# FDLI'S FOOD and DRUG POLICY FORUM

A Series of Reflections on "Food Fight: An Examination of Recent Trends in Food Litigation and Where We Go From Here"

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VOLUME 5, ISSUE 3 // APRIL 3, 2015

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1155 15TH STREET NW, SUITE 910 // WASHINGTON, DC 20005

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## 1

# A Series of Reflections on "Food Fight: An Examination of Recent Trends in Food Litigation and Where We Go From Here" 1

Michael T. Roberts and Kim Kessler, UCLA School of Law

In late 2013 we set about planning our first major conference as the newly established Resnick Program in Food Law and Policy at UCLA Law School.<sup>2</sup> Despite the expansive range of topics encompassed by food law and policy, there was a clear and obvious subject choice: food litigation. The growth in food litigation in recent years is striking and has significantly and distinctively helped shape the emerging field of food law. Numerous major law conferences across the country in recent years have addressed food litigation, though until now no law school has hosted a conference on this topic. From the outset, the aim for our conference was to take a step back from the tactical aspects of the cases and to consider broader questions about the implications of food litigation through an academic lens.

We developed a four panel event, bringing together academics and leading practitioners in food litigation to discuss: 1) the social utility of food litigation, 2) recent rulings and trends, 3) the regulatory landscape and its implications for the burgeoning litigation, and finally 4) food litigation in contexts beyond labeling. For each of these panels, we asked one of our presenters to prepare a reflection piece on an idea that was sparked by the conference discussion. What emerged both in the pieces that follow and at the conference itself is a rich dialogue about the role of litigation in shaping not only the discipline of food law, but also the modern food system. For purposes of the conference, the "modern food system" was regarded as the components involved in the feeding of people: the growing or production, processing, packaging, transporting, marketing, consuming, and disposing of food and food packages.

The discussion of food litigation in the context of the food "system" is compelling. Both for practitioners and academics, it is typical to come to food system issues by looking at discrete questions within one area, for example as through the lens of public health, administrative law, land use, or food safety. Yet the food system in modern times—with its complexity, interconnectedness, and scope of impacts—is unlike anything previously experienced and is much larger than any of its pieces. Indeed, the problems emanating from this system—from hunger to diabetes to environmental costs—demonstrate a need to think about solutions, including those from law, in a holistic way.

An important aspect in the response of food law to changes in the modern food system is addressing the changing consumer. It is undeniable that consumer attitudes and desires towards food and the system that produces food have and are changing. Thus, it is no surprise that throughout the conference the role of consumers and their desire for information about the food they consume was discussed. Indeed, the relationships between consumers, the modern food system, the social food movement, food litigation, and regulatory bodies feature prominently in the reflection pieces written by presenters. For example, Sam Wiseman writes in his piece: "Americans' fascination with food—be it local, raw, organic, 'natural,' or safe food—has drawn food-based issues squarely into the public-private law debate."

Within this framework, the conference presentations and panel discussions covered numerous high-profile notable food litigation issues with broad social meaning to consumers and other stakeholders in the modern food system. Notable amongst these litigation issues was the labeling of genetically modified food. In dozens of cases, the question of whether products containing genetically modified organisms (GMOs) can be labeled "natural" – a term the Food and Drug Administration (FDA) has declined to define in a meaningful

way – has been raised and, sometimes reluctantly, addressed by courts. While historically thought of as a food safety issue, GMOs must also be considered a foods system issue because of the questions they raise with regard to pesticide use, biodiversity, and food security. A driving force behind GMO-related labeling litigation is frustration by the inability to have these concerns regarding GMOs heard by the FDA.

The reflection pieces that follow all acknowledge the serious challenges FDA and other government agencies have faced in managing changes in the food landscape. Still, each piece takes a different view on food regulation and the role for litigation in it. Sam Wiseman extracts lessons from other areas of administrative law and concludes that while many factors weigh in favor of more robust regulatory activity over private enforcement, agency resource constraints means that courts will remain the primary arbiter of many food-related issues. Diana Winters also sees a continued role for food litigation, but draws finer distinctions between issues that are well suited to FDA versus those that are more amorphous and arguably less rooted in science. Denis Stearns laments FDA's promotion of itself as a force for public health, given what he argues are serious shortcomings that the agency is unlikely to overcome. Finally, Sean Hecht looks at the growing litigation on the issue of factory farming and analyzes the role of the broader food movement in both galvanizing and responding to what happens in the courtroom, concluding that now is a particularly ripe time for lawsuits to drive food system change. While the authors each have a different take on the interaction between regulation and litigation, there is one clear consensus: food litigation is here to stay.

It is unlikely that this consensus over the durability of food litigation will surprise observers of food law and policy; however, this conclusion does lend itself to three policy recommendations that extend beyond the authors' panel summaries. The first recommendation is that given the stakes involved, it behooves the food litigation bar to put its best foot forward by doing quality work. A good example of how this aspiration might be achieved is the newly formed Food Law Committee of the Litigation Section of the California State Bar, where food litigation lawyers in California for plaintiffs and defendants and academics host education forums and share ideas, data, and expertise with one another.<sup>3</sup> Second is for academics and policy makers to continue monitoring and addressing the implications of food litigation. Food litigation is still relatively new and measuring the affects that litigation has on stakeholders, including consumers, is imperative in order to determine its social utility. Third, government agencies and policy makers with responsibility over food should be aware of the phenomenon of food litigation and its trend lines and trajectories. For example, a warning letter from FDA to a food company in this litigious environment may trigger class action litigation against the company and other food companies, making the consequences of agency action reverberate throughout the food industry in a way not previously envisioned by agencies. Such awareness may not alter agency action or shape governance, but it certainly will provide valuable context and understanding. Agencies with jurisdiction over food should also understand that unclear and ambiguous standards might induce litigation to fill in gaps.

#### I. COURTS, AGENCIES, AND FOOD LABELING

Sam Wiseman, Florida State University College of Law

#### A. Introduction

Americans' fascination with food—be it local, raw, organic, "natural," or safe food—has drawn food-based issues squarely into the public-private law debate. A growing set of consumers pays close attention to particular short phrases or words on labels<sup>4</sup>—the terms "natural" or "GMO free" can be the deciding factor in whether a parent purchases a product for a child, for example. As groups like the Center for Science in

the Public Interest (CSPI), along with consumers who feel deceived by food claims—aided by attorneys drawn by the possibility of the fees associated with a large class settlement—take their grievances to court, scholarly debates over the merits of public and private enforcement will be revived in a new context. Certain food manufacturers attempted to quickly squelch this debate, arguing that a federal, uniform public law regime should prevail. But these attempts have met with limited success. Most prominently, in 2014 the U.S. Supreme Court rejected the argument that the Federal Food, Drug, and Cosmetic Act (FDCA) displaces Lanham Act legal claims involving misleading labeling that creates unfair competition. 5 Courts will thus likely continue to see a fair amount of food labeling litigation. Yet agencies could also assert more authority in this area by rule-making, increased enforcement, or both, thus demanding closer analysis of the benefits and drawbacks of relying on agencies, consumers and courts, or a combination to address food labeling issues.

The well-developed literature on the relative merits of public and private enforcement in addressing various public issues, from product safety to antitrust, provides a rich set of concerns to be addressed in the food context. Among the most relevant are, first, the complexity of the issue and the expertise and resources available to those attempting to set and enforce standards. In the securities context, scholars have suggested that individual litigants are not likely to accurately analyze the complex economic issues involved or to bring good cases—often assuming that individuals, as opposed to an expert, centralized agency, will over-litigate.<sup>6</sup> Others have questioned the ability of individual plaintiffs to best identify environmental risks.7 Relatedly, efficiency must be considered: setting and enforcing standards nationally avoids the costs of piecemeal litigation and limits the potential for producers to have to comply with varying rules across jurisdictions, but also limits the potential for useful experimentation. A third set of concerns encompasses political accountability and fairness<sup>8</sup>—ensuring that standards and enforcement represent a varied set of stakeholder interests. The independence of courts makes them less likely to bend to the demands of any one group, yet individual claimants might not represent the interests of the broader public,9 and courts' independence makes them less accountable to the public. Agencies, on the other hand, while receiving substantial direction from the legislature, are more accountable yet potentially subject to capture by groups with valuable, concentrated interests in the substance and quantity of rules and enforcement—typically industry. Further, the quality of the standard produced by agencies or courts and its usefulness for industry and consumers of course matters substantially—whether the standard in fact reflects consumer concerns and is sufficiently uniform for realistic industry compliance. Food law could benefit from an importation of these and other concerns into the food labeling context, where individual claimants, frustrated with agency inaction, have taken to the courts.

This short piece reflecting on the Resnick Program for Food Law & Policy's recent conference, "Food Fight: An Examination of Recent Trends in Food Litigation and Where We Go From Here," examines the growing issue of food labeling litigation and explores the role of agencies and private litigants in this area. It then considers the public-private law literature in the food law context, applying some of the concerns associated with consumer or agency involvement to food litigation specifically. The piece concludes that although these concerns might point us toward relying more on agencies than consumers and courts to develop and enforce standards, 10 resource limitations and non-labeling-related priorities of agencies will likely leave consumers an important role in the regulatory process—for better or worse.

