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## A “Natural” Stand Off Between the Food and Drug Administration and the Courts: The Rise in Food-Labeling Litigation & the Need for Regulatory Reform

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# A “NATURAL” STAND OFF BETWEEN THE FOOD AND DRUG ADMINISTRATION AND THE COURTS: THE RISE IN FOOD-LABELING LITIGATION & THE NEED FOR REGULATORY REFORM

**Abstract:** Faced with the health and financial toll from escalating rates of chronic disease, consumers are demanding healthier food products and increased transparency regarding the ingredients in their food. Food labels provide the primary means for businesses to communicate with customers about their food products. In response to consumer demand, food companies are stocking grocery store shelves with products claiming to be wholesome, “natural” and healthy. Yet, many of these products are not as healthy or natural as purported. Although both consumers and food manufacturers place importance on the term “natural,” the Food and Drug Administration has refused to define the term. In the absence of a legally enforceable definition, there has been a rise in class action litigation against allegedly mislabeled “all natural” food products. This Note evaluates the impact of the courts, rather than the FDA, on the interpretation of food-labeling laws. The Note discusses the confusion among courts over whether primary jurisdiction should apply and litigation should be stayed due to possible agency action. This Note goes on to analyze the results of the FDA’s public comment process initiated in May 2016 to determine whether the agency should define the term “natural.” Finally, this Note explores how and why the FDA, not the courts or legislature, should define the term “natural.”

## INTRODUCTION

Six out of ten adults in the United States suffer from a chronic disease that is linked to lifestyle and food consumption, such as heart disease, type two diabetes, arthritis, or obesity.<sup>1</sup> A mere 100 years ago, these chronic conditions

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<sup>1</sup> See *About Chronic Disease Overview*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/chronicdisease/about/index.htm> [<https://perma.cc/3AW7-QVP6>] (providing statistics on the prevalence of chronic disease and its implications for healthcare costs); see also SHUSHANA CASTLE & AMY-LEE GOODMAN, *RETHINK FOOD: 100+ DOCTORS CAN’T BE WRONG* (2014) (discussing the scientific evidence illustrating the relationship between the rise in chronic disease and the consumption of animal-based food). Once known as degenerative diseases, chronic diseases are rising in the United States and those countries that follow Western diets, which focus on the heavy consumption of meat and dairy. CASTLE & GOODMAN, *supra*, at 5. Studies and research indicate that these chronic diseases can be prevented and even reversed through dietary changes, and specifically by adopting a plant-based diet. *Id.*

were considered degenerative diseases, which only affect the elderly.<sup>2</sup> As of 2018, two out every three twelve-year-olds have atherosclerosis, and children as young as eleven are displaying the first signs of heart disease.<sup>3</sup> These health conditions come with a hefty price, totaling nearly \$750 billion in direct medical costs annually.<sup>4</sup> The costs related to obesity alone total a staggering \$190.2 billion per year.<sup>5</sup> Given this current health crisis, consumers are demanding healthier food products and increased transparency regarding the ingredients in their food.<sup>6</sup>

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<sup>2</sup> See CASTLE & GOODMAN, *supra* note 1, at 3 (noting that degenerative conditions are those thought to only affect the elderly). In the 1900s, less than ten percent of deaths were attributed to cardiovascular disease. *Id.* at 4. In the United States, heart disease is now the most prominent health condition and affects a younger population, including those in their thirties and forties. *Id.* at 99.

<sup>3</sup> *Id.* at 89. Atherosclerosis is the first stage of coronary artery disease. *Id.* at 107. The condition is caused by systemic inflammation that causes plaque to accumulate in the arteries of the body and can eventually block blood flow, causing a heart attack or stroke. *Id.* at 111.

<sup>4</sup> See *About Chronic Disease Overview*, *supra* note 1 (discussing the economic costs of chronic diseases); Linda Fried, *America's Health and Healthcare Depend on Preventing Chronic Disease*, HUFFINGTON POST (Mar. 14, 2017), [https://www.huffingtonpost.com/entry/americas-health-and-healthcare-depends-on-preventing\\_us\\_58c0649de4b070e55af9eade](https://www.huffingtonpost.com/entry/americas-health-and-healthcare-depends-on-preventing_us_58c0649de4b070e55af9eade) [<https://perma.cc/BVQ7-VEHE>] (discussing how preventable chronic diseases are economically crippling America's healthcare system and providing strategies for improvement). Direct costs include medical expenses, whereas indirect costs include lost productivity or lost earnings caused by premature death or inability to work. *Chronic Disease Overview*, *supra* note 1. A study commissioned by the American Heart Association estimates that the annual direct medical costs of treating cardiovascular disease will double from \$318 billion to \$749 billion between 2015 and 2035. OLGA KHAVJOU, ET AL., RTI INT'L, PROJECTIONS OF CARDIOVASCULAR DISEASE PREVALENCE AND COSTS: 2015–2035: TECHNICAL REPORT ES-1 (2016). Indirect medical costs from lost productivity are expected to increase from \$237 billion in 2015 to about \$368 billion per year by 2035. *Id.*

<sup>5</sup> See *Economic Costs of Obesity*, NAT'L LEAGUE OF CITIES, <https://www.healthycommunitieshealthyfuture.org/learn-the-facts/economic-costs-of-obesity> [<https://perma.cc/9S4J-ATVJ>] (finding that the health cost of childhood obesity alone is fourteen billion dollars in direct costs).

<sup>6</sup> See CASTLE & GOODMAN, *supra* note 1, at 95 (noting that cardiologist Dr. Caldwell Esselstyn has called heart disease in America an epidemic); *Cardiovascular Disease Costs Will Exceed \$1 Trillion by 2035, Warns the American Heart Association*, AM. HEART ASS'N (Feb. 14, 2017), <https://newsroom.heart.org/news/cardiovascular-disease-costs-will-exceed-1-trillion-by-2035-warns-the-american-heart-association> [<https://perma.cc/D6YK-L5VK>] (discussing how the rise in heart disease could cripple the American economy). The American Heart Association noted that, in 2016, death rates from heart disease rose by one percent and cost \$555 billion dollars. *Cardiovascular Disease Costs Will Exceed \$1 Trillion by 2035, Warns American Heart Association*, *supra*; see also John Kell, *Fresh, Healthy Food Is Not a Trend, It's a Movement*, FORTUNE MAG. (Nov. 30, 2016), <https://fortune.com/2016/11/30/food-healthy-trend-mpw> [<https://perma.cc/M3M5-A72E>] (claiming that consumer desire for healthy products is about food that is not artificial or synthetic); Christopher McDonald & Ani Adjemian, *State of Litigation Over 'Natural' Food Labels*, FOOD MANUFACTURING (June 8, 2017), <https://www.foodmanufacturing.com/article/2017/06/state-litigation-over-natural-food-labels> [<https://perma.cc/C22G-XL9P>] (noting that the results of the Food and Drug Administration's 2015 public comment proposal on whether the agency should define the term "natural" indicated that the majority of consumers value transparency on their labels and feel that current "natural" labels on food are deceptive).

Food labels provide the primary means for businesses to communicate with customers about their food products.<sup>7</sup> Properly labeled products allow consumers to make more informed and healthier food choices.<sup>8</sup> In response to consumer demand for healthier products, food companies are stocking grocery store shelves with products claiming to be “wholesome,” “natural,” and “healthful.”<sup>9</sup> Many of these products, however, are not as healthy or natural as purported.<sup>10</sup>

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<sup>7</sup> See INST. OF MED., FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS: PHASE I REPORT 15 (2010) (discussing the evolution of food labels as the primary means of communicating with consumers about the nutritional content of food products); see also Margot Pollans, *The Labeling Shortcut*, SLATE (May 5, 2016), <https://slate.com/technology/2016/05/the-fdas-quest-to-define-natural-wont-give-us-better-food.html> [<https://perma.cc/S5UC-BRQM>] (discussing labeling as an alternative to direct regulation because it gives consumers the ability to make better health choices). The theory is that, with better labeling, the market will respond to consumer preferences and offer healthier products without being forced to do so by regulation. Pollans, *supra*. In essence, proper labeling protects consumers' choice. *Id.*

<sup>8</sup> See David Lazarus, *Trump's Answer to the Obesity Epidemic: Here, Have a Cookie*, L.A. TIMES (June 20, 2017), <https://www.latimes.com/business/lazarus/la-fi-lazarus-food-labels-20170620-story.html> [<https://perma.cc/ADT8-ZJNN>] (stating new food labeling requirements instituted by the Obama administration, which obligate manufacturers to disclose the presence of added sugars in their foods and will permit consumers to make better food choices). The Trump administration's decision to delay implementation could have negative impacts for American consumers. *Id.*; see also FDA's *Obesity Working Group Report - Questions and Answers*, U.S. FOOD & DRUG ADMIN. (Nov. 17, 2017), <http://wayback.archive-it.org/7993/20180424211134/https://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm082094.htm> [<https://perma.cc/9DK9-HRTH>] (overviewing proposed changes to food labeling intended to combat rising obesity by providing consumers with better nutritional information). The FDA considered changes to the nutritional label including how to display caloric content and serving sizes. FDA's *Obesity Working Group Report - Questions and Answers*, *supra*. The FDA report also recommended that manufacturers provide dietary guidance to consumers such as, “have a carrot, not the carrot cake.” *Id.*

<sup>9</sup> See Nicole E. Negowetti, *Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority*, BROOKINGS GOVERNANCE STUDIES, June 2014, at 6, [https://www.brookings.edu/wp-content/uploads/2016/06/Negowetti\\_Food-Labeling-Litigation.pdf](https://www.brookings.edu/wp-content/uploads/2016/06/Negowetti_Food-Labeling-Litigation.pdf) [<https://perma.cc/5SVU-DCKK>] [hereinafter Negowetti, *Food Labeling Litigation*] (noting that the increased use of health claims on products can be due to the “health halo” effect). The “health halo” effect means that consumers might be more inclined to buy products that are labeled as “organic” or “natural” because they believe that these attributes make the food healthier than it actually is. *Id.* Consumers, then, feel better about eating these products. See Roberto Ferdman, *The Word ‘Natural’ Helps Sell \$40 Billion Worth of Food in the U.S. Every Year—and the Label Means Nothing*, WASH. POST (June 24, 2014), <https://www.washingtonpost.com/news/wonk/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> [<https://perma.cc/5MJG-AWCM>] (reporting that the thirty-five most used health claims helped the food industry sell more than \$377 billion in food items over a one-year period). Foods labelled as “natural” now account for over forty billion dollars in annual sales and those sales have increased three percent year over year. *Id.*

<sup>10</sup> See Brandon McFadden, *Gluten-Free Water and Other Absurd Labelling Trends*, BBC (Jan. 27, 2018), <https://www.bbc.com/capital/story/20180126-gluten-free-water-and-absurd-labelling-of-whats-absent> [<https://perma.cc/2K94-KZYZ>] (noting that the rise in manufacturers labeling products as “natural” and “organic” is in response to consumer demand for knowledge about what is in their food products). Economist Kevin Lancaster suggested that consumers might acquire more happiness from the perceived qualities of a product and not from the actual product that they buy. *Id.* Because manufacturers have more information about their food products than consumers, companies can ex-

Although both consumers and food manufacturers place importance on the term, “natural,” the Food and Drug Administration (FDA) has refused to define the term.<sup>11</sup> In the absence of a legally enforceable definition, there has been a rise in class action litigation against allegedly mislabeled “all natural” food products.<sup>12</sup> Some consumers assert that these labels are misleading because the products are made with artificial, synthetic, or genetically modified ingredients.<sup>13</sup> Although mislabeling cases are often criticized as frivolous, businesses are changing their practices by removing “natural” claims from their products and reformulating their products to match consumer desires for healthier food.<sup>14</sup>

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exploit this information gap by putting misleading labels on their products to increase sales. *Id.* This asymmetry of information between consumers and manufacturers can directly and negatively influence market outcomes. *Id.*; see also George A. Akerlof, *The Market for “Lemons”: Quality Uncertainty and the Market Mechanism*, 84 Q.J. ECON. 488, 495 (1970) (discussing how information asymmetry between consumers and manufacturers can negatively influence the market by allowing companies to sell poor quality products).

<sup>11</sup> See Erik Benny, Essay, *Natural Modifications: The FDA’s Need to Promulgate an Official Definition of “Natural” That Includes Genetically Modified Organisms*, 80 GEO. WASH. L. REV. 1504, 1506 (2012) (discussing the rise in food-labeling litigation due to the FDA’s lack of a legal definition for “natural” and commenting on the need for a national definition).

<sup>12</sup> See Richard Blau & Anna Wiand, *FDA’s Next Action on Defining “Natural” for Food Labels Purposes Remains Unclear*, GRAY ROBINSON (July 21, 2016), <http://www.gray-robinson.com/blog/post/1247/fda-next-action-on-defining-natural-for-food-labeling-purposes-remains-unclear> [<https://perma.cc/2EEY-ZXLS>] (discussing allegations of false advertising against well-known brands for products that claim to be “natural” but contain synthetic ingredients). Examples of lawsuits include: claims against Snapple for using the label “natural” when the products contain high-fructose corn syrup; claims against Dole for its packaged fruits labeled as “all natural” but containing citric and ascorbic acid; claims against Kellogg’s for its Kashi cereal, labeled as “nothing artificial” but containing synthetic ingredients; and claims against Chobani for its yogurt, labeled as “natural” but containing “evaporated cane juice.” *Id.*; see also U.S. CHAMBER INST. FOR LEGAL REFORM, *THE FOOD COURT: TRENDS IN FOOD & BEVERAGE CLASS ACTION LITIGATION 3* (2017), [http://www.instituteforlegalreform.com/uploads/sites/1/TheFoodCourtPaper\\_Pages.pdf](http://www.instituteforlegalreform.com/uploads/sites/1/TheFoodCourtPaper_Pages.pdf) [<https://perma.cc/H2M6-XU38>] (noting that food litigation has reached the appellate level with no signs of slowing down); Stephanie Strom, *Lawyers from Suits Against Big Tobacco Target Food Makers*, N.Y. TIMES (Aug. 18, 2012), <https://www.nytimes.com/2012/08/19/business/lawyers-of-big-tobacco-lawsuits-take-aim-at-food-industry.html> [<https://perma.cc/CXE8-3FZD>] (discussing how the class action lawyers that litigated claims against tobacco companies are now using similar litigation tactics in suits against companies that are mislabeling food products).

<sup>13</sup> See U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 5–7 (noting that, although snack products are the most popular targets for litigation, food-related class actions cover a wide variety of products including pastas, bread, orange juice, cereals, protein bars, yogurt, cheese, frozen meals, olive oil, tuna, and ice tea).

<sup>14</sup> See Greg Trotter, *Lawsuits Challenging Food Labels on the Rise, but Are They Good for Consumers?*, CHI. TRIB. (May 6, 2016), <https://www.chicagotribune.com/business/ct-food-labeling-lawsuits-0506-biz-20160506-story.html> [<https://perma.cc/4YPT-6XRE?type=image>] (discussing the debate over whether food litigation represents the right of consumers to demand transparency in their food products or merely represents frivolous litigation). The primary criticism of this litigation is that these suits benefit lawyers more than consumers because these cases are generally multimillion-dollar class actions. See U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 4 (noting that lawyers often receive about half of the multimillion-dollar awards, whereas plaintiffs only receive minimal

In addition to the courts, congressional action seeks to fill this regulatory void.<sup>15</sup> Congress has twice attempted to pass labeling laws that would cure the FDA’s inaction by defining the term “natural.”<sup>16</sup> In response to mounting pressure from the courts, industry, and consumers, the FDA initiated a public comment process that closed in May of 2016 concerning whether the agency should define the term “natural.”<sup>17</sup> Since closing comments, the FDA has remained silent on issuing a definition, sustaining a disagreement among the

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monetary compensation or coupons); *see also* Jackie Dulen, *How Millennials Are Driving Movement for Clean Labels on Our Food*, CHI. TRIB. (Feb. 18, 2016), <https://www.chicagotribune.com/business/sc-clean-labels-food-0219-20160218-story.html> [<https://perma.cc/99RA-AFZ5?type=image>] (over-viewing changes to food products in response to the consumer-driven movement for “clean labels,” meaning food products that contain no artificial ingredients); Monica Watrous, *Trend of the Year: Clean Label*, FOOD BUS. NEWS, <http://features.foodbusinessnews.net/corporateprofiles/2015/trend-index.html> [<https://perma.cc/GA53-7ENP>] (noting that companies such as Campbell, Kellogg, and Nestle have committed to removing artificial ingredients from their products). Some major industry changes include: Kraft Mac & Cheese removing synthetic ingredients and substituting paprika, turmeric, and annatto; Nestle Crunch using natural vanilla flavor rather than artificial vanilla; and General Mills stating that Trix cereal will no longer be made with artificial colors but will instead contain natural ingredients. Dulen, *supra*; *see* Elaine Watson, *What Next for ‘Natural’ Claims? KIND Urges Court to Leave Issue with the FDA*, FOODNAVIGATOR-USA (Apr. 26, 2016), <https://www.foodnavigator-usa.com/Article/2016/04/25/All-natural-lawsuit-should-be-stayed-argues-KIND#> [<https://perma.cc/8PW4-ZL5W>] (noting that the percentage of new food products labeled with “natural” claims has decreased). There has been a steady decline in companies using the “all natural” label on new products—decreasing from 13.76% newly introduced products in 2013 to 12.63% in 2014 to only 11% in 2015. Watson, *supra*. Aside from the risk of litigation, industry attitudes toward the word “natural” may have also contributed to this trend. *Id.* For example, the president of Annie’s Foods stated that the company has not used the term for over a decade because it has no meaning anymore. *Id.* He predicted that the term “natural” would give way to and be encompassed in “organic” labeling. *Id.* Similarly, the CEO of Good Food Made Simple, which makes frozen foods, stated that the term “natural” is “abused,” which is why the company removed the claim from its foods. *Id.*

<sup>15</sup> *See* Nicole E. Negowetti, *Defining Natural Foods: The Search for a Natural Law*, 21 REGENT UNIV. L. REV. 329, 352 (2014) [hereinafter Negowetti, *Defining Natural Foods*] (noting that, in the absence of FDA regulation, legislatures are attempting to define the term “natural”).

<sup>16</sup> *See* Nilda Isidro, *It’s Only Natural: Recent Developments Regarding the Term “Natural” in Food Labeling*, FOOD SAFETY MAG. (May 3, 2016), <https://www.foodsafetymagazine.com/enews/letter/ite28099s-only-natural-recent-developments-regarding-the-term-e2809cnaturale2809d-in-food-labeling> [<https://perma.cc/W4E2-56L2>] (discussing the failed congressional attempts to pass the Food Modernization Act in 2013 and 2015 and the Safe and Accurate Food Labeling Act in 2015, both of which would have defined the term “natural”); *see also* Food Labeling Modernization Act of 2015, H.R. 4061, 114th Cong. (as proposed Nov. 18, 2015) (proposing a definition for the term “natural”); Food Labeling Modernization Act of 2015, S. 2301, 114th Cong. (as proposed Nov. 18, 2015) (over-viewing the Food Modernization Act of 2015 that would have defined the term “natural”); Safe and Accurate Food Labeling Act, H.R. 1599, 114th Cong. (as passed by H.R. July 23, 2015) (failing to receive enough Senate votes to pass).

<sup>17</sup> *“Natural” on Food Labeling*, U.S. FOOD & DRUG ADMIN. (Oct. 22, 2018), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm> [<https://perma.cc/E4CE-2TQR>] (noting that the FDA sought comments after pressure from courts and citizen petitions to define the term “natural,” and noting that the FDA closed public comment in May of 2016).

courts over whether primary jurisdiction should apply and litigation should be stayed due to possible agency action.<sup>18</sup>

Part I of this Note discusses reasons for the rise in food mislabeling litigation, provides an overview of the regulatory agencies and laws governing food labeling, and discusses the causes of actions that some consumers are bringing against food manufacturers.<sup>19</sup> Part II discusses the impact of the FDA's decision to not define the term "natural," leaving a substantial grey area ripe for litigation and congressional attempts at regulation.<sup>20</sup> Part III analyzes the impact of courts determining food-labeling laws rather than the regulatory agency and argues for the FDA to define what "natural" means to provide certainty for consumers, the industry, and the courts.<sup>21</sup>

## I. OVERVIEW OF FDA FOOD LABELING REGULATIONS & THE RISE OF FOOD-LABELING LITIGATION

### *A. The Federal Food & Drug Administration: The Agency & Laws Behind the Food Labels*

In 1901, twelve government volunteers, nicknamed "The Poison Squad" agreed to eat food laced with the most commonly used—but untested—food additives, including toxins such as borax, copper sulfate, and formaldehyde.<sup>22</sup>

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<sup>18</sup> Compare *Kane v. Chobani, LLC*, 645 F. App'x 593, 594 (9th Cir. 2016) (deciding to stay the litigation under primary jurisdiction because the FDA had requested comments on defining "natural"), and *Coyle v. Hornell Brewing Co.*, No. 08-cv-02797, 2010 WL 2539386, at \*4 (D.N.J. June 15, 2010) (holding that determining whether high-fructose corn syrup is "natural" or artificial is a task for the regulatory agency and not the courts), with *Bohac v. Gen. Mills, Inc.*, No. 12-CV-05280-WHO, 2013 WL 5587924, at \*3 (N.D. Cal. Oct. 10, 2013) (noting that making a ruling on the term "natural" has zero risk of undercutting the FDA's authority when there are no rules or regulations in place), and *Brazil v. Dole Food Co.*, 935 F. Supp. 2d 947, 960 (N.D. Cal. 2013) (noting that primary jurisdiction doctrine does not mean that a court cannot decide a case when presented with an issue within the agency's purview).

