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## ARTICLES

### POMEGRANATE JUICE CAN DO THAT? NAVIGATING THE JURISDICTIONAL LANDSCAPE OF FOOD HEALTH CLAIM REGULATION IN A POST-*POM WONDERFUL* WORLD

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#### INTRODUCTION

Thirty years ago, the most the consumer expected out of his or her morning glass of juice was a little extra vitamin C. By 2010, the consumer expected a lot more. POM Wonderful's pomegranate juice, for instance, promised to improve cardiovascular health, treat erectile dysfunction, and combat prostate cancer.<sup>1</sup> Those claims made orange juice look a little pathetic. Of course, those wild promises also landed POM Wonderful in hot water with the Federal Trade Commission ("FTC") for misleading the public with scientifically unsubstantiated health claims.<sup>2</sup>

POM Wonderful, like many food manufacturers, sought to capitalize on the American consumers' quest for the panacea: the magic-bullet food product.<sup>3</sup> The number of health claims made by food producers has skyrocketed in recent years.<sup>4</sup> Whether the consumer can rely on these claims as true and scientifically

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1. See *POM Wonderful LLC v. Fed. Trade Comm'n*, 777 F.3d 478, 484-88 (D.C. Cir. 2015).

2. *Id.* at 488.

3. See Jennifer L. Pomeranz, *A Comprehensive Strategy to Overhaul FDA Authority for Misleading Food Labels*, 39 AM. J. L. & MED. 617, 621 (2013) ("Consumers are in fact increasingly seeking healthier foods, so it is not surprising that sales of new products with such claims are higher than those without them.").

4. See Nicole E. Negowetti, *Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority*, GOVERNANCE STUD. BROOKINGS INST. 5-6 (2014), available at <http://www.brookings.edu/research/papers/2014/06/26-food-labeling-litigation-fda-negowetti> [<http://perma.cc/R4FM-JMMN>] (noting that consumer demand for healthier food has increased markedly in recent years); see also Alexandra Ledyard, *Snake Oil in Your Pomegranate Juice: Food Health Claims and the FTC*, 47 U.S.F. L. REV. 783, 784 (2013) ("In order to capitalize on this trend of health-conscious consumerism, advertisers have begun aggressively touting their

supported is an open question. Although federal administrative agencies such as the Food and Drug Administration (“FDA”) and the FTC have authority to police health claims on product labels and in product advertising, these agencies lack the resources to do so fully.<sup>5</sup> Lanham Act claims and consumer state law claims can fill this regulatory void,<sup>6</sup> but these lawsuits are often met with the affirmative defenses of preclusion, preemption, and primary jurisdiction—doctrines that, if successful, take claims out of the hands of private parties and place them back in the lap of the FDA, an agency that cannot pursue every scientifically shaky health claim.<sup>7</sup> Moreover, the preclusion and primary jurisdiction doctrines create interagency jurisdictional questions between the FDA and the FTC—the two agencies expressly authorized to regulate food health claims.<sup>8</sup>

Even where courts decline to apply these jurisdictional doctrines, parties spend an inordinate amount of time addressing them in pretrial motions, thereby delaying resolution on the merits.<sup>9</sup> The uneven system of federal enforcement, coupled with the vexing jurisdictional objections posed by defendants in opposition to both private litigation and FTC enforcement actions, leads to a tortured and woefully inefficient system of food health claim regulation.<sup>10</sup> The solution is to remove the jurisdictional barriers to private lawsuits where plaintiffs seek to enforce the federal food labeling requirements by eliminating the express preemption provision in the Nutrition Labeling and Education Act (“NLEA”)<sup>11</sup> and creating a private right of action for NLEA violations. In addition, Congress should clarify the respective obligations of the FDA and the FTC with regard to food health claims on labels and advertisements, which

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products’ alleged health benefits.”).

5. See Lisa Heinzerling, *The Varieties and Limits of Transparency in U.S. Food Law*, 70 FOOD & DRUG L.J. 11, 14 (2015) (“Resource limits at federal agencies charged with regulating food hollow out enforcement programs aimed at false or misleading representations.”).

6. *Id.* at 12–14.

7. See, e.g., *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-cv-585, 2015 U.S. Dist. LEXIS 67187, at \*5 (S.D.N.Y. Mar. 24, 2015) (“SPD moved to dismiss C&D’s Complaint and opposed C&D’s motion for a preliminary injunction primarily by asserting a preclusion defense.”).

8. See generally Peter E. Masaitis & Evan W. Woolley, *Enforcement of FDA Qualified Health Claims: Who’s on the Case?*, INSIDE COUNS. (Jan. 9, 2015), <http://www.insidecounsel.com/2015/01/09/enforcement-of-fda-qualified-health-claims-whos-on> [<http://perma.cc/4Y8V-HPVH>]; see also Diana R. H. Winters, *The Magical Thinking of Food Labeling: The NLEA as a Failed Statute*, 89 TUL. L. REV. 815, 846–56 (2015) (discussing the defenses of preemption and primary jurisdiction in the context of food labeling litigation).