#### The Current Role of Consumers and Agencies in Food Labeling Standards and Enforcement

Several U.S. agencies have broad authority over food, including food labeling, and could potentially play a large role in policing the accuracy of food claims. FDA is primarily tasked with overseeing the accuracy of descriptions on packaged foods under the FDCA, as amended by the Nutrition and Labeling Education Act (NLEA).<sup>11</sup> This Act and associated regulations dictate the health claims that food manufacturers make on

products, statements regarding how foods affect the "structure and function" of the human body, labeling of foods as "substitutes" for others, and other claims such as whether foods are "light" and have "fewer calories" or "less fat" than others. 12 The Federal Trade Commission (FTC) has similar authority in food labeling, as it is also tasked with prohibiting false and misleading advertising of foods, and FTC and FDA coordinate their responsibilities through a Memorandum of Understanding that has been in place since 1971. 13 Similar agreements have existed between the agencies since 1954. 14 Although these agencies have broad authority to regulate misleading or confusing labels, their regulation and enforcement appear to have lagged behind certain consumer preferences. 15 Consumers increasingly pay attention to terms such as "natural" when buying products, for example, yet FDA and FTC have not yet defined how this term should be used. 16

Consumers have filled these regulatory gaps by taking enforcement into their own hands, filing a large number of claims relating to alleged misrepresentation in food labeling, often under state consumer protection acts. Claimants, both individually and through class actions, have challenged a long line of statements and omissions on both packaged and restaurant food, from McDonald's'® suggestion that it is part of a balanced or nutritious diet<sup>17</sup> to Kashi's® and Barbara's® cereals claims of "all natural." Many of these cases have been successful. Even where they do not result in a final judgment from a court that is favorable to plaintiffs, the companies sued have sometimes changed their advertising mid-lawsuit. These cases, particularly in the wake of the *POM Wonderful* decision, show no sign of letting up.<sup>20</sup>

#### C. Concerns Associated with Food Labeling Standards Developed by Courts versus Agencies

Is the trend toward food labeling standards created and enforced by consumers a good one in the context of agency versus court concerns already hashed out in other legal debates? The claims being challenged seem relatively simple—a far cry from the sometimes impenetrable economics of securities and antitrust claims—and are easily addressed by non-expert consumers and courts. As one judge said in dismissing a claim that the name of Cap'n Crunch's® Crunch Berries cereal is misleading because it contains no berries, "These cereal balls do not even remotely resemble any naturally occurring fruit of any kind."<sup>21</sup> Similarly, no great expertise is probably required to determine that "aspartame[,] acesulfame-potassium, artificial colors such as Red 40, Yellow 5, and Blue 1, the factory-produced texturizer maltodextrin, and . . . butylated hydroxyanisole, or BHA," should not be found in "natural" iced tea.<sup>22</sup> On the other hand, determining, for example, whether it is misleading to label a product containing genetically-modified ingredients as "all-natural" is clearly a more difficult question. Agencies like FDA clearly have a great deal of knowledge about food and food labels, as they approved much of the content of the labels. But courts also have extensive experience interpreting misleading claims in other contexts, and growing experience with food labeling—particularly in the Northern District of California, the so-called "Food Court."<sup>23</sup>

With respect to efficiency, relying on FDA and FTC to develop clearer standards ex ante, rather than consumers (and plaintiffs' attorneys) and public interest groups to complain about misleading labels after they have been released, has clear advantages, including reduced litigation costs and a significant reduction in meritless claims.<sup>24</sup> Yet in light of agencies' seeming unwillingness to take on this task—particularly for non-safety-related issues such as "naturalness," which seem to be a priority of the public but not the agency<sup>25</sup>—lawsuits might well continue, despite the expense of litigating similar issues for hundreds of different products. Moreover, agencies' greater accountability to the public might be outweighed in this instance by potential capture by the food industry, particularly given the individually small but widespread nature of the harms from mislabeling, which makes effective lobbying difficult. Groups like CSPI are a partial solution to the resulting collective action problem but may not be as effective as class action lawsuits in aggregating interests.<sup>26</sup>

And finally, with respect to the standards that will emerge from hundreds of lawsuits decided by different state and lower federal courts, a uniform, national standard would likely be preferable, although it would mean forgoing some useful experimentation in the "laboratory of the states." Industry would benefit from the clarity and predictability of this standard, and it might help in assuring consumers everywhere—not just in certain jurisdictions—that claims are accurate. Further, and relating to the concerns of accountability and independence noted above, a standard developed by an agency might represent a carefully considered rule that balanced a number of national interests, as opposed to the potentially idiosyncratic, incomplete, and sometimes frivolous concerns presented to the courts. On the other hand, such a standard might fail to reflect the "food movement" values that are increasingly important to consumers, and the agencies may, in any case, lack the resources or will to enforce it.<sup>27</sup>

#### D. Conclusion

Although it might be preferable for agencies to address food labeling issues due to their existing jurisdiction over this subject matter, their expertise in food claims, their accountability to a democratically elected legislature, and their ability to create a uniform standard that would potentially encapsulate a broad range of interests,<sup>28</sup> agencies seem unlikely to act in this area. FDA and FTC are flooded with mandates, including high-priority safety concerns, and have already indicated an unwillingness to fully prioritize what they view as lower-level concerns such as whether foods are in fact natural.

While many consumers genuinely care about the quantity of real pomegranate juice in their drink or what, exactly, evaporated cane juice is, others are likely to remain more concerned about the drink's taste. Barring Congressional action,<sup>29</sup> these and similar issues in the labeling context will likely be left to the courts to hash out for the near future.

#### II. FDA IN/ACTION AND FOOD LITIGATION: NOT AN ALL OR NOTHING PROPOSITION

Diana R. H. Winters, Indiana University McKinney School of Law

The 2014 Food Litigation Conference held by the Resnick Program for Food Law & Policy provided a rich exploration of the role of food litigation in food safety and public health and a window into the potential for litigation to spur change in a broad sense. I am going to use this opportunity to reflect on the conference to discuss one persistent theme—the failure of FDA to meet the challenge of regulating food in the twentyfirst century. FDA inaction and the systemic barriers preventing action were discussed during every panel, as was the utility of litigation to address the regulatory gaps caused by this breakdown of authority. Panelists addressed various reasons why FDA is unable to fulfill its mandate, including the agency's close affinity with regulated industry (or, in other words, the agency's "capture"), and its truncated budget. Litigation, remarked several panelists, is an imperfect tool but an available one, and does at least have the potential to spark regulatory change. Other panelists noted that litigation has other, independent benefits, such as its tendency to raise public awareness, and its ability to affect industry behavior.

All in all, though, litigation was characterized as a poor substitute for national regulation. This is not, however, always the case. In certain circumstances, litigation can play an integral role in achieving the goals of a regulatory scheme, and can supplement and enhance national regulation.<sup>30</sup> In regards to food litigation, FDA's role and relevance will vary depending on the specific issue. For example, we should ask whether FDA should be the ultimate arbiter of what is "healthy," and what is "natural," whether definitive statements by the agency on these matters would reduce the amount of food litigation, and whether such a reduction in and

of itself would be desirable? The goal of food regulation in general, panelists seemed to agree, is to ensure a safe food supply, and to maintain a fair marketplace where accurate information permits informed decisionmaking. To some panelists, litigation is a valuable and necessary tool, but to others, it is costly, inefficient, and at worst, frivolous. The question of whether national regulation would do a better job than litigation, however, in achieving the ultimate goals of a fair marketplace and improved health outcomes related to nutrition, varies by context. Below, I look briefly at two specific labeling issues in regards to the necessity and desirability of FDA (or other agency) action—the use of the word "natural" on food labels and the use of the term "evaporated cane juice"—both of which have been the subject of litigation, and both of which were addressed at the conference.31

FDA has not defined the term "natural" for use on food labels.<sup>32</sup> Moreover, in January 2014, the agency declined to decide whether food products containing genetically engineered ingredients can be labeled "Natural," "All Natural," or "100% Natural." In a letter to three district court judges who had requested a formal determination on the matter, the agency cited limited resources and the need for public process in making such a declaration.<sup>33</sup> This decision to not to make a decision has garnered much criticism,<sup>34</sup> and much litigation.<sup>35</sup> Numerous commentators, policymakers, and consumer advocates have called for FDA regulation of the issue,<sup>36</sup> and confusion over the definition of "natural" was mentioned repeatedly at the conference as an area of frequent litigation easily addressed by FDA action.

This clamor for a definitive FDA definition of "natural," 'all-natural," or "100% natural," is unfounded. Although the agency cited limited resources as its justification for not issuing a regulation defining these terms, the matter is unsuited for FDA regulation more broadly. First, the question of what is "natural" and what is not is a matter of philosophy, not science. To some, "natural" refers to process, and to others, it signifies specific ingredients.<sup>37</sup> For example, consider high fructose corn syrup, made without artificial ingredients, but highly processed. Moreover, defining "natural" would force FDA's hand in regards to genetically modified (GM) ingredients. Currently, GM ingredients are regulated on a continuum with existing food; in the absence of any verified hazards, the United States has taken the position that GM foods should be regulated according to what they are rather than how they are made.<sup>38</sup> Prohibiting the use of GM ingredients in foods labeled "natural" would require the agency to alter this policy with no sound basis for doing so,<sup>39</sup> and permitting their use in "natural" products would be a public relations disaster.