<sup>19</sup> See *infra* notes 22–116 and accompanying text.

<sup>20</sup> See *infra* notes 117–206 and accompanying text.

<sup>21</sup> See *infra* notes 207–243 and accompanying text.

<sup>22</sup> See Bruce Watson, *The Poison Squad: An Incredible History*, *ESQUIRE* (June 27, 2013), <https://www.esquire.com/food-drink/food/a23169/poison-squad> [<https://perma.cc/X2ND-V4GE?type=image>] (overviewing the creation and purpose of the Poison Squad). Wiley persuaded the federal government to give him \$5,000 to fund the human trials. *Id.* The twelve members willingly agreed not to sue the federal government for any damages including death. *Id.* The first additive the Squad tried was borax—commonly used to hide the appearance of rotting meat. *Id.* The conclusion was that consuming borax could lead to headaches, stomachaches, and digestive problems. *Id.* One of the most troubling food additives tried was copper sulfate, a substance that today is used as a pesticide, but historically was used to change the color of canned peas to bright green. *Id.* Consuming this additive resulted in significant health problems such as kidney, brain, and liver damage. *Id.* See generally DEBORAH BLUM, *THE POISON SQUAD: ONE CHEMIST'S SINGLE-MINDED CRUSADE FOR FOOD SAFETY AT THE TURN OF THE CENTURY* (2018) (chronicling Dr. Harvey Wiley's creation of the Poison

Dr. Harvey Wiley, dubbed the “Father of the FDA” headed the experiment with the goal of showing the effects of adulterated food and the need for food regulation and proper labeling.<sup>23</sup> Historically, states were charged with regulating food.<sup>24</sup> With the increase in interstate commerce and technological innovations, reformers called for Congress to provide federal regulations to prevent potentially dangerous adulterated food additives from infiltrating the food market nationally.<sup>25</sup> Congress responded and has introduced about 100 bills concerning food and drug regulation since 1879.<sup>26</sup> The findings of the Poison Squad as well as Upton Sinclair’s book, *The Jungle*—exposing the horrendous conditions in meatpacking plants—finally provided the impetus for Congress to enact a law to prevent adulterated food products from reaching the market.<sup>27</sup>

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Squad, a group of young men who tried commonly used food additives to illustrate the health dangers of these food additives).

<sup>23</sup> See Wallace F. Janssen, *The Story of the Laws Behind the Labels*, FDA CONSUMER, June 1981, at 32, 35 (stating that the principles behind the Poison Squad form the backbone of today’s food law and regulations: proving safety of the products should be on the producer, consumers should be properly informed by labels of what ingredients are in their food, and synthetic food additives should be sparingly used in food); Watson, *supra* note 22 (stating that volunteers would eat each additive in meals in increasing amounts to determine the level of toxicity or other effects); Bernard Weisberger, *Doctor Wiley and His Poison Squad*, AMERICAN HERITAGE, Feb./Mar. 1996, at 14, 16 <https://www.americanheritage.com/content/doctor-wiley-and-his-poison-squad> [<https://perma.cc/6XVC-J846>] (discussing Harvey Wiley’s crusade to enact food labeling regulation to prevent against adulterated food).

<sup>24</sup> See Marc T. Law, *History of Food and Drug Regulation in the United States*, EH.NET ENCYCLOPEDIA (Oct. 11, 2004), <https://eh.net/encyclopedia/history-of-food-and-drug-regulation-in-the-united-states> [<https://perma.cc/JE6Z-TU7Q>] (overviewing the history of food regulation and events leading up to the 1906 Food and Drug Act). Massachusetts passed the first food adulteration law in 1641 to regulate beef, pork and fish. *Id.* Prior to the passage of the 1906 Pure Food and Drug Act, there was limited and piecemeal federal regulation of food and drug products. *Id.* Congress enacted the 1886 oleomargarine tax on margarine products, which also required margarine producers to label their products in specific ways. *Id.* The 1891 Meat Inspection Act required live cattle to be inspected prior to slaughter and export. State and local food regulation laws were largely enacted to help placate business interests by reducing competition. *Id.*; see also Janssen, *supra* note 23, at 32 (naming two reasons for the enactment of regulatory laws: the invention of new products that threatened current business interests, like glucose as a replacement for sugar, and the state’s patchwork system of laws that made it difficult for manufacturers to navigate).

<sup>25</sup> See Weisberger, *supra* note 23, at 14, 16 (noting that technological innovations in the late nineteenth century gave rise to the production of coloring agents and preservatives that were ubiquitously used but unregulated). See generally LORINE SWAINSTON GOODWIN, *THE PURE FOOD, DRINK AND DRUG CRUSADERS, 1879–1914* (1999) (discussing how women’s organizations played a key role in the passage of the 1906 Food and Drug Act and subsequent enforcement of the laws).

<sup>26</sup> See Part 1: *The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/History/FOrgsHistory/EvolvingPowers/ucm054819.htm> [<https://perma.cc/EFF5-V56M>] (providing an overview of the history of the FDA leading up to the passage of the 1906 Food and Drug Act).

<sup>27</sup> See Eric F. Greenberg, *The Changing Food Label: The Nutrition Labeling and Education Act of 1990*, 3 LOY. CONSUMER L. REP. 10, 10 (1990) (noting that until 1906, states regulated the safety of food); Law, *supra* note 24 (discussing how *The Jungle*, Upton Sinclair’s vivid exposé of meat pro-



President Theodore Roosevelt signed the 1906 Pure Food and Drug Act—the first federal law regulating food mislabeling.<sup>28</sup> The Act focused on promoting accurate labeling by outlawing misbranded food products.<sup>29</sup> The Pure Food and Drug Act was enforced by the Bureau of Chemistry, which later became the Food and Drug Administration.<sup>30</sup> As of 2018, the Food and Drug Administration—tasked with protecting the public health and ensuring proper labeling—regulates over eighty percent of the United States’ food supply, equating to \$417 billion in fresh fruits and vegetables, baked foods, dairy products, and seafood, as well as about \$49 billion in imported food products.<sup>31</sup> The 1906 Act, however, fell short of providing legal standards for addressing misleading statements on food packaging.<sup>32</sup>

The Federal Food, Drug, and Cosmetic Act (“FDCA”), passed in 1938, gave the FDA the power to define standards for food quality and food labels.<sup>33</sup>

cessing plants, provided an impetus for Congress to pass the 1906 Act); *see also* Janssen, *supra* note 23, at 35 (discussing the grassroots Pure Food Movement as an impetus for the Pure Food and Drug Act).

<sup>28</sup> Pure Food and Drug Act, ch. 3915, 34 Stat. 768 (1906) (repealed 1938); *see* Andrea Pezzullo, Note, *The Crusade Against Misleading Labels, Are Manufacturers the Protectors of Consumer Interests?*, 49 SUFFOLK U. L. REV. 323, 326–27 (2016) (stating that the 1906 Act did not have guidelines to enforce compliance, prompting Congress to replace the 1906 Act with the Food, Drug, and Cosmetic Act of 1938).

<sup>29</sup> *See* Law, *supra* note 24 (noting that, for the first time in food and drug law, the 1906 Act regulated impurities in drug products). The Act also required manufacturers to indicate the presence of food additives on food labels. *Id.*

<sup>30</sup> *Id.* The Bureau of Chemistry was originally a division within the U.S. Department of Agriculture (USDA). *Id.* In 1927, the division was renamed the Food, Drug, and Insecticide Administration. *Id.* The name was shortened to the Food and Drug Administration in 1931. *Id.*

<sup>31</sup> *See* Negowetti, *Food Labeling Litigation*, *supra* note 9, at 2–3 (overviewing the FDA’s regulatory authority and noting that the FDA is also responsible for overseeing drugs, vaccines, medical devices, tobacco products, and dietary supplements).

<sup>32</sup> *See* Holk v. Snapple Beverage Corp., 575 F.3d 329, 331 (3d Cir. 2009) (noting that the 1906 Food and Drug Act lacked mechanisms for the agency to enforce compliance and only instituted moderate reforms). For example, a label did not need to provide accurate weight or measurements. *Id.*; *see also* Pezzullo, *supra* note 28, at 327 (discussing the problems with the 1906 Food and Drug Act that prompted Congress to pass the Food, Drug, and Cosmetic Act (FDCA)); Janssen, *supra* note 23, at 37 (noting that a prominent disadvantage of the 1906 Act was that it failed to regulate therapeutic claims that manufacturers made about their products). It was difficult for the government to prove that misleading claims were fraudulent under the Act because the Act required that the government prove a manufacturer’s intent to defraud. Janssen, *supra* note 23, at 37. The difficulty in holding manufacturers accountable under these rules allowed adulterated products to continue to be sold on the market. *Id.* Food-labeling and standardization problems were so prevalent that the FDA created an exhibit of deceptive food packaging nicknamed the “American Chamber of Horrors.” *See generally* *The American Chamber of Horrors*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/History/ProductRegulation/ucm132791.htm> [<https://perma.cc/TXE2-BDHV>] (describing the Chamber of Horrors display including food containers with false bottoms to deceive consumers about the amount of product in the package).

<sup>33</sup> *See* Federal Drug and Cosmetic Act, 21 U.S.C. §§ 301–399f (2012) (prohibiting the sale of misbranded or adulterated foods, drugs, and cosmetics); *Fellner v. Tri-Union Seafoods*, 539 F.3d 237,

The FDCA’s primary purpose is to protect consumers against misbranded food.<sup>34</sup> The FDCA defines food as misbranded if its labeling is false or misleading.<sup>35</sup> The Act provides that the FDA can (1) protect the public health by ensuring food products sold are properly labeled and (2) issue and enforce regulations pursuant to this authority.<sup>36</sup> This power includes the ability to regulate and assess nutritional or health claims, such as if a manufacturer labels a food product as “low in fat.”<sup>37</sup> The Act, however, did not mandate labeling, which limited the agency to addressing nutritional claims that companies were already putting on food products.<sup>38</sup>

In the 1970s, there was an increase in scientific research showing the connection between diet and disease, prompting companies to begin making health claims on their food products.<sup>39</sup> Many of these claims were not FDA

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251 (3d Cir. 2008) (noting that the FDA’s powers include the ability to regulate nutritional claims). Although passage of legislative reforms was hotly contested for five years, the Elixir Sulfanilamide tragedy provided the impetus for congressional action. *See* Law, *supra* note 24 (discussing how a Tennessee drug company manufactured a liquid drug using an antifreeze solvent, killing over 100 people). This tragedy highlighted the lack of regulation within the food and drug industries. *Id.* *See generally* Julian G. West, *The Accidental Poison That Founded the FDA*, THE ATLANTIC (Jan. 16, 2018), <https://www.theatlantic.com/technology/archive/2018/01/the-accidental-poison-that-founded-the-modern-fda/550574> [<https://perma.cc/Q5Y7-CFR7>] (discussing the lack of regulation that led to the Elixir Sulfanilamide tragedy and the establishment of the modern FDA regulations).

<sup>34</sup> *See* Roseann B. Termini, *The Prevention of Misbranded Food Labeling: The Nutrition Labeling and Education Act of 1990 and Alternative Enforcement Mechanisms*, 18 OHIO N.U. L. REV. 77, 80 (discussing the purpose of the FDCA and providing an overview of national food and drug laws); *see also* Kordel v. United States, 335 U.S. 345, 349 (1948) (noting that the purpose of the FDCA is to protect consumers from misbranded products); *United States v. Bradshaw*, 840 F.2d 871, 874 (11th Cir. 1988) (noting that the congressional intent in passing the FDCA was to protect the public against adulterated or misbranded food and drug products).

<sup>35</sup> 21 U.S.C. § 343(a) (2012).

<sup>36</sup> *Id.* § 393(b)(2)(A); Food and Drugs, 21 C.F.R. §§ 7.1, 10.25, 10.40, 10.50 (2013). The FDCA defines a label as anything that includes graphic, written, or printed materials on the container of a food or beverage. *See* 21 U.S.C. § 321(k) (defining “label”); *id.* § 321(n) (requiring that, when determining if a food is misbranded, the FDA consider if the marketing claims made on the label would mislead a reasonable consumer into believing a product had attributes that it did not).

<sup>37</sup> *See* 21 U.S.C. § 343(a) (defining a food product as misbranded if its label is false or in any way misleading to consumers). The statute provides guidelines for food labels to reflect accurate nutritional information. *See id.* § 343(e) (outlining the information that must be provided on the label); *see also* MORGAN LEWIS, APPETITE FOR LITIGATION: WHY PLAINTIFFS’ LAWYERS HUNGER FOR FOOD LABELING LAWSUITS 5 (2015), <https://www.morganlewis.com/-/media/files/publication/morgan-lewis-title/white-paper/lit-appetite-for-litigation-november-2015.ashx> [<https://perma.cc/H9Q6-7KB2>] (noting that the most commonly cited sections in labeling cases are § 201(n) and § 403(a) of the FDCA). *See generally* 21 U.S.C. § 321(n) (providing that a label is misleading if it fails to reveal facts that are material to the representation made on the label).

<sup>38</sup> *See* Termini, *supra* note 34, at 89 (noting that including nutritional information on food packaging was optional prior to passage of the Nutrition Labeling Act).

<sup>39</sup> *See* INST. OF MED., *supra* note 7, at 20 (noting that as scientific research increased that intimated a relationship between diet and disease, so did consumer demand for information concerning what was in their food products). By comparison, up until the 1960s, most food was prepared in the home,

verified, as the FDA had a policy of not prohibiting labeling on food products that claimed to mitigate or prevent against disease.<sup>40</sup> Further, the emergence of processed foods lining grocery store shelves made it more difficult for consumers to understand the ingredients in their food products.<sup>41</sup> In response, the 1969 White House Conference on Food, Nutrition, and Health recommended that the FDA establish a more uniform system of identifying and assessing nutritional claims.<sup>42</sup>

Consumer interest in nutritional information, and specifically in food labeling, was further spurred by two 1980s reports discussing the relationship between diet and disease.<sup>43</sup> The 1988 *Surgeon's General Report on Nutrition and Health* focused on the link between diet and some of the leading causes of

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so consumers were familiar with the ingredients and were not demanding nutritional information about food products. *Id.* at 19.

<sup>40</sup> See *id.* at 20 (noting that a food is misbranded if it in any way implies that it could cure, mitigate, or treat disease); Termini, *supra* note 34, at 91 (explaining that the FDA prohibited manufacturers from labeling food products with marketing claims that a food could “cure” a disease). This inability to put health claims on packaging was challenged in 1984 when the Kellogg Company, in collaboration with the National Cancer Institute, initiated a labeling campaign claiming that Kellogg cereal was high in fiber that could reduce the risk of cancer. INST. OF MED., *supra* note 7, at 20. In the absence of regulatory reform, other companies followed suit. *Id.* In response to the proliferation of claims, the FDA proposed a rule in 1987 to permit health claims on labels so long as certain criteria were met. *Id.* at 21. See generally JULIAN MELLENTIN & MICHAEL HEASMAN, FUNCTIONAL FOODS REVOLUTION: HEALTHY PEOPLE, HEALTHY PROFITS 149 (2001) (discussing *Businessweek* magazine calling attention to inaccurate labeling with its headline in 1989, “Can Cornflakes Cure Cancer?”).

<sup>41</sup> See INST. OF MED., *supra* note 7, at 19 (noting that, with the increased prevalence of processed foods in the market, consumers had less of an understanding of what ingredients were in their food products); Elizabeth Maurer, *How Highly Processed Foods Liberated 1950s Housewives*, NAT'L WOMEN'S HIST. MUSEUM (May 11, 2017), <http://www.womenshistory.org/articles/how-highly-processed-foods-liberated-1950s-housewives> [<https://perma.cc/U5B4-KZRH>] (noting that the period following World War II saw the rise of convenience and pre-packaged foods resulting from technological innovations); see also Jill Filipovic, *To Save American's Health, Government Must Intervene in Food Industry*, ALJAZEERA AMERICA (Nov. 17, 2013), <http://america.aljazeera.com/opinions/2013/11/fda-food-trans-fatban.html> [<https://perma.cc/2EPW-UXR5>] (noting that processed food is a one-trillion-dollar industry and that snacks, many of which are at the center of natural food litigation, account for \$90 billion of the processed food industry).

<sup>42</sup> See INST. OF MED., *supra* note 7, at 19 (discussing how the rise of processed foods and consumer demand for nutritional information contributed to the White House Conference on Food, Nutrition, and Health); WHITE HOUSE CONFERENCE ON FOOD, NUTRITION AND HEALTH: FINAL REPORT 51 (1969) (assessing the state of the American diet in 1969 and finding that, in general, Americans had a poor diet that was contributing to disease). The conference sought to encourage truthful labeling on food products to enable consumers to follow dietary recommendations. INST. OF MED., *supra* note 7, at 19; see also Greenberg, *supra* note 27, at 11 (noting that the White House Conference was concerned with setting new regulations due to studies showing the presence of vitamin deficiencies and malnutrition in the American public).

<sup>43</sup> See INST. OF MED., *supra* note 7, at 21 (discussing how the reports spurred consumer interest in having nutritional information on their food products).

death in America and called on the food industry to reform food labels.<sup>44</sup> The 1989 report by the National Research Council, *Diet and Health: Implications for Reducing Chronic Disease Risk*, found a correlation between chronic disease and the American diet’s high levels of fat.<sup>45</sup> Both reports called for a reduction in fat consumption, cholesterol, and sodium, while increasing consumption of carbohydrates and fiber.<sup>46</sup> These reports were the impetus for Congress and the FDA to review nutritional guidelines and require nutritional labeling for packaged foods.<sup>47</sup>

The lack of regulation of nutrition labeling under the FDCA created congressional concern that consumers would not be able to abide by dietary guidelines.<sup>48</sup> Thus, Congress enacted the Nutrition and Labeling Education Act (“NLEA”) in 1990.<sup>49</sup> The NLEA amends the FDCA by allowing the FDA to regulate health claims on food packaging, standardize nutrient-content claims, and require detailed nutrient information.<sup>50</sup> Significantly, for the first time in

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<sup>44</sup> See PUB. HEALTH SERV., U.S. DEP’T OF HEALTH & HUMAN SERVICES, PUB. NO. 88-50210, SURGEON GENERAL’S REPORT ON NUTRITION AND HEALTH 1–5 (1988) (recommending dietary changes such as reduction of foods high in fat and consumption of carbohydrates and fiber to combat rising chronic diseases such as heart disease, cancers, and diabetes).

<sup>45</sup> See COMM. ON DIET & HEALTH ET AL., DIET AND HEALTH: IMPLICATIONS FOR REDUCING CHRONIC DISEASE RISK 7–9 (1989), [https://www.ncbi.nlm.nih.gov/books/NBK218743/pdf/Bookshelf\\_NBK218743.pdf](https://www.ncbi.nlm.nih.gov/books/NBK218743/pdf/Bookshelf_NBK218743.pdf) [<https://perma.cc/E2FV-9MVX>] (concluding that there is a relationship between diet and chronic disease).

<sup>46</sup> See *supra* notes 44–45 and accompanying text (overviewing the two reports and findings).

<sup>47</sup> See INST. OF MED., *supra* note 7, at 21 (discussing the conclusions of the two reports and their impact on legislative efforts).

<sup>48</sup> See *id.* (noting that the Secretary of the Department of Health and Human Services claimed that Americans could not take advantage of nutritional guidelines given the current state of food labeling). The FDA responded to requests for improved food labeling by initiating rulemaking in 1989 for labels listing nutritional content. *Id.* The FDA used the Surgeon General’s and National Research Council’s reports as a guide to determine how fat, sugar, and calories should be displayed on a nutrition label. *Id.* at 22; see also Greenberg, *supra* note 27, at 11 (stating that the NLEA represented a “race to regulate” food labels between the agency and Congress). While the FDA initiated a rule-making process, Congress had several bills proposed to address the issue of food labeling. Greenberg, *supra* note 27, at 11. Some argue that the congressional action may have been due to the high priority of the issue for the American consumer. *Id.*

<sup>49</sup> 21 U.S.C. § 343. To implement the NLEA, in 1991, the FDA announced twenty-six regulations regarding proper food product labeling. See INST. OF MED., *supra* note 7, at 23 (noting that the FDA claimed that these proposals had three purposes: (1) to help eliminate confusion regarding nutrition labels, (2) to aid consumers in choosing foods that can promote a healthier diet, and (3) to encourage companies to improve the nutrient content of their food products). The Act, however, did not apply to meat and poultry product labels, which are overseen by the Food Safety and Inspection Service, an agency within the USDA. *Id.* at 23–24; see also MORGAN LEWIS, *supra* note 37, at 5 (noting that the NLEA expressly preempts state requirements and requires all states to adhere to federal guidelines).