9. See *id.* at 849 (“The determination of whether petitioners’ claims are preempted in food labeling cases takes an enormous amount of resources—those of the parties litigating the claim and the judiciary. The express preemption provisions of the NLEA and the interaction between the NLEA’s requirements and the balance of the FDCA are complex and difficult to parse.”).

10. *Id.* at 836.

11. See Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended at 21 U.S.C. § 343 (2012)).

would allow better coordination of agency enforcement.

Part I of this Article discusses the legal pressure points that bear on food health claims on labels and in advertisements, from both a federal regulatory standpoint and a private enforcement standpoint. Part II discusses the doctrines of preclusion, preemption, and primary jurisdiction in the wake of the U.S. Supreme Court's decision in *POM Wonderful LLC v. Coca-Cola Co.*<sup>12</sup> This section explains how these doctrines create jurisdictional hurdles for private parties—and even the FTC—when they challenge health representations on food labels. In particular, Part II discusses the recently filed case of *Federal Trade Commission v. Gerber Products Co.*,<sup>13</sup> in which the preclusion and primary jurisdiction doctrines were raised in an effort to thwart the FTC's authority to challenge health claims that have been regulated—at least in part—by the FDA.<sup>14</sup> Part III of this Article analyzes these jurisdictional doctrines and makes policy recommendations regarding the appropriate balance between federal regulation, private litigation, and interagency enforcement efforts with regard to food health claims. The Article concludes with industry guidance.

#### I. REPRESENTATIONS ABOUT FOOD AND HEALTH: REGULATORY LANDSCAPE

Representations about the health benefits of a food are regulated in two ways.<sup>15</sup> First, there is an extensive federal regulatory scheme applicable to food labels and advertisements.<sup>16</sup> Food labels must comply with the requirements set forth by the FDA.<sup>17</sup> Representations made in advertisements and promotional materials are subject to enforcement actions by the FTC.<sup>18</sup> Second, there is potential civil liability arising from private litigation involving misleading health claims.<sup>19</sup> In particular, competitors may pursue Lanham Act claims if they have been injured due to the defendant manufacturer's misrepresentations.<sup>20</sup> Additionally, individual consumers may challenge food-related misrepresentations under state consumer protection statutes or any other number of state law causes of action; the number of these cases has increased in recent years.<sup>21</sup> Each of these forces bears on manufacturer conduct and is discussed in

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12. 134 S. Ct. 2228 (2014).

13. Complaint for Permanent Injunction and Other Equitable Relief, Fed. Trade Comm'n v. Gerber Products Co., No. 2:14-cv-06771-SRC-CLW (D. N.J. Oct. 29, 2014) [hereinafter Complaint].

14. See discussion *infra* Part II.B.

15. Memorandum of Understanding Between The Federal Trade Commission and The Food and Drug Administration, 4 TRADE REG. REP. (CCH) ¶ 9,850.01 (1971), available at <http://www.fda.gov/aboutFDA/partnershipsCollaborations/MemorandaofUnderstandingMOUs/domesticmo/us/ucm115791.htm> [<http://perma.cc/AU3H-PWUV>] [hereinafter Memorandum of Understanding].

16. See 21 U.S.C. § 331 (2012).

17. See discussion *infra* Part I.A.1.

18. See discussion *infra* Part I.A.2.

19. See Heinzerling, *supra* note 5, at 14.

20. See discussion *infra* Part I.B.1.

21. See discussion *infra* Part I.B.2; see also Winters, *supra* note 8, at 818 (noting that since

more detail below.

### *A. Federal Regulation*

For well over fifty years, the FDA and the FTC have shared enforcement authority with regard to the misbranding of food.<sup>22</sup> Pursuant to an agreement between the agencies, the FDA has “primary responsibility for preventing misbranding of foods . . . [and] will exercise primary jurisdiction over all matters regulating the labeling of foods.”<sup>23</sup> The FTC, on the other hand, has “primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods.”<sup>24</sup> The agencies also agree to engage in liaison activities where “[t]he same, or similar claims are found in both labeling and advertising.”<sup>25</sup> Thus, the FDA and the FTC have traditionally divided labor with regard to representations about food and health as follows: the FDA handles claims on labels; the FTC handles claims in advertising.<sup>26</sup>

1. *Food Drug and Cosmetics Act and NLEA*.—The Food Drug and Cosmetics Act (“FDCA”)<sup>27</sup> is a federal statute that, among other purposes, prohibits the misbranding of food.<sup>28</sup> It was passed in 1938 with the goal of ensuring the health and safety of the consuming public with regard to food, beverages, drugs, and cosmetics.<sup>29</sup> A food or beverage is misbranded if its label is false or misleading, if the required label information is not “prominently” displayed,<sup>30</sup> or if the label does not feature the “common or usual name of the food [or beverage].”<sup>31</sup> In 1990, Congress passed the NLEA, a comprehensive food-labeling regime.<sup>32</sup> Not only did the NLEA give consumers the now-familiar “nutrition facts” panels<sup>33</sup> on food packaging, but it also authorized the FDA to regulate other aspects of food labels, such as claims regarding the health benefits or nutritional value of the product.<sup>34</sup>

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1990, the amount of litigation involving food labeling has increased).