Second, any FDA-regulated definition of "natural" would create an artificial and ossified construct of the term. It would no longer signify the concept "natural," but rather the definitional components FDA chose to reify. Think, for example, of the term "organic." To receive a USDA-approved "organic" label, food producers must adhere to a specific set of guidelines, but the food need not necessarily comply with the plain meaning of the term. <sup>40</sup> This lacuna is a source of confusion and may delegitimize the label. Finally, FDA regulation of the term "natural" would not reduce the amount of food-related litigation. Even after the inevitable challenges to the regulation itself, the boundaries of the definition will be contested and the terms themselves complicated. For example, as the term "natural" becomes a target for litigation, food manufacturers have begun to increase the use of terms such as "fresh," and "minimally processed," which may present similar issues. 41

While defining "natural" presents a weak case for FDA action, the agency has a more meaningful role to play in the use of the term "evaporated cane juice." Evaporated cane juice (ECJ) is a term used by food manufacturers to describe sweetener derived from cane syrup. In October 2009, FDA published a draft guidance on the use of the term ECJ, explaining that "FDA's current policy is that sweeteners derived from sugar cane syrup should not be declared as 'evaporated cane juice' because that term falsely suggests that the sweeteners are juice."<sup>42</sup> This draft guidance explicitly states that it is non-binding and is not legally enforceable.<sup>43</sup> On March 14, 2014, FDA reopened the comment period on this draft guidance to "obtain additional data and information to better understand the basic nature and characterizing properties of the ingredient, the methods of producing it, and the differences between this ingredient and other sweeteners."44

In 2013, a slew of litigation was filed in California against food manufacturers alleging that the use of the term ECJ violated federal and state law.<sup>45</sup> While courts have differed in responding to these claims, the overwhelming trend after FDA reopened the comment period in March 2014 has been to dismiss these claims under the doctrine of primary jurisdiction. <sup>46</sup> The primary jurisdiction doctrine provides a court a mechanism to delay deciding a case (by staying proceedings or dismissing without prejudice) that it determines to involve an issue within the expertise of an administrative agency.<sup>47</sup> Because FDA appears to be in the process of making a final determination about whether the use of ECJ is lawful, the courts considering the issue view judicial determination of the issue as inappropriate.<sup>48</sup>

Here, FDA action on this issue will answer the question litigants are bringing to the courts—whether or not ECJ is an acceptable labeling term, or whether it renders food products misbranded under the FDCA and therefore California's Sherman law. ECJ is not a term with wide common meaning, and for this reason, a definition by FDA is not fraught as would be a definition of "natural." The use of the term ECJ either does or does not comport with FDA's regulations regarding the use of standard terms, and this question is one that is appropriate for FDA to decide. For these reasons, the dismissal of ECJ lawsuits may make sense.

On the other hand, courts are now dismissing ECJ lawsuits in deference to FDA's decision-making process. Current practice is therefore acceptable until and unless FDA decides otherwise. The benefits of state law litigation, including increased information disclosure and incentives to change food-labeling practice, are no longer available.<sup>49</sup> If FDA does not issue guidance, or inordinately delays the issue of the guidance it promises,<sup>50</sup> litigants will either have to bring these cases again and hope a court will agree that the delay is excessive, or petition FDA to issue its policy.<sup>51</sup> Moreover, if FDA issues guidance on this issue and if this guidance is in a legally enforceable form, this does not mean that food litigation will lessen or cease. To the contrary, any missive by FDA will be challenged and its boundaries tested. For these reasons, there is a stronger case for FDA action on the issue of ECJ than in the case of "natural," but the benefits will be modest at best.

The conference participants delved deeply into many aspects of food litigation. These two examples, however—"natural" as a labeling term, and the use of the term "evaporated cane juice"—show us that it is important to parse the claims that more FDA action is needed and that increased federal action would reduce the amount of food-related litigation.

#### III. IS FDA'S OWN BRAND MISLEADING THE PUBLIC? HOW THE IRONIES OF THE AGENCY'S ORIGIN-STORY HELP EXPLAIN MUCH OF ITS MISSION-FAILURE TODAY.

Denis Stearns, Seattle University School of Law

"Whereof what's past is prologue, what to come *In yours and my discharge."*<sup>52</sup>

The FDA has been described by a former Director of the Office of Enforcement as "a scientifically-based law enforcement agency" with a mission "to protect the public health, and to promote honesty and fair-dealing in the marketplace."53 Today, if you go to the FDA website, beneath the agency's name at the top of the home page you will see a slogan that reads, "Protecting and Promoting Your Health."54 The italics for emphasis is in the original, added it seems, as a kind of typographic argument meant to convince us that the focus of the agency is truly for and about the public health, yours and mine, and each and every other consumer in the United States. But just as the labels on food products can be both convincing and misleading for purposes of promoting sales and protecting a brand, so too is the FDA's slogan seemingly an act of salesmanship and brand-protection. To the extent that the public accepts that the FDA brand stands for the protection of public health, then the agency actions to which the brand is attached can be said to stand for the same thing. But is the FDA brand itself misleading?

To determine whether something on a label is misleading, the question to ask is whether it accurately describes that to which the label is affixed. Thus, for example, if FDA affixes its name to a regulation, the question to ask is whether the regulation protects the public health. For if the public is not better-protected by a given FDA regulation than it would be in its absence, then there is no reason for the regulation to exist—or, by extension, the FDA itself, at least within that particular regulated area. Conversely, if the absence of a regulation leaves the public unprotected in a dangerous way, then FDA's failure to issue a protective regulation similarly calls into question the agency's reason to exist, because the public has been left to fend for itself anyway. In the end, it is not enough for the agency to rely on the slogan-driven power of its brand, stamping its actions as "FDA-approved" as both justification and proof of efficacy. If FDA wants, in fact, to be all about "Protecting and Promoting Your Health," then there needs to be a lot more truth-in-advertising when it comes to the agency itself.

The third-panel of the Food Fight conference, "Regulatory and Legislative Landscape: A Look Ahead," was tasked with looking at how recent legislative and regulatory changes would affect future litigation and liability risks with regard to the food industry. Focusing on FDA, the speakers were unanimously skeptical about the efficacy of the agency's actions of late, and agreed that the rise of food-related litigation was proof of the agency's failure. The topics presented were varied, but all touched on issues related to the trustworthiness of available product information. The presenters discussed FDA's ongoing efforts to regulate nutrition-labeling and health claims, which are falling significantly short of what consumer groups are demanding; how FDA has failed to recognize poly-hydrogenated oils that contain trans fatty acid do not qualify as being Generally Recognized As Safe (GRAS), thus, are illegal food additives, and that ongoing efforts to regulate supposedly safe levels are inconsistent with existing regulations; how FDA's laudable efforts to create accreditation standards for third-party auditors of imported food ignores the misleading and dangerous use of unaccredited auditors domestically; and the efforts, so far unsuccessful, to get FDA action on GMO-labeling, leaving it to the States to try to enact legislation demanded by consumers wanting to avoid consumption of food containing GMOs, often for reasons that extend beyond public health.<sup>55</sup> Taken together, the presentations depicted an agency that in most important respects was failing to take actions demanded by the consuming public, contrary to FDA's own claim to be acting to protect and promote "your health," and raising interesting questions about the scope of the agency's regulatory powers.

While most presenters were willing to cut FDA some slack because of "limited resources," there was still the unmistakable sense that the agency only took a significant action when forced to do so—usually by lawsuit. Consequently, it becomes hard, if not impossible, to square the agency's inertia with a slogan that contains not one, but two, verbs—protecting and promoting. Yet, even if FDA action does not, in fact, protect and promote the public health as consistently, or to the extent, needed, there is still no question that the agency claims to be doing so. Moreover, the fact of FDA regulation—regardless of its actual efficacy—still goes a long way toward assuring the public that, in general, food is safer than it would be in the absence of FDA

action. And it is exactly in this way that FDA regulation—effective or not—acts like a brand stamped on all food, vouching for quality, safety, and authenticity.

The use of agency branding or approval as a signal of food safety and quality has a long history, going back to the origins of FDA with the enactment of the 1906 Pure Food Act. As such, the historical origins of FDA arguably both presage and explain the current state of affairs when it comes to food standards and labeling. Just as the battle over the Food Safety Modernization Act stalled until enough industry support appeared, one of the things that proved decisive in coalescing the support of the Pure Food Act was the fact that some food companies began to lobby in favor of the its passage "with the hope of using such a law as a weapon against competitors." Indeed, FDA's first Commissioner, Harvey Washington Wiley, was instrumental in obtaining industry support for the Act, while at the same time having worked hard for two decades fomenting public anger over food quality, including through his "Poison Squad." Wiley's experiments "persuaded him that chemical preservatives in food ... were hazardous to health and should be taboo." But it was not until public and commercial interests sufficiently aligned that Wiley was finally able to take action with the support of explicit legislative authority.