<sup>50</sup> 21 U.S.C. § 343; see Greenberg, *supra* note 27, at 11 (detailing the history of the NLEA and noting that, prior to the passage of the NLEA, nutrition labeling on packaged foods was voluntary). At the time that the NLEA was enacted, about sixty percent of food products had nutritional labels, but there was no uniformity in labeling to guide consumer purchases. Greenberg, *supra* note 27, at 11. The NLEA requires labeling on food products that states the serving size, the number of servings, the

food and drug law, the NLEA included an express preemption provision to aid in uniform compliance with food labeling laws.<sup>51</sup> The NLEA regulates three types of claims on food labels: (1) health claims, (2) nutrient-content claims, and (3) structure and function claims.<sup>52</sup> The NLEA permits the agency to define terms, such as “free,” “low,” and “light.”<sup>53</sup> The FDA has never used its authority to define the term “natural.”<sup>54</sup> Thus, the most widely litigated claims are health and nutrition content claims, particularly those against products claiming to be “natural.”<sup>55</sup> Moreover, the FDA has limited authority to enforce

calorie count, the presence of any vitamins and minerals, and the breakdown of the fat, cholesterol, sodium, fiber, protein, carbohydrates, and sugars in the product. *Id.* at 12.

<sup>51</sup> 21 U.S.C. § 343-1(a); see Greenberg, *supra* note 27, at 13 (noting that the preemption provision was the culmination of a compromise between states and lobbying interests). States were opposed to a preemption clause because they preferred flexibility. Greenberg, *supra* note 27, at 13; see Pezzullo, *supra* note 28, at 330–32 (noting that the preemption language was largely added as a result of a need for uniformity in the marketplace because each state had its own laws regulating labels, which made it difficult for manufacturers to comply). The NLEA provides for no private right of action for consumers to enforce its provisions. Pezzullo, *supra* note 28, at 330–32; see also J. Christian Nemeth et al., *Expansion of Liability in Product Labeling Cases*, NAT’L L. REV. (Nov. 22, 2016), <https://www.natlawreview.com/article/expansion-liability-product-labeling-cases> [<https://perma.cc/BER9-HZ9W>] (providing an overview of state consumer protection laws identical to the federal FDCA and NLEA that provide a private right of action).

<sup>52</sup> See 21 U.S.C. § 343(a) (overviewing the types of claims that the FDA can regulate); 21 C.F.R. § 101.13(B) (2017) (providing the requirements for using a nutrient-content claim—a claim that describes the amount of a nutrient in the food); 21 C.F.R. § 101.14 (stating that health claims are limited to those that show how a substance has a relationship to a disease or health condition); 21 C.F.R. § 101.93 (discussing the requirements for using structure and function claims, being claims that “describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans”). Structure and function claims do not reference a disease. See 21 C.F.R. § 101.93 (noting that “these statements are not disease claims”); see also Negowetti, *Food Labeling Litigation*, *supra* note 9, at 5–7 (discussing how nutrient-content claims are the most widely used type of claim and the subject of the majority of food-labeling litigation, such as litigation over what constitutes a “healthy” or “natural” product). See generally FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVICES, FOOD LABELING GUIDE: GUIDANCE FOR INDUSTRY 72–87 (2013) (discussing nonbinding recommendations for food and nutritional labeling concerning nutrient; health; and structure and function claims).

<sup>53</sup> See 21 U.S.C. § 343(c) (listing the specific types of claims that can be defined as well as allowing similar words to be defined); 21 C.F.R. § 101.13 (detailing the requirements that food company must meet to use nutrient-content claims such as “light,” “reduced,” or “fortified” on a food label); INST. OF MED., *supra* note 7, at 35 (noting that the FDA defined the term “healthy” for use on food labels in 1994).

<sup>54</sup> See Deena Shanker, *After More Than 30 Years, the US Government May Finally Define “Natural” Food*, QUARTZ (Nov. 10, 2015), <https://qz.com/546118/after-more-then-30-years-the-us-government-may-finally-define-natural-food> [<https://perma.cc/4YTU-RUU3>] (overviewing the FDA’s policy on the term “natural” and noting that the FDA has declined to issue a formal definition).

<sup>55</sup> See U.S. CHAMBER INST. FOR LEGAL REFORM, THE NEW LAWSUIT ECOSYSTEM: TRENDS, TARGETS AND PLAYERS 90 (2013) [hereinafter NEW LAWSUIT ECOSYSTEM], [https://www.instituteforlegalreform.com/uploads/sites/1/The\\_New\\_Lawsuit\\_Ecosystem\\_pages\\_web.pdf](https://www.instituteforlegalreform.com/uploads/sites/1/The_New_Lawsuit_Ecosystem_pages_web.pdf) [<https://perma.cc/D6FX-WWR3>] (discussing the factors leading to the rise in food-labeling litigation); Shanker, *supra* note 54 (noting the rise in food-labeling litigation).

its definitions.<sup>56</sup> The agency can only issue warning letters in an attempt to regulate companies using labeling terms inappropriately.<sup>57</sup>

### B. *The Conscious Consumer and the Rise in Food-Labeling Litigation*

Today, grocery store shelves are lined with pre-packaged foods.<sup>58</sup> These foods are dense with added sugars, fats, and calories.<sup>59</sup> Lifestyle changes, exercise, and food consumption directly impact rates of chronic disease and weight gain.<sup>60</sup> In response to the obesity and rise in chronic diseases, consumers are pushing for a return to healthy and fresh food.<sup>61</sup>

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<sup>56</sup> See Nicole E. Negowetti, *A National “Natural” Standard for Food Labeling*, 65 ME. L. REV. 581, 588–89 (2013) [hereinafter Negowetti, *National “Natural” Standard*] (explaining that the goal of these warning letters is to achieve voluntary compliance and provide notice); Negowetti, *Food Labeling Litigation*, *supra* note 9, at 3 (noting that the FDA can issue injunctions, seize products to remove them from commerce, and seek civil penalties, but these enforcement mechanisms do not apply to mislabeling issues). The FDA can issue penalties if the misbranding of the food, such as missing allergen information, could result in severe health consequences. Negowetti, *Food Labeling Litigation*, *supra* note 9, at 4.

<sup>57</sup> See Isidro, *supra* note 16 (discussing how the FDA’s undefined stance on the term “natural” can be somewhat illustrated by their warning letters); Negowetti, *Food Labeling Litigation*, *supra* note 9, at 4 (noting that these warning letters indicate what the FDA considers to be a misbranded food product, but these letters have little effect in gaining compliance from companies). For example, the agency issued a warning letter to Alexia Foods in 2011 regarding its “all natural” label on its “Roasted Red Potatoes & Baby Portabella Mushrooms” food product. Isidro, *supra* note 16. The agency claimed the company had improperly used the claim “all natural” because the food contained synthetic chemical preservatives. *Id.* The FDA claimed that this ingredient is not one that consumers would expect to find in the food, and thus the ingredient is not “natural.” *Id.*

<sup>58</sup> See CASTLE & GOODMAN, *supra* note 1, at 297 (discussing the rise in packaged foods and the consequential impact on health). Modern junk and processed foods filled with fats, sugars, and salts stimulate the same areas of human brains as drugs such as cocaine and morphine. *Id.* at 299. These high concentrations of fats, sugars, and salts can cause people to become addicted to unhealthy food products. *Id.* at 300.

<sup>59</sup> *Id.* at 300.

<sup>60</sup> See CASTLE & GOODMAN, *supra* note 1, at 5 (discussing how rising rates of chronic disease are directly related to lifestyle changes); Eliza Barclay et al., *It’s Easy to Become Obese in America. These Seven Charts Explain Why*, VOX (Oct. 13, 2017), <https://www.vox.com/2016/8/31/12368246/charts-explain-obesity> [<https://perma.cc/BQL6-XXXM?type=image>] (discussing seven factors that drive rising obesity rates in the United States, including that Americans eat more calories than they burn).

<sup>61</sup> See Kell, *supra* note 6 (noting that consumers’ brand loyalty is overridden by their desire for fresh food and cleaner labels that provide transparency about food ingredients); Negowetti, *Food Labeling Litigation*, *supra* note 9, at 6 (explaining that a USDA Economic Research Service study found that, from 2001 to 2010, health and nutrition claims were a prominent and important feature on labels for new food products). See generally NIELSON, WE ARE WHAT WE EAT: HEALTHY EATING TRENDS AROUND THE WORLD 7, 11 (2015), <https://www.nielsen.com/content/dam/nielsen/global/nielseninsights/pdfs/Nielsen%20Global%20Health%20and%20Wellness%20Report%20-%20January%202015.pdf> [<https://perma.cc/85ZM-G4SP>] (overviewing a study finding that consumers desire foods that are fresh, minimally processed, and “natural,” and that consumers are willing to pay premium prices for foods that they view as having health benefits).

Manufacturers responded to consumer demand with the “all natural” label.<sup>62</sup> The American public spends over forty billion dollars per year on food products labeled as “natural.”<sup>63</sup> In 2011, “all natural” was the second most widely used claim on food products, gracing a range of products from Nature Valley granola bars to SunChips and Skinny Girl margaritas.<sup>64</sup>

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<sup>62</sup> See Karlene Lukovitz, ‘Natural’ Claims Most Common on New F&B Products, MEDIAPOST-NEWS (Jan. 19, 2009), <https://www.mediapost.com/publications/article/98562/natural-claims-most-common-on-new-fb-products.html> [<https://perma.cc/DE8N-TLG9>] (noting that claims of “natural” were the most used claim on new food products, constituting thirty-three percent of new U.S. products launched). Labeling claims reflect consumer lifestyle changes. *Id.* For example, the decrease in labels advertising foods as “low-fat” and “low-calorie” indicate that consumers view these dieting trends as passé. *Id.* See generally, DAVID L. TER MOLEN & DAVID S. BECKER, FREEBORN & PETERS LLP, AN “ALL NATURAL” DILEMMA: AS THE MARKET FOR “ALL NATURAL” FOODS CONTINUES TO GROW, SO DO THE RISKS FOR THE UNWARY 2 (2014), [https://www.freeborn.com/assets/white\\_papers/freeborn\\_peters\\_white\\_paper-an\\_all\\_natural\\_dilemma-0.pdf](https://www.freeborn.com/assets/white_papers/freeborn_peters_white_paper-an_all_natural_dilemma-0.pdf) [<https://perma.cc/95R5-VG2U>] (stating that the Frito-Lay company reformulated over half of their products in 2011 in order to be able to state “natural” on their labels, representing the single largest product transformation in the company’s history).

<sup>63</sup> See Anahad O’Connor, *Is Your Food “Natural”?* F.D.A to Weigh In, N.Y. TIMES: WELL (May 17, 2016), <https://well.blogs.nytimes.com/2016/05/17/is-your-food-natural-f-d-a-to-weigh-in> [<https://perma.cc/856R-VZWR>] (claiming that consumers favor “all natural” products because they believe that the products are more wholesome and devoid of synthetic substances); see also Negowetti, *Defining Natural Foods*, *supra* note 15, at 329 (finding that 51% of consumers look for food products labeled as “all natural” while grocery shopping); Andrea Rock, *Peeling Back the “Natural” Food Label*, CONSUMER REP. (Jan. 29, 2016), <https://www.consumerreports.org/food-safety/peeling-back-the-natural-food-label> [<https://perma.cc/8P5V-YQMP>] (detailing the finding from a consumer study that 87% of people noted they would spend more money on a product labeled as “natural” if it met their expectations for the definition of natural). Over 80% of consumers studied said that “natural” meant no chemicals, meaning synthetic ingredients, were used and that the product does not contain artificial ingredients, colors, toxic pesticides, or genetically modified organisms (“GMOs”). See Kell Haws et al., *Why Is Healthy Food So Expensive? Maybe Because We Expect It to Be*, WASH. POST (Jan. 5, 2017), <https://www.washingtonpost.com/posteverything/wp/2017/01/05/why-is-healthy-food-so-expensive-maybe-because-we-expect-it-to-be> [<https://perma.cc/NL9Z-DSCN>] (finding that, despite evidence about the actual health benefits of the food, consumers were more likely to associate healthier foods with higher costs and be willing to pay more for those products); Catherine Roberts, *Why Healthy Food Doesn’t Have to Cost More*, CONSUMER REP. (Mar. 23, 2017), <https://www.consumerreports.org/healthy-eating/healthy-food-does-not-have-to-cost-more> [<https://perma.cc/DRB9-5JW6>] (noting an Ohio University study finding that consumers thought more expensive products were “healthier” based on health claims on the package compared to health claims on cheaper products); Rock, *supra* at 63 (discussing a study about the importance of the marketing label “natural” to consumers). See generally Mayuree Rao et al., *Do Healthier Foods and Diet Patterns Cost More Than Less Healthy Options? A Systematic Review and Meta-Analysis*, BMJ OPEN (Dec. 5, 2013), <https://bmjopen.bmj.com/content/3/12/e004277> [<https://perma.cc/KC2H-F8ZR>] (announcing a study finding that eating an overall healthier diet only costs about \$1.50 more per day, quashing the myth that a healthy diet is prohibitively expensive).

<sup>64</sup> See *In re Frito-Lay N. Am., Inc., “All Natural” Litig.*, No. 12-MD-2413, 2013 WL 4647512, at \*1 (E.D.N.Y. Aug. 29, 2013) (noting that plaintiffs alleged Frito-Lay and SunChips are mislabeled as “all natural” because they contain genetically modified ingredients); *Janney v. Gen. Mills*, 944 F. Supp. 2d 806, 809 (N.D. Cal. 2013) (noting plaintiffs’ allegations that Nature Valley granola bars are mislabeled as “natural” because they contain artificially produced ingredients); *Stewart v. Beam Glob. Spirits & Wine*

There is a discrepancy, however, between how consumers understand and manufacturers use the term “natural.”<sup>65</sup> To consumers, the word “natural” conveys a sense of wholesomeness and an understanding that the food was not produced using pesticides, artificial colorings, synthetic ingredients, or genetically modified organisms (“GMOs”).<sup>66</sup> Manufacturers often use the term “natural” as a marketing tool, and their products may contain ingredients that do not align with consumer expectations.<sup>67</sup>

Food and beverage manufacturers’ use and misuse of the word “natural” on food labels has contributed to the surge in lawsuits alleging false advertising.<sup>68</sup> The FDA has not engaged in rulemaking to define the term “natural.”<sup>69</sup> Rather, the FDA adopted a nonbinding, informal policy in 1991, stating “natural” means, “nothing artificial or synthetic has been added to the food product besides what would otherwise be expected.”<sup>70</sup> The FDA recognized consumer

Inc., 877 F. Supp. 2d 192, 193 (D. N.J. 2012) (noting plaintiff’s allegations that Skinny Girl margaritas are mislabeled as “all natural” because they contain a chemical preservative); Negowetti, *National “Natural” Standard*, *supra* note 56, at 582 (discussing food companies’ marketing of the term “natural” because of consumer demand). See generally, *Natural Food Lawsuits*, CLASSACTION.ORG, <https://www.classaction.org/natural-foods> [<https://perma.cc/NTC5-EYJX>] (tracking the numerous class actions against food companies for making misleading “all natural” claims, including suits against Popchips, Healthy Choice, Whole Foods, Chipotle, Ghiradelli, Bear Naked, Vans, Synder’s, Mott’s, and Annie’s).

<sup>65</sup> See *supra* notes 62–63 and accompanying text (overviewing how consumers define the term “natural” compared to how manufacturers use the term on food labeling).

<sup>66</sup> See Rock, *supra* note 63 (discussing a *Consumer Reports* study revealing how consumers understand the term “natural”).

<sup>67</sup> See Julie Creswell, *Is It “Natural?” Consumers, and Lawyers, Want to Know*, N.Y. TIMES (Feb. 16, 2018), <https://www.nytimes.com/2018/02/16/business/natural-food-products.html> [<https://perma.cc/PM65-B3NA>] (discussing how manufacturers are willing to risk litigation to capitalize on the “natural” market by labeling products such as Pop-Tarts and 7UP as “natural” when they are made with artificial ingredients); *supra* note 64 and accompanying text (discussing the liability claims against a variety of name-brand products that allegedly misuse the term “natural”).

<sup>68</sup> See MORGAN LEWIS, *supra* note 37, at 14 (noting that plaintiffs’ claims are not generally based on actual injury but on paying premium prices for products); Paul Chan, *Liabile Labels: Consumer Groups and Regulators Are continuing to Test New Theories Against Manufacturers Over Food Labels*, L.A. LAW., Feb. 2015, at 25, <https://www.lacba.org/docs/default-source/lal-magazine/2015-issues/2015-test-articles/february2015testarticle.pdf> [<https://perma.cc/96P6-MPSY>] (observing that food-labeling lawsuits are not traditional liability suits, as they are seeking damages for paying higher prices, not for harms to their health).

<sup>69</sup> Use of the Term “Natural” in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg. 69,905 (proposed Nov. 12, 2015) (to be codified at 21 C.F.R. pt. 101) (noting that the FDA has had a long-standing policy on the term “natural” but has yet to define the term).

<sup>70</sup> Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (proposed Nov. 27, 1991) (codified at 21 C.F.R. pts. 5, 101, 105). This definition includes artificial or synthetic flavoring and colors. *Id.*; see Negowetti, *National “Natural” Standard*, *supra* note 56, at 585 (noting that the policy is only an advisory opinion and does not establish a legal requirement forcing companies to comply with its definition). The FDA has declined to engage in rulemaking and define “natural,” which would result in a regulation that would have legal effect. Negowetti, *National “Natural” Standard*, *supra* note 56, at 585. See generally *FDA Rules and Regulations*,



interest in defining the term “natural” after reviewing comments from implementing the NLEA in 1990.<sup>71</sup> The agency declined to adopt a formal definition in 1991.<sup>72</sup> The agency claimed that the four thousand comments reflected too many interpretations of the term “natural”—making it difficult to formulate a single definition.<sup>73</sup>

In 2006, the Sugar Association petitioned the FDA to define the term to alleviate ambiguity and consumer confusion.<sup>74</sup> One year later, the FDA also received a petition from the Sara Lee Corporation urging the agency to collaborate with the United States Department of Agriculture (USDA) to define the term “natural.”<sup>75</sup> In response to these industry petitions, the agency issued a letter declining to adopt a uniform definition.<sup>76</sup> The FDA outlined several rea-

U.S. FOOD & DRUG ADMIN. (Apr. 23, 2014), <https://www.fda.gov/RegulatoryInformation/RulesRegulations/default.htm> [<https://perma.cc/446J-TPNF>] (overviewing FDA procedure for rulemaking, including the requirement for a notice and public comment process during which the public can weigh in on the FDA’s proposed rule). Once the FDA reviews the comments, it proposes a rule that is reviewed by other agencies before it is published in the Federal Register. *FDA Rules and Regulations, supra*; see *Holk*, 575 F.3d at 342 (holding that FDA policy is informal and not legally compelling). The *Holk* court held that the FDA has not taken actions that would result in their informal policy having preemptive legal effect. 575 F.3d at 339. To determine whether an agency policy has legal effect, the court stated that it is necessary to consider the process by which the agency arrived at its decision and not whether or how an agency has enforced the policy. *Id.* at 341.

<sup>71</sup> See Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. at 60,466 (recognizing consumer interest in defining the term “natural”).

<sup>72</sup> See *id.* (stating that resource limitations preclude the agency from promulgating a formal definition).

<sup>73</sup> *Id.*

<sup>74</sup> Sugar Association Citizen Petition re Definition of the Term “Natural” for Making Claims on Foods and Beverages Regulated by FDA, at 8–9 (Feb. 28, 2006), [https://cspinet.org/sites/default/files/attachment/sugar\\_fda\\_petition.pdf](https://cspinet.org/sites/default/files/attachment/sugar_fda_petition.pdf) [<https://perma.cc/5UCS-VF9V>]. The Sugar Association proposed adopting the definition of “natural” as given in the USDA Food Standards and Labeling Policy Book, which define “natural” food as food that (1) does not contain any artificial or synthetic ingredients and (2) is minimally processed. *Id.* The Sugar Association, originally formed in 1943 as the Sugar Research Foundation, is a trade organization composed of members of the United States sugar industry. *About Us*, THE SUGAR ASS’N, <https://www.sugar.org/about> [<https://perma.cc/SVC9-8DR4>] (noting that the organization’s stated goal is to fund research and educate the public about sugar’s role in food and diet).

<sup>75</sup> Use of the Term “Natural” in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg. at 69,907 (discussing the citizen petition received from Sara Lee urging the FDA to define the term “natural”); see also Negowetti, *National “Natural” Standard, supra* note 56, at 586 (explaining that the Sara Lee Corporation argued that the FDA should provide a definition for “natural” that included food-processing methods).