22. Memorandum of Understanding, *supra* note 15, at 4.

23. *Id.*

24. *Id.*

25. *Id.*

26. See Ledyard, *supra* note 4, at 791.

27. See 21 U.S.C. § 331 (2012).

28. See Stephen J. White, Jr., Note, *How Far Does the Apple (Pomegranate) Fall from the Tree? Preclusion of Lanham Act Claims by the Food, Drug, & Cosmetic Act and POM Wonderful LLC v. Coca-Cola Co.*, 15 WAKE FOREST J. BUS. & INTELL. PROP. L. 262, 269 (2015) (“The main goals of the FDCA remained consistent, one of which is to protect the public from the misbranding of food . . .”).

29. *POM Wonderful LLC v. Coca Cola Co.*, 134 S. Ct. 2228 (2014).

30. 21 U.S.C. § 343(f) (2012).

31. *Id.* § 343(i); see also Pomeranz, *supra* note 3, at 620.

32. See 21 U.S.C. § 343; see also Winters, *supra* note 8, at 820-27 (discussing the history of the NLEA).

33. See 21 C.F.R. § 101.2 (2015).

34. *Id.* § 101.14.

In particular, the FDA regulates three types of claims under the NLEA: nutrient content claims, structure/function claims, and health claims.<sup>35</sup> A nutrient content claim “characterizes the level of a nutrient in the food (e.g., ‘low fat,’ ‘high in oat bran,’ or ‘contains 100 calories’).”<sup>36</sup> A manufacturer may assert only those nutrient content claims that have been approved by the FDA.<sup>37</sup> Structure/function claims, on the other hand, do not have to be approved by the FDA prior to use on a product label so long as they are “truthful and not misleading.”<sup>38</sup> These claims “focus on effects derived from nutritive value” in the food.<sup>39</sup> For example, a food product’s assertion that “calcium builds strong bones” is a structure/function claim.<sup>40</sup>

The third category of claims regulated by the FDA is health claims, which assert that the risk of a disease or health condition is lessened by a substance in the product.<sup>41</sup> For example, the FDA has approved the following health claim describing the relationship between calcium and osteoporosis: “Calcium and Osteoporosis: Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.”<sup>42</sup> FDA approval is required for all health claims on food labels.<sup>43</sup> It is important to note that health claims can only assert a reduced *risk* of disease;<sup>44</sup> a claim that asserts a connection between consumption of the food and the “cure, mitigation, treatment, or prevention of disease” results in the food being treated as a drug under the FDCA and thus subjects the food to the FDA’s regulations regarding drug labeling.<sup>45</sup>

A health claim can either be “authorized,” which requires a showing that the claim is supported by “significant scientific agreement,”<sup>46</sup> or it can be “qualified,” which requires a lesser showing of “credible” evidence.<sup>47</sup> To satisfy

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35. *Id.*; see also Ellen A. Black, *Keep Out the FDA: Food Manufacturers’ Ability to Effectively Self-Regulate Front-of-Package Food Labeling*, 17 DEPAUL J. HEALTH CARE L. 1, 4 (2015) (discussing the difference between nutrient content claims, structure/function claims, and health claims).

36. See CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FOOD & DRUG ADMIN., A FOOD LABELING GUIDE: GUIDANCE FOR INDUSTRY 72 (2013), available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf> [<http://perma.cc/J4KJ-M2R5>] [hereinafter CTR. FOR FOOD SAFETY & APPLIED NUTRITION].

37. 21 C.F.R. § 101.13(b).

38. See *Structure/Function Claims*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006881.htm#conventional> [<http://perma.cc/6Y5C-295G>] (last updated Dec. 23, 2014).

39. *Id.*

40. *Id.*

41. 21 C.F.R. § 101.14(a)(1).

42. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, *supra* note 36, at App. C.

43. *Id.* at 80.

44. *Id.*

45. 21 U.S.C. § 321(g)(1) (2012).

46. *Id.* §§ 101.14(c), 343(r)(3)(B)(i).

47. See *Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation*

the “significant scientific agreement” standard, the manufacturer must show that “based on the totality of publicly available scientific evidence . . . there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.”<sup>48</sup> In evaluating whether the significant scientific agreement standard is met, the FDA considers the number of studies relevant to the claim, the methodological quality of those studies, the studies’ outcomes, the degree to which those outcomes are consistent, and the relevance to the U.S. population.<sup>49</sup> While conclusive evidence is not required, the FDA will generally approve the health claim only if there appears to be near-consensus in the scientific community regarding the validity of the claim.<sup>50</sup> Historically, the significant scientific agreement standard has been hard to satisfy.<sup>51</sup> To date, the FDA has recognized only eighteen authorized health claims.<sup>52</sup> Qualified health claims arose as a result of the FDA’s reluctance to authorize health claims under the significant scientific agreement standard.<sup>53</sup> In the 1999 D.C. Circuit Court of Appeals opinion *Pearson v. Shalala*, the court found that where the scientific uncertainty surrounding a health claim could be mitigated by a disclaimer, the FDA’s outright refusal to authorize the health claim violated the manufacturer’s First Amendment commercial speech rights.<sup>54</sup> In response to the court’s order requiring the FDA to clarify the significant scientific agreement standard, the FDA ultimately created qualified health claims, which allow manufacturers to make health claims if they are supported by “credible evidence.”<sup>55</sup> The credible evidence standard is ill defined, but it is less stringent than the significant scientific agreement standard.<sup>56</sup> Health claims supported by credible evidence must be “qualified” by an appropriate disclaimer that includes “language that identifies limits to the level of scientific evidence to support the relationship.”<sup>57</sup>