Despite having brokered the support of a diverse array of factions, Wiley's subsequent enforcement of the Act was idiosyncratic and played favorites among companies in the food industry, mostly those who did not use chemical preservatives and other "commercial tamperings with nature." More controversially, Wiley also allowed certain approved companies to include the following statement on food labels: "Guaranteed by the Food and Drug Act of 1906, guarantee number"

Not surprisingly, consumers began to rely on the guarantees, believing that the government had expressly vouched for the purity of the product. Also not surprisingly, "[a]s consumers began to use the guarantees as guides to quality, firms found them commercially valuable."<sup>61</sup> Moreover, companies that were allowed to use the guarantee, like the H.J. Heinz Company, which did not use chemical preservatives, were given a competitive edge over companies that Wiley denied use of the guarantee.<sup>62</sup> Two historians drew this lesson from the Act's passage and early enforcement: "That personal opinion and special interest can masquerade as objective science and public good, thereby corrupting even potentially useful law, reveals one of the chief dangers of regulation in a democratic society."<sup>63</sup> In short, even the best law depends on agency willingness to take the needed steps to effectively enforce the law in favor of the public good.

Although FDA touts its core mission as "your health," claiming to put the public good at the core of everything the agency does, its regulatory actions (and its inaction) tell a whole different story, as the presentations at the conference so amply demonstrated. So what would real transparency—real truth-in-advertising—look like should FDA ever decide to embrace its own branding slogan? Firstly, the agency would admit publicly what it occasionally states privately: FDA is an organization with severe limits, of both finance and fortitude. For example, FDA's reluctance to do anything to bring clarity, let alone transparency, to the definition of "naturalness" leaves the public to assume that buying—and paying more for—food labeled "natural" protects consumers from potential hazards. Indeed, a recent consumer survey estimated that the word "natural" helps sell \$40 billion worth of food in the United States annually, <sup>64</sup> while another study suggests that such terms work precisely to the extent that the public is misled into thinking foods so labeled are healthier. <sup>65</sup> Even when asked by courts faced with pending litigation to weigh in on the question of whether a product containing GMOs is "natural," FDA failed to take a position. <sup>66</sup> Instead, the public is left to fend for itself, with some people, like me, left to wonder, "What is 'unnatural' food, and is it even legal to sell?"

Secondly, FDA would add an asterisk to its mission statement, one that made clear the unstated caveat that "protecting the public health" really means, (1) attempting to avoid being sued, or (2) failing to prevent the kind of shocking, publicity-creating outbreaks that call its own existence into serious question. But as Professor Neal Fortin pointed out, even lawsuits against the agency and large-scale outbreaks have not been enough to spur agency action; "industry acquiescence or agreement" is also required. This point has been made before, and aptly so in an article about the 1906 Food and Drug Act:

It cannot be denied that each of the major food and drug laws—passed in 1906, 1938, and 1962—followed closely upon shocking disclosures....Consumer concern about product safety and accurate information was clearly at stake in the controversies preceding the enactment of the food and drug laws. But a large number of business interests were also involved, and the legislative outcomes were by no means detrimental to many of those interests as well.<sup>67</sup>

Reflecting the political reality of the food industry's stake in the regulatory process, it is not a surprise when legislative and regulatory efforts to protect the public health are enacted only insofar as affected commercial interests are sufficiently addressed to prevent successful opposition. For example, when the major changes to federal meat safety regulations were being developed and implemented, what would become the safe-handling label on all raw meat products was created as a result of USDA negotiating with the meat industry.<sup>68</sup> Consequently, perhaps the FDA slogan should really be, "protecting and promoting *your* health (to the extent that the commercial interests of the food industry are not harmed)."

Finally, if FDA truly embraced truth-in-advertising, it might start with including a more complete biography of its first Commissioner – including the whole, complicated story about Wiley's role in the origins of FDA and federal food regulation, right down to Wiley's resignation and accusation that the agency had committed a "crime" against the Pure Food Act by failing to protect the public health against commercial interests.<sup>69</sup> As someone easy to depict as both a hero and a villain, at once advancing the interests of the food industry over the interests of public health, while ultimately vilifying those same commercial interests that he accused FDA of selling-out to, Wiley remains an apt figurehead for an agency that continues to be deeply conflicted. Past is prologue, indeed.

## IV. FOOD SUSTAINABILITY, CAFO LITIGATION, AND PUBLIC SENTIMENT: THE ROLE OF LAWSUITS IN TODAY'S FOOD MOVEMENT

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#### A. Introduction

Factory farms have significant impacts on food safety, animal welfare, water quality, air quality, and other indicators of a safe, healthy environment and food production system. These operations—typically, though not exclusively, the domain of vertically-integrated corporations that now dominate the livestock industry in the United States—have been identified as major threats to public health, safety, and the environment, while our food suppliers rely on them for an ever-increasing proportion of our animal-based food supply. At the same time, public awareness of our food production and distribution system has been growing. From that awareness has emerged a growing movement of people concerned about food sustainability. This essay explores the ways in which litigation to internalize the costs imposed by factory farms (officially

termed Concentrated Animal Feeding Operations, or CAFOs) on society might interact with that movement, and suggests that now is an opportune time for litigation to support food sustainability efforts.

Significantly, the costs of CAFOs' impacts on health, safety, communities, and the environment typically are externalized, because of market failures in capturing the societal cost of these impacts as well as the related under-regulation of the CAFOs' operations. Moreover, many of the impacts of CAFOs fall disproportionately on particular communities and consumers. Advocates and consumers concerned about food sustainability are justifiably concerned about these impacts.

Although federal and state regulators have engaged with some of the harms caused by CAFOs, over the past two decades it has become apparent that private enforcement of our laws is necessary for three reasons: first, to force CAFO operators to internalize some of the costs that CAFOs impose; second, to provide remedies for the harms they have caused; and third, to pressure government agencies to prohibit practices that may be particularly harmful to food safety or health and either are prohibited under current law or could be prohibited with lawful regulatory action.

I moderated the final session at the recent conference, "Food Fight: An Examination of Recent Trends in Food Litigation and Where We Go From Here," hosted by the Resnick Program for Food Law and Policy at UCLA School of Law. Two of the panelists in this session focused on ways in which their public interest organizations have used litigation or the threat of litigation to attempt to accomplish some or all of the goals outlined above. This litigation has included environmental citizen-suit litigation and common law nuisance litigation against CAFO operators, as well as litigation to require federal agencies to regulate CAFOs more robustly.

Litigation is not itself a solution to the challenges posed by factory farming. Some commentators have noted that the goals of some social movements interested in limiting factory farming—for example, the animal rights movement and the food sustainability movement—are imperfectly aligned with the focus and likely outcomes of each of these types of litigation, which typically involve environmental or public health harms. Some have even argued that the goals of animal protection-oriented social movements may even be at cross-purposes with the regulatory goals these litigation tactics support. Moreover, even the attorneys litigating these cases will readily admit that their path is an uphill one, in light of agency inertia and inaction, as well as some courts' indifference and even hostility to some of the types of claims that underpin these lawsuits. And most fundamentally, litigation is simply a tool; it can change societal norms or practices only by functioning within a larger context for that change.

All these limitations notwithstanding, I believe that lawsuits are crucial tools to change the way the livestock industry operates, and that now is a particularly good time to pursue them. These lawsuits will not, by themselves, solve all the problems with CAFOs. Nor will advocacy lawsuits align with or support each and every value supported by myriad interest groups including sustainable-food advocates, environmental justice advocates, animal-rights advocates, and public health professionals. But lawsuits nonetheless have the potential to nudge, if not drive, agriculture towards practices that will support animal welfare as well as increased food safety and sustainability, protection of natural resources, and public health. Lawsuits have the potential both to create changes and reforms directly through litigation victories or settlements, and also to stimulate political action through their ability to affect public sentiment, public awareness, and other drivers of policy change. As support for food sustainability grows and as understanding of the impacts of factory farms becomes deeper, litigation will provide increasing value.

#### B. The Problem: Environmental Health and Social Costs of CAFOs

The proportion of U.S. livestock raised in CAFOs has grown dramatically over the past several decades, with the vast majority of beef cattle, pigs, and egg-laying hens raised in CAFO environments.<sup>74</sup> The conditions that define CAFOs are well-established and I will not dwell on them here,<sup>75</sup> but it is worth noting briefly that CAFOs have little in common with traditional farms or ranches, and are appropriately labeled informally as "factory farms" given their industrial methods, containment structures, and focus on generating maximum output from a small physical area that the animals inhabit. CAFOs typically feature industrial waste-handling processes to process and hold vast amounts of animal waste, cramped conditions for the animals, and intensive use of pharmaceutical products and other technological innovations to attempt to maximize production, thwart disease, and manage the consequences of industrial livestock conditions.<sup>76</sup> And CAFOs tend to be units within vertically-integrated corporate structures that encompass many aspects of food production, processing, and distribution.<sup>77</sup>

The primary economic comparative advantage of factory farming lies in its higher marginal productivity. Factory farms produce more animals per square foot or per unit of resource input; more meat, milk, or eggs per animal; and more meat, milk, or eggs per dollar spent to produce those products. Factory farming relies on the ability of technology to facilitate crowding more animals into a limited space, to hasten the time for each unit of product to be produced from these animals, and to increase the quantity of marketable commodities such as meat produced from each animal.