<sup>76</sup> See Lorraine Heller, “Natural” Will Remain Undefined, *Says FDA*, FOODNAVIGATOR-USA (Jan. 4, 2008), <https://www.foodnavigator-usa.com/Article/2008/01/04/Natural-will-remain-undefined-says-FDA> [<https://perma.cc/9D7S-AC6X>] (reporting that the FDA declined to adopt a formal definition despite increasing litigation and consumer confusion over the term “natural”); Letter from Geraldine A. June, Supervisor of the Prod. Evaluation and Labeling Team, FDA, Dep’t of Health & Human Servs., to Audrae Erickson, President of the Corn Refiners Ass’n (July 3, 2008) [hereinafter FDA Letter to Corn Refiners Ass’n], <http://www.corn.org/wp-content/uploads/2008/07/FDAdecision7-7->

sons for not adopting a formal definition including: (1) defining “natural” was not a priority for the agency and (2) lawsuits should be evaluated on a case-by-case basis, because no agency or consumer can agree on a definition.<sup>77</sup>

In addition to the FDA, three other federal agencies regulate foods and beverages labeled as “natural”: the United States Department of Agriculture, the Federal Trade Commission (“FTC”), and the United States Alcohol and Tobacco Tax & Trade Bureau.<sup>78</sup> The FTC and the FDA share authority over the regulation of marketing claims on food product labels.<sup>79</sup> Although no agency has issued a formal definition of what constitutes a “natural” product, each agency has issued limited guidance on what qualifies as misuse of the term.<sup>80</sup>

Although experts predicted that food-labeling suits would peter out, courts have experienced a substantial increase in such lawsuits.<sup>81</sup> Four states

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08.pdf [https://perma.cc/7APC-UDTJ] (qualifying the FDA’s policy position and declining to issue decision on for the term “natural”).

<sup>77</sup> See Negowetti, *National “Natural” Standard*, *supra* note 56, at 587 (stating that the FDA added confusion to its stance on “natural” when, in 2008, the agency claimed high-fructose corn syrup does not align with its definition of “natural”); FDA Letter to Corn Refiners Ass’n, *supra* note 76 (noting that determining whether high-fructose corn syrup is “natural” would require an evaluation of whether there were synthetic agents used in making the product).

<sup>78</sup> See Blau & Wiand, *supra* note 12 (discussing the interaction between the various federal agencies overseeing food regulation).

<sup>79</sup> See 21 U.S.C. § 343(a) (2012) (prohibiting misbranding of food and regulating labeling); Negowetti, *Food Labeling Litigation*, *supra* note 9, at 3 (discussing § 403(a) of the FDCA, which prohibits its claims on food labels that are false or would mislead consumers). The Federal Trade Commission (“FTC”) oversees food advertising and regulates false advertisements that can be misleading to consumers. 15 U.S.C. § 52 (2012). Under the FTC Act, Section 5 prohibits “unfair” competition and deceptive practices whereas Sections 12 and 15 prohibit false advertising of food products that can materially mislead consumers and influence buying decisions. *Id.* § 45.

<sup>80</sup> See Blau & Wiand, *supra* note 12 (noting that the USDA defines “natural” products on a case-by-case basis in relation to regulation of organic products); see also Negowetti, *National “Natural” Standard*, *supra* note 56, at 584 (explaining that the FTC initially proposed a rule in 1974 defining “natural” foods as those that are minimally processed and free of artificial ingredients, but that the FTC withdrew this rule in 1983 based on problems with enforcement and a lack of understanding about how consumers defined the term “natural”). The FTC has since refrained from making any definitive statements about the definition of “natural.” Negowetti, *National “Natural” Standard*, *supra* note 56, at 584; see also Product Labeling: Use of the Voluntary Claim “Natural” in the Labeling of Meat and Poultry Products, 9 C.F.R. §§ 317, 381 (2006) (discussing that the Food Safety and Inspection Service (FSIS) issued advanced notice of proposed rulemaking in 2006 to define the term “natural”). The FSIS is the public health agency in the USDA that is responsible for regulating the nation’s meat, poultry, and egg products. 9 C.F.R. §§ 317, 381. The FSIS received over 12,000 comments on its proposed rulemaking on the term “natural.” *Id.* The FSIS did not issue a final rule but decided to request further comments to understand the economic effects of a potential rule. *Id.*

<sup>81</sup> See U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 5 (noting that consumer class actions are increasing rather than decreasing); see also Jessica Dye, *Food Companies Confront Spike in Consumer Fraud Lawsuits*, REUTERS LEGAL, June 13, 2013 (noting that the “litigation explosion” of food-labeling claims could not have been predicted five years ago); August Horvath et al., *Food Litigation Trends: New and Undefined Claims in 2017*, FOOD & DRUG LAW INST. (Nov./Dec. 2017), <https://www.fdpi.org/2017/12/food-litigation-trends-new-undefined-label-claims-2017> [https://perma.

(California, New York, Illinois, and Florida) are preferred venues for food litigation with over three-quarters of all food-labeling class action cases filed in these states.<sup>82</sup> The Northern District of California has been dubbed the “Food Court,” as more than thirty-six percent of the cases are filed in this state.<sup>83</sup> In 2015 and 2016, more than 425 suits regarding food labeling were filed in the United States, a staggering increase from the mere twenty suits filed in 2008.<sup>84</sup> If the FDA decides to issue a ruling on defining “natural,” this could impact the litigation landscape.<sup>85</sup>

### C. Causes of Actions Against Misleading-Labeling Claims

Food-labeling litigation is mostly based on false advertising claims.<sup>86</sup> The most prominent litigation tactic is to assert violations of state consumer protec-

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cc/3RNT-PG2B] (finding that food-labeling litigation cases have continued to increase, with over sixty-nine federal cases filed in the first forty weeks of 2017).

<sup>82</sup> See U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 2 (stating that California, New York, Illinois, and Florida are preferred venues for food-labeling litigation for plaintiffs as those states have the most consumer-friendly protections statutes). These states allow consumers to bring causes of action because the state statutes mirror the federal FDCA and NLEA. *Id.*

<sup>83</sup> See U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 8–9 (noting that California is a preferred venue for food-labeling litigation because the state is known to have some of the most comprehensive consumer protection statutes). California is known to have some of the most comprehensive consumer protection statutes in the United States. *Id.* at 9; see Negowetti, *Defining Natural Foods*, *supra* note 15, at 333 (describing the California false advertising claims that plaintiffs bring against products labeled as “natural”). Plaintiffs generally allege violations of California’s Uniform Competition Law, False Advertising Law, or the Consumer Legal Remedies Act, all of which bar misleading marketing claims on consumer products. Negowetti, *Defining Natural Foods*, *supra* note 15, at 333. Claims challenged under these laws are subject to the “reasonable consumer” test, which evaluates the likelihood that the public would be deceived by the marketing claim. *Id.* This analysis essentially requires courts to assess what an average and reasonable consumer would consider to be “natural.” *Id.* at 334.

<sup>84</sup> U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 1. There has been a steady rise each year in the number of class actions suits: from about 20 in 2008, to 102 in 2012, to 120 in 2015, to over 170 filings in 2016. *Id.* at 5. In the first 40 weeks of 2017, an average of 1.7 cases regarding food labels were filed per week. See Horvath et al., *supra* note 80 (discussing trends in food-labeling litigation and the continued prominence of such suits).

<sup>85</sup> See Administrative Procedure Act, 5 U.S.C. § 553 (2012) (stating that before issuing a rule, an agency is required to elicit public input on its proposed rule and allow consumers time to weigh in); *FDA Rules and Regulations*, *supra* note 70 (stating that the FDA engages in “notice and comment rulemaking”); *Use of the Term “Natural” in the Labeling of Human Food Products: Request for Information and Comments*, REGULATIONS.GOV (May 10, 2016), <https://www.regulations.gov/docket?D=FDA-2014-N-1207> [<https://perma.cc/94JD-7TUT>] (cataloging over 7,000 comments from citizens on what the term “natural” should mean on packaging). The first step of rulemaking is to issue a proposed rule and request public comments. 5 U.S.C. § 553. The FDA will review the comments in order to define a specific policy. *FDA Rules and Regulations*, *supra* note 70. If the FDA decides to issue a final rule, it will be published in the *Federal Register*. *Id.*

<sup>86</sup> See MORGAN LEWIS, *supra* note 37, at 14 (noting that plaintiffs in food-labeling suits are not asserting actual injury from using the product, but rather their claim rests on being deceived into pay-

tion law and common-law theories of fraud, breach of warranties, and misrepresentation.<sup>87</sup>

### 1. Causes of Action for “All Natural” Suits

The first wave of food litigation consisted of claims against companies selling products that are labeled as “natural.”<sup>88</sup> The two most common claims of false advertising are regarding (1) food products mislabeled as “natural” and (2) food products with misleading claims about the product’s supposed health benefits.<sup>89</sup> Beginning in 2007, lawsuits targeted companies such as Arizona Beverages and Snapple for claiming their foods were “100% natural” when the foods contained high-fructose corn syrup.<sup>90</sup> The 2009 case against Dannon—alleging that Dannon made false claims about the health benefits of its Activia yogurt—changed the litigation landscape.<sup>91</sup> The case’s forty-five-million-

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ing higher prices for a product); NEW LAWSUIT ECOSYSTEM, *supra* note 55, at 90 (summarizing a plaintiff’s typical motives for bringing false advertising claims in food-labeling litigation).

<sup>87</sup> See MORGAN LEWIS *supra* note 37, at 14 (discussing current theories of liability). The NLEA expressly preempts state-imposed labeling requirements and only allows states to adopt standards identical to federal labeling standards. *Id.* at 5. Consumers then rely on state consumer protection statutes that guard against deceptive and unfair business practices by mirroring the federal bar on “false and misleading” food labeling in the FDCA and NLEA. *Id.* at 14.

<sup>88</sup> See U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 17–20 (noting that theories of liability and claims against food mislabeling have evolved over time).

<sup>89</sup> JOHN BURLINGAME & ADAM FOX, SQUIRE PATTON BOGGS, THE ROLE OF SCIENCE IN BURGEONING HEALTH LITIGATION: A NEW PERSPECTIVE ON FOOD & BEVERAGE FALSE ADVERTISING CLAIMS 4 (2015), <https://www.squirepattonboggs.com/~media/files/insights/publications/2015/10/the-role-of-science-in-burgeoning-health-litigation/20984--food-and-beverage-false-advertising-claims-brochure.pdf> [<https://perma.cc/2PCJ-F7AP>]; see also MORGAN LEWIS, *supra* note 37, at 9–10 (stating that the four most common targets of suits are foods labeled as “natural” that (1) contain high-fructose corn syrup, (2) contain GMOs, (3) contain artificial preservatives, or (4) have been chemically processed or contain unnatural ingredients, such as added sugar or artificial colorings).

<sup>90</sup> See *Holk*, 575 F.3d at 332 (discussing the plaintiff’s allegations that Snapple labeling its beverages as “all natural” was misleading because the beverages contain high-fructose corn syrup); *Coyle*, 2010 WL 2539386, at \*1 (holding that Arizona Iced Tea’s claims of being “100% natural” were misleading because the tea contains high-fructose corn syrup); see also U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 19 (discussing how the FDA did issue a policy statement in May 2016 stating that manufacturers cannot describe sweeteners made from sugar cane as “evaporated cane juice,” but instead should label such sweeteners as “sugar” or “cane sugar” in order to not mislead consumers).

<sup>91</sup> See Troy McMullen, *Dannon to Pay \$45M to Settle Yogurt Lawsuit*, ABC NEWS (Feb. 26, 2010), <https://abcnews.go.com/Business/dannon-settles-lawsuit/story?id=9950269> [<https://perma.cc/9PT5-AFLQ>] (stating that Dannon claimed that Activia yogurt could help with digestion and aid in improving the immune system, but the company’s own studies failed to show this correlation). The suit, originally filed by Trish Weiner in Los Angeles, claimed that Dannon’s health claims misled consumers. *Id.* Weiner bought the product to aid in her digestion but noticed no difference. *Id.* Dannon sold their product at a thirty-percent markup because of their health claims. *Id.* The company argued that their product is not designed to cure health issues. *Id.* The Judge approved the settlement, noting the company had made claims that it could not prove. *Id.*

dollar settlement was touted as one of the first major victories against the food industry.<sup>92</sup>

Food-labeling litigation has expanded against companies that use genetically modified or synthetic ingredients, and plaintiffs are targeting some of the most prominent and well-known brands.<sup>93</sup> For example, in 2017, one of the largest class action suits was filed against a variety of brands and retailers for mislabeling Parmesan cheese that contained cellulose powder, as “100% Grated Parmesan Cheese.”<sup>94</sup> The plaintiffs claimed that the presence of cellulose powder, a type of synthetic additive, deceptively undermined the quality of the product.<sup>95</sup> The court dismissed the case in 2017, reasoning that reasonable consumers would understand that dairy products would contain some additives to keep it fresh.<sup>96</sup> Given that “natural” remains an undefined label, litigants are now using new tactics such as claiming that meat and dairy products are not “natural” if the animals were fed genetically modified feed.<sup>97</sup>

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<sup>92</sup> See NEW LAWSUIT ECOSYSTEM, *supra* note 55, at 90 (noting that food-labeling litigation increased after the Dannon settlement); *Dannon Settles Lawsuit, to Pay Yogurt Buyers \$35 Million*, ABC NEWS, <https://abcnews.go.com/Business/dannon-settles-lawsuit-pay-yogurt-buyers-35m/story?id=8620700> [<https://perma.cc/ZT8P-S62G>] (noting that Dannon agreed to settle to avoid further litigation and expense).

<sup>93</sup> See *Figy v. Frito-Lay N. Am., Inc.*, 67 F. Supp. 3d 1075, 1080 (N.D. Cal. 2014) (discussing how Rold Gold Thin Pretzels being labeled as “Made with All Natural Ingredients” is misleading because the products were made with artificial ingredients including riboflavin and ammonium bicarbonate); Complaint at 1–3, *Newton v. Kraft Heinz Foods Co.*, No. 1:16-cv-04578 (E.D.N.Y. Aug. 17, 2016) (discussing plaintiffs’ claim that Kraft’s Daisy Brand sour cream cannot be labeled as “all natural” because the cows were fed genetically modified feed); see also Michele Simon, *Lawsuit Alleges Frito-Lay’s GMO Snacks Aren’t “Natural,”* HUFFINGTON POST (Dec. 27, 2011), [https://www.huffingtonpost.com/michele-simon/lawsuit-alleges-fritolays\\_b\\_1171533.html](https://www.huffingtonpost.com/michele-simon/lawsuit-alleges-fritolays_b_1171533.html) [<https://perma.cc/EW2D-NDZ5>] (discussing how Frito-Lay was sued for claiming it was making fifty percent of its biggest brands with “natural” ingredients when the products were actually made with artificial ingredients).

<sup>94</sup> See Chris Moran, *Judge Throws Out Dozens of Lawsuits Over Cellulose in ‘100% Grated Parmesan Cheese,’* CONSUMERIST (Aug. 24, 2017), <https://consumerist.com/2017/08/24/judge-throws-out-dozens-of-lawsuits-over-cellulose-in-100-grated-parmesan-cheese> [<https://perma.cc/6LD3-C94M>] (discussing the judge’s dismissal of the plaintiff’s claims against brands and companies marketing “100% Grated Parmesan Cheese” for lack of merit).

<sup>95</sup> See Tina Bellon, *U.S. Judge Tosses Lawsuits About Labels on Parmesan Cheese*, REUTERS (Aug. 24, 2017), <https://www.reuters.com/article/us-kraft-heinz-lawsuit-cheese/u-s-judge-tosses-lawsuits-about-labels-on-parmesan-cheese-idUSKCN1B429G> [<https://perma.cc/6YD4-RKFN>] (noting that the court held that the plaintiffs’ claims lacked merit because the ingredient panel on the label disclosed the presence of synthetic food additives for freshness).

<sup>96</sup> See *In re 100% Grated Parmesan Cheese Marketing & Sales Practice Litig.*, 275 F. Supp. 3d 910, 924 (N.D. Ill. 2017) (finding that a reasonable consumer would know that a dairy product could contain synthetic additives to preserve freshness). Interestingly, the court noted that it is immaterial whether consumers expected to find cellulose in a container of cheese and held that consumers should expect there to be some additives to keep the cheese fresh. *Id.*

<sup>97</sup> See Horvath et al., *supra* note 80 (discussing new tactics in suits over the term “natural”); Paul Tessin, *Sargento Cheese Class Action Says ‘Natural’ Label Is Misleading*, TOP CLASS ACTIONS (May 22, 2017), <https://topclassactions.com/lawsuit-settlements/lawsuit-news/684747-sargento-cheese->

## 2. Rising Litigation Against Foods Labeled as “Healthy”

Recently, false advertising claims have increased against food products labeled as “healthy.”<sup>98</sup> Plaintiffs claim that even though these labels display all of the ingredients, the label “healthy” can deceive consumers into erroneously believing that foods are nutritious, when they are actually packed with sugar and high in fat.<sup>99</sup> The most notorious health-claims case is the 2012 suit against Nutella.<sup>100</sup> The plaintiff, a mother of a four-year-old, filed a class action lawsuit alleging deceptive marketing practices.<sup>101</sup> She argued that Nutella induced the plaintiff to pay premium prices for the product based on Nutella’s marketing of its hazelnut spread as a “healthy” breakfast food that could be part of a balanced breakfast.<sup>102</sup> The Nutella advertisements focused on the product’s positive attributes such as containing hazelnuts and skim milk but did not mention the sugar and fat content.<sup>103</sup> Nutella contains 21 grams of sugar, 200 calories, and 11 grams of fat per serving.<sup>104</sup> Nutella agreed to a three-

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class-action-says-natural-label-misleading [<https://perma.cc/YVL5-GN34>] (discussing one of the newest suits over “natural” labeling, which challenges the “natural” label on packaged Sargento cheese because the cows are fed genetically modified corn or soy). The cows are also injected with a hormone, rbST, which increases milk production. Tessin, *supra*. The plaintiff states that because the growth hormones are not naturally occurring, consumers are being misled into paying more for products than they otherwise would. *Id.*; see, e.g., Complaint at 2, Stanton v. Sargento Foods Inc., No. 3:17-cv-02881 (N.D. Cal. May 19, 2017) (alleging that Sargento cheese products are mislabeled because the cows are fed genetically modified organisms).

<sup>98</sup> See U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 17–20 (discussing common food-labeling claims and the evolution of litigation strategies). The most recent surge in litigation is against the makers of sugary cereals such as Lucky Charms and Cocoa Puffs. *Id.* at 30. The claims against these manufacturers focus on the companies highlighting one positive aspect of the food, such as that it contains whole grains, in an effort to mislead consumers into thinking that the product is healthy when it is really more akin to a candy bar than a health food. *Id.*

<sup>99</sup> *Id.* at 19–20 (discussing the rise in lawsuits challenging food labeled as “healthy” even when the food product completely discloses all of its ingredients).

<sup>100</sup> See *id.* at 43–44 (noting that the news media widely mocked the Nutella case as illegitimate).

<sup>101</sup> See Ted Burnham, *Nutella Maker May Settle Deceptive Ad Lawsuit for \$3 Million*, NPR (Apr. 26, 2012), <https://www.npr.org/sections/thesalt/2012/04/26/151454929/nutella-maker-may-settle-deceptive-ad-lawsuit-for-3-million> [<https://perma.cc/EQL8-MEHF>] (providing background information on the Nutella case).

<sup>102</sup> Complaint at 1, Hohenberg v. Ferrero U.S.A., Inc., No. 3:11-cv-00205-H (S.D. Cal. Feb. 1, 2011) (alleging five causes of action: (1) violation of the California Unfair Competition Law, (2) violation of the California Unfair Competition Law, (3) violation of the California False Advertising Law, (4) violation of the Consumer Legal Remedies Act, (5) Breach of Express Warranty). The plaintiff claimed that she relied on the images of a mother feeding Nutella to “healthy” children as part of breakfast as the reason for feeding her own child Nutella. *Id.* at 3.

<sup>103</sup> See *id.* at 6 (noting that the plaintiff stated that Nutella is primarily made of high-saturated-fat palm oil and sugar, both of which are substantial contributors to childhood obesity and childhood type-2 diabetes).