The process for obtaining FDA approval of a health claim or permission for a qualified health claim begins with a petition filed by the manufacturer.<sup>58</sup> If the FDA determines that the health claim meets the significant scientific agreement

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*of Health Claims—Final*, U.S. FOOD & DRUG ADMIN. (2009), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm073332.htm> [<http://perma.cc/7UGL-CSRK>] [hereinafter *Guidance for Industry*].

48. 21 C.F.R. § 101.14(c).

49. See *Guidance for Industry*, *supra* note 47.

50. *Id.*

51. See CTR. FOR FOOD SAFETY & APPLIED NUTRITION, *supra* note 36, at App. C.

52. *Id.*

53. Masaitis & Woolley, *supra* note 8.

54. *Pearson v. Shalala*, 164 F.3d 650, 658 (D.C. Cir. 1999).

55. See *Guidance for Industry*, *supra* note 47.

56. *Id.*

57. *Id.*

58. *Label Claims for Conventional Foods and Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (2013), <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm> [<http://perma.cc/WZ7A-ZDT6>].

standard, the FDA authorizes the claim through issuance of a rule.<sup>59</sup> A health claim that fails to meet the significant scientific agreement standard will not be approved.<sup>60</sup> If, however, the FDA finds that the health claim is nonetheless supported by credible evidence, the FDA may issue a letter to the manufacturer outlining the circumstances under which the FDA may refrain from enforcement activity pursuant to its discretion.<sup>61</sup> Such a letter also informs the manufacturer of the disclaiming language that must appear on the label.<sup>62</sup> If the FDA determines that the claim is not supported by either the significant scientific agreement standard or the credible evidence standard, the FDA will deny the petition.<sup>63</sup> A manufacturer that makes false or misleading representations regarding health claims has engaged in “misbranding” in violation of the FDCA.<sup>64</sup>

The FDA engages in comparatively little food health claim enforcement activity in light of the staggering number of products it is expected to regulate.<sup>65</sup> The FDA is burdened with regulating eighty percent of the United States’ food supply.<sup>66</sup> Although the FDA has authority to issue injunctions and impose monetary penalties, the FDA is authorized to do so only when it appears that a serious safety concern is at issue; misleading health claims on food products do not rise to this level.<sup>67</sup> Instead, the agency’s primary enforcement mechanism is the issuance of warning letters that request that the manufacturer voluntarily correct its behavior.<sup>68</sup> The efficacy of these letters is in serious doubt.<sup>69</sup> As noted by Lisa Heinzerling, “[a] recent FDA oversight initiative on food labeling involved a mere seventeen warning letters. It is not clear that even these few letters sparked compliance from the relevant companies.”<sup>70</sup> The bulk of the FDA’s regulatory activities target drugs, medical devices, and cigarettes<sup>71</sup>—products that have a greater potential to harm consumers physically than food. It is not surprising then that the FDA’s enforcement of its food

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59. *Id.*

60. *Id.*

61. *Id.*

62. *Id.*

63. *Id.*

64. 21 U.S.C. § 343(a)(1) (2012).

65. See Black, *supra* note 35, at 11 (“As the agency tasked with so many diverse and wide-ranging areas, the FDA has a reputation for being overworked, underfunded, and incapable of effectively governing its responsibilities.”); see also Negowetti, *supra* note 4, at 3 (“Although the FDA is responsible for enforcing labeling regulations, it lacks the enforcement authority to effectively deter food companies from making misleading claims.”).

66. See Negowetti, *supra* note 4, at 2. The U.S. Department of Agriculture regulates the remaining food products, including meat, eggs, and poultry. *Id.*

67. See *id.* at 3–4.

68. See *id.* at 3.

69. Heinzerling, *supra* note 5, at 15.

70. *Id.*

71. See Black, *supra* note 35, at 11.

labeling guidelines gets put on the back burner.