At the same time, factory farms possess these economic advantages largely because they externalize significant costs; in short, neither the industry nor its consumers directly pay for the harms imposed by industrial livestock-raising practices. Advocates, government officials, and others have linked CAFOs to various social and environmental ills. First, CAFOs have been associated with uncleanliness, disease, and bacterial contamination in the food supply, all of which stem from CAFOs' crowded conditions, focus on production quantity and profit, and industrial approach to animal-raising. Second, CAFOs have contributed significantly to the proliferation of subtherapeutic doses of antibiotics in livestock—which themselves have been linked to the rise of "superbugs" resistant to antibiotics. Third, CAFOs result in contamination of both groundwater and surface water by pathogens and nutrients from manure and other waste. Fourth, CAFOs release pollutants such as ammonia, methane gas, methanol, and hydrogen sulfide into the air. Fifth, CAFOs undercut more sustainable agricultural practices that have fewer impacts on the environment and health and support local economies. Sixth, CAFOs' negative economic and ecological impacts typically and disproportionately affect neighboring communities that are already overburdened. And finally, animals confined in CAFOs lead demonstrably worse lives than animals raised in other settings.

As a consequence of widespread understanding of the externalities that CAFOs impose on society, the social and environmental consequences of CAFOs have aligned advocates of environmental quality, public health, food safety, environmental justice, food sustainability, and animal rights in opposition to many of CAFOs' practices, if not their very existence.

#### C. The Context: An Increasingly Established Sustainable Food Movement

A sustainable food movement—or perhaps more precisely, multiple movements with overlapping goals that include food safety and security, less reliance on technology, and supporting local farming community—has been growing in the United States over the past two decades.<sup>86</sup> This movement, which has support from urban consumers, animal welfare advocates, and small farmers, has the potential to transform our food supply.

Authors such as Michael Pollan have called public attention to the downsides of industrial agriculture and food production. Nonprofit organizations focusing on food sustainability are beginning to thrive. These organizations often link together issues of environmental health, nutrition, access to healthy food, food safety, and the increasing integration of food production and distribution.<sup>87</sup>

Official action has followed nongovernmental advocacy efforts. In some cases, governments have even been leaders in food sustainability. Cities throughout the United States have developed food security and sustainability programs supporting awareness of food sustainability issues, dissemination of information about nutrition and sustainability, and access to safe healthy food.88 These programs include support for community-based agriculture, development and maintenance of networks of farmers' markets, and resources on nutrition and environmental impacts of food choices.<sup>89</sup>

One component of food sustainability is to ensure that food production systems, including factory farming, bear the social and economic costs of their practices. As support for food sustainability values grows, the increased attention to, acceptance of, and resources for food security, safety, and sustainability make this an opportune time for advocates to develop tactics involving litigation and advocacy for more stringent regulation in support of these goals.

#### D. Litigation as a Key Strategy in Addressing CAFO Impacts

Strategic lawsuits against CAFOs are designed to support sustainable agriculture, by attacking the economic advantage that CAFOs enjoy through externalizing their impacts. These lawsuits also can serve to frame a public narrative about the environmental and health impacts of factory farming, which can build interest, political support, and alliances among diverse interest groups for efforts to change livestock-raising practices. These features together demonstrate the strategic importance of litigation as a tool.

As described in detail by other scholars, as well as by Public Justice attorneys Leslie Brueckner, Jessica Culpepper, and Leah Nicholls in their written submission for this conference, several avenues exist for challenging the practices of CAFOs directly in court.90 These include citizen suits under the Clean Water Act,91 the Resource Conservation and Recovery Act,92 and the Clean Air Act,93 as well as state-court tort suits under nuisance, trespass, or related theories.94 Litigation against CAFO operators provides a tool for advocates to attempt to force these operators to internalize the costs they externalize, or to end certain practices entirely, through court injunctions requiring changes in business practices, monetary judgments, or injunctions requiring remediation of harms such as contamination.

At the same time, advocates have also pursued a different type of litigation, seeking to require government agencies to regulate more rigorously or effectively under federal or state statutes. This type of litigation has included programmatic lawsuits against the Environmental Protection Agency to require it to regulate CAFOs under Clean Water Act permitting provisions, 95 as well as lawsuits, including a recently-decided case by the Natural Resources Defense Council (NRDC) against FDA, to break decades-long inaction in regulation of antibiotic use in livestock.96

All these types of litigation, if successful, are likely to reduce the comparative advantage of factory farms over more sustainable practices. Even more significantly, limiting or eliminating the use of production methods that are most likely to enrich factory farm operators at the expense of the environment, public health, local economies, or the welfare of animals may threaten the very business model of industrial farming. So, for example, as another researcher has noted, "[t]he use of subtherapeutic doses of antibiotics makes factory

farm practices feasible."<sup>97</sup> If factory farming is feasible only because of practices that externalize significant harms, litigation to force internalization of these costs has the potential to create profound change in our livestock-raising practices. Integrator liability, for example, would render "the major corporations responsible for the harm caused by the farm rather than the local grower contracting with them (the party traditionally liable for any waste from the facility)."<sup>98</sup> If successful, establishing integrator liability would require the corporations that are ultimately responsible for CAFO conditions to internalize the costs of CAFOs' practices, creating a direct economic threat to these companies' business model.

Litigation can support larger campaign goals even where lawsuits do not succeed in court. Litigation can be an effective strategic and tactical tool within a larger context, supporting and complementing the work of organizers, policy advocates, and sustainable farmers. In their important analysis of the role of public interest litigation within social movements, Professors Scott Cummings and Deborah Rhode have noted that "litigation can build public awareness, help frame problems as injustices, and reinforce a sense of collective identity, all of which can build a political base for reform." In this vein, the tactic has already brought together diverse advocates from the food sustainability, environmental advocacy, and animal-rights communities to join in litigation. It thus serves to build and frame political alliances and build public awareness in order to broaden the base supporting reform.

Recent events relating to the effort to ensure FDA regulation of antibiotics in animal feed illustrate the potential for litigation to build public awareness. FDA regulatory efforts have stalled after almost three decades, now that the FDA has determined that—contrary to its decision in 1977 to develop rules on the subject—it will rely on voluntary compliance with best practices or guidelines. New FDA policies enacted in 2013 confirmed this path.<sup>101</sup> NRDC's recent lawsuit sought to reverse FDA's path and provide a basis for the agency to move forward with a more robust regulatory initiative.<sup>102</sup> The Second Circuit rejected NRDC's arguments, but this rejection itself created an opportunity for visibility and organizing around the issue.<sup>103</sup> Within a week of that decision, three influential U.S. senators wrote a letter to FDA expressing concern about what they characterized as the weakness of FDA policies regarding antibiotics in livestock, and requesting responses from the agency to key questions.<sup>104</sup> Media sources linked the timing of the letter to the court decision.<sup>105</sup> The failed lawsuit provided a means to direct mainstream media attention to a set of policies that otherwise were not the subject of significant public scrutiny, providing an opportunity to influence public opinion and potential legislative action.

#### E. Conclusion

Now is a particularly opportune time to pursue impact litigation to change livestock-raising practices. To be sure, employing litigation as a tactic to address concerns about CAFOs is not a new idea. It has been over a decade since Waterkeeper Alliance, Inc. v. EPA was filed, for example. But for many years, these efforts were cries in the wilderness, without significant public support for, or knowledge of, the underlying issues. The convergence of these litigation strategies with growing movements for food sustainability and safety, animal welfare, and environmental protection may make this an important moment in the history of CAFOs.