<sup>104</sup> See Burnham, *supra* note 101 (noting that there are 200 calories in every two-tablespoon serving of Nutella, and half of those calories are from fat).

million-dollar class action settlement.<sup>105</sup> The settlement also required the company to remove any misleading health claims from its ads.<sup>106</sup> This lawsuit, however, remains highly criticized because many claim that it was unreasonable to believe that a chocolate spread is healthy.<sup>107</sup>

The FDA is currently reconsidering what it means to designate a product as “healthy.”<sup>108</sup> A 2016 case against Krispy Kreme alleged that the artificial berry and fruit fillings of the company’s doughnuts deprived consumers of the real health benefits of consuming these fruits whose nutrients are known to be preventative of cancer and vascular disease.<sup>109</sup> Instead, the doughnuts were high in fat and devoid of the premium ingredients known to combat heart disease.<sup>110</sup> This litigation prompted the FDA to issue guidelines in June 2015 requiring manufacturers to remove trans fat from food within three years.<sup>111</sup> The

<sup>105</sup> Rachel Tepper, *Nutella Lawsuit: Ferrero Settles Class-Action Suit Over Health Claims for \$3 Million*, HUFFINGTON POST (Dec. 6, 2017), [https://www.huffingtonpost.com/2012/04/26/nutella-lawsuit\\_n\\_1457183.html](https://www.huffingtonpost.com/2012/04/26/nutella-lawsuit_n_1457183.html) [<https://perma.cc/5BTA-7YKF>]. Initially, the plaintiffs proposed \$5.5 million to settle, but plaintiffs’ attorneys requested \$3.75 million in fees. See U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 44 (noting that Judge Wolfson approved of the lower settlement and the Third Circuit upheld it). Attorney’s fees totaled about \$625,000. *Id.*

<sup>106</sup> See Tepper, *supra* note 105 (discussing the consequences of the Nutella lawsuit).

<sup>107</sup> See U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 44 (criticizing the litigation as meritless); Whitney Wyckoff, *A Mom Sues Nutella Maker for Deceptive Advertising*, NAT’L PUB. RADIO (Feb. 10, 2011), <https://www.npr.org/sections/health-shots/2011/02/10/133565759/a-mom-sues-nutella-maker-for-deceptive-advertising> [<https://perma.cc/Q7CA-P3VW>] (questioning how a mother could be surprised that chocolate spread is unhealthy).

<sup>108</sup> Maggie Fox, *Are Kind Bars ‘Healthy?’ FDA Settles Battle Over Snack Label*, TODAY (May 10, 2016), <https://www.today.com/health/are-kind-bars-healthy-fda-settles-battle-over-snack-label-t91851> [<https://perma.cc/39JK-83TS>] (noting that the FDA will re-examine what it defines as “healthy”).

<sup>109</sup> Class Action Complaint at 3, *Saidan v. Krispy Kreme Doughnut Co.*, No. 2:16-cv-08338 (C.D. Cal. Nov. 9, 2016) (alleging that Krispy Kreme engaged in deceptive practices by selling doughnuts not made with real ingredients while charging premium prices).

<sup>110</sup> See *id.* at 9–10 (stating that the doughnuts did not contain real raspberries, which are known to help fight against heart disease and cancers, or blueberries, which are rich in antioxidants that prevent disease); *Glazed Blueberry Doughnut Holes: Nutrition Facts*, KRISPY KREME (Mar. 22, 2016), <http://kkd-nutritional-panels.s3.amazonaws.com/2018GlazedBlueberryCakeDoughnutHolesRetailPanel.pdf> [<https://perma.cc/U5BZ-8EMY>] (noting that a serving of four of Krispy Kreme’s blueberry-filled doughnut holes contain fifteen percent of the daily recommended value of saturated fat and eleven percent of the total fat recommended for daily consumption).

<sup>111</sup> See Final Determination Regarding Partially Hydrogenated Oils, 80 Fed. Reg. 34,650 (June 17, 2015); U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 26 (discussing the evolution of trans-fat litigation along with scientific research illustrating that trans fat is no longer generally recognized as safe by the medical health community); Helen Evich, *It’s Official: Obama Axes Trans Fat*, POLITICO (June 2015), <https://www.politico.com/story/2015/06/obama-bans-trans-fat-119050> [<https://perma.cc/QR9E-JKJL>] (stating that the new FDA guidance gives the food industry until 2018 to phase out trans fats but could prompt heightened litigation to hold corporations accountable in the interim). The FDA recognized trans fats as safe beginning in the 1950s. Evich, *supra*. Despite the purported safety of trans fats, public health officials estimate that reducing consumption of trans fat would prevent about 20,000 heart attacks per year. *Id.* See generally *Trans Fat*, AM. HEART ASS’N (Mar. 24,

FDA’s definition of “healthy” reflects an old understanding of what qualifies as healthy or unhealthy fat, and conflicts with current scientific consensus.<sup>112</sup> For example, a Pop-Tart can be labeled as “healthy” but almonds cannot.<sup>113</sup>

### 3. Expanding Causes of Action Under the Lanham Act

In 2010, in *POM Wonderful v. Coca-Cola*, the Supreme Court recognized that competitors could bring claims against each other under the Lanham Act, signaling that food litigation focused on false advertising claims could continue to hold a prominent place in the courts.<sup>114</sup> *POM Wonderful* filed suit against competitor Coca-Cola for its prominently displayed blueberry juice label claiming that, because the product contained only 0.3% pomegranate juice and

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2017), <https://www.heart.org/en/healthy-living/healthy-eating/eat-smart/fats/trans-fat> [<https://perma.cc/HZC6-WZZY>] (overviewing the types of trans fat and the health consequences of consuming it). There are two types of trans fats: natural and artificial. *Trans Fat*, *supra*. Natural trans fats occur in the gut of animals and are contained in milk and meat products. *Id.* Artificial trans fats are industrially produced, normally in the form of hydrogenated oils. *Id.* Companies use trans fats because they are inexpensive and can extend a product’s shelf life. *Id.*

<sup>112</sup> See Adam Chandler, *What’s Healthy? What’s Natural?*, THE ATLANTIC (Oct. 13, 2016), <https://www.theatlantic.com/business/archive/2016/10/food-labeling-lawsuits-healthy-natural/503990> [<https://perma.cc/VP6C-UM4Q>] (stating that the FDA redefining “healthy” is a result of food companies and litigants seeking an update to the 1994 health standards on which the term’s definition is based); Fox, *supra* note 108 (discussing how the FDA defines what is “healthy” based on two decades old research and fat content in food products). KIND filed a citizen petition after receiving a warning letter from the FDA, which claimed KIND could not put “healthy” on their snack bars as the bars exceeded the amount of fat allowed. *Id.* The FDA definition of healthy requires that foods meet the government criteria on their content of fat, saturated fat, sodium, cholesterol, and nutrients. Chandler, *supra*; see James Hamblin, *KIND Bars to U.S. Government: Redefine ‘Healthy’*, THE ATLANTIC (Dec. 8, 2015), <https://www.theatlantic.com/health/archive/2015/12/hands-off-nuts-govt/419352> [<https://perma.cc/BE4T-AHWM>] (explaining that, according to the FDA guidelines, any food containing more than four grams of fat is not considered to be healthy, reflecting an antiquated nutritional focus on macronutrients rather than the collective effect of the food product on health).

<sup>113</sup> See Hamblin, *supra* note 112 (noting that the FDA guidelines for healthy food are out of date with current scientific consensus, and giving the example that a Pop-Tart meets the FDA definition of “healthy” because it is low in fat but an almond does not because it is high in fat).

<sup>114</sup> See Lanham Act, 15 U.S.C. § 1051 (prohibiting trademark infringement as well as false advertising claims on products); *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 120–21 (2014) (noting that the FDCA and Lanham Act complement each other and permitting *POM Wonderful*’s claim against Coca-Cola to proceed). Industry competitors can bring actions against each other under the Lanham Act for placing misleading labels on products, but consumers cannot bring claims under the law. *POM Wonderful*, 573 U.S. at 107. By comparison, the FDCA limits causes of actions primarily to federal enforcement and contains an express preemption provision over state laws. *Id.*; see also Pezullo, *supra* note 28, at 333 (noting that the Lanham Act only permits commercial competitors that have an economic interest to bring suits against competitors). See generally BURLINGAME & FOX, *supra* note 89, at 4 (noting that, although consumers do not have standing to sue under the Lanham Act, the *POM Wonderful* decision is significant for commercial false advertising lawsuits).



0.2% blueberry juice, the company was misleading consumers.<sup>115</sup> In a unanimous decision, the Court reasoned that the Food, Drug, and Cosmetic Act complements the Lanham Act and therefore does not preclude unfair competition claims based on allegations of mislabeling or deceptive food labeling.<sup>116</sup>

## II. THE COURTS, CONGRESS, AND THE FDA: IMPACTS ON THE FOOD-LABELING LITIGATION LANDSCAPE

Current food litigation largely stems from an absence of regulatory guidance, as the FDA has declined to define the term “natural” as of 2018.<sup>117</sup> The rise in food litigation against deceptive labeling and false advertising is an indication of regulation by litigation, with plaintiffs seeking to police brands that misuse the term “natural.”<sup>118</sup> In 2004, the Center for Science in the Public Interest (“CSPI”) established a litigation department with the primary purpose of filling the void left by the FDA’s lack of oversight on food labels.<sup>119</sup> The CSPI has successfully pursued claims against the products of some of the largest food companies, including General Mills’ Nature Valley Granola bars, Kraft’s

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<sup>115</sup> *POM Wonderful*, 573 U.S. at 105 (noting that POM Wonderful competes with Coca-Cola and sells pomegranate blueberry juice). *But see* Tiffany Ikeda & James Blackburn, *Coca-Cola Defeats POM Wonderful’s Misleading Labeling Claims: A Key Takeaway for Food and Beverage Manufacturers*, SELLER BEWARE (Mar. 25, 2016), <https://www.consumeradvertisinglawblog.com/2016/03/coca-cola-defeats-pom-wonderfuls-misleading-labeling-claims-a-key-takeaway-for-food-and-beverage-man.html> [<https://perma.cc/3YWY-NRNZ>] (noting that, after an eight-year litigation between POM Wonderful and Coca-Cola, a jury ultimately rejected POM’s allegations against its rival).

<sup>116</sup> *See POM Wonderful*, 573 U.S. at 106 (holding that both statutes are complementary in scope—the Lanham Act protects against unfair competition, whereas the FDCA has a broader reach addressing public health and safety).

<sup>117</sup> *See* Chan, *supra* note 68, at 25 (discussing how the absence of clear federal guidelines opens the floodgates for litigation); Heller, *supra* note 76 (noting that the FDA has declined to adopt a formal definition despite increasing litigation and consumer confusion over the term “natural”).

<sup>118</sup> *See* MORGAN LEWIS, *supra* note 37, at 2 (stating that, in the absence of FDA definition of “natural,” plaintiffs have attempted to fill the regulatory void using litigation).

<sup>119</sup> *See In the Courts*, CTR. FOR SCI. PUB. INT. (2018), <https://cspinet.org/protecting-our-health/courts> [<https://perma.cc/J95D-CY9J>] (noting that CSPI is a non-profit organization established in the 1970s that seeks to provide information on nutrition, food safety, and health for consumer protection and was one of the first leaders in food law). One of the first cases CSPI brought was against Kellogg in 2006 for marketing sugary breakfast foods to children as healthy. *See Kellogg Makes Historic Settlement Agreement, Adopting Nutrition Standards for Marketing Foods to Children*, CTR. FOR SCI. PUB. INT. (June 14, 2007), <https://cspinet.org/news/kellogg-makes-historic-settlement-agreement-adopting-nutrition-standards-marketing-foods> [<https://perma.cc/3XRW-VANW>] (noting that CSPI dropped the suit because Kellogg’s agreed to change its marketing as well as the content of its products). CSPI also brought suit against PepsiCo for its NAKED Juice products, alleging that its fruit juices were not low in sugar and misled consumers by touting vegetables on their labels when they were mainly composed of apple and orange juice. *In the Courts*, *supra*. Although NAKED denied that their labels misled consumers, the company agreed to substantially revise their labels. *Id.*

Capri Sun, and Cadbury’s 7UP.<sup>120</sup> As a result of these lawsuits, each company eliminated the “all natural” label on the food products at issue in the suits.<sup>121</sup>

The lack of FDA guidance has effectively left the door open for litigants to define the amorphous term “natural” and for courts to provide consumers with clarity.<sup>122</sup> Litigants have brought suits successfully challenging the labels of Dole fruits, Tostitos chips, Kellogg’s Kashi brand of cereal, Naked Juices fruit and vegetable juices, Blue Diamond almond milk, Tropicana orange juice, and Ben & Jerry’s ice cream.<sup>123</sup> These suits have prompted these companies to change their labeling as well as the ingredients in their food products.<sup>124</sup> For

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<sup>120</sup> See *General Mills to Drop “100% Natural” Claims on Nature Valley Granola Bars with Artificial Ingredients*, CTR. FOR SCI. PUB. INT. (Nov. 18, 2014), <https://cspinet.org/news/general-mills-drop-100-natural-claims-nature-valley-granola-bars-artificial-ingredient-20141118> [<https://perma.cc/V4W5-UAN9>] (stating that CSPI’s suit against General Mills was one of the first successful lawsuits over the term “all natural”). CSPI filed suit based on General Mills using high-maltose corn syrup and maltodextrin—both ingredients that do not occur in nature and are chemically synthesized—while claiming that their granola bars were “100% natural.” *Id.* CSPI claims that their threats of litigation have resulted in changes for products including 7UP and Capri Sun. *Id.* CSPI’s stated goal in resorting to litigation is to fill in the lack of oversight from the FDA and police companies. *Id.*

<sup>121</sup> See *General Mills to Drop “100% Natural” Claims on Nature Valley Granola Bars with Artificial Ingredients*, *supra* note 120 (discussing General Mills dropping the “100% Natural” label from its Nature Valley granola bars); *In the Courts*, *supra* note 119 (discussing NAKED dropping “all natural” from its fruit juice labels).

<sup>122</sup> See *Astiana v. Kashi Co.*, 291 F.R.D. 493, 508 (S.D. Cal. 2013) (holding that the term “natural” on products has disparate meanings according to different consumers). Compare *Natural*, BLACK’S LAW DICTIONARY (10th ed. 2014) (defining “natural” as “in accord with the regular course of things in the universe and without accidental or purposeful interference” or “brought about by nature as opposed to artificial means”), with *Natural*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/natural> [<https://perma.cc/ZG3M-7NHP>] (defining “natural” as “existing in or produced by nature; not artificial” or “relating to or being natural food,” among other definitions). But see Negowetti, *National “Natural” Standard*, *supra* note 56, at 596 (stating that the FDA has acknowledged that the word “natural” connotes that food products are not manmade).

<sup>123</sup> See Blau & Wiand, *supra* note 12 (overviewing the following “natural” suits: (1) a suit against Naked Juice for claiming its juices to be “natural” despite containing GMOs; (2) a suit against Ben & Jerry’s for its claim that its ice cream is “all natural” when the product contains alkalized cocoa, which is made with processed ingredients; (3) a suit against Tropicana for selling as “natural” orange juice that underwent engineering in a laboratory; (4) a suit against Kashi Cereal for labeling products as containing “nothing artificial” when they actually contained synthetic ingredients; and (5) a suit against Blue Diamond for selling almond milk labeled as “all natural” when it contained potassium citrate—a synthetic ingredient).

<sup>124</sup> See McDonald & Adjemian, *supra* note 6 (discussing how Trader Joe’s agreed in a multimillion-dollar settlement in 2014 to remove the label “all natural” from their food products); Monica Watrous, *Mondelez to Remove Artificial Flavors by 2020*, FOOD BUS. NEWS (Oct. 1, 2015), <https://www.foodbusinessnews.net/articles/5178-mondelez-to-remove-artificial-colors-flavors-by-2020> [<https://perma.cc/4RCF-8DE4?type=image>] (reporting that the manufacturer of Triscuit crackers and Oreo cookies is removing artificial flavors to address consumer expectations); Monica Watrous, *Kellogg to Remove Artificial Colors, Flavors from Cereal*, FOOD BUS. NEWS (Aug. 4, 2015), <https://www.foodbusinessnews.net/articles/6576-kellogg-to-remove-artificial-colors-flavors-from-cereal> [<https://perma.cc/2MUB-MUNK?type=image>] (reporting that, in response to consumer concerns,

example, in 2017 Frito-Lay agreed to remove “all natural” from its products that were made with genetically modified organisms.<sup>125</sup> In response to this wave of litigation, lawyers and experts in the field are advising food companies to refrain from using “natural” because of the high risk of litigation given that the term is not currently regulated.<sup>126</sup>

Although some of this litigation is meritorious, there are numerous claims filed that call into question the validity of these lawsuits.<sup>127</sup> For example, plaintiffs in one suit challenged the “all natural” label on Buitoni pasta.<sup>128</sup> The court dismissed the case with prejudice, reasoning that reasonable consumers would not be misled into believing that processed pasta would be “all natural.”<sup>129</sup> Some of these suits could lend credence to critics’ claims that food-labeling lawsuits are merely for the benefit of the lawyers.<sup>130</sup> In the 2012 class action against Kashi for claiming that its cereal and granola bars, which contain synthetic ingredients, are “all natural,” the lawyers involved were awarded about \$1.5 million in fees out of the total settlement amount of \$3.99 million.<sup>131</sup> The plaintiffs only received a maximum of \$27.50 per household.<sup>132</sup>

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Kellogg’s agreed to remove artificial colors from its branded cereals, including Froot Loops and Apple Jacks, by 2018).

<sup>125</sup> See Andrew Levad & Jason Gordon, *Chipped Away: Frito-Lay Removes “All-Natural” Label from Products Containing GMOs*, ADLAW BY REQUEST (Nov. 14, 2017), <https://www.adlawbyrequest.com/2017/11/articles/in-the-courts/chipped-away-frito-lay-removes-all-natural-label-from-products-containing-gmos> [<https://perma.cc/4HRC-JZYC>] (discussing the five-year class action litigation against PepsiCo, which is the parent company of Frito-Lay, SunChips and Tostitos).

<sup>126</sup> See Watrous, *supra* note 14 (noting that lawyers are urging manufacturers to be wary of using the term “natural” because of its broad applicability, which opens companies to liability suits). See generally Stephen Safranski & Adam Welle, *Natural-Labeling Litigation: Preparing for the Next Five Years*, ROBINS KAPLAN (Apr. 8, 2014), <https://www.robinskaplan.com/resources/articles/natural-labeling-litigation-preparing-for-the-next-five-years> [<https://perma.cc/UF5L-4CTW>] (providing tips and guidance for managing the “natural” litigation risk). Recommendations for managing litigation risk include auditing ingredients, advising manufacturers to consider providing their own definition of what “natural” means on their products, and discussing the importance of “natural” to the brand. *Id.*

<sup>127</sup> See *Kelly v. Cape Cod Potato Chip Co.*, 81 F. Supp. 3d 754, 760 (W.D. Mo. 2015) (holding that the plaintiff’s reliance on the dictionary definition of “natural” was inadequate, because potato chips are processed and so cannot be natural); U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 32 (discussing lawsuits that have relied on claims of questionable merit).

<sup>128</sup> See *Pelayo v. Nestle USA, Inc.*, 989 F. Supp. 2d 973, 980 (C.D. Cal. 2013) (holding that no consumer would believe pasta to be natural because pasta is mass produced and processed).

<sup>129</sup> *Id.*

<sup>130</sup> See Strom, *supra* note 12 (discussing how lawyers who led class action lawsuits against tobacco companies see food-labeling lawsuits as the next large-settlement cases). Critics argue that many of the plaintiffs in food-labeling suits are not real victims because they are not getting sick, so plaintiff’s lawyers may be looking for the next big payout rather than seeking compensation for truly injured clients. *Id.* Class action lawsuits against tobacco giants like R.J. Reynolds and Phillips Morris were notorious for record settlements totaling hundreds of millions of dollars. *Id.* Others argue that, because food gives rise to chronic disease, false or misleading false labeling is not a victimless crime. *Id.*

<sup>131</sup> See U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 43 (comparing settlement amounts to actual plaintiff damages). For example, Red Bull settled a suit for thirteen million dollars,

Because many lawsuits settle, a common criticism of “natural” litigation is that it does not produce real change for the consumer.<sup>133</sup> Despite the criticism that these suits only benefit lawyers, many of these cases have provided refunds to consumers and, more significantly, caused defendants to change their marketing practices and product labels by removing the “all natural” label.<sup>134</sup>

### A. Courts’ Reluctance to Define the Term “Natural”

There is a lack of consensus among courts regarding who should be defining the term “natural”—the courts or the agency.<sup>135</sup> The principal reason that courts dismiss or stay food-labeling litigation is the doctrine of primary jurisdiction.<sup>136</sup> Primary jurisdiction is a common law doctrine promoting the rela-

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with lawyers receiving about three million dollars in fees, despite the questionable merit of the claim that plaintiffs believed the tagline proclaiming that “Red Bull gives you wings.” *Id.* Although the lawyers’ fees were steep, consumers were given a choice of ten dollars or the equivalent value in free products. *Id.* Notably, consumers did not need to prove that they had actually purchased the product in order to collect those damages. *Id.*

<sup>132</sup> *Id.*

<sup>133</sup> *See id.* at 43–44 (discussing the multimillion-dollar fees that lawyers receive while individual plaintiffs obtain minimal awards); Benny, *supra* note 11, at 1506 (arguing that lawsuits over the term “natural” do little more than benefit plaintiffs’ lawyers).

<sup>134</sup> *See* MORGAN LEWIS *supra* note 37, at 23–24 (overviewing class action settlements and subsequent changes that companies made to their products). For example, Jamba Juice agreed to re-label its products labeled as “all natural” because the smoothie kits contained synthetic ingredients. *Id.* at 24.