Commentators have been sharply critical of the FDA's ability to regulate food labeling given its lack of resources compared to the volume of products it must oversee.<sup>72</sup> These concerns are deepened by the fact that the FDA's policies and priorities are subject to change with the political climate, often at the expense of the consumer:

Such subjectivity leads to inconsistent, capricious decisions at the whim of whichever political party is in power. The consumer, who likely lacks knowledge of the agency's arbitrariness, endures the consequences of the FDA's lack of perpetual lucidity and is bound by regulations that may or may not reflect the consumer's true desires.<sup>73</sup>

Nor can the consumer easily take matters into his or her own hands when a manufacturer fails to conform to the FDA's labeling requirements, as there is no private right of action to enforce the NLEA.<sup>74</sup>

2. *Federal Trade Commission Act*.—While the FDCA and the NLEA deal primarily with product labeling, the Federal Trade Commission Act (“FTC Act”) addresses product advertising.<sup>75</sup> The purpose of the FTC Act is to protect consumers from false and misleading advertisements and business practices.<sup>76</sup> This statute delegates authority to the FTC to promulgate rules and issue guidance regarding acts that constitute deceptive practices.<sup>77</sup> In the context of deceptive advertising, the FTC considers the content of the advertisement, whether the representations made are “false, misleading or unsubstantiated,” and whether a consumer would find those representations to be material in deciding whether to purchase the product.<sup>78</sup>

Unlike the FDA's preapproval process for health claims on food labels, the FTC does not preapprove health claims in advertisements; rather, the FTC regulates unsubstantiated claims through enforcement actions.<sup>79</sup> The level of scientific substantiation the FTC requires is similar to, but not precisely the same as, the level of evidence required by the FDA in its preapproval process.<sup>80</sup> While the NLEA requires the FDA to follow the significant scientific agreement

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72. See, e.g., *id.* at 12 (“These deficiencies elucidate the public's well-founded perspicacity that the FDA is overburdened and incapable of effectively regulating yet another matter.”).

73. *Id.* at 12-13.

74. 21 U.S.C. § 337 (2012); see also *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2235 (2014).

75. See Federal Trade Commission Act, Pub. L. No. 63-203, § 1, 38 Stat. 717 (1914) (codified as amended at 15 U.S.C. § 41-58 (2011)).

76. 15 U.S.C. § 45 (2012).

77. *Id.*

78. *POM Wonderful, LLC v. Fed. Trade Comm'n*, 777 F.3d 478, 490 (D.C. Cir. 2015).

79. See Ledyard, *supra* note 4, at 792.

80. See *Enforcement Policy Statement on Food Advertising*, FED. TRADE COMMISSION (May 13, 1994), <https://www.ftc.gov/public-statements/1994/05/enforcement-policy-statement-food-advertising> [<http://perma.cc/K99J-EZ8F>] [hereinafter *FTC Enforcement Statement*].



standard, the FTC follows a “competent and reliable scientific evidence” standard.<sup>81</sup> The FTC has defined the competent and reliable scientific evidence standard to mean “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”<sup>82</sup>

In an action challenging a manufacturer’s health claims, the FTC begins by determining whether the advertisement is making “efficacy claims” or “establishment claims.”<sup>83</sup> The level of substantiation required for a health claim depends on this categorization.<sup>84</sup> Efficacy claims do not purport to be scientifically established; rather, they simply suggest “that a product successfully performs the advertised function or yields the advertised benefit.”<sup>85</sup> An advertiser making an efficacy claim need only show that it possessed a “reasonable basis” for the assertion.<sup>86</sup> To evaluate whether such a reasonable basis exists, the FTC considers several factors, including the type of product and claim, the benefits of a truthful claim, the consequences of a false claim, “the ease of developing substantiation for the claim,” and, “the amount of substantiation experts in the field would consider reasonable.”<sup>87</sup> Establishment claims, on the other hand, suggest, “that a product’s effectiveness or superiority has been scientifically established.”<sup>88</sup> A higher level of scientific substantiation is required for establishment claims.<sup>89</sup> If the claim makes a “specific” reference to a particular type of substantiation, then the advertiser must be able to produce that type of substantiation.<sup>90</sup> “Non-specific” claims, such as a representation that the claim is “medically proven,” must be supported by evidence sufficient to satisfy the relevant scientific community that the claim is true.<sup>91</sup>

The level of scientific substantiation required to support health claims in advertisements received significant analysis by the D.C. Circuit Court of Appeals in the recent case of *POM Wonderful, LLC v. Federal Trade Commission*.<sup>92</sup> In that case, the FTC alleged that POM Wonderful misled consumers in a series of advertisements purportedly supported by over \$35 million in research and over 100 studies.<sup>93</sup> POM Wonderful represented consumption of its pomegranate juice

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81. *Id.*

82. *Id.*

83. *POM Wonderful*, 777 F.3d at 490.

84. *See id.*

85. *Id.*

86. *Id.*

87. *Id.* at 490-91 (quoting *In re Daniel* Chapter One, No. 9329, 2009 FTC LEXIS 259, at \*25 (U.S. Fed. Trade Comm’n Dec. 24, 2009)).

88. *Id.* at 490.

89. *See id.* at 491.

90. *Id.*

91. *Id.*

92. *See id.* at 478-505.