#### **ENDNOTES**

- 1. Michael T. Roberts is the Executive Director and Kim Kessler is the Policy and Special Programs Director of the UCLA School of Law Resnick Program for Food Law.
- 2. On April 11, 2014, the UCLA School of Law Resnick Program for Food Law and Policy, in conjunction with the Litigation Section of the State Bar of California, hosted a conference titled, "Food Fight: An Examination of Recent Trends in Food Litigation and Where We Go From Here." The conference program and video recordings from each of the panels are available at https://www.law.ucla.edu/centers/social-policy/resnick-program-for-food-law-and-policy/ events/food-law-conference/
- 3. New Standing Committee on Food Law, The State Bar of California, http://litigation.calbar.ca.gov (last visited Dec. 22, 2014).
- See Andrew J. Scholz et al., The New Wave of Food Labeling Litigation: Primary Defense and Practical Considerations, 42 Torts, Ins. & Compensation Sec. L.J. 37, 37 (Winter 2013), available at http://www.goldbergsegalla.com/sites/default/files/uploads/AJS-MRS-MDC NYSBA-TICL Journal\_Winter2013.pdf (noting that "the bulk of the litigation is focused on alleged 'false advertising' associated with food labeling").
- 5. POM Wonderful v. Coca Cola, 134 S. Ct. 2228 (2014). For discussion of federal preemption claims in the food labeling context—many of them unsuccessful, see Scholz et al., supra note 4, at 38.
- See, e.g., James J. Park, Rules, Principles, and the Competition to Enforce the Securities Laws, 100 Cal. L. Rev. 115, 124-25 (2012) (summarizing the literature's arguments for centralized SEC enforcement of securities laws and noting that some scholars assume that the SEC's expertise will cause it to bring the right types of cases and will produce optimal enforcement levels).
- 7. Richard A. Nagareda, In the Aftermath of the Mass Tort Class Action, 85 GEO. L.J. 295, 317-18 (1996); Peter Huber, see also Safety and the Second Best: The Hazards of Public Risk Management in the Courts, 85 COLUM. L. REV. 277, 305-306 (1985) (arguing that "individual consumers exposed to public risks may have insufficient information or incentive to enforce their individual risk rights" and might, in addition to assuming that others will do the job of enforcing risk, also overstate risk in an attempt to extract a high price from collective consumers, who might prefer some level of risk).
- 8. See Mark Seidenfeld, Who Decides Who Decides: Federal Regulatory Preemption of State Tort Law, 65 N.Y.U. Ann. Surv. Am. L. 611, 617 (2010) (identifying concerns of political accountability as one factor that might favor agency development and enforcement of standards of mass tortbased approaches).
- 9. See Scholz et al., supra note 4.

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- 10. See Jennifer L. Pomeranz, Litigation to Address Misleading Food Label Claims and the Role of the State Attorneys General, 26 REGENT U. L. Rev. 421, 432 (2014) (arguing that consumers are not the best entities to raise food labeling issues).
- 11. Federal Food, Drug, and Cosmetic Act, ch. 675, § 301(a), (b), (g), 52 Stat. 1040, 1042-43 (1938) (codified at 21 U.S.C. §§ 331 (2013)). See also Nicole E. Negowetti, Brookings Institution, Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority 3 (2014), available at http://www.brookings.edu/~/media/research/files/papers/2014/06/26%20food%20labeling%20 litigation/negowetti\_food%20labeling%20litigation.pdf (describing the acts).
- 12. See U.S. Food & Drug Admin., A Food Labeling Guide: Guidance for Industry, 72-80 (2013), available at http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf.
- 13. Federal Trade Commission Act, ch. 311, 38 Stat. 717 (1914) (codified as amended at 15 U.S.C. §§ 41-64) (2014); See also Negowetti, supra note 11, at 3 (describing the role of the FTC and FDA and their coordination); Memorandum of Understanding Between the Federal Trade Commission and the Federal Drug Administration, U.S. Food and Drug Admin., http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm (last updated Mar. 10, 2009).
- 14. *Id*.
- 15. Some scholars point to large gaps in agency standards and enforcement in the food labeling context. See, e.g., Bruce A. Silverglade, Responding to Heightened Enforcement Risks from Consumer Class Actions Challenging Food Labeling, UPDATE (FDLI) 20, 20 (2012), available at http://www.ofwlaw.com/CM/FirmAnnouncements/FDLI%20Update%202012%20FN3%20 PRINTED.pdf (noting that FDA "has avoided a number of key labeling controversies"); Negowetti, supra note 11, at 1 (concluding that "plaintiffs' attorneys are seeking to fill a void in the FDA's regulatory authority and enforcement of food labeling laws.").
- 16. See Negowetti, supra note 11, at 6 (providing statistics showing that growing numbers of consumers seek "natural" foods); Silverglade, supra note 15, at 21 (describing the issue of "all natural" labeling as a "lightning rod").
- 17. Pelman v. McDonald's Corp., 396 F.3d 508 (2d Cir. 2005).

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18. First Amended Class Action Complaint, Trammel v. Barbara's Bakery, Case 3:12-cv-02664-CRB (N.D. Cal. 2012); Final Judgment, Trammel v. Barbara's Bakery, Case 3:12-cv-02664-CRB (N.D. Cal. 2013), *available at* https://barbarasbakerysettlement.com/Portals/0/Documents/71%20 FINAL%20JUDGMENT.pdf; Sethavanish v. Kashi Co., No. 11- cv-4453-JCS (N.D. Cal., filed Sept. 7, 2011); Bates v. Kashi Co., No. 11-cv- 01967-HBGS (S.D. Cal. Aug. 24, 2011). For discussions of these and many other cases, *see* Pomeranz, *supra* note 10; Negowetti, *supra* note 11; Scholz et al., *supra* note 4; Silverglade, *supra* note 15.

- 19. See, e.g., Scholz et al., supra note 4, at 38-39 (explaining that even though a court did not certify a class for the case, McDonald's changed its advertising campaign, leading the plaintiffs to voluntarily dismiss their claim).
- 20. *Id.* at 37 (noting that lawsuits "increasing at a blistering pace").
- 21. Werbel v. Pepsico, Inc., 2010 U.S. Dist. LEXIS 76289 at \*10 (N.D. Cal. July 2, 2010) (quoted in Silverglade, *supra* note 15, at 21).
- 22. Letter from Stephen Gardner, Litigation Director, et al., to Mr. W. Anthony Vernon, Chief Executive Officer, Kraft Foods Group, Inc. (Jan. 9, 2013) (on file with Center for Science in the Public Interest), *available at* http://cspinet.org/images/Crystal-Light-Demand.pdf.
- 23. See, e.g., Anthony J. Anscombe & Mary Beth Buckley, Jury Still Out on the "Food Court:" An Examination of Food Law Class Actions and the Popularity of the Northern District of California, Bloomberg BNA (June 28, 2013), http://www.bna.com/jury-still-out-on-the-food-court/.
- 24. It could also be argued that because of the negative reputational effects of mislabeling on a brand's value and the ease of consumer information-sharing via social media, it may be more efficient to allow the market to police itself, at least where mislabeling is readily discoverable and does not pose a threat to human health. Given the limits of consumer attention and the huge number of food products in the marketplace, however, government intervention is probably warranted even in those cases.
- 25. As Negowetti observes, after soliciting comments on a potent definition of "natural" for labeling in the 1990s, FDA declined to regulate, citing agency resources and priorities. Negowetti, *supra* note 11, at 12 (citing 58 CFR § 2407 (1993)).
- 26. See Highlights from 40 Years of Accomplishments, Center for Science in the Public Interest, http://www.cspinet.org/about/accomplishments.html (last visited Dec. 22, 2014).
- 27. *Cf.* Park, *supra* note 6, at 178-181 (describing how relying on multiple enforcers can have advantages in the securities context).
- 28. *Cf.* Pomeranz, *supra* note 10 (providing many reasons for why government entities like state attorneys general would better address food labeling claims than would consumer lawsuits).
- 29. See Neal J. Fortin, Food Regulation: Law, Science, Policy, and Practice 117 (1st ed. 2007) (describing the history of the Nutrition Labeling and Education Act, which, after consumers' challenges to the truthfulness of food nutrition claims, attempted to "rein in exaggerated claims by reinforcing FDA's authority to regulate health claims").
- 30. See, e.g. Diana R. H. Winters, Not Sick Yet: Food-Safety-Impact Litigation and Barriers to Justiciability, 77 Brook. L. Rev. 905, 928 (2012) (discussing the difference between legal advocacy in environmental and food safety contexts); Robert L. Glicksman, The Value of Agency-Forcing

- *Citizen Suits to Enforce Nondiscretionary Duties*, 10 Widener L. Rev. 353 (2004) (discussing citizensuit litigation).
- 31. The need for a definition of "natural" was discussed in Panels One, Two, and Three, and the FDA's inaction on ECJ was discussed in Panels One and Two.
- 32. What is the meaning of 'natural' on the label of food?, ABOUT FDA, http://www.fda.gov/aboutfda/transparency/basics/ucm214868.htm (last updated Apr. 10, 2014).
- 33. Letter from Leslie Kux, FDA Assistant Commissioner for Policy, to Judges Gonzales, Rogers, White, and McNulty (Jan. 7, 2014), available at http://files.dlapiper.com/files/upload/FDA-Letter-to-Judges-Declining-Natural-1-6-13.pdf.
- 34. See, e.g. Nicole E. Negowetti, A National "Natural" Standard for Food Labeling, 65 Me. L. Rev. 581, 596-597 (2013); 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).
- 35. Katie O'Sullivan discussed the prevalence of all-natural claims in her presentation at the Food Litigation Conference, Panel 1, stating that a quarter of the 100 food class actions filed last year had a natural claim. See also Elaine Watson, Have 'all-natural' lawsuits peaked? And what defense strategies are working?, Food Navigator-usa.com/(Feb. 21, 2014), http://www.foodnavigator-usa.com/Regulation/Have-all-natural-lawsuits-peaked-And-what-defense-strategies-are-working (discussing prevalence of all-natural lawsuits).
- 36. See, e.g., CSPI Supports Proposed Nutrition Facts Revisions, CENTER FOR SCIENCE IN THE PUBLIC INTEREST (Feb. 27, 2014), http://www.cspinet.org/new/201402271.html (noting CSPI support for the Food Labeling Modernization Act, which would require FDA to define "natural").
- 37. See, e.g., Agata Blaszczak-Boxe, What does 'natural' really mean on food labels?, CBSNEws, (Jun. 14, 2014), http://www.cbsnews.com/news/what-does-natural-really-mean-on-food-labels/ (noting consumers varied understanding of term "natural"); Daniel Engber, Against Nature, SLATE (Nov. 16, 2012), available at http://www.slate.com/articles/life/food/2012/11/\_natural\_on\_food\_labels\_why\_the\_fda\_doesn\_t\_and\_shouldn\_t\_regulate\_the\_term.html (discussing varied meanings of term "natural").
- 38. Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. Rev. 733, 734 (2003).
- 39. While proponents of stronger GM regulation argue that a change in policy is warranted, any such action would require public process and agency coordination, and will take years to accomplish.
- 40. *See, e.g.,* 7 C.F.R. § 205.600 (2014) (National Organic Program, The National List of Allowed and Prohibited Substances).