<sup>135</sup> *See* G. Edward White, *Allocating Power Between Agencies and the Courts: The Legacy of Justice Brandeis*, 1974 DUKE L.J. 195, 198 (1974) (discussing the history of the relationship between agencies and the courts). Administrative agencies were originally created to handle technical and complex questions that required expertise beyond the judicial system. *Id.* at 199. There has long existed a tension between the courts and agencies on interpretation. *Id.* at 207; *see also* *Tex. & Pac. Ry. v. Abilene Cotton Oil Co.*, 204 U.S. 426, 441 (1907) (noting that the Court created the primary jurisdiction doctrine to ensure standardization and uniformity).

<sup>136</sup> *Bohac v. Gen. Mills, Inc.*, No. 12-CV-05280-WHO, 2013 WL 5587924, at \*3 (N.D. Cal. Oct. 10, 2013) (holding that the court could rule on whether the “natural” labels were misleading without risk of undercutting the FDA’s authority because the FDA had issued no formal regulation or rules, including informal policy statements); Lisa Sokolowski, *Judges Vary in Deference to FDA’s Primary Jurisdiction Over “All-Natural” Food Labeling Claims*, PROD. LIAB. MONITOR (July 25, 2013), <https://product-liability.weil.com/class-action-law-suits/judges-vary-in-deference-to-fdas-primary-jurisdiction-over-all-natural-food-labeling-claims> [<https://perma.cc/2RB4-WF5W>] (noting when and why courts invoke primary jurisdiction doctrine and explaining that there is no fixed formula). In addition to defendants raising the primary jurisdiction doctrine, some defendants have unsuccessfully raised preemption claims, stating that the federal FDCA and NLEA preempt state consumer protection statutes. *See Barnes v. Campbell Soup Co.*, No. C12-05185 JSW, 2013 WL 5530017, at \*7 (N.D. Cal. July 25, 2013) (reasoning that because the FDA had not provided an actual federal requirement regarding the term “natural,” the FDCA does not preempt state law claims); Negowetti, *Defining Natural Foods*, *supra* note 15, at 334 (noting that federal courts, however, have consistently declined to uphold defendants’ preemption claims). The *Barnes* court noted that, until the FDA issues a ruling regarding the term “natural,” the court would hold that plaintiffs’ claims are not preempted. *Barnes*, 2013 WL 5530017, at \*7; *see also* *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 341–42 (3d Cir. 2009) (concluding that the plaintiff’s state law claims were not preempted).

tionship between courts and administrative agencies by allocating the initial decision-making to the agencies when the subject matter overlaps.<sup>137</sup> The doctrine is appropriately invoked when the legislature places the resolution of issues under a regulatory scheme within the special competence of an agency.<sup>138</sup> When a court believes that litigation should be suspended until the agency has had adequate time to review the issue, then the court will defer to the agency for a decision.<sup>139</sup> In deciding whether to invoke primary jurisdiction, courts

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<sup>137</sup> *United States v. Philip Morris USA, Inc.*, 686 F.3d 832, 837 (D.C. Cir. 2012) (noting that primary jurisdiction is invoked when resolution of issues has been placed within the competence of a regulatory agency); see also Michael Botein, *Primary Jurisdiction: The Need for Better Court/Agency Interaction*, 29 RUTGERS L. REV. 867, 876 (1976) (noting that primary jurisdiction can impact the outcome of court decisions because it can limit a court's role as the doctrine decides which authority—the court or the agency—has the first right of review). One explanation for the Court's creation of primary jurisdiction doctrine was the Court's desire to protect a new agency, the Interstate Commerce Commission, from judicial encroachment. Botein, *supra*, at 879.

<sup>138</sup> See White, *supra* note 135, at 214 (noting that Justice Louis Brandeis created the four criteria that became the principal test for allocating power between courts and regulatory agencies). Brandeis' four factors to determine when primary jurisdiction applies are:

- (1) whether the complexity of the social problem necessitated that it be addressed by a body of experts with specialized training; (2) whether the question presented was one that could be conclusively resolved in one sitting or needed to be addressed over time by a decision-making body; (3) whether the controversy presented questions that were by their very nature "administrative" and (4) whether particular issues raised were issues of "fact" or "law."

*Id.* In establishing the four-factor criteria, Brandeis noted both a role for agencies to handle complex questions and a role for the judiciary limiting those powers. *Id.* at 214–15. The Ninth Circuit has modified this list of four factors. See *United States v. Gen. Dynamics Corp.*, 828 F.2d 1356, 1362 (9th Cir. 1987) (discussing the four factors present when courts invoke primary jurisdiction); see also *Cox v. Gruma Corp.*, No. 12-CV-06502, 2013 WL 3828800, at \*1 (N.D. Cal. July 11, 2013) (noting that the court considered four factors enumerated in the Ninth Circuit when determining whether to stay proceedings under the primary jurisdiction doctrine). The four factors considered by the Ninth Circuit are:

- (1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory scheme that (4) requires expertise or uniformity in administration.

*Cox*, 2013 WL 3828800, at \*1 (quoting *Syntek Semiconductor Co. v. Microchip Tech., Inc.*, 307 F.3d 775, 781 (9th Cir. 2002)). The *Cox* court found that the case could be stayed as it met all four factors. See *id.* (applying the four-factor primary jurisdiction test and deciding to stay the case against the Gruma Corporation for claims that its corn products are mislabeled as "all natural").

<sup>139</sup> See *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 65 (1956) (explaining that, when primary jurisdiction applies, the issue should be referred to the administrative body for review before judicial interference). The Court noted that primary jurisdiction is more than just a procedural doctrine as it transfers the power to decide an issue from the courts to the agencies. *Id.*

consider the need for uniform decisions and the specialized knowledge of the agency involved.<sup>140</sup>

Without federal guidance, courts consistently hold that suits against misleading food labels are not preempted.<sup>141</sup> Significantly, in 2010 in *Holk v. Snapple Beverage Corp.*, the Third Circuit held that the FDA’s informal policy on “natural” did not have preemptive effect over state claims.<sup>142</sup> The Third Circuit reasoned that the informal policy does not have the effect of law.<sup>143</sup>

### 1. Why Courts Defer to Agency Discretion for Defining “Natural”

There is a lack of uniformity among the courts on when to invoke the primary jurisdiction doctrine and defer to the FDA in “natural” mislabeling cases.<sup>144</sup> In 2010 in *Coyle v. Hornell Brewing Co.*, the federal district court in

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<sup>140</sup> See Sokolowski, *supra* note 136 (noting that there is no defined test for deciding when courts invoke primary jurisdiction, but agency expertise is the most commonly invoked reason for applying the doctrine of primary jurisdiction).

<sup>141</sup> See *Holk*, 575 F.3d at 342 (reasoning that the FDA’s informal policy stance on “natural” is not legally compelling but is only an advisory opinion and is not preemptive of claims brought under state law). The plaintiff in *Holk* filed claims based on the New Jersey Fraud Act, asserting breach of express and implied warranty and unjust enrichment. *Id.* at 332. Snapple argued that *Holk*’s state law claims were preempted by the federal NLEA. *Id.* at 335. A claim is preempted when federal regulation leaves no room for state regulation. *Id.* at 336; see also *Barnes*, 2013 WL 5530017, at \*7 (holding that a plaintiffs’ state law claims were not preempted); *Astiana v. Ben & Jerry’s Homemade Inc.*, Nos. C10-4387 PJH & C10-4937 PJH, 2011 WL 2111796, at \*7–8 (N.D. Cal. May 26, 2011) (holding that the plaintiff’s claims were not preempted by the FDCA); *Hitt v. Ariz. Bev. Co.*, No. 08CV809 WQH, 2009 WL 449190, at \*3 (S.D. Cal. Feb. 4, 2009) (stating that deliberate agency inaction does not by itself preempt state law).

<sup>142</sup> *Holk*, 575 F.3d at 341. The case concerned whether Snapple could label its beverages as “all natural” when they contain high-fructose corn syrup, which is made of processed cornstarch. *Id.* at 332. The plaintiff claimed that she was deceived into paying premium prices for a product that is not “all natural.” *Id.*; see Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (proposed Nov. 27, 1991) (codified at 21 C.F.R. pts. 5, 101, 105) (noting that the FDA’s informal definition of “natural” means that “nothing artificial or synthetic has been added to the food product besides what would otherwise be expected to be there”).

<sup>143</sup> *Holk*, 575 F.3d at 341–42. The court found that the FDA’s informal policy did not have the weight of law because of the FDA’s lack of formal procedure in issuing that policy. *Id.* The court focused on the FDA’s lack of formal process in establishing the definition and stated that isolated instances of enforcement did not constitute a legally binding precedent that would have the weight of federal law. *Id.*

<sup>144</sup> Compare *Kane v. Chobani, LLC*, 645 F. App’x 593, 594 (9th Cir. 2016) (deciding to stay the litigation under primary jurisdiction doctrine because the FDA has requested comments showing interest in defining “natural”), and *Coyle v. Hornell Brewing Co.*, No. 08-cv-02797, 2010 WL 2539386, at \*4 (D.N.J. June 15, 2010) (deciding that determining whether high-fructose corn syrup is “natural” or artificial is a task for the regulatory agency and not the courts), with *Bohac*, 2013 WL 5587924, at \*3 (noting that making a determination on the term “natural” when there are no rules or regulations in place is within the court’s competence), and *Brazil v. Dole Food Co.*, 935 F. Supp. 2d 947, 960 (N.D. Cal. 2013) (stating that primary jurisdiction doctrine does not mean that a court cannot decide a case when presented with an issue within the agency’s purview). See generally *Reiter v. Cooper*, 507 U.S.

New Jersey declined to decide what was meant by the term “natural” without FDA guidance.<sup>145</sup> The court stated that the FDA should decide whether high-fructose corn syrup could be considered “natural.”<sup>146</sup> Central to the court’s conclusion was determining whether the use of word “natural” falls solely within the FDA’s discretion.<sup>147</sup> The court expressed concern about the lack of uniformity in court rulings by noting that other federal courts could come to vastly different conclusions on what is defined as “natural.”<sup>148</sup> Ultimately, the court reasoned that this judicial rulemaking would impose a burden on the industry, because the industry would have to conform to the judicial definition, which could change if the FDA chooses to speak directly to the question.<sup>149</sup>

Similarly, in dismissing *Cox v. Gruma Corp.* in 2014, the U.S. District Court for the Northern District of California held that it was the FDA’s job to determine whether the term “natural” could be used for products that contain genetically modified organisms.<sup>150</sup> The court noted that the FDA should be provided an opportunity to decide the issue before the court addresses the

258, 268 (1993) (stating that if the primary jurisdiction doctrine does apply, the Court will “refer” the issue of defining the term “natural” to the appropriate agency); Negowetti, *Defining Natural Foods*, *supra* note 15, at 341 (discussing discrepancy in court decisions regarding primary jurisdiction).

<sup>145</sup> *Coyle*, 2010 WL 2539386, at \*4 (concluding that determining whether high-fructose corn syrup is “natural” or artificial is a task for the regulatory agency and not the courts). Central to the court’s determination was the concern that its definition of “natural” would be inconsistent with that of other courts and the FDA, especially because the defendants were involved in another suit in a different jurisdiction. *Id.* The court concluded that the FDA has the primary responsibility to resolve this dispute. *Id.* Of note, the court stated that if the FDA did not revisit the question of defining the term “natural” in six months, then the court would consider extending the length of the stay. *Id.*

<sup>146</sup> *Id.* at \*4–5.

<sup>147</sup> *Id.* at \*4.

<sup>148</sup> *Id.*

<sup>149</sup> *Id.* The court was eventually forced to lift the stay because the FDA declined to define “natural” or address whether high-fructose corn syrup could be considered to be “natural.” See Mark D. Anstoetter & Madeline M. McDonough, *Stay in Snapple “Natural” Beverage Lawsuit Extinguished*, FOOD & BEVERAGE LITIGATION UPDATE (Shook, Hardy, & Bacon L.L.P., Kansas City, Mo.), Oct. 22, 2010, at 7 (noting that the stay in *Coyle* was eventually lifted because the agency failed to address the issue). Because of the FDA’s refusal to decide whether high-fructose corn syrup falls into the “natural” label, several district courts have ruled that primary jurisdiction doctrine does not apply. *Id.*; see *Janney v. Gen. Mills*, 944 F. Supp. 2d 806, 814–15 (N.D. Cal. 2013) (reasoning that referring the matter to the FDA would be futile because of the agency’s prior refusal to step in during *Coyle*). In response, the FDA stated that consumers already had some protection under the FDCA because the Act requires all food products to be properly labeled. See Negowetti, *National “Natural” Standard*, *supra* note 56, at 588 (noting the FDA’s reasons for not wanting to define the term “natural”). But see *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011) (stating that if federal courts decide the meaning of “natural” differently based on varied state laws it may have negative consequences for the food and beverage industry). The Seventh Circuit in *Turek* stated that the potential for different labels to be either permitted or banned in different jurisdictions would place undue burdens on the industry, which would be resolved if the FDA directly addressed the issue. 662 F.3d at 426.

<sup>150</sup> *Cox*, 2013 WL 3828800, at \*2 (holding that, because the FDA has authority to issue a definition of “natural,” the court should give deference to the FDA’s authority).

question, as the FDCA gives the FDA authority to regulate food labeling.<sup>151</sup> Central to the court’s decision to refer this question to the agency was the court’s observation that the FDA had yet to resolve whether foods containing GMOs can be labeled as “natural.”<sup>152</sup>

In the wake of the FDA initiating public comment, the Ninth Circuit in *Kane v. Chobani, LLC* stayed litigation based on primary jurisdiction in March 2016.<sup>153</sup> The plaintiff claimed that *Chobani* yogurt could not be labeled as “natural” because the product contains evaporated cane sugar, a processed substance.<sup>154</sup> Noting that the goal of primary jurisdiction is to ensure uniform outcomes for cases, the Ninth Circuit stayed proceedings to avoid creating conflicting interpretations of the term “natural.”<sup>155</sup>

Following the Ninth Circuit’s holding in *Kane*, other courts have followed suit to stay litigation.<sup>156</sup> For example, the Federal District Court for the Eastern District of New York stayed litigation based on primary jurisdiction in *Forsher v. J.M. Smucker*, where plaintiffs alleged that the defendant company deceptively labeled their peanut butter spread as “natural” when the product contains GMOs.<sup>157</sup> The court acknowledged that the FDA never adopted a formal defi-

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<sup>151</sup> *Id.*

<sup>152</sup> *See id.* (ordering the action stayed for six months with the possibility of extending the stay upon a showing of good cause, including the FDA demonstrating an intention to address this issue); *see also* MORGAN LEWIS, *supra* note 37, at 7 (listing the five reasons for the FDA’s refusal to issue a uniform policy on the definition of “natural,” being (1) that changing the policy would require undergoing a public comment process; (2) that changing the policy would require the FDA to coordinate and cooperate with the USDA and other federal agencies that oversee food and beverages; (3) that the process would entail an extensive consideration of a variety of issues including consumer beliefs, First Amendment implications, and food production methods; (4) that the FDA lacks the resources to undertake the process and there are more pressing matters that require the agency’s attention; and (5) that defining “natural” has implications that go beyond the scope of the parties who have litigated the issue).

<sup>153</sup> *See Kane*, 645 F. App’x at 594 (deciding to stay the litigation under primary jurisdiction because the FDA has requested comments showing interest in defining “natural”).

<sup>154</sup> *See id.* (noting that the plaintiff claims that calling its product as “natural” is misleading).

<sup>155</sup> *See id.* (noting the term “natural” implies technical and policy questions that are best addressed by the agency designed to regulate the area rather than by the judicial branch).

<sup>156</sup> *See, e.g.,* *George v. Blue Diamond Growers*, No. 4:15-cv-962 (CEJ), 2016 WL 1464644, at \*3 (E.D. Mo. Apr. 14, 2016) (staying litigation based on primary jurisdiction because the FDA has the appropriate authority and expertise to determine the question); *see also* U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 33 (noting that other courts have followed the Ninth Circuit’s example and stayed litigation pending an FDA rule). Because the Ninth Circuit has been rife with food litigation in the past, the decision to stay *Kane* is significant in shaping the future of food litigation. U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12, at 33; *see also* *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 761–62 (9th Cir. 2015) (looking to other court decisions that have stayed proceedings as persuasive authority to support invoking primary jurisdiction by finding that regulating the term “natural” for cosmetics is a technical question).

<sup>157</sup> *Forsher v. J.M. Smucker Co.*, CV 2015-7180, 2016 WL 5678567, at \*1 (E.D.N.Y. Sept. 30, 2016).



nition of the term “natural” and held that the FDA could best address the technical and policy issues raised.<sup>158</sup> The court cited recent stays in other circuits as persuasive and similarly invoked primary jurisdiction pending an FDA decision regarding “all natural” claims.<sup>159</sup>

The FDA’s extended silence since issuing public comment has not completely deterred courts from invoking primary jurisdiction.<sup>160</sup> The stays of litigation in the wake of *Chobani* has also not persuaded consumers to refrain from bringing suits.<sup>161</sup> Rather, in 2017, there continued to be an uptick in “all natural” lawsuits being filed, such as a suit against Wal-Mart for its “all-natural” pita chips.<sup>162</sup>

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<sup>158</sup> See *Forsher*, 2016 WL 5678567, at \*2 (noting that determining whether genetically modified ingredients are “natural” is a technical question); *Coyle*, 2010 WL 2539386, at \*4 (stating that whether a product can use the term “natural” is an issue that does not fall within the conventional expertise of judges).

<sup>159</sup> See *Forsher*, 2016 WL 5678567, at \*2 (deciding to stay litigation based on other district courts granting stays pending an FDA decision); *In re KIND LLC “Healthy and All Natural” Litig.*, 209 F. Supp. 3d 689, 695, 697 (S.D.N.Y. 2016) (deciding to stay the litigation as the FDA guidance would harmonize court holdings on “natural” litigation). The plaintiffs in *KIND* alleged that *KIND* products are deceptively labeled as “all natural” because they contain synthetic and processed ingredients such as soy protein isolate and ascorbic acid. *In re KIND LLC*, 209 F. Supp. 3d at 691. The court reasoned that the volume of litigation creates the potential for inconsistent rulings. *Id.* at 696. Central to the court’s decision was the fact that the FDA had already initiated the comment process to define “natural.” *Id.*

<sup>160</sup> See *Rosillo v. Annie’s Homegrown, Inc.*, No. 17-cv-02474- JSW, 2017 WL 5256345, at \*3 (N.D. Cal. Oct. 17, 2017) (rejecting the plaintiff’s claims that primary jurisdiction should not be invoked based on the FDA’s silence on the definition of “natural”). The *Rosillo* court held that the FDA’s resolution of the term “natural” will bear on how a reasonable consumer understands the term and thus will impact the landscape of mislabeling litigation. *Id.* Also central to the court’s conclusion were its observations that (1) the FDA’s regulatory framework around labeling is particularly broad and (2) Congress explicitly designated the resolution of technical and complex terms like “natural” to the FDA. *Id.*

<sup>161</sup> See Mike Helenthal, *Judge Denies Injunctive Relief for Plaintiff in Newman’s Own Pasta Sauce Case*, LEGAL NEWS LINE (June 6, 2017), <https://legalnewsline.com/stories/511122718-judge-denies-injunctive-relief-for-plaintiff-in-newman-s-own-pasta-sauce-case> [<https://perma.cc/7CCB-6PF8>] (overviewing a case against Newman’s Own regarding the company’s “all natural” pasta sauce, which was brought a year after *Chobani*). A federal judge in Brooklyn issued a stay based on primary jurisdiction in the class action lawsuit brought against Newman’s Own for its allegedly misleading “all natural” pasta sauce labels. *Id.* The plaintiffs alleged that the presence of citric acid is not “natural” and thus in violation of New York’s consumer protection statute. *Id.*

<sup>162</sup> See Caitlin Dewey, *The Raging Legal Battle Over What Makes Food “Natural,”* WASH. POST (Aug. 30, 2017), <https://www.washingtonpost.com/news/wonk/wp/2017/08/30/the-raging-legal-battle-over-what-makes-a-food-natural> [<https://perma.cc/6DFE-NVCT>] (noting the increase in “natural” lawsuits filed in 2017); Jacqueline C. Gorbey, *Class Actions Involving “Natural” Labeling Remain on Hold in Anticipation of FDA Guidance*, LEXOLOGY (Oct. 25, 2017), <https://www.lexology.com/library/detail.aspx?g=3416deb7-10fd-4b82-8b70-08b4876a22aa> [<https://perma.cc/A3XB-GP4E>] (noting that nineteen lawsuits regarding “natural” claims were filed between January and July of 2017, indicating that plaintiffs are not deterred by the recent litigation stays).