93. *Id.* at 484.

could improve cardiovascular health, treat prostate cancer, and treat erectile dysfunction.<sup>94</sup> In making these representations, POM Wonderful referenced scientific studies that supported its position, but it failed to disclose to consumers that in many instances, the studies were based on small sample sizes and numerous other studies found no link between consumption of pomegranate juice and the aforementioned health conditions.<sup>95</sup> The FTC sanctioned POM Wonderful for this conduct in a three-part order, which drew a distinction between the level of substantiation required for “disease treatment” claims and the level of substantiation required for “general health benefit” claims.<sup>96</sup> Part I of the FTC’s order dealt with POM Wonderful’s disease treatment claims and mandated that POM Wonderful support any such unqualified claim with “at least two randomized and controlled human clinical trials (RCTs).”<sup>97</sup> For the purposes of the order, the FTC defined unqualified health claims as any representation regarding the disease treatment properties of POM Wonderful’s juice that was not accompanied by an unambiguous disclaimer.<sup>98</sup> Part II of the FTC’s order prohibited POM Wonderful from “misrepresenting the results of scientific studies in their ads.”<sup>99</sup> Part III of the FTC’s order prohibited POM Wonderful from making any representation about “the general health benefits” of its products unless those claims were supported by “competent and reliable evidence.”<sup>100</sup> The FTC did not require POM Wonderful to support general health claims with RCTs, but it did impose a level of substantiation that required the existence of accurate and reliable studies that are generally accepted by others in the field.<sup>101</sup>

On review, the D.C. Circuit agreed with many of the FTC’s findings regarding the deceptive nature of POM Wonderful’s health claims<sup>102</sup> and the court left undisturbed Parts II and III of the FTC’s order.<sup>103</sup> The court instead focused on Part I of the FTC’s order,<sup>104</sup> which required POM Wonderful to support its unqualified disease treatment claims with two RCTs.<sup>105</sup> The court affirmed the FTC’s finding that the scientific community would require some type of clinical trial to substantiate POM’s unqualified disease treatment claims,

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94. *Id.* at 483.

95. *Id.* at 484-88.

96. *Id.* at 488-89.

97. *Id.* at 489.

98. *Id.* at 501.

99. *Id.* at 489.

100. *Id.*

101. *Id.* at 500.

102. *Id.* at 498. The court affirmed the FTC’s finding that the bulk of the representations at issue were deceptive because they were not adequately substantiated under either the scientific standard for establishment claims or the reasonable basis test for efficacy claims. *Id.*

103. *Id.* at 505.

104. *Id.*

105. *Id.* at 489.

but the court took issue with the FTC's decision to require *two* RCTs.<sup>106</sup> The two-RCT requirement was overly broad and could deny the public access to valuable information about a food product's potential health benefits.<sup>107</sup> Thus, the court ruled that POM Wonderful's unqualified disease treatment claims need only be supported by one RCT.<sup>108</sup>

*POM Wonderful, LLC v. Federal Trade Commission* provides important guidance regarding the FTC's substantiation expectations for food health claims in advertisements. The FTC can require manufacturers to come forward with an RCT to support unqualified disease-treatment claims.<sup>109</sup> General health claims, however, may not be subject to a mandatory RCT requirement; thus, other forms of "competent and reliable scientific evidence" may suffice to support such a representation.<sup>110</sup> Although the trend with FTC enforcement actions in recent years has been to require more scientific substantiation of health claims,<sup>111</sup> the FTC does not have the resources to litigate every case with the same vigor with which it pursued POM Wonderful.<sup>112</sup> Thus, the FTC is increasingly relying on warning letters and consent orders to secure manufacturers' voluntary compliance.<sup>113</sup> It is important to note that the FTC has exclusive authority to enforce its rules; thus, neither a consumer nor a competitor may bring a private cause of action under the FTC Act.<sup>114</sup>

3. *FDA/FTC Regulatory Overlap*.—At times, both the FDA and the FTC have jurisdiction to regulate the same food health claim. For instance, the FTC

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106. *Id.* at 505.

107. *Id.* at 502-03. Because the FTC narrowly defined an "unqualified" health claim as any representation without an unambiguous disclaimer stating that the evidence is "inconclusive" or that "additional research is necessary," a disclaimer using the words "preliminary" or "initial" would be prohibited unless it were supported by two RCTs. Thus, even a health claim supported by one RCT and characterized as "preliminary" would be insufficient. Accordingly, the public could be denied access to a health claim that was supported by the "gold standard" of research: one RCT. The court found that the FTC failed to demonstrate that the requirement of a second RCT would yield enough benefit to overcome this hurdle. *Id.*

108. *Id.* at 505.

109. *Id.*

110. *Id.*

111. See Eric Berman, *FTC Orders in Health-Related Advertising Cases: From A New Approach to the New Normal*, 29 ANTITRUST 98, 101 (2015); see also Ledyard, *supra* note 4, at 794-95 (noting recent FTC trend to rely on consent orders to "leverage" companies into "greater compliance").

112. See Ledyard, *supra* note 4, at 794.

113. See *id.* ("While the FTC and FDA have the enforcement power to stop false and misleading claims, both agencies are subjected to continuous budget pressure, and in practice, only the most egregious offenders are addressed. For this reason, the FTC is seeking voluntary consent agreements from offending businesses through consent orders.").