- 41. Maggie Hennessy, *Slowdown in natural claims 'inevitable', say market researchers*, Food NAVIGATOR-USA.com (Aug. 19, 2014), http://www.foodnavigator-usa.com/Markets/Mintel-Datamonitor-Slowdown-in-natural-claims-inevitable/?utm\_source=newsletter\_daily&utm\_medium=email&utm\_campaign=20-Aug-2014&c=LhROXIJKKI%2BZ6tWFrnUliZJUI5HhfEf7.
- 42. U.S. Food & Drug Admin., Draft Guidance for Industry: Ingredients Declared as Evaporated Cane Juice (2009), *available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments RegulatoryInformation/LabelingNutrition/ucm181491.htm.
- 43. *Id*.
- 44. U.S. Food & Drug Admin., FDA Reopens Comment Period on Draft Industry Guidance on Evaporated Cane Juice as a Food-Labeling Term (2014), available at http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm387849.htm.
- 45. See, e.g., Elaine Watson, What exactly is evaporated cane juice, Food Navigator USA (Mar. 10, 2014) (term has "prompted a tsunami of civil litigation"), available at http://www.foodnavigator-usa. com/R-D/SPECIAL-FEATURE-What-exactly-is-evaporated-cane-juice.
- 46. See, e.g., Gitson v. Clover Stornetta Farms, 2014 WL 2638203 (N.D. CA Jun. 9, 2014); Smedt v. Hain Celestial Group, 2014 WL 2466881 (N.D. CA May 30, 2014); Swearingen v. Yucatan Foods, L.P., 2014 WL 2115790 (N.D. CA May 20, 2014); Swearingen v. Attune Foods, Inc., 2014 WL 2094016 (N.D. CA May 19, 2014).
- 47. See, e.g., Clark v. Time Warner Cable, 523 F.3d 1110, 1114 (9th Cir. 2008) ("The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency.").
- 48. See, e.g. Smedt, 2014 WL 2466881, at \*5 ("If the Court proceeds with this action and issues a decision that is contrary to the FDA's formal position on ECJ, it would disrupt the uniform application of the FDA's regulatory rules.").
- 49. See, e.g., Diana R. H. Winters, The Magical Thinking of Food Labeling: The NLEA as a Failed Statute, Tul. L. Rev. \_\_ (forthcoming 2015), available at http://papers.ssrn.com/sol3/papers. cfm?abstract\_id=2394250, at 45-47.
- 50. Such delay by FDA is not uncommon. *See, e.g.,* Diana R. H. Winters, *Intractable Delay and the Need to Amend the Petition Provisions of the FDCA,* 90 IND. L.J. \_\_\_ (forthcoming 2015), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2412662.
- 51. *Id.*
- 52. WILLIAM SHAKESPEARE, THE TEMPEST act II, scene i, lines 253–54 (Signet Classics Ed. 1998).

53. Alan L. Hoeting, *The FDA's Enforcement Program*, 47 Food & Drug L.J. 405, 405 (1992) (noting that the mission statement was included in a 1935 U.S. Senate Committee on Commerce report

- and that "[d]espite over fifty-five amendments to the Federal Food, Drug, and Cosmetics Act, the agency's basic mission has not changed.").
- 54. See http://www.fda.gov/.
- 55. The GMO issue is not solely—or, for many, even primarily—a public health issue, but instead an issue of the right to know. Interestingly (and also ironically), FDA itself seems to focus solely on the unproven health risks as a justification for its inaction, thus ignoring that the call for transparency is as much a concern to the public as the possibility that consumption of GMO ingredients might cause harm.
- 56. James H. Young, Food and Drug Enforcers in the 1920's: Restraining and Educating Business, 21 Business and Economic History, Second Series, 119, 119 (1992).
- 57. Young, *supra* note 56; *see also* Arlene Kantor, *Upton Sinclair and the Pure Food and Drugs Act of 1906*, 66 Am. J. Pub. Health 1202, 1202 (Dec. 1976) ("The issue of pure food and drugs was publicized in 1902 by journal coverage of Dr. Wiley's experiments with 12 men fed adulterated meals. The 'Poison Squad', as it came to be known, was, according to Wiley, 'the most highly advertised boarding-house in the world."); Donna J. Wood, *The Strategic Use of Public Policy: Business Support for the 1906 Food and Drug Act*, 59 Bus. Hist. Rev. 403, 407 (1985) ("Poison Squad experiments . . . were a media sensation.")
- 58. Young, *supra* note 56, at 119.
- 59. *Id*.
- 60. CLAYTON A. COPPIN & JACK HIGH, THE POLITICS OF PURITY: HARVEY WASHINGTON WILEY AND THE ORIGINS OF FEDERAL FOOD POLICY 95 (U. of Mich. Press 1999).
- 61. *Id*.
- 62. *Id.* at 96. *See also* Wood, *supra* note 57, at 419-21 (describing how the founders of H.J. Heinz and Pabst Brewing Company lobbied for the Act's passage in order to use it to convince the public that their products were pure and safe).
- 63. Coppin, *supra* note 60, at 171.

- 64. Roberto A. Ferdman, *The word "natural" helps sell \$40 billion worth of food in the U.S. every year—and the label means nothing*, Washington Post (June 24, 2014), http://www.washingtonpost.com/blogs/wonkblog/wp/2014/06/24/the-word-natural-helps-sell-40-billion-worth-of-food-in-the-u-s-every-year-and-the-label-means-nothing/.
- 65. Temple Northrup, *Truth, Lies, and Packaging: How Food Marketing Creates a False Sense of Health* 3 Food Stud: An Interdisc. J., 9-18 (March 2014) (arguing that while many individuals may be trying to increase the health of their diets, food marketers are taking advantage of them by misleading those consumers with deceptive labeling).

- 66. See e.g., Barnes v. Campbell Soup Co., No. C-12-05185-JSW, 2013 WL 5530017 (N.D. Cal. 2013).
- 67. Wood, *supra* note 57, at 404.
- 68. Marion Nestle, Safe Food: Bacteria, Biotechnology, and Bioterrorism 77-78 (2003) ("industry protests caused critical delays but failed to prevent the USDA from requiring warning labels"). Those so-called warning labels are notable for providing the ambiguous and unhelpful advice that consumers should "cook thoroughly," advice that meat companies have used to argue that consumers are the ones ultimately responsible for making meat safe to eat. Denis Stearns, *Preempting Food Safety: An Examination of USDA Rulemaking and Its* E. coli *O157:H7 Policy in Light of* Estate of Kriefall ex rel. Kriefall v. Excel Corporation, 1 J. Food L. & Pol'y 375, 418-20 (2005) (describing and critiquing the meat industry's effort to defend a *caveat essor*—or eater beware—policy as a defense to liability in E. coli O157:H7 cases).
- 69. Twenty-three years after the passage of the Pure Food and Drugs Act, and seventeen years after having resigned the agency in protest, Wiley published a jeremiad that accused FDA and the food industry of a "crime," with the subtitle of his book nicely summarizing his thesis: The Amazing Story of the National Food and Drug Law Intended to Protect the Health of the People, Perverted to Protect Adulteration of Food and Drugs. See Harvey Washington Wiley, M.D., The History of a Crime Against the Food Law (Lee Foundation for Nutritional Research, Facsimile Ed. 1955) (original pub. date 1929) available at https://www.seleneriverpress.com/images/pdfs/HISTORY\_OF\_A\_CRIME\_AGAINST\_THE\_FOOD\_LAW\_by\_HW\_WILEY\_MD\_1929.pdf.
- 70. This essay relates to comments of conference panelists Leslie Brueckner of Public Justice and Avinash Kar of the Natural Resources Defense Council. Robert Bodzin of Burnham Brown also provided insightful remarks but on topics that do not directly relate to the subject of this essay at this conference session.
- 71. See, e.g., Lars Johnson, Pushing NEPA's Boundaries: Using NEPA to Improve the Relationship Between Animal Law and Environmental Law, 17 NYU ENVTL. L. J. 1367, 1384-85 (2009) (discussing divergences between interests of environmental advocates and animal advocates).
- 72. See David E. Solan, Et Tu Lisa Jackson?: An Economic Case for Why the EPA's Sweeping Environmental Regulatory Agenda Hurts Animal Welfare on Factory Farms, 8 J. Animal & Nat. Resource L. 27 (2012).
- 73. See Stephanie Tai, *The Rise of U.S. Food Sustainability Litigation*, 85 S. Cal. L. Rev. 1130-35 (2012) for an account of the relationship between litigation and the food sustainability movement.
- 74. U.S. Gov't Accountability Office, GAO-08-944, Concentrated Animal Feeding Operations: EPA Needs More Information and a Clearly Defined Strategy to Protect Air and Water Quality from Pollutants of Concern (2008), *available at* http://www.gao.gov/new.items/d08944.pdf.
- 75. See Pew Charitable Trusts, Putting Meat on the Table: Industrial Farm Animal Production in America 5-6 (2008), available at http://www.ncifap.org/\_images/PCIFAPFin.pdf; for a detailed discussion of CAFO conditions; see also Tai, supra note 73, at 1081, and sources cited therein, for a general summary of the conditions in CAFOs as well as the regulatory definitions applicable to CAFOs.