## 2. Deciding “Natural” Is Within the Court’s Competence

Although primary jurisdiction is mainly invoked because the agency is seemingly more competent than the court to define technical terms, some courts hold that deciding whether a product is “natural” is within the court’s purview.<sup>163</sup> Some district courts are reluctant to use the primary jurisdiction doctrine, stating that the doctrine does not apply to mislabeling claims.<sup>164</sup> For example, in September 2013, in *Brazil v. Dole Food Co.*, the court held that the doctrine of primary jurisdiction does not mean that an agency rather than the court should decide all claims within an agency’s discretion.<sup>165</sup> The plaintiffs in *Dole Food Co.* alleged that some of Dole’s products are misbranded as “all natural.”<sup>166</sup> The court agreed with the plaintiffs’ claims that consumers could be misled by “all natural” claims when food contains synthetic ingredients.<sup>167</sup> The court opined that a case about misbranding is within its competence because resolving the issues does not depend on questions about pure scientific claims.<sup>168</sup> Thus, deciding whether a reasonable consumer can be deceived is within the court’s realm of expertise.<sup>169</sup> Further, the court reasoned that there was little risk of undermining the FDA’s authority because the agency had not promulgated an enforceable rule.<sup>170</sup>

Similarly, in 2013, in *In re Frito-Lay North America, Inc., All Natural Litigation*, the U.S. District Court for the Eastern District of New York denied a stay on litigation, deciding that the primary jurisdiction doctrine did not apply.<sup>171</sup> The plaintiffs alleged that PepsiCo’s decision to label products such as Tostitos, SunChips, and Frito-Lays with “all natural” was misleading because

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<sup>163</sup> See *Coyle*, 2010 WL 2539386, at \*4 (holding that deciding the definition of “natural” is within the FDA’s competence); *In re KIND*, 209 F. Supp. 3d at 695 (stating that courts consistently address scientific and technical questions); *Ault v. J.M. Smucker Co.*, No. 13-cv-3409, 2014 WL 1998235, at \*5 (S.D.N.Y. May 15, 2014) (noting that a court can determine whether a food label is likely to mislead a reasonable consumer).

<sup>164</sup> See *Ault*, 2014 WL 1998235, at \*5 (holding that the court can decide mislabeling cases because these cases are less about science and more about deciding legally whether a reasonable consumer would be misled). See generally Negowetti, *Defining Natural Foods*, *supra* note 15, at 336 (discussing when courts decide to invoke primary jurisdiction and noting that many courts conclude that deciding mislabeling claims concerning the term “natural” is within a court’s competence).

<sup>165</sup> See *Dole Food Co.*, 935 F. Supp. at 960 (stating that primary jurisdiction doctrine does not mean that a court cannot decide a case when presented with an issue within an agency’s purview).

<sup>166</sup> *Id.* at 950–51.

<sup>167</sup> See *id.* (reasoning that the FDA’s warning letters informed companies that consumers could be deceived by “all natural” claims if the food product contained synthetic citric acid).

<sup>168</sup> *Id.* at 960.

<sup>169</sup> *Id.*

<sup>170</sup> *Id.* at 959–60.

<sup>171</sup> *In re Frito-Lay N. Am., Inc. All Natural Litig.*, No.12- MD-2413, 2013 WL 4647512, at \*8 (E.D.N.Y. Aug. 29, 2013).

the products contained genetically modified organisms.<sup>172</sup> The court reasoned that even if the FDA defined the term “natural,” there is no legal guidance on what the term will cover and therefore the question of whether PepsiCo’s labeling was misleading was a proper question for the court to decide.<sup>173</sup>

The FDA’s inaction on defining “natural” has been central to courts’ decisions on when to invoke primary jurisdiction.<sup>174</sup> In the 2013 case *In re ConAgra Food, Inc.*, the court refused to stay the litigation because it was highly speculative whether the FDA would ever choose to define the term “natural.”<sup>175</sup> The case concerned allegations that the Wesson brand cooking oil labeled as “100% Natural” was misleading because the oils are made from genetically modified organisms.<sup>176</sup> The court noted the FDA’s history of refusing to define “natural” and opined that any regulatory action was highly uncertain.<sup>177</sup> Further, in *Morales v. Kraft Foods Group, Inc.*, in 2016, the judge refused to grant a stay based on primary jurisdiction.<sup>178</sup> Distinguishing the case from *Kane*, the *Morales* court held that deciding if the label “natural cheese” is deceptive to a consumer is different than determining whether the term “natural” is being misused.<sup>179</sup> The *Morales* court’s decision to stay litigation is an outlier among the courts, as most courts stayed litigation after the FDA initiated rulemaking in 2016.<sup>180</sup>

<sup>172</sup> *Id.* at \*1.

<sup>173</sup> *Id.* at \*8 (noting that primary jurisdiction doctrine does not apply when the matter is legal in nature, such as deciding whether a reasonable consumer would be misled by certain marketing claims).

<sup>174</sup> *See Bohac*, 2013 WL 5587924, at \*3 (noting that FDA has not undertaken to enact any rules or regulations regarding the use of the term “natural”); *In re ConAgra Foods, Inc.*, No. CV 11–05379–MMM, 2013 WL 4259467, at \*4 (C.D. Cal. Aug. 12, 2013) (stating that it was uncertain whether the FDA would define “natural”).

<sup>175</sup> *In re ConAgra*, 2013 WL 4259467, at \*5.

<sup>176</sup> *Id.* at \*1.

<sup>177</sup> *Id.* at \*4–5.

<sup>178</sup> Order re Defendant’s Renewed Motion to Stay Case Pending the FDA Action on “Natural” Guidance at 6–7, *Morales v. Kraft Foods Group, Inc.*, No. 14-04387 (C.D. Cal. Dec. 6, 2016).

<sup>179</sup> *Id.* (noting the question is whether the label “natural cheese” is deceptive to the reasonable consumer which is not a technical and policy question that should be deferred to an agency); *see also Kane*, 645 F. App’x at 594 (holding that whether Chobani’s labeling of its product as “natural” is misleading is a technical policy question for the agency to decide).

<sup>180</sup> *See* Marisa Maleck, King & Spaulding, *The Viability of the “Primary Jurisdiction Doctrine” Defense and Other Ways to Stem the Tide of Food & Beverage Class Actions*, JD SUPRA (Feb. 17, 2017), <https://www.jdsupra.com/legalnews/the-viability-of-the-primary-10480> [(<https://perma.cc/5SZL-YBB5>)] (noting that the *Morales* decision is a departure from other court decisions to stay); *see also* Order re Defendant’s Renewed Motion to Stay Case Pending the FDA Action on “Natural” Guidance, *supra* note 178, at 6–7 (declining to stay the litigation despite the FDA taking action to define the term “natural”).

### B. Congressional and State Efforts to Define “Natural”

Beginning in 2005, the Senate and House Appropriations Committees pressed the FDA to ensure labels were accurate because they were concerned with consumers losing confidence in food labels.<sup>181</sup> In the absence of regulatory and judicial guidance, Congress attempted to establish a standard definition for the term “natural” in the Food Labeling and Modernization Act of 2013.<sup>182</sup> The Act would have prevented foods from being branded as “natural” if they contained any artificial ingredients, such as flavors or colors that were not naturally occurring substances.<sup>183</sup> The Act would also have barred products from being labeled as “natural” if they included high-fructose corn syrup or corn syrup, which are deemed to be artificial ingredients.<sup>184</sup> The Act did not address the presence of GMOs, however, which has become a significant area of litigation in the “all natural” suits.<sup>185</sup> The Act failed to pass Congress in 2013 and was re-proposed in 2015 and again in 2018.<sup>186</sup>

The 2015 Act would have amended the FDCA to clarify when labeling a food as “natural” would be considered misbranding, and would have directed the Secretary of Human Services to define the term “natural.”<sup>187</sup> In addition,

<sup>181</sup> See BRUCE SILVERGLAD & ILENE RINGEL HELLER, CTR. FOR SCI. PUB. INT., REBUTTAL TO FDA REPORT TO CONGRESS ON AGENCY ENFORCEMENT ACTIONS REGARDING HEALTH RELATED CLAIMS ON FOOD LABELS 1 (2006), <https://cspinet.org/sites/default/files/attachment/fn5rep.pdf> [<https://perma.cc/5SZL-YBB5>] (noting that congressional committees want to ensure consumers retain confidence in food labels).

<sup>182</sup> See H.R. 3147, 113th Cong. § 4(aa) (2013) (deeming a food to be misbranded if it is labeled as “natural” but contains any artificial ingredients, including artificial flavors and colors). To address consumer confusion, the proposed act’s primary goal was to establish a uniform front-of-package labeling system. *Id.* § 2(2). Part of this label standardization would have defined the term “natural.” *Id.* § 4(aa).

<sup>183</sup> *Id.* § 4(aa).

<sup>184</sup> *Id.*

<sup>185</sup> See Claire Mitchell & Thomas Wood, *Federal Judge Orders FDA to Address “All Natural” Labeling on GMO Foods*, FOOD LIABILITY L. (June 24, 2013), <https://www.foodliabilitylaw.com/2013/07/articles/litigation/federal-judge-orders-fda-to-address-all-natural-labeling-on-gmo-foods> [<https://perma.cc/6WUL-8KEK>] (noting that consumer cases targeting products that make “all natural” claims but contain GMOs have become common). See generally H.R. 3147, 113th Cong. (2013) (making no mention of GMOs in the proposed bill).

<sup>186</sup> See Isidro, *supra* note 16 (providing an overview of the Food Labeling and Modernization Act legislation and discussing the Act’s failure); see also Food Labeling Modernization Act of 2018, H.R. 5425, 115 Cong. (as proposed on Apr. 2, 2018) (introducing a House Bill to define the term “natural” and the definition should at minimum exclude the use of any artificial food or flavoring). In April 2018, the House introduced a new version of the Food Labeling Modernization Act of 2018 that seeks to modify the FDCA. H.R. 5425. This act directs the Secretary of Health and Human Services to promulgate a definition of “natural” no less than two years after the enactment of the Act. *Id.*

<sup>187</sup> See Food Labeling Modernization Act of 2015, H.R. 4061, 114 Cong. (as proposed Nov. 18, 2015) (directing the Secretary of Health and Human Services, within two years of enactment of the Act, to provide a definition of “natural” that excludes products containing any “artificial food or in-

Congress proposed the Safe and Accurate Food Labeling Act (“SAFLA”) in 2015 that specifically addressed genetically modified foods.<sup>188</sup> SAFLA would have prohibited labeling using the term “natural” on foods containing GMOs.<sup>189</sup> SAFLA failed to pass in the Senate.<sup>190</sup>

The goal of SAFLA was to provide a uniform approach to food labeling as states began enacting legislation to address GMOs and the term “natural.”<sup>191</sup> Vermont was one of the first states in 2014 to pass a law (Act 120) prohibiting the use of the label “natural” on any food product that is produced, even in part, with genetic engineering.<sup>192</sup> Other states, including Maine and Connecticut, have passed laws mandating the labeling of products that contain GMOs, while a similar bill in California was defeated.<sup>193</sup>

In July 2017, the House Committee on Appropriations praised the FDA for undertaking efforts to define the term “natural” on food labels.<sup>194</sup> The 2018 Agricultural, Rural Development, Food and Drug Administration and Related Agencies Appropriations Bill contains an express direction to the FDA to report on the agency’s timeline for proposing a definition, and requires a reply within sixty days of passing the bill.<sup>195</sup> In requesting a timeline, the House noted the need for a uniform definition in order to provide certainty to manufacturers and

redient . . . or any synthetic substance” and that is based partially on “consumers’ understanding of the term”).

<sup>188</sup> Safe and Accurate Food Labeling Act, H.R. 1599, 114th Cong. (as proposed on Feb. 12, 2015) (introducing the bill to establish labeling for food products containing genetically engineered organisms).

<sup>189</sup> *Id.*

<sup>190</sup> See Isidro, *supra* note 16 (noting that the Safe and Accurate Food Labeling Act (“SAFLA”) would have established a voluntary labeling of GMOs, but the Act failed to pass the Senate).

<sup>191</sup> See Carey Gillam, *U.S. Bill Seeks to Block Mandatory GMO Food Labeling by States*, REUTERS (Apr. 9, 2014), <https://www.reuters.com/article/usa-gmo-lawmaking/u-s-bill-seeks-to-block-mandatory-gmo-food-labeling-by-states-idUSL2N0N115F20140409> [<https://perma.cc/NS8F-KX7Q>] (reporting that the impetus for SAFLA was to avoid a patchwork system of state laws). See generally Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733 (2003) (overviewing the United States’ historical policy on genetically modified foods).

<sup>192</sup> See Mark Strauss, *The Congressional Debate Over What Makes Food “Natural,”* GIZMODO (Dec. 11, 2014), <https://io9.gizmodo.com/the-congressional-debate-over-what-makes-food-natural-1669787308> [<https://perma.cc/5LH9-GQSB>] (discussing the provisions of the state legislation to address GMO labeling on food).

<sup>193</sup> See Pollans, *supra* note 7 (discussing various state legislation seeking to regulate and label GMOs to address concerns about “natural” ingredients). Forty-five million dollars were spent in lobbying to defeat the proposed California bill, indicating industry interest in food regulation. *Id.*

<sup>194</sup> See COMM. ON APPROPRIATIONS, AGRIC., RURAL DEV. FOOD & DRUG ADMIN., & RELATED AGENCIES APPROPRIATIONS BILL, H.R. REP. NO. 115-232, at 72 (2017) (commending the FDA for initiating steps to define the term “natural” by undertaking the public comment process that began in November of 2015).

<sup>195</sup> See *id.* (noting that the FDA must report on its next steps towards defining the term “natural”).

consumers.<sup>196</sup> This state and congressional action illustrates that the “natural” label and lack of FDA regulation has sparked a national conversation concerning who is best to regulate food labels: the courts, the legislature, or the FDA.<sup>197</sup>

### C. The FDA’s Next Steps for Defining the Term “Natural”

Beginning in November 2015, the FDA initiated the process to define the term “natural” by opening a public comment period.<sup>198</sup> The agency stated that it was initiating the public comment process because of three citizen petitions as well as the federal courts urging the FDA to define the term.<sup>199</sup> The FDA closed the public comment process in May 2016.<sup>200</sup> The FDA received 7,690 comments from industry representatives, public interest groups, and consumers.<sup>201</sup> The majority of the input indicated that both consumers and businesses want the FDA to define the term “natural.”<sup>202</sup> Many consumers cited the Mer-

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<sup>196</sup> *Id.*; see also Stephen McConnell, *For N.D. Cal., Primary Jurisdiction Is the “Natural” Outcome*, DRUG & DEVICE L. (Nov. 22, 2017), <https://www.druganddeviceblog.com/2017/11/for-n-d-cal-primary-jurisdiction-is-the-natural-outcome.html> [<https://perma.cc/YLY6-XB4D>] (noting that the bill must pass for this requirement to take effect, and thus the sixty-day timeframe has not yet commenced).

<sup>197</sup> See McConnell, *supra* note 196 (discussing the labeling controversy and arguing for the FDA to regulate the term “natural” rather than leaving it to the courts).

<sup>198</sup> Use of the Term “Natural” in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg. 69,905 (proposed Nov. 12, 2015) (to be codified at 21 C.F.R. 101). The FDA’s request for comments asked several questions including (1) whether the agency should define “natural,” (2) whether, alternatively, the use of the term “natural” should be prohibited, (3) what kind of food should be considered “natural,” (4) if “natural” should apply to single- or multi-ingredient foods, (5) what types of ingredients would bar a multi-ingredient food from bearing the term “natural,” (6) if agricultural and animal husbandry practices should be considered in the term’s definition, (7) whether manufacturing processes should be considered in defining “natural,” (8) if “natural” should encompass only unprocessed foods, and (9) whether how an ingredient is sourced should impact if it may be called “natural.” *Id.* at 69,908; see also “Natural” on Food Labeling, *supra* note 17 (announcing the public comment process with an ending date of February 10, 2016). The FDA later extended the deadline to May of 2016. “Natural” on Food Labeling, *supra* note 17.

<sup>199</sup> See Isidro, *supra* note 16 (discussing a petition from the Grocery Manufacturers Association asking the FDA to define the term “natural” as including food products that are made from or derived using biotechnology). By contrast, the Consumers Union asked the FDA to prohibit use of the term on food products. *Id.*

<sup>200</sup> See Blau & Wiand, *supra* note 12 (noting that the agency closed public comment in May). The agency does not need to respond to every comment because the agency has not undergone formal rulemaking. *Id.*

<sup>201</sup> See *Use of the Term “Natural” in the Labeling of Human Food Products; Request for Information and Comments*, *supra* note 85 (noting that the FDA received comments from organizations and public interest groups such as the Vinegar Institute, Snacking Nutrition Convenience International, the Center for Food Safety, the Sugar Association, the Organic Trade Association, the Humane Society of the United States, Tyson Foods, and the Calorie Control Council).

<sup>202</sup> *Id.*; see also McDonald & Adjemian, *supra* note 6 (reporting that the public comment process revealed that most companies and consumers agree that the FDA should define the term “natural”); Unilever, Comment Letter on Proposed Rule on Use of the Term “Natural” in the Labeling of Human

riam-Webster dictionary definition of “natural,” which is “existing in kind or caused by nature; not made or caused by human kind.”<sup>203</sup> Consumer opinions overwhelmingly stated that the term “natural” does not encompass biotechnology or genetically modified organisms.<sup>204</sup> By contrast, industry and food associations urged the FDA to include biotechnology and GMOs in the definition of “natural.”<sup>205</sup> Since the FDA closed comment, however, the agency has re-

Food Products (May 10, 2016) [hereinafter Unilever Comment Letter], <https://www.regulations.gov/document?D=FDA-2014-N-1207-6928> [<https://perma.cc/6HVQ-8ETL>] (noting that a central concern among businesses for defining the term “natural” was that this label was important to the business and there is a need to level the playing field). *But see* Consumers Union, Comment Letter on Proposed Rule on Use of the Term “Natural” (May 10, 2016), <https://www.regulations.gov/document?D=FDA-2014-N-1207-6891> [<https://perma.cc/383K-CR48>] (arguing that use of the term “natural” should be prohibited on food labels).

<sup>203</sup> *Natural*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/natural> [<https://perma.cc/ZG3M-7NHP>]. *See generally*, McDonald & Adjemian, *supra* note 6 (discussing consumer comments received during the FDA’s public comment period).

<sup>204</sup> *See* McDonald & Adjemian, *supra* note 6 (noting that most if not all consumers stated that they did not want genetically modified foods included in the definition of “natural”); *see also* *Biotechnology, Genetic Engineering, and “GMOs”: Why All the Controversy?*, INST. FOOD TECH., <http://www.ift.org/Knowledge-Center/Learn-About-Food-Science/Food-Facts/Biotechnology-Genetic-Engineering-GMOS.aspx> [<https://perma.cc/WM4S-XUQS>] (defining biotechnology as “a number of methods other than selective breeding and sexually crossing of plants to endow new characteristics in organisms). By comparison, genetic engineering is defined as: “The introduction or change of DNA, RNA, or proteins by human manipulation to effect a change in an organism’s genome or epigenome.” *Biotechnology, Genetic Engineering, and “GMOs”: Why All the Controversy?*, *supra*.

<sup>205</sup> *See* American Frozen Food Institute, Comment Letter on Proposed Rule on Use of the Term “Natural” in Labeling of Human Food Products (May 10, 2016) at 2, <https://www.regulations.gov/document?D=FDA-2014-N-1207-6929> [<https://perma.cc/A959-HU7X>] (stating that processed foods should be included in the definition of “natural”); International Dairy Foods Association, Comment Letter on Use of the Term “Natural” in Labeling of Human Food Products (May 10, 2016) at 5 [hereinafter International Dairy Foods Association Comment Letter], <https://www.regulations.gov/document?D=FDA-2014-N-1207-6798> [<https://perma.cc/R7TG-PVGZ>] (stating that containing GMOs should not disqualify a food from being labeled as “natural”); Tyson, Comment Letter on Proposed Rule on Use of the Term “Natural” in Labeling of Human Food Products (Apr. 25, 2016) at 3 [hereinafter Tyson Comment Letter], <https://www.regulations.gov/document?D=FDA-2014-N-1207-6453> [<https://perma.cc/79J8-JCNF>] (arguing that the definition of “natural” should include GMOs). *But see* Humane Society of the United States, Comment Letter on Proposed Rule on Use of the Term “Natural” in Labeling of Human Food Products (May 10, 2016) at 1, <https://www.regulations.gov/document?D=FDA-2014-N-1207-7289> [<https://perma.cc/6RRG-CBGH>] (stating that biotechnology should not be included in the definition of “natural”); Vinegar Institute, Comment Letter on Proposed Rule on Use of the Term “Natural” in Labeling of Human Food Products (May 9, 2016) at 2, <https://www.regulations.gov/document?D=FDA-2014-N-1207-6733> [<https://perma.cc/2H33-JJHC>] (stating that including genetically modified foods in the definition of “natural” would undermine the essence of what consumers think is “natural” and does not provide adequate information to consumers); American Nurses Association, Comment Letter on Proposed Rule on Use of the Term “Natural” in Labeling of Human Food Products (Dec. 7, 2015) at 1, <https://www.regulations.gov/document?D=FDA-2014-N-1207-2217> [<https://perma.cc/NDB3-TVJS>] (noting that the definition of “natural” excludes genetically modified organisms).

mained silent on whether it will engage in formal rulemaking to define the term.<sup>206</sup>

### III. THE FDA SHOULD DEFINE “NATURAL”

There is a benefit to the FDA providing a uniform standard: it would prevent corporations from making misleading claims on food labels and prevent the development of a patchwork of state labeling laws across the country.<sup>207</sup> When the FDA skirts its responsibility to provide adequate definitions, there exists a grey area that gives rise to litigation, as evidenced by the rise of litigation and prominence of the “Food Court” in California.<sup>208</sup> Additionally, it is beneficial for the industry to have national standards that define ambiguous terms, as it ensures an equal playing field for all food products.<sup>209</sup> Food producers also desire a formal definition because it could curb the risk of litigation.<sup>210</sup>

#### 1. Courts Should Give Deference to the FDA

Because of the current tension between the courts and the agency on defining “natural,” a central issue is whether the courts should stay litigation in

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<sup>206</sup> See McDonald & Adjemian, *supra* note 6 (noting that the FDA has not given a definitive ruling after closing public comment in May of 2016).

