictional silos).

96. 15 U.S.C. § 45(a)(1) (2006).

97. 15 U.S.C. § 45(a)(1).

98. NEAL D. FORTIN, FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE 56 (2009).

99. Wheeler-Lea Amendments of 1938, Pub. L. No. 75-447, 52 Stat. 111 (1938) (codified as amended at 15 U.S.C. § 45).

100. 15 U.S.C. § 45.

101. Fed. Trade Comm'n, FTC Policy Statement on Deception (Oct. 14, 1983), *available at* http://www.ftc.gov/bcp/policystmt/ad-decept.htm.

102. 15 U.S.C. § 45(n).

rejected the idea that regulation of false advertising has been committed exclusively to the FTC, noting that "[e]very labeling is in a sense an advertisement" and that advertising can "[perform] the same function as it would if it were on the article or on the containers or wrappers."[103] Today, the basis for FDA and FTC cooperation is a 1971 Memorandum of Understanding that outlines each agency's general responsibilities for the regulation of deceptive food labeling and advertising.[104] Absent any contrary agreement, the Memorandum states that the FTC retains primary jurisdiction over the regulation of food advertising other than labeling, while the FDA retains primary jurisdiction over food labeling.[105] While the Memorandum encourages joint coordination of programs and information-sharing between the two agencies, it emphasizes that parallel proceedings against the same parties by both agencies "shall be restricted to those highly unusual situations where it is clear the public interest requires two separate proceedings."[106]

Congress further clarified the agencies' roles in cases of overlapping jurisdiction in 1976, when it amended the FDCA to include § 707, which requires the FDA to notify the FTC in advance if the FDA plans to take action against a particular food product that is misbranded due to its advertising.[107] If the FTC takes action against the violators identified in the FDA's notice within sixty days, the FDA may not initiate its own action and instead must defer to the FTC action.[108] Because the Memorandum of Understanding between the FDA and the FTC does not carry the force of law, and because § 707 is the fallback statutory provision in the event that one or both agencies withdraw from the agreement, it seems clear that the FTC's jurisdiction can in some cases trump that of the FDA's with respect to food advertising.[109]

The jurisdictional picture is further complicated by the fact that the line between advertising and labeling has been blurred by the rise of e-commerce, as the FDA has pointed out. In a 2001 letter,

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103. Kordel v. United States, 335 U.S. 345, 351 (1948).

104. Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18,539 (Sept. 16, 1971).

105. *Id.*

106. *Id.*

107. 21 U.S.C. § 378(a).

108. 21 U.S.C. § 378(b).

109. *See, e.g.,* Childs, *supra* note 95, at 2413 ("The fact that the FDA must defer to the FTC in a situation of overlapping jurisdiction indicates that, 'where the authority is unclear, [Congress] would prefer the FTC to pursue enforcement proceedings' with regard to food advertising.").

the FDA rejected a suggestion from a policy group to adopt a formal rule or policy stating that information presented on a company's website could never constitute "labeling" as contemplated by the FFDCA, which defines the term "labeling" as "all labels and other written, printed, or graphic matter upon any article..or accompanying such article."[110] Instead, the FDA reiterated that courts have interpreted the term "accompanying" broadly, to include such items as brochures, booklets, films, and sound recordings.[111] By way of example, the agency noted that if a company were to promote a regulated product on its website, and allowed consumers to purchase the product directly from the website, the website would likely be labeling. The website, in that case, would be written, printed, or graphic matter that supplements or explains the product and is designed for use in the distribution and sale of the product.[112]

Therefore, some of the deceptive and false-advertising allegations leveled by the FTC against the acai berry supplement companies likely come within the FDA's expansive regulation of labeling, which flatly prohibits the use of false or misleading claims on product labels.[113] For example, the FTC alleges that the websites of the acai supplement marketers: (1) falsely claimed that their products could facilitate rapid weight loss—in some cases up to twenty-five pounds in the first month of use;[114] (2) falsely represented that celebrities such as Rachael Ray and Oprah Winfrey endorsed their weight-loss products;[115] (3) baited consumers through "free" thirty-day trial offers of their products and then automatically enrolled them in a monthly membership program in which they were charged full price for additional monthly shipments of the supplements;[116] (4) failed to disclose that the companies would automatically charge consumers for additional supplemental products unless

110. 21 U.S.C. § 321(m); Letter from Ctr. For Food Safety & Applied Nutrition, Food & Drug Admin., to Daniel J. Popeo & Paul D. Kamenar, Wash. Legal Found. (Nov. 1, 2001), *available at* http://www.stoplabelinglies.com/complaint/FDA-Letter-on-Labeling-Food-Products-Presented-or-Available-on-the-Internet.html [hereinafter FDA Letter].

111. FDA Letter, *supra* note 110.

112. *Id.*

113. *See* 21 U.S.C. § 343(a) (a food is misbranded if its labeling is false or misleading in any particular); 21 U.S.C. § 352(a) (a drug or device is misbranded if its labeling is false or misleading in any particular).