114. *Holloway v. Bristol-Myers Corp.*, 485 F.2d 986, 987 (D.C. Cir. 1973); see also Black, *supra* note 35, at 25 ("[T]here is no private right of action based upon an alleged violation of the FTC Act.").

may pursue a manufacturer that uses a nutrient content claim in an advertisement in a manner that is “inconsistent with FDA’s definitions.”<sup>115</sup> In addition, the FTC may be faced with a health claim in an advertisement that is also subject to the FDA’s petition process for an authorized or qualified health claim.<sup>116</sup> Under these circumstances, the FTC generally defers to the FDA’s determination of scientific substantiation for the health claim.<sup>117</sup> Qualified health claims, however, are a different matter. The FTC recognizes that there may be circumstances where a producer does not have FDA approval to make a qualified health claim on a food label, but the manufacturer may nonetheless be able to make such a representation in an advertisement under the FTC’s “competent and reliable scientific evidence” standard.<sup>118</sup> Where the FDA has not acted, the FTC will make its own determination regarding the adequacy of the scientific support for the claim and its accompanying disclaimer.<sup>119</sup> The FTC claims that it closely monitors qualified health claims in advertisements to ensure their reliability:

The Commission will therefore be especially vigilant in examining whether qualified claims are presented in a manner that ensures that consumers understand both the extent of the support for the claim and the existence of any significant contrary view within the scientific community. In the absence of adequate qualification, the Commission will find such claims deceptive.<sup>120</sup>

Thus, the FTC will generally defer to the FDA where the FDA has affirmatively recognized a health claim, qualified health claim, or nutrient content claim, but in the absence of such FDA action, the FTC will engage in its own analysis to assess the claim’s validity.<sup>121</sup>

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115. See *FTC Enforcement Statement*, *supra* note 80.

116. *Id.*; see also Ledyard, *supra* note 4, at 791.

117. See *FTC Enforcement Statement*, *supra* note 80 (“The Commission regards the ‘significant scientific agreement’ standard, as set forth in the NLEA and FDA’s regulations, to be the principal guide to what experts in the field of diet-disease relationships would consider reasonable substantiation for an unqualified health claim. Thus, it is likely that the Commission will reach the same conclusion as FDA as to whether an unqualified claim about the relationship between a nutrient or substance in a food and a disease or health-related condition is adequately supported by the scientific evidence.”).

118. *Id.* (“While the Commission’s approach to evaluation of unqualified health claims will generally parallel FDA’s assessment of whether there is significant scientific agreement supporting the relevant diet-disease relationship, the Commission recognizes that there may be certain limited instances in which carefully [crafted] qualified health claims may be permitted under Section 5 although not yet authorized by the FDA, if the claims are expressly qualified to convey clearly and fully the extent of the scientific support.”).

119. *Id.*

120. *Id.*

121. *Id.*

### *B. Private Litigation*

1. *Lanham Act*.—Although representations about the health benefits of a food are formally regulated and monitored by the FDA and the FTC, additional checks on food labeling and advertising exist in the form of private litigation. Although a private actor cannot sue a product manufacturer for misbranding in violation of NLEA or deceptive advertising in violation of the FTC Act, the Lanham Act creates a private cause of action for unfair competition where a manufacturer makes deceptive, false, or misleading representations about its own products or a competitor's products.<sup>122</sup> To succeed on a Lanham Act claim, the plaintiff must prove that:

- (1) The defendant has made false or misleading statements of fact concerning his own product or another's;
- (2) the statement actually or tends to deceive a substantial portion of the intended audience;
- (3) the statement is material in that it will likely influence the deceived consumer's purchasing decisions;
- (4) the advertisements were introduced into interstate commerce; and
- (5) there is some causal link between the challenged statements and harm to the plaintiff.<sup>123</sup>

The private cause of action under the Lanham Act extends only to competitors, however, not to individual consumers.<sup>124</sup> Thus, consumers cannot sue manufacturers for violations of the Lanham Act.<sup>125</sup> Instead, consumers who want to pursue manufacturers for misleading food health claims must do so under state law theories.<sup>126</sup>

2. *Consumer Actions Under State Law*.—The only remedy open to consumers—the end users who actually purchase, ingest, and stand to be harmed by these products—is a grab-bag of state law claims.<sup>127</sup> Some states have consumer protection statutes, unfair trade practices statutes, or causes of action for false advertising.<sup>128</sup> Consumers may also bring breach of warranty or common law fraud claims.<sup>129</sup> Most often, it appears consumer claims are not pursued by individuals as the amount at issue is too small to justify litigation.<sup>130</sup> Instead, such cases are generally brought as consumer class actions.<sup>131</sup>

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122. 15 U.S.C. § 1125 (2012); *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2234 (2014).

123. *Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc.*, 185 F.3d 606, 613 (6th Cir. 1999).

124. *POM Wonderful LLC*, 134 S. Ct. at 2234.

125. *Id.*

126. *See* Winters, *supra* note 8, at 846-48.

127. *Id.*

128. Negowetti, *supra* note 4, at 11.

129. *Id.*

130. *See* Shea Thompson, *Artificially "Natural": Class Action Lawsuits Attack Misleading "Natural" Claims in FDA's Absence*, 47 IND. L. REV. 893, 898 (2014).

131. *See id.* ("The majority of these lawsuits are punitive class action lawsuits brought by plaintiff lawyers, representing the class members.").