<sup>207</sup> See Blau & Wiand, *supra* note 12 (discussing that, in the absence of a legally enforceable definition of “natural,” there has been a rise in food-labeling litigation against companies allegedly misusing the term on products that contain synthetic ingredients); Negowetti, *Food Labeling Litigation*, *supra* note 9, at 19 (advocating for the FDA to promulgate a definition of “natural” to promote uniformity).

<sup>208</sup> See U.S. CHAMBER INST. FOR LEGAL REFORM, *supra* note 12 (discussing how the Northern District of California is nicknamed the “Food Court” because of the numerous food-labeling lawsuits filed in that state); Strom, *supra* note 12 (noting that lawyers have been selective in where to file their suits, and most food-labeling suits are filed in California).

<sup>209</sup> See Carolyn Heneghan, *Experts: Food Labeling Overhaul Could Level the Playing Field or Have Unintended Consequences*, FOOD DIVE (Jan. 21, 2016), <https://www.fooddive.com/news/experts-food-labeling-overhaul-could-level-the-playing-field-or-have-unintended-consequences/412289> [<https://perma.cc/K3MP-ARTP>] (discussing the impacts of the FDA defining the term “natural” for the industry).

<sup>210</sup> *Id.*; see also Chobani, Comment Letter on Proposed Rule on Use of the Term “Natural” in the Labeling of Human Food Products (May 10, 2016) at 1–2, <https://www.regulations.gov/document?D=FDA-2014-N-1207-7286> [<https://perma.cc/X3WG-97VA>] (stating that having a legal definition of “natural” is important for branding purposes); Consumer Healthcare Products Association, Comment Letter on Proposed Rule on Use of the Term “Natural” in the Labeling of Human Food Products (May 10, 2016) at 1–2, <https://www.regulations.gov/document?D=FDA-2014-N-1207-7151> [<https://perma.cc/ZKQ6-SN9K>] (noting that a uniform definition would level the playing field between those businesses that are misleading using the term “natural” and those businesses that do not misbrand their products); Flavor and Extract Manufacturers Association of the United States, Comment Letter on Proposed Rule on Use of the Term “Natural” in the Labeling of Human Food Products (May 10, 2016) at 5, <https://www.regulations.gov/document?D=FDA-2014-N-1207-6933> [<https://perma.cc/87WC-AEJZ>] (noting that having a definition for “natural” is important because consumers make buying decisions based on labels).



anticipation of the FDA ruling.<sup>211</sup> Applying the four-factor primary jurisdiction test promulgated by the Ninth Circuit, courts should continue to stay litigation pending an FDA decision.<sup>212</sup> First, given that the term “natural” has had no single, agreed-upon definition and will greatly affect industry interests, this is a policy decision that should be determined by the agency.<sup>213</sup> While courts such as the *Dole Food Co.* court made a valid point that determining whether a reasonable consumer could be deceived by a food label is within a court’s competence, determining what will deceive a consumer also requires a court to decide what is defined as “natural.”<sup>214</sup> Secondly, the issue of defining “natural” is specifically within the FDA’s discretion, as Congress noted in the FDCA and NLEA that the agency has discretion to regulate food and nutrition labels.<sup>215</sup> The third factor—preventing a substantial danger of inconsistent rulings—is the most convincing policy argument for invoking primary jurisdiction.<sup>216</sup> A central concern is that, because many of these lawsuits involve the same types of claims, different courts may fashion a definition of “natural” that is inconsistent with other courts’ interpretations and, even, inconsistent with the FDA’s stated informal policy.<sup>217</sup> Judges are already being criticized for setting their

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<sup>211</sup> See generally Negowetti, *Defining Natural Foods*, *supra* note 15, at 336 (discussing when courts decide to invoke primary jurisdiction); *supra* notes 162–163 and accompanying text (overviewing the cases in which courts stayed litigation and deferred to the FDA to define the term “natural” compared to cases where courts held that deciding the term “natural” was within the court’s competence).

<sup>212</sup> See *United States v. Gen. Dynamics Corp.*, 828 F.2d 1356, 1362 (9th Cir. 1987) (naming the four factors that courts use to determine primary jurisdiction); *supra* note 138 and accompanying text (providing background on the creation of the four-factor test).

<sup>213</sup> See *Heller*, *supra* note 76 (noting that “natural” is too hard to define); *supra* note 119 and accompanying text.

<sup>214</sup> See *Brazil v. Dole Food Co.*, 935 F. Supp. 2d 947, 960 (N.D. Cal. 2013) (stating that primary jurisdiction doctrine does not mean that a court cannot decide a case when presented with an issue within the agency’s purview). *But see In re KIND LLC “Healthy and All Natural” Litig.*, 209 F. Supp. 3d 689, 695 (S.D.N.Y. 2016) (declining to find that courts are not competent to determine “natural” claims but still invoking primary jurisdiction). See generally Negowetti, *Defining Natural Foods*, *supra* note 15, at 349 (arguing that judge-made determinations on misleading-labeling claims lead to judicial advocacy and de-facto definitions of “natural”).

<sup>215</sup> See 21 U.S.C. § 343 (2012) (empowering the FDA to prohibit the use of labels that are in any way false or misleading); see also *Coyle v. Hornell Brewing Co.*, No. 08-cv-02797, 2010 WL 2539386, at \*4 (D.N.J. June 15, 2010) (noting that the FDA employs numerous scientific experts to address public health and safety issues and holding that the question of whether a substance is “natural” is distinctly within the discretion of the FDA, not the court).

<sup>216</sup> See *In re KIND LLC*, 209 F. Supp. 3d at 696 (noting that FDA guidance would be necessary to decide whether products containing soy protein isolate can properly be labeled as “natural”). More importantly, the court recognized the need for uniform and consistent rulings. *Id.*

<sup>217</sup> See *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011) (stating that Congress wanted to expressly prevent states from issuing rules that would subject manufacturers to different requirements in every state). See generally Negowetti, *Defining Natural Foods*, *supra* note 15, at 349 (discussing how a court’s conclusion about what could deceive a reasonable consumer might vary from

own meaning of the term “natural” with no basis in definitive regulations or standards.<sup>218</sup> Ultimately, judicially defined terms will result in a patchwork of laws—a phenomenon that Congress previously sought to prevent by passing the FDCA.<sup>219</sup> Finally, the fourth factor states that primary jurisdiction should be invoked when prior application is made to the agency—meaning when the question at issue is principally within the agency’s discretion.<sup>220</sup> Because the FDA closed comment on defining the term “natural” in 2016, courts should currently stay the litigation for an appropriate period.<sup>221</sup>

Further, a principle reason that courts invoked primary jurisdiction in the past was the FDA’s silence, which the agency cured by undertaking public comment in 2015.<sup>222</sup> Previous courts heavily weighed that the FDA never undertook public comment on “natural” in deciding to reject primary jurisdiction claims.<sup>223</sup> Moreover, many of the courts that invoked primary jurisdiction in the past were forced to revoke stays because the FDA declined to take a stance.<sup>224</sup> Although courts have validly noted that the FDA consistently shows a lack of interest in defining the term “natural,” most of these decisions rejecting primary jurisdiction occurred in 2013, and thus pre-dated the FDA’s initia-

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state to state). For example, if a court equates “natural” with organic, this would be inconsistent with the FDA’s policy. Negowetti, *Defining Natural Foods*, *supra* note 15, at 349–50.

<sup>218</sup> See Negowetti, *Defining Natural Foods*, *supra* note 15, at 349–52 (noting that the court decisions, such as *Pelayo v. Nestle USA, Inc.*, 989 F. Supp. 2d 973 (C.D. Cal. 2013), rely on the judges’ interpretations of the term “natural”).

<sup>219</sup> See Janssen, *supra* note 23, at 32 (noting that federal food labeling laws were passed to cure the patchwork of varying state food regulations); see also Benny, *supra* note 11, at 1514–17 (discussing the need for national regulation). Given that a few states have already passed some labeling laws and food today is shipped nationwide, it is inefficient and ineffective to have a patchwork of labeling laws. Benny, *supra* note 11, at 1515–17; see FEDERAL DRUG AND COSMETIC ACT, 21 U.S.C. §§ 301–399f (2012) (prohibiting the sale of misbranded or adulterated food, drugs, and cosmetics); *supra* note 24 and accompanying text (overviewing the history of food labeling laws and congressional desire for uniformity).

<sup>220</sup> See *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 65 (1956) (explaining that when primary jurisdiction applies, the issue should be referred to the administrative agency for review before judicial interference).

<sup>221</sup> *Id.*

<sup>222</sup> See *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 341 (3d Cir. 2009) (discussing the FDA’s inaction on defining the term “natural” as a reason for ruling against invoking primary jurisdiction); *supra* note 174 and accompanying text (overviewing court decisions where the FDA’s inaction on the term “natural” was central to the court’s decision not to stay litigation).

<sup>223</sup> See *Bohac*, 2013 WL 5587924, at \*3 (noting that FDA has not undertaken to enact any rules or regulations); *In re ConAgra Foods, Inc.*, No. CV 11–05379–MMM, 2013 WL 4259467, at \*4 (C.D. Cal. Aug. 12, 2013) (stating it was uncertain whether the FDA will act to determine the definition of “natural”).

<sup>224</sup> See *supra* note 149 and accompanying text (overviewing cases where the courts lifted stays because the FDA did not take action to define “natural”).

tive to undergo public comment.<sup>225</sup> It is likely that these courts would reach a different conclusion today, because the FDA undergoing public comment indicates the type of agency interest that the courts found previously lacking.<sup>226</sup>

Although the FDA has yet to initiate formal rulemaking following closing comment, it is likely the FDA will resolve the tension around “natural” in the near future.<sup>227</sup> The FDA has previously noted that it would take a substantial amount of time to evaluate and respond to public comments.<sup>228</sup> Moreover, the FDA commissioner, Dr. Scott Gottlieb, mentioned in an October 2017 statement to the *Wall Street Journal* that he is seriously considering how to make “natural” claims on food packaging more uniform.<sup>229</sup> As Congress has also recently pressured the FDA to provide a timeline for defining “natural” in the 2018 House Appropriations bill, it is likely that courts can invoke primary jurisdiction because the FDA will provide a definition.<sup>230</sup>

## 2. How the FDA Should Define the Term “Natural”

The FDA should define “natural” consistent with consumer expectations rather than business interests.<sup>231</sup> A division exists between whether genetically

<sup>225</sup> See *Rojas v. Gen. Mills, Inc.*, No. CV-05099-WHO, 2013 WL 5568389, at \*6 (N.D. Cal. Oct. 9, 2013) (reasoning that the FDA has shown little interest in regulating the term “natural”); *Parker v. J.M. Smucker Co.*, No. C 13-0690 SC, 2013 WL 4516156, at \*7 (N.D. Cal. Aug. 23, 2013) (noting that parties have repeatedly asked the FDA to define the term and the agency has consistently refused); *Janney v. Gen. Mills*, 944 F. Supp. 2d 806, 814–15 (N.D. Cal. 2013) (concluding that the FDA considers defining “natural” a minor issue and thus there exists little reason for the court to give the agency a chance to address the issue); *supra* note 174 and accompanying text (discussing the cases in 2013 that cited the FDA’s inaction as central to the court’s decision to not stay litigation).

<sup>226</sup> See *Parker*, 2013 WL 4516156, at \*7 (considering parties who have repeatedly asked the FDA to define the term and the agency has consistently refused); see also *supra* note 162 and accompanying text. *But see* *Gorbey*, *supra* note 162 (noting courts continuing to institute and hold stays on litigation in anticipation of an FDA determination).

<sup>227</sup> See Heather Haddon, *FDA Commissioner Wants Closer Look at Health Claims on Packaging*, WALL STREET J. (Oct. 10, 2017), <https://www.wsj.com/articles/fda-commissioner-wants-closer-look-at-health-claims-on-packaging-1507673335> [<https://perma.cc/M49K-G3QT>] (noting the FDA commissioner stating that he wants to see the FDA take action on labeling issues).

<sup>228</sup> See *Heller*, *supra* note 76 (noting the substantial amount of time required to define the term “natural” because the FDA must undergo the public comment process).

<sup>229</sup> See Haddon, *supra* note 225 (noting that the FDA commissioner wants the FDA to take action on labeling issues).

<sup>230</sup> See COMM. ON APPROPRIATIONS, AGRIC., RURAL DEV. FOOD & DRUG ADMIN., & RELATED AGENCIES APPROPRIATIONS BILL, H.R. REP. NO. 115-232, at 72 (2017) (demanding that the FDA issue a timeline for defining “natural” following the public comment process in November of 2015).

<sup>231</sup> See McDonald & Adjemian, *supra* note 6 (noting that the comment process revealed consumer frustration over existing food labels and an overwhelming demand for accurate labels); see also Center for Food Safety, Comment Letter on Proposed Rule on Use of the Term “Natural” in the Labeling of Human Food Products (May 10, 2016) at 2, <https://www.regulations.gov/document?D=FDA-2014-N-1207-6884> [<https://perma.cc/CH97-ZX7V>] (stating that current consumer confusion results from a discrepancy between manufacturer and consumer expectations for “natural”); Unilever Comment

modified organisms should be included in the definition.<sup>232</sup> Many consumers cited to the Merriam-Webster dictionary definition, which states that “natural” does not include man-made or bio-engineered products.<sup>233</sup> Based on consumer comments, the FDA’s current informal policy of “no artificial or synthetic ingredients” in “natural” foods could still be used by adding the additional limitation that “natural” cannot encompass products containing genetically modified organisms.<sup>234</sup> As companies are currently reformulating their products, providing a stable definition that matches consumer expectations could curb litigation and aid businesses in remaining competitive.<sup>235</sup>

One potential issue with the FDA promulgating a definitive rule is that industry influence might provide a rule less aligned with consumer expectations.<sup>236</sup> The FDA has been sharply criticized for allowing industry influence to affect its guidelines and rules.<sup>237</sup> One of the primary indicators of the potential for industry influence is lobbying efforts.<sup>238</sup> For example, when Congress was

Letter, *supra* note 202, at 3 (noting that promulgating a definition that aligns with consumer interest is important).

<sup>232</sup> Compare McDonald & Adjemian, *supra* note 6 (noting that most if not all consumers stated that they did not want genetically modified foods included in the definition of “natural”), with International Dairy Foods Association Comment Letter, *supra* note 205, at 5 (arguing that including GMOs should not disqualify a food from being labeled as natural), and Tyson Comment Letter, *supra* note 205, at 3 (arguing that the definition should include GMOs). See generally *supra* notes 204–205 and accompanying text (providing an overview of the disagreement between consumers, who do not want genetically modified organisms included in the definition of “natural,” and food manufacturers, which do want GMOs included in the definition).

<sup>233</sup> *Natural*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/natural> [<https://perma.cc/ZG3M-7NHP>]; see McDonald & Adjemian, *supra* note 6 (discussing consumer comments received during the FDA’s public comment period).

<sup>234</sup> See “Natural” on Food Labeling, *supra* note 17 (stating the current informal policy on “natural”).

<sup>235</sup> See McDonald & Adjemian, *supra* note 6 (noting that the most recent cases regarding “natural” concern GMOs); see also Nielson, *supra* note 61, at 22 (noting that consumers are more loyal to the quality of a product than they are to labels); *supra* note 14 and accompanying text.

<sup>236</sup> See *supra* notes 202–205 and accompanying text (discussing the differences in consumer expectations of the term “natural” versus how corporations would want to define the term).

<sup>237</sup> See Markham Heid, *Experts Say Lobbying Skewed the U.S. Dietary Guidelines*, TIME (Jan. 8, 2016), <https://time.com/4130043/lobbying-politics-dietary-guidelines> [<https://perma.cc/HYM5-WKXX>] (discussing industry influence on the 2015 FDA Dietary Guidelines). Prominent nutrition experts criticized the FDA’s 2015 Dietary Guidelines for America stating that food manufacturers and producers heavily influenced the guidelines. *Id.* The final guidelines deviated substantially from the Advisory Committee’s report. *Id.* Consequently, the guidelines, which are supposed to reflect the most up-to-date scientific research on nutrition, continued to promote outdated research such as continuing to endorse processed meat consumption. *Id.*

<sup>238</sup> See Cory Herro, *Is the FDA Ready to Take on the Powerful Food Industry?*, THINKPROGRESS (June 2, 2016), <https://thinkprogress.org/is-the-fda-ready-to-take-on-the-powerful-food-industry-6cc5e1e3576> [<https://perma.cc/VC3H-6XX2>] (noting that, beginning in 2009, the industry substantially increased its lobbying efforts and spent about \$175 million during the first Obama administration, compared to the \$83 million spent on lobbying during the previous three years).

considering a soda tax, the American Beverage Association and its allies spent more than forty-million dollars in lobbying efforts to defeat the tax in 2009.<sup>239</sup> Although there is potential for the food lobbying industry to influence the FDA's ultimate definition of the term "natural," the FDA is the most appropriate body to define this term.<sup>240</sup> The legislature has continuously failed to pass a suitable food labeling law since 2013.<sup>241</sup> Reliance on the courts to define the term would not promote a uniform definition nor curb the current consumer confusion surrounding the term natural.<sup>242</sup> In order to enable consumers to make informed choices in order to eat a healthier diet, there remains more value in the FDA, rather than the courts or legislature to provide the necessary regulatory guidance for food labeling.<sup>243</sup>

### CONCLUSION

The rise in food-labeling litigation regarding the term "natural" is symptomatic of an FDA regulatory void. These cases highlight a national conversation about diet, nutrition, and health. Although some cases, like *Nutella*, make less meritorious claims, the vast majority of cases show legitimate consumer concern about understanding what is in their food. Labels provide the most transparent mechanism for manufacturers to communicate with the public about what is in a food product. Without regulatory guidelines defining the term "natural," there is a distinct clash between consumer expectations and manufactured food products. This discrepancy gives rise to numerous false-labeling suits and is creating the opportunity for the courts to define the term

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<sup>239</sup> See Duff Wilson & Janet Roberts, *Special Report: How Washington Went Soft on Childhood Obesity*, REUTERS (Apr. 27, 2012), <https://www.reuters.com/article/us-usa-foodlobby/special-report-how-washington-went-soft-on-childhood-obesity-idUSBRE83Q0ED20120427> [<https://perma.cc/DZZ4-R6EZ>] (reporting that, in 2009, the American Beverage Association and its allies spent more than eight times their previous year's spending in a successful bid to defeat the soda tax). After the group defeated the proposal, the association spent only \$24 million in 2010 and \$10 million in 2011. *Id.*

<sup>240</sup> See Negowetti, *Food Labeling Litigation*, *supra* note 9, at 19 (advocating for the FDA to promulgate a definition of "natural"); see also *Rosillo v. Annie's Homegrown, Inc.*, No. 17-cv-02474-JSW, 2017 WL 5256345, at \*3 (N.D. Cal. Oct. 17, 2017) (noting that Congress explicitly designated the resolution of technical and complex terms like "natural" to the FDA); Janssen, *supra* note 23, at 32 (noting that federal food labeling laws were passed to cure the patchwork of varying state food regulations).

<sup>241</sup> See Isidro, *supra* note 16 (providing an overview of failed legislation addressing the definition of the term "natural").

<sup>242</sup> See Negowetti, *Defining Natural Foods*, *supra* note 15, at 349–52 (noting that judicial interpretations of the term "natural" do not provide uniform or consistent definitions).

<sup>243</sup> See *id.* at 365 (arguing that the FDA has the appropriate expertise to define the term "natural"); Lazarus, *supra* note 8 (stating that food labeling permits consumers to make better food choices); McDonald & Adjemian, *supra* note 6 (noting that consumers value transparency on their labels); Pollans, *supra* note 7 (discussing how proper labeling is a means to protect consumer choice).

“natural.” Although some courts have chosen not to stay litigation based on primary jurisdiction doctrine, the courts’ role should be to serve as interpreters and enforcers of regulations, not creators. Thus, to ultimately curb litigation and provide consumers with the necessary information to achieve health goals, the FDA should engage in formal rulemaking to promulgate a definition.

AMY-LEE GOODMAN