114. Complaint at 12-13, Fed. Trade Comm'n v. Cent. Coast Neutraceuticals, Inc., No. 10-cv-4931 (N.D. Ill. Aug. 5, 2010), *available at* http://www.ftc.gov/os/caselist/1023028/100816centralcoastcmpt.pdf.

115. *Id.* at 15.

116. *Id.* at 8.

they affirmatively opted out on the order form;[117] and (5) falsely claimed to have a "no questions asked" return policy that in fact contained onerous terms and conditions.[118] To the extent that these website statements "accompany" the acai berry supplement as an explanation of the product—as the FDA has suggested they could—they would constitute labeling and would technically come within the FDA's jurisdiction.[119]

That being said, the FDA has previously taken little action on the issue of acai berry supplements, issuing just three warning letters to three different companies in the past four years.[120] In those letters, the FDA generally took the position that the companies' claims about their acai berry supplement products (e.g., that the product "reduces bad cholesterol," or "helps relieve joint/muscle pain and inflammation") caused the products to become "new drugs"—and therefore unmarketable without FDA pre-approval—because they were not generally recognized as safe treatment of the applicable diseases or conditions.[121] The FTC's action, filed on August 5th in federal district court in Illinois, is more drastic. It asks for a permanent injunction to prevent the defendants from engaging in further violations of the FTC Act.[122] Several weeks later, the court took a first step in that direction by entering a preliminary injunction ordering the defendants to temporarily stop selling their products.[123] The commencement of a civil action by the FTC under § 5 of the

117. *Id.* at 10-11.

118. *Id.* at 9-10.

119. *See* Kordel v. United States, 335 U.S. 345, 350 (1948) (holding that articles or literature "accompany" a product, and therefore constitute a "label," when the literature "supplements or "accompany" a product, and therefore constitute a "label," when the literature "supplements or explains" the product, and that "no physical attachment of one to the other is necessary. It is the textual relationship that is significant.")

120. *See* Warning Letter from Food & Drug Admin. To Guilherme C. Moreira, President, Universal Taste, Inc. (Aug. 7, 2009), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/ucm183392.htm; Warning Letter from Food & Drug Admin. to Kevin Vokes (July 6, 2007), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/CyberLetters/ucm056937.pdf; Warning Letter from Food & Drug Admin. to Dzung Pham, Life Dynamics Tech. (May 8, 2007), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/CyberLetters/ucm056948.pdf.

121. *Id.*

122. Complaint at 23, Fed. Trade Comm'n v. Cent. Coast Neutraceuticals, Inc., No. 10-cv-4931 (N.D. Ill. Aug. 5, 2010), *available at* http://www.ftc.gov/os/caselist/1023028/100816centralcoastcmpt.pdf.

123. FTC Press Release, *supra* note 87.

FTC Act is one of the statutory triggers that prevents the FDA from initiating its own labeling proceedings,[124] so even though the acai berry websites likely constitute "labeling," it's unlikely that we'll see any formal action from the FDA against the defendants tagged by the FTC.

Despite the FTC's regulatory action, however, a quick Google search of the term "acai berry" suggests that deceptive practices on the part of companies not party to the FTC action have continued. Consider a website labeled "Consumer Health Reporter," which purports to tell the personal story of "Julia Miller," an initially skeptical "Health and Diet Reporter" who tries the Fusion 5 acai berry weight loss supplement and finds—miraculously!—that it helps her lose twenty-five pounds in four weeks.[125] Though the website does contain the word "advertorial" in nine-point font at the top of the page, it is clear that the site is designed to mimic a legitimate, objective news source. Cynical lawyers may be able to see through such trickery, but less savvy consumers may not.

In sum, the issue of acai berry weight-loss supplements illustrates the regulatory game of Whac-a-Mole that often plays out in enforcement actions against online sellers: shut one website down, and another immediately pops up somewhere else. As noted above, the Memorandum of Understanding between the FTC and FDA allows parallel proceedings in "highly unusual situations" where the public interest requires it, and it isn't clear (especially given the sheer number of dubious diet product websites on the Internet) that the outbreak of deceptive acai berry websites is one of those situations. However, as the FTC action moves forward, the agencies certainly could benefit from the information sharing and joint planning that the Memorandum of Understanding contemplates.

b. FTC's Authority to Regulate Health Claims Challenged

A spat over the purported therapeutic benefits of pomegranate juice has led to a challenge in federal court to the FTC's ability to regulate health claims. On September 27, the FTC initiated action against POM Wonderful, LLC, asserting that the company made false and unsubstantiated health claims about its pomegranate juice

124. 21 U.S.C. § 378(b)(1)(B).