- 76. Pew Charitable Trusts, *supra* note 75, at 5-6.
- 77. *Id*.
- 78. See *Id.* for a discussion of the costs externalized by CAFOs and industrial feedlots generally.
- 79. *Id.*
- 80. Meghan F. Davisa & Lainie Rutkow, *Regulatory Strategies to Combat Antimicrobial Resistance of Animal Origin: Recommendations for a Science-Based U.S. Approach*, 25 Tul. EnvTl. L.J. 327, 333 n.33 (2012) (collecting articles discussing the relationship between livestock antibiotic use and antibiotic resistance, and regulatory strategies for addressing this relationship).
- 81. Carrie Hribar, Understanding Concentrated Animal Feeding Operations and Their Impact on Communities 3-5 (National Association of Local Boards of Health 2010), available at http://www.cdc.gov/nceh/ehs/docs/understanding\_cafos\_nalboh.pdf; see also U.S. Gov't. Accountability Office, Concentrated Animal Feeding Operations: EPA Needs More Information and a Clearly Defined Strategy to Protect Air and Water Quality from Pollutants of Concern (2008), available at http://www.gao.gov/products/GAO-08-944 (collecting studies with various conclusions of CAFOs' contribution to air and water pollution).
- 82. Hribar, supra note 81, at 5-7.
- 83. *See* Tai, *supra* note 73, at 1085-89 (presenting various concerns raised about CAFOs in the sustainable food movement).
- 84. Kelley J. Donham et al., *Community Health and Socioeconomic Issues Surrounding Concentrated Animal Feeding Operations*, 115 Environmental Health Perspectives 317 (2007).
- 85. See, e.g., Pew Charitable Trusts, supra note 74, at 31-35.
- 86. See Tai, supra note 72, at 1074-80; see also, e.g., Michael Pollan, Frequently Asked Questions, Michael Pollan, http://michaelpollan.com/resources/politics-policy/ (last visited Dec. 22, 2014) (listing, collecting, and linking to organizations and other resources focusing on food sustainability); Local Good Food Organizations, Los Angeles Food Policy Council, http://goodfoodla.org/resources/local-good-food-organizations/labor-worker-justice/ (last visited Dec. 22, 2014); http://www.rootsofchange.org/content/about-us-1; New York City Food Policy Center, http://nycfoodpolicy.org/ (last visited Dec. 22, 2014).
- 87. See sources collected in note 86, supra.

- 88. *See, e.g., Eat for the Environment*, NYC FOOD, http://www.nyc.gov/html/nycfood/html/environment/environment.shtml (last visited Dec. 22, 2014).
- 89. See NYC Food, http://www.nyc.gov/html/nycfood/html/about/about.shtml.

- 90. Leslie Brueckner et al., Litigation Strategies for Reforming Unsafe and Illegal Practices in Industrialized Animal Agriculture (2014) (on file with author).
- 91. See 33 U.S.C. § 1365(a)(1) (2014). Litigation efforts under the Clean Water Act so far have met with mixed success, since courts have been reluctant to interpret permitting requirements to apply robustly to CAFOs. See, e.g., Waterkeeper Alliance, Inc. v. EPA, 399 F.3d 486 (2nd Cir. 2005) (limiting the application of permitting requirements to CAFOs under the Clean Water Act); Christopher R. Brown, Uncooperative Federalism, Misguided Textualism; The Federal Courts' Mistaken Hostility Toward Pre-Discharge Regulation of Confined Animal Feeding Operations Under the Clean Water Act, 30 Temp. J. Sci. Tech. & Envit. L. 175 (2011).
- 92. See 42 U.S.C. § 6972(a)(1) (2014).
- 93. See 42 U.S.C. § 7604 (2014).
- 94. *See, e.g.,* Complaint, Blackwood, et al. v. Mary De Vries, et al., No. CV-14-C0395 JGB (C.D. Cal. 2014) (alleging private nuisance, trespass, and Resource Conservation and Recovery Act (RCRA) citizen suit causes of action).
- 95. See, e.g., Waterkeeper Alliance, Inc. v. EPA, 399 F.3d 486 (2nd Cir. 2005).
- 96. See, e.g., Natural Resources Defense Council v. United States Food and Drug Administration, Docket Nos. 12–2106–cv(L), 12–3607–cv(CON) (2d Cir. July 24, 2014), available at http://caselaw.findlaw.com/us-2nd-circuit/1673611.html.
- 97. Barbara O'Brien, *Animal Welfare Reform and the Magic Bullet: The Use and Abuse of Subtherapeutic Doses of Antibiotics in Livestock*. <sup>67</sup> U. Colo. L. Rev. <sup>407, 413</sup> (1996).
- 98. Brueckner et al., *supra* note 93, at 7; *see* Letter from Jessica Culpepper Re: 60-Day Notice of Intent to File Citizen Suit Under Clean Water Act Section 505(a)(1) for Violation of Terms and Conditions of North Carolina NPDES General Permit NCA200000, *available at* http://publicjustice.net/sites/default/files/downloads/FINAL-Stantonsburg-NOI-031314.pdf (naming multiple parties, including Smithfield Foods subsidiary Murphy-Brown LLC and other affiliated companies, as potential defendants in action for alleged violations of the Clean Water Act by CAFO owner Stantonsburg Farm).
- 99. See Scott L. Cummings & Deborah L. Rhode, *Public Interest Litigation: Insights from Theory and Practice*, 36 Fordham Urb. L.J. 603, 646-48 (2009).
- 100. See, e.g., Complaint, Environmental Integrity Project et al. v. Gina McCarthy et al., No. 1:13-cv-01306 ((D.D.C. August 28, 2013) (rulemaking case under the Clean Water Act seeking more stringent regulation of CAFOs, with diverse plaintiffs including food safety and security advocates Center for Food Safety and Food and Water Watch; environmental advocacy group the Environmental Integrity Project; and animal-rights advocacy group the Humane Society of the United States).

- 101. U.S. Food & Drug Admin, Guidance for Industry: The Judicious Use of Medically Important Antimicrobial Drugs in Food Producing Animals (2012), available at http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf; U.S. Food & Drug Admin, Guidance for Industry: New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209; Veterinary Feed Directive (VFD), 21 CFR § 558 (2014).
- 102. Natural Resources Defense Council, Docket Nos. 12–2106–cv(L), 12–3607–cv(CON) (holding that the FDA is not required by 21 U.S.C. § 360b(e)(1) to convene hearings "to determine whether to withdraw approval for the use of penicillin and tetracyclines in animal feed").
- 103. Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin., 760 F.3d 151 (2d Cir. 2014).
- 104. Letter from U.S. Senators Elizabeth Warren, Dianne Feinstein, and Kirsten E. Gillibrand, to Dr. Margaret Hamburg, Commissioner, U.S. Food and Drug Administration (July 28, 2014), *available at* http://freepdfhosting.com/765667bc5b.pdf.
- 105. See, e.g., Ruth Reichl, The F.D.A.'s Blatant Failure on Food, N.Y. Times, July 30, 2014, at A23, available at http://www.nytimes.com/2014/07/31/opinion/the-fda-blatant-failure-on-food.html; Ed Silverman, FDA Plan for Antibiotics in Food-Producing Livestock is Weak: Senators, Wall Street Journal's Pharmalot (July 29, 2014, 8:45 AM), http://blogs.wsj.com/pharmalot/2014/07/29/fda-plan-for-antiobiotics-in-food-producing-livestock-is-weak-senators/; David Siegel, Sens. Press FDA For Plan On Antibiotic Use In Farm Animals, Law360 (July 28, 2014, 5:59 PM), http://www.law360.com/articles/561727/sens-press-fda-for-plan-on-antibiotic-use-in-farm-animals.

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