## II. JURISDICTIONAL QUESTIONS

Food health claims are thus shaped by competing forces: regulation by the FDA on product labels; enforcement actions by the FTC for unsubstantiated representations in advertisements; private lawsuits from competitors who claim that misrepresentations regarding a product's health benefits interfere with the market; and private lawsuits from consumers who claim that they were induced to purchase products they otherwise would have passed in the grocery aisle. Although each of these forces does, in theory, incentivize food producers to be honest about their products, they are also the source of jurisdictional confusion when they converge over the same representation.

First, defendants commonly raise jurisdictional defenses where the food health claim is subject to both regulation by the FDA and lawsuits from private actors.<sup>132</sup> The answer to this public-versus-private enforcement question frequently turns on the doctrines of preclusion, preemption, and primary jurisdiction.<sup>133</sup> Second, interagency jurisdictional issues arise between the FDA and the FTC with regard to policing food health claims.<sup>134</sup> Claims on food labels, which are traditionally regulated by the FDA, may substantively overlap with claims in advertisements, which are traditionally regulated by the FTC.<sup>135</sup> This precise issue is before a federal district court in New Jersey in the case of *Federal Trade Commission v. Gerber Products Co.*<sup>136</sup> Which agency should be on point in this case? The doctrines of preclusion and primary jurisdiction bear on this question as well.

### *A. Preclusion, Preemption, Primary Jurisdiction, and the Private Litigation of Food Health Representations*

1. *Preclusion.*—The preclusion doctrine addresses the interplay between federal laws.<sup>137</sup> The purpose of the doctrine is to ensure that one piece of federal legislation does not interfere with or frustrate the purpose of another federal statute.<sup>138</sup> Where two federal statutes regulate the same conduct, courts often look to the preemption doctrine for guidance because “its principles are instructive

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132. See Winters, *supra* note 8, at 848-57 (discussing the defenses of preemption and primary jurisdiction in the context of food labeling litigation).

133. *Id.*

134. See Masaitis & Woolley, *supra* note 8 (discussing application of preclusion and primary jurisdiction doctrines to an FTC lawsuit challenging a manufacturer's representations about a FDA-regulated qualified health claim).

135. See Chelsea M. Childs, *Federal Regulation of the “Smart Choices Program”: Subjecting Front-of-Package Nutrition Labeling Schemes to Concurrent Regulation by the FDA and the FTC*, 90 B.U. L. REV. 2403, 2404 (2010) (“In today's world of mass marketing, however, labeling and advertising often overlap.”).

136. See discussion *infra* Part II.B.

137. *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236 (2014).

138. See generally *id.* (discussing similarities between preclusion and preemption doctrines).

insofar as they are designed to assess the interaction of laws that bear on the same subject.”<sup>139</sup> In evaluating whether to apply the preclusion doctrine, courts consider the existence of an express provision in the statute that creates a preclusive effect<sup>140</sup> and whether the two federal statutes complement each other.<sup>141</sup> If the court determines that the two statutes cannot be applied simultaneously, the court will determine which statute should be given preclusive effect.<sup>142</sup>

In the context of FDA-regulated products, defendant manufacturers commonly raise the preclusion doctrine as a defense to Lanham Act claims.<sup>143</sup> Essentially, the defense argument is that the product has been regulated by the FDA; thus, any private Lanham Act suit interferes with FDA regulation and should thus be precluded.<sup>144</sup> Until 2014, it was an open question whether a business could sue a competitor for unfair competition based on a competitor’s product label that was also subject to regulation by the FDA.<sup>145</sup> The Supreme Court answered that question in *POM Wonderful LLC v. Coca-Cola Co.*<sup>146</sup> In that case, POM Wonderful made a pomegranate-blueberry juice blend.<sup>147</sup> Coca-Cola’s Minute Maid brand began marketing and selling a “pomegranate-blueberry” juice blend, which was, in fact, only .3% pomegranate juice and .2% blueberry juice.<sup>148</sup> The rest of Minute Maid’s product was a mixture of apple, grape, and raspberry juice.<sup>149</sup> POM Wonderful sued Coca-Cola under the Lanham Act alleging that Minute Maid’s labeling of the product, which touted its pomegranate-blueberry components, was misleading.<sup>150</sup> Thus, POM Wonderful argued, consumers were tricked into buying the less expensive Minute Maid product, which caused POM Wonderful to lose sales.<sup>151</sup> Coca-Cola invoked the preclusion doctrine and argued that its product label was exclusively regulated by the FDA; thus, to the extent its juice label was misleading, only the FDA had authority to raise the issue—not a competitor.<sup>152</sup>

The Court found that although the Minute Maid beverage label was regulated

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139. *Id.*

140. *Id.* at 2237.

141. *Id.* at 2238.

142. *Id.*

143. See, e.g., *Church & Dwight Co v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-cv-585, 2015 U.S. Dist. LEXIS 67187, at \*17 (S.D.N.Y. Mar. 24, 2015).

144. *Id.*

145. *POM Wonderful*, 134 S. Ct. at 2236. The Supreme Court “granted certiorari to consider whether a private party may bring a Lanham Act claim challenging a