125. Julia Miller, *Acai Berry Diet Exposed: Miracle Diet or Scam?*, WEBHEADLINES.INFO., http://www.webheadlines.info/consumerreports247/ (last visited June 2, 2011).

and pills.[126] Two weeks earlier, POM Wonderful (perhaps seeing the writing on the wall) filed a complaint for declaratory relief in District of Columbia federal court, arguing that the FTC has exceeded its statutory authority by creating a new rule that mandates FDA pre-approval of all health-related claims on food products.[127] Essentially, the complaint alleges that the FTC has informally created a "new standard" for deceptive advertising claims. POM Wonderful bases this allegation on two prior consent orders that required the manufacturers to stop making certain health claims until securing FDA approval—regardless of the scientific evidence supporting the claim.[128] In the declaratory judgment action, POM Wonderful alleges that this is a drastic departure from FTC policy, thereby violating the agency's own rulemaking procedures, as well as the First and Fifth Amendments of the U.S. Constitution.[129] Calling the allegations "baseless," the FTC has filed a motion to dismiss, which is pending as of this writing.[130]

2. Consumer Rights Litigation: A victory (sort of) for Snapple Beverage in High Fructose Corn Syrup Litigation

A federal district court in New York has granted summary judgment for Snapple Beverage Co. in a putative class action suit brought by consumers who alleged that the company deceived consumers by marketing its beverages as "all natural" when in fact they contained high fructose corn syrup (HFCS).[131] The court ruled that the plaintiffs failed to show that the defendant's actions caused them injury—a required element of the New York laws under which the claims were brought.[132] The court had also previously denied class

126. Press Release, Fed. Trade Comm'n, FTC Complaint Charges Deceptive Advertising By POM Wonderful (Sept. 27, 2010), *available at* http://www.ftc.gov/opa/2010/09/pom.shtm.

127. *See* Complaint at 2, POM Wonderful LLC v. Fed. Trade Comm'n, No. 10-cv-10539-RWR (D.D.C. Sept. 13, 2010), *available at* http://www.scribd.com/doc/38553210/POM-Wonderful-vs-FTC-September-13-2010.

128. *Id.*

129. *Id.*

130. Defendant's Motion to Dismiss at 2, POM Wonderful, LLC v. Fed. Trade Comm'n, No. 10-cv-10539-RWR (D.D.C. Nov. 16, 2010), *available at* http://legaltimes.typepad.com/files/ftc_motion_dismiss.pdf.

131. Weiner v. Snapple Beverage Corp., No. 07-CV-8742-DLC, 2011 WL196930 (S.D.N.Y. Jan. 21, 2011).

132. *Id.*

certification in the action, which is one in a series of similar cases brought against the maker of Snapple in the past few years.[133]

The decision, *Weiner v. Snapple Beverage Co.*,[134] illustrates the burden of proof that courts will demand in consumer fraud cases. The plaintiffs in *Weiner* tried to establish injury in two ways: (1) they alleged that they personally paid a premium amount for Snapple beverages based on its "all natural" labeling; (2) they claimed that the price charged for Snapple was comparatively higher than the prices charged for beverages of the same size and type that were not labeled or marketed as "all natural."[135] The court rejected these assertions, noting that the two plaintiffs "had only vague recollections of the locations, dates, and prices of their purchases of Snapple."[136] The court found that testimony to the effect of paying "$1.79 total, or something around there" or "somewhere south of $2" was insufficient to establish the price paid for particular Snapple products on specific occasions.[137] Furthermore, neither plaintiff could testify that they specifically purchased an "all-natural" Snapple product despite the fact that its price was *in fact* higher than that of its competitors.[138] Instead, the plaintiffs testified that their perception that Snapple was more expensive was based on recollection of the approximate prices paid for comparable products and that they "hadn't actually looked at the prices of comparable products" on the days that they purchased Snapple.[139] The court hinted that any plaintiff making a similar claim faces an uphill battle to establish injury, given the fact that "it is undisputed that the prices of beverages in the retail market vary widely and are affected by the nature and location of the outlet in which they are sold, and the availability of discounts, among many other factors."[140] The court's decision implies that only a receipt or a direct recollection of exact price paid on a specific occasion would suffice to establish concrete personal injury—a high bar for most consumers to clear.

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133. *See* A. Bryan Endres et al., *United States Food Law Update: Health Care Reform, Preemption, Labeling Claims and Unpaid Interns: The Latest Battles in Food Law*, 6 J. FOOD L. & POL'Y 328 n.107. *See also* Holk v. Snapple Beverage Corp., 575 F.3d 329 (3d. Cir. 2009); Von Koenig v. Snapple Beverage Corp., 713 F.Supp.2d 1066 (E.D. Cal. 2010).

134. 2011 WL196930.

135. *Id.* at *3.

136. *Id.*

137. *Id.* at *4.

138. *Id.*

139. *Weiner*, 2011 WL196930 at *4-*5.

140. *Id.* at *3.

Nonetheless, the *Weiner* case stands as a cautionary tale for companies who wish to market their products as "all natural," for two reasons. One is the cost of defending litigation: once the *Weiner* case was denied class certification, it proceeded as a claim by two individuals seeking aggregated monetary damages of less than one dollar (the price difference between Snapple and its non-all-natural competition). Despite that fact, Snapple still likely expended hundreds of hours and thousands of dollars in attorneys' fees defending the case. Second is the fact that the *Weiner* litigation, despite its eventual dismissal, likely produced the plaintiffs' desired result. From the outset, it was undisputed that Snapple disclosed its use of HFCS on the ingredients list of its beverages at the same time it was using "all natural" labels. Therefore, there was no claim that Snapple hid its use of HFCS; the only issue was whether the company hoodwinked consumers by calling a beverage "all natural" despite it containing HFCS. And on this point, Snapple essentially conceded: after the *Weiner* case was filed, Snapple began substituting sugar for HFCS in all of its products labeled "all natural," thereby mooting the plaintiffs' claims for injunctive relief.[141] It did so even though the FDA has not taken an official position on whether HFCS is a "natural" ingredient.[142] So lesson learned: some consumers (or perhaps their lawyers) set a very high bar for what constitutes an "all natural" product, and food companies should take this into consideration when labeling their products.

B. Regulatory Measures to Prevent Deceptive Labeling:

1. USDA adopts new standards for grades of olive oil

In April, amid growing concern that some olive-oil producers and importers are mislabeling their products, the USDA's Agricultural Marketing Service (AMS) announced major revisions to its

141. *Id.* at *1.

142. For an insightful history of the FDA's failure to define the term "natural," see April L. Farris, *The "Natural" Aversion: The FDA's Reluctance to Define a Leading Food Industry Marketing Claim, and the Pressing Need for a Workable Rule*, 65 FOOD & DRUG L.J. 403 (2010). For an argument that the FDA should adopt a rule banning the use of high fructose corn syrup in food and beverages with "natural" labeling, see Adam C. Schlosser, *A Healthy Diet of Preemption: The Power of the FDA and the Battle Over Restricting High Fructose Corn Syrup From Food and Beverages Labeled "Natural,"* 5 J. FOOD L. & POL'Y 145 (2009).

standards for grades of olive oil and olive-pomace oil.[143] The new standards, which supersede standards that had been in force since 1948, took effect in October 2010 and harmonize U.S. olive-oil grade standards with internationally recognized standards of quality used by the world's major olive-oil producing countries.[144]

The genesis of the revised standards was a petition to USDA by the California Olive Oil Council (COOC), which emphasized that the 1948 standards, by using categories such as "U.S. Grade A" or "U.S. Fancy," did not reflect current olive-oil industry standards used both in the U.S. and abroad.[145] The COOC stressed that "because there is no definition for olive oil in the U.S., some unscrupulous blenders can produce low quality olive oil and market it as extra virgin olive oil, at a premium price."[146] This point was bolstered by a study published in July by researchers at the University of California-Davis' Olive Center, who analyzed a sample set of olive oils on California grocery store shelves and concluded that 69% of the imported oils and 10% of the domestic oils tested did not meet internationally accepted standards for extra-virgin olive oil.[147] Virgin olive oil, which is unprocessed and is often touted as a healthier alternative to vegetable oils, commands a significant price premium over lower-quality olive oils and olive oil blends.[148]

Therefore, in an effort to define quality ratings more clearly, the revised USDA standards list eight grades of olive oil in two major categories: olive oil and olive-pomace oil.[149] "U.S. Extra Virgin Olive Oil," for example, is defined as virgin olive oil that has "excellent flavor and odor (median of defects equal to zero and median of fruitiness greater than zero) and a free fatty acid content..of not more than 0.8 grams per 100 grams..."[150] Among other things, the

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143. United States Standards for Grades of Olive Oil and Olive-Pomace Oil, 75 Fed. Reg. 22,363 (Apr. 18, 2010).

144. AGRIC. MKTG. SERV., U.S. DEP'T OF AGRIC., UNITED STATES STANDARDS FOR GRADES OF OLIVE OIL AND OLIVE-POMACE OIL (2010), *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3011889 [hereinafter REVISED OLIVE OIL STANDARDS].

145. 75 Fed. Reg. at 22,363-64.

146. *Id.* at 22,364.

147. P.J. Huffstutter & Kristena Hansen, *Lab Tests Cast Doubt on Olive Oil's Virginity*, L.A. TIMES (July 15, 2010), http://articles.latimes.com/2010/jul/15/business/la-fi-olive-oil-20100715.

148. *See id.* (noting that at one retailer, a bottle of extra-virgin olive oil cost $14.29, while a bottle of "extra-light" olive oil of the same brand cost $7.99).

149. *See* REVISED OLIVE OIL STANDARDS, *supra* note 144, at § 52.1534 (grades of olive oil) and § 52.1535 (grades of olive-pomace oil).

150. *Id.* at § 52.1534(a).

revised standards set forth specific definitions for "U.S. Virgin Olive Oil," "U.S. Olive Oil," and "U.S. Refined Olive Oil," as well as a separate grading scale for olive-pomace oil.[151] The standards list twenty-two tests used to ascertain the grade of olive oil, including quality tests (flavor, odor, color, free fatty acid content, peroxide value, and UV-light absorbance) and purity tests (tests to determine olive oil origin and degree of processing, if any).[152]

In revising the olive oil standards, the USDA hopes that consumers will be ensured "product quality through inspection and..objective chemical and organoleptic testing."[153] And indeed, since taking effect in October, the revised guidelines have produced some "small but noticeable" changes in the marketing of olive oil, including increased use of "best by" dates on bottles and the dropping of the "extra virgin" designation on bottles of extra virgin olive oils infused with extra ingredients such as garlic or citrus.[154] But the main problem, at least according to some industry trade groups, is that the new USDA standards are, as before, entirely voluntary, and there is no mechanism for agency enforcement of the rules. That fact is particularly troubling considering that state agencies have previously found that oils labeled as "extra virgin" (and therefore supposedly pure) were in fact blended with cheaper canola, seed, or nut oils.[155] This raises not only issues of fraud and false advertising, but also serious health concerns for people with food allergies. Some states (e.g., California and Oregon) have passed their own standards for olive oil,[156] but many others have not.

Therefore, private actors can be expected to continue their own efforts to ensure that olive oil is properly labeled and marketed, and unscrupulous marketers may continue to skirt the rules in states without mandatory regulations. In California, the COOC has employed its own testers and scientists to create its own "certified extra virgin" marketing label. Olive oils that meet the COOC standards–

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151. *Id.*

152. *See id.* at § 52.1540 ("methods of analysis"); § 52.1541 ("ascertaining the grade of a lot"); § 52.1542 ("score sheet for olive oil and olive-pomace oil").

153. 75 Fed. Reg. 22,367 (Apr. 18, 2010).

154. Lisa McKinnon, *New USDA Olive Oil Standards Support What Producers Already Do*, VENTURA COUNTY STAR (Oct. 19, 2010), http://www.vcstar.com/news/2010/oct/19/new-usda-olive-oil-standards-to-take-affect-say/

155. Hufstutter and Hansen, *supra* note 147.

156. *See* CAL. HEALTH AND SAFETY CODE § 112877 (West 2011) (setting forth olive oil grades); OR. REV. STAT. ANN. § 616.761 (West 2011) (authorizing the Oregon Department of Agriculture to establish standards of identity and grades for olive oil).

which are stricter than those put into place recently by the USDA—are permitted to bear a sticker distinguishing them from their non-certified counterparts.[157] Not surprisingly, the legal system has also been used to push for truth-in-olive-oil advertising: in July, just days after the findings of the U.C.-Davis report were published in the *L.A. Times,* a group of plaintiffs (led by Bravo TV "Top Chef" David Martin) filed a putative class-action suit in California state court against a group of defendant olive-oil producers and importers, alleging state-law claims of fraud, negligent misrepresentation, breach of warranty, false advertising, and unjust enrichment.[158] A similar suit was filed in Florida state court in August.[159]

2. *USDA Issues Final Nutrition Labeling Requirements for Meat and Poultry*

In an effort to more clearly communicate nutrition information, in December 2010 the USDA enacted regulations that require major cuts of meat and poultry, as well as ground meat and poultry products, to carry nutrition labels.[160] The mandatory labels were prompted by the USDA's own regulations, which require the agency to provide nutrition labeling for major cuts of meat and poultry if the agency finds that there isn't sufficient participation in voluntary labeling efforts.[161] There wasn't sufficient participation,[162] and so beginning in 2012, the USDA will require producers of a final, packaged meat product to place nutrition content labels on forty of the most popular meat and poultry products.[163] Under the rule, packages of ground or chopped meat and poultry will be required to carry a nutrition label.[164] Whole, raw cuts of meat will be required to

157. McKinnon, *supra* note 154.

158. Shook, Hardy & Bacon LLP, *California Chefs Claim EVOO Fails to Meet Regulatory Standards,* FOOD & BEVERAGE LITIG. UPDATE, Aug. 6, 2010, *available at* http://www.shb.com/newsletters/FBLU/FBLU359.pdf.

159. Shook, Hardy Bacon LLP, *Florida Consumers Bring Fraud Claims Against EVOO Companies,* FOOD & BEVERAGE LITLG. UPDATE, Aug. 27, 2010, *available at* http://www.shb.com/newsletters/FBLU/FBLU362.pdf.

160. Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products, 75 Fed. Reg. 82,148 (Dec. 29, 2010).

161. *See* 9 C.F.R. § 317.343 (2010) (requiring FSIS to assess retailer participation in voluntary labeling efforts every two years and requiring rulemaking for mandatory labeling if fewer than 60% of all companies surveyed were participating); 9 C.F.R. § 381.443 (same with respect to poultry).

162. 75 Fed. Reg. at 82,148.

163. *See* 9 C.F.R. § 317.300 (meat); 9 C.F.R. § 381.400 (poultry).

164. 9 C.F.R. § 317.300(a); 9 C.F.R. § 381.400.

carry a nutrition label *either* on the package *or* on a sign at the point of consumer purchase.[165] The labels must indicate the total number of calories and the grams of total fat and saturated fat that the meat or poultry product contains.[166] In addition, any product that contains a "percentage lean" statement on its label (e.g., "80% lean") must also list the corresponding fat percentage.[167]

The new rules include a number of exemptions. First, the labeling rules exempt products intended for further processing, so long as these products bear no nutritional claims or nutrition information.[168] Second, the rules exempt products that are not for sale to consumers, so long as these products do not bear nutrition claims or nutritional information.[169] Third, ground or chopped meat or poultry products produced by small businesses do not have to comply with the new nutritional labeling requirements.[170] The USDA defines a "small business" for purposes of this exception as a facility that employs 500 or fewer people and produces no more than 100,000 pounds of meat per year.[171] This exception holds even if small producers use "percent fat" and "percent lean" labels on their ground meat and poultry products, so long as they include no other nutritional claims or nutritional information on their labels. However, unlike for ground products, the nutritional labeling rules for major whole cuts of meat or poultry do not exempt small producers.[172] Nonetheless, this requirement should not be overly burdensome, because USDA plans to make point-of-purchase labeling materials available over the Internet, free of charge.[173] Finally, the rules exempt meat and poultry in small packages,[174] or custom slaughtered,[175] or intended for export,[176] or prepared and sold at retail.[177]

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165. 9 C.F.R. § 317.345; 9 C.F.R. § 381.445.
166. 75 Fed. Reg. at 82,148.
167. 9 C.F.R. § 317.362; 9 C.F.R. § 381.462.
168. 9 C.F.R. § 317.400(a)(2); 9 C.F.R. § 381.500(a)(2).
169. 9 C.F.R. § 317.400(a)(3); 9 C.F.R. § 381.500(a)(3).
170. 9 C.F.R. § 317.400(a)(1); 9 C.F.R. § 381.500(a)(1).
171. 9 C.F.R. § 317.400(a)(1)(ii); 9 C.F.R. § 381.500(a)(1)(ii).
172. *See* 9 C.F.R. § 317.400(a)(1) (exempting food "other than the major cuts of single-ingredient, raw meat products identified in § 317.344 produced by small businesses"); 9 C.F.R. § 381.500(a)(1) (same as to poultry products).
173. Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products, 75 Fed. Reg. 82,151 (Dec. 29, 2010).
174. 9 C.F.R. § 317.400(a)(4); 9 C.F.R. § 381.500(a)(4).
175. 9 C.F.R. § 317.400(a)(5); 9 C.F.R. § 381.500(a)(5).
176. 9 C.F.R. § 317.400(a)(6); 9 C.F.R. § 381.500(a)(6).
177. 9 C.F.R. § 317.400(a)(7); 9 C.F.R. § 381.500(a)(7).

C. Private Standards Labeling Initiatives

In January 2011, the Grocery Manufacturers' Association (GMA) and the Food Marketing Institute (FMI) unveiled an industry-wide, front-of-the-package (FOP) labeling system that highlights key nutritional information about many packaged foods sold in grocery stores. The GMA and FMI, whose members include the vast majority of food manufacturers and retailers, argue that the new labeling will "help busy consumers - especially parents - make informed decisions when they shop."[178] In essence, the labeling program, called "Nutrition Keys," consists of four icons that will be prominently displayed together on the front of a food package. Each icon represents a key nutrient that dietary guidelines recommend consuming in limited quantities: calories, saturated fat, sugars, and sodium.[179] Small food packages that don't have the space to display all four icons may display only the icon containing calorie information.[180]

The GMA and the FMI say that they have developed the new standards directly in response to a challenge from first lady Michelle Obama, who, as part of her "Let's Move" healthy eating campaign, asked the industry to help consumers make healthier food choices.[181] But in fact, the Obama administration and the FDA parted ways with the food industry over the Nutrition Keys program after industry insisted on retaining the most controversial aspect of the program: voluntary "nutrients to encourage" labeling.[182] In addition to the four "nutrients to limit" icon, certain packages could also include up to two labels that include information about "nutrients to encourage," including potassium, fiber, Vitamin A, Vitamin C, Vitamin D, calcium, and iron.[183] A package could contain these icons only if the product contained more than 10% of the daily value of the nutrient and meets FDA requirements for a "good source" nutrient content claim.[184] This juxtaposition of unhealthy nutrients

178. *Nutrition Keys Front-of-Pack Labeling Initiative*, GROCERY MANUFACTURER'S ASS'N, http://www.gmaonline.org/issues-policy/health-nutrition/providing-innovative-and-healthy-choices/nutrition-keys-front-of-pack-labeling-initiative/ (last visited Apr. 13, 2011).

179. *Id.*

180. *Id.*

181. *Id.*

182. William Neuman, *Food Makers Devise Own Label Plan*, N.Y. TIMES, Jan. 24, 2011, http://www.nytimes.com/2011/01/25/business/25label.html?_r=1&scp=3&sq=front%20of%20package%20labeling&st=cse.

183. *Nutrition Keys*, *supra* note 178.

184. *Id.*

with healthy ones, with no means of differentiation, led one Obama administrative official to conclude that " 'the label [is] going to be confusing, because [healthy nutrients] would be included out of context, and it could make unhealthy foods appear like they had some redeeming quality...[For example], ice cream would be deemed healthy because it would have calcium in it.' "[185]

In any case, the Nutrition Keys labeling program is the latest effort by the food industry to stay ahead of pending FDA action to establish uniform, voluntary guidelines for FOP labeling on food products.[186] The FDA has made it clear that its goal for any FOP labeling system is to "provide a more convenient and effective information tool for consumers seeking quick and accurate information about the nutritional quality of the food they are purchasing," thereby allowing them to make more nutritious food choices and "reduce obesity and other diet-related diseases."[187] What food manufacturers are worried about—and surely what they're trying to prevent by placing "nutrients to encourage" FOP labels right next to "nutrients to avoid" FOP labels—is FDA's assessment that an FOP labeling scheme that uniformly focuses on healthy choices "may foster industry reformulation of products because some consumers may notice the information and make their product selection accordingly."[188] But as the olive oil and Snapple litigation efforts show, consumers appear to be increasingly demanding full clarity about the nutritional content of food products. An industry FOP labeling program that discloses the 12 grams of sugar per serving in Froot Loops (more than many cookies) while at the same time labeling the cereal as a good source of fiber and Vitamin C[189] may not produce that level of clarity.

The Nutrition Keys program is reminiscent to the highly touted, but quickly terminated, "Smart Choices" FOP labeling scheme developed by the Keystone Center in 2009 with funding from fourteen major food companies.[190] Processed food products

185. Neuman, *supra* note 182.

186. *New Front-of-Package Labeling Initiative*, FDA.GOV, http://www.fda.gov/food/labelingnutrition/ucm202726.htm (last visited Apr. 13, 2011).

187. Front-of-Package and Shelf Tag Nutrition Symbols; Establishment of Docket; Requests for Comments and Information, 75 Fed. Reg. 22,602, 22,603 (Apr. 29, 2010).

188. *Id.*

189. William Neuman, *For Your Health, Froot Loops*, N.Y. TIMES, Sept. 4, 2009, http://www.nytimes.com/2009/09/05/business/05smart.html.

190. Rubecca Ruiz, *Smart Choices Foods: Dumb As They Look?*, FORBES (Sep. 17, 2009), http://www.forbes.com/2009/09/17/smart-choices-labels-lifestyle-health-

meeting the Smart Choices criteria could place a green seal with a check mark on the front of the package to indicate a "healthier" food product.[191] The problem, from a nutritional standpoint, was that although the product may have contained relative high marks in one aspect (e.g., low in fat, sodium or sugar; high in vitamins or calcium), these scores could offset relatively poor nutritional value in other areas. For example, a sixty-calorie Fudgsicle qualified for a Smart Choice label due to its low fat content, but the product had no other nutritional value and contained three types of sugar—hardly what one would term a "healthy" product.[192] Other particularly egregious examples noted by the media included Froot Loops and a "Magical Cheese Stuffed Crust Pizza" that contained 23% of the recommended daily salt and fat intake.[193]

In addition to engendering significant ridicule from the media and nutrition experts,[194] the FDA issued a letter expressing concern to the General Manager of the Smart Choices Program.[195] Noting the proliferation of competing FOP labeling symbols and research suggesting a likelihood of consumer confusion, the agency expressed concern that the criteria used to qualify products for the Smart Choices label was inconsistent with government dietary guidelines, could mislead consumers and could encourage consumers to eat highly processed foods rather than healthier fruits, vegetables and whole grains.[196] Shortly thereafter, the Smart Choices program voluntarily shut down the labeling initiative.[197]

Whether the Nutrition Keys labeling program shares a similar fate with regard to FDA remains to be seen. Meanwhile, the agency has committed to studying a uniform FOP labeling scheme based, at

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foods.html. *See also* Childs, *supra* note 95, at 2414-15 (discussing the background of the Smart Choices program).

191. Ruiz, *supra* note 190.

192. *Id.*

193. *Id.*

194. *Id.*; Neuman, *supra* note 189 (citing objections by noted food policy experts to the Smart Choices program); Tom Laskawy, *Big Food's 'Smart Choices' label raises eyebrows at the FDA*, THE GRIST (Sept. 8, 2009), *available at* http://www.grist.org/article/2009-09-08-big-foods-smart-choices-label-raises-eyebrows-at-the-fda.

195. Letter From Food & Drug Admin. To Sarah Krol, Gen. Manager, Smart Choices Program (Aug. 19, 2009), *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm180146.htm.

196. *Id.*

197. Press Release, Smart Choices Program, Smart Choices Program™ Postpones Active Operations (Oct. 23, 2009), *available at* http://www.smartchoicesprogram.com/pr_091023_operations.html.

least in part, on the "traffic light" symbol currently used in the United Kingdom.[198]

IV. CONCLUDING THOUGHTS

This update marks a milestone in food law: the long-awaited enactment of the FDA Food Safety Modernization Act. Although the Act fills some jurisdictional gaps and provide mandatory recall authority, it most likely will not extinguish calls for further food-safety regulatory reform such as the consolidation of food-safety responsibilities into a single agency.[199] So perhaps the development of food law captured in this series of articles will mean "more of the same." That certainly holds true with respect to litigation over allegedly deceptive or misbranded food labels. As in section III of this update, the prior version detailed several important deceptive labeling cases and preemption issues.[200] An earlier article analyzed the various "all natural" lawsuits[201]—still the subject of litigation and likely to continue until both the FDA and USDA settle on a firm definition. On the other hand, perhaps this is a high point in the litigation, and the trend in food law for the future will not be more of the same. Perhaps after courts resolve this round of disputes there will be more predictability in both federal and state law that will define for food manufacturers and the consuming public more precisely where the line is between product promotion and deceptive labeling.

Meanwhile, outside the courthouse door, American consumers continue their push for healthier and more locally sourced food products that, in some cases, can lift some areas of the country out of "food deserts" while strengthening local and regional food networks in other areas. The normative question raised by many of the legal efforts discussed in this article is precisely who stands to benefit from them. And the early answer, by and large, seems to be

198. *Guidance for Industry: Letter Regarding Point of Purchase Food Labeling*, FDA.GOV (Oct. 2009), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm187208.htm.

199. *See e.g.*, Single Food Safety Agency Act of 2010, H.R. 6552, 111th Cong. (2010) (introduced immediately after passage of the FDA Food Safety Modernization Act).

200. Endres et al., *supra* note 133.

201. A. Bryan Endres, *United States Food Law Update: Labeling Controversies, Biotechnology Litigation, and the Safety of Imported Food*, 3 J. FOOD L. & POL'Y 253, 261-70 (2007) (discussing petitions to FDA and USDA to define "natural" and accompanying litigation).

"wealthy people." To be sure, nearly every one of the legal developments discussed in these pages benefits all food consumers in some way. Consumers benefit from labels and advertising that truthfully describe a particular food's nutritional content (or genetically modified status), and they also benefit from regulatory efforts that aim to reduce the incidence of harmful disease-causing pathogens in food. The *Pelman* litigation and San Francisco's Happy Meal ordinance are two very visible (if also extreme) efforts to highlight the ever-growing problem of childhood obesity—in the end, a noble goal.

The Los Angeles moratorium on fast-food restaurant development, however, is a more disturbing trend. It is at once over-inclusive (it broadly prohibits all new fast-food restaurants without regard to their actual menu offerings) and under-inclusive (it prohibits construction of a fast-food restaurant that serves a 1,000-calorie burger, but not a sit-down restaurant that serves the same thing, and also allows convenience stores that contain shelves upon shelves of junk food and soda). More fundamentally, the ordinance does not get to the heart of *why* fast food restaurants have proliferated in economically impoverished areas such as South Los Angeles. City council members have defended the moratorium as a mere zoning restriction that aims to reserve space for food outlets that provide healthier fare, such as grocery stores, but building a grocery store doesn't change the fact that many people—and especially those living in poor neighborhoods—eat fast food not because they don't have access to healthier alternatives, but because it's the only thing they can afford. According to USDA data, more than 50 million Americans live in households that sometimes run out of money to buy food (USDA gives these households the unfortunate moniker "food insecure").[202] The problem is most severe in big cities like Los Angeles.[203] Faced with severely limited budgets and often inflexible, hourly-wage jobs, "food insecure" individuals eat fast food because it's quick, filling, and cheap. A gleaming new Whole Foods won't have much impact on these people when a pound of low-fat, grass-fed ground beef costs as much as an entire Big Mac value meal.

Thus, rather than trying to get rid of bad food, state and local governments might instead explore ways to make good food more affordable. An increasing number of farmers' markets now accept food stamps, and in New York, food-aid recipients are given extra

202. Lisa Miller, *Divided We Eat*, NEWSWEEK, Nov. 22, 2010, *available at* http://www.newsweek.com/2010/11/22/what-food-says-about-class-in-america.html.
203. *Id.*

credit toward purchases made at farmers' markets.[204] Municipalities should consider providing tax credits and other development incentives to companies that have made a public commitment to providing affordable, locally sourced food—Wal-Mart being the most notable recent example. And if cities can't bring good food to their residents, they can bring residents to the food by taking simple measures such as establishing bus routes between poor neighborhoods and well-stocked supermarkets,[205] or encouraging community garden projects.

Finally, we could do without the undercurrent of elitism that runs beneath the swells of the local food movement, as illustrated by the recent legal tussles over the exact purity of fifteen-dollar olive oil and "all-natural" labeling on sugary, two-dollar-a-bottle juice. The goal, as author and foodie Michael Pollan argues, should be to encourage the scalability of reasonably healthy, reasonably priced food items, rather than the absolute healthiest, most organic foods at any cost—so as to get away from a system in which "wealthy farmers feed the poor crap and poor farmers feed the wealthy high-quality food."[206] The FSMA's exemption for small producers and the Healthy, Hunger-Free Kids Act's directive to create a healthier school lunch program are important legislative efforts that dovetail with private retailer efforts to further advance the ultimate goal of a scalable healthy food system. Achieving this goal will take a coordinated effort involving all the players mentioned on these pages: consumers, lawyers, food companies, scientists and nutritionists, academics and gadflys, and policymakers at the local, state, and federal levels. From that perspective, the "healthy food" movement has just begun.

204. *Id.*
205. *Id.* (describing municipalities' bussing efforts).
206. *Id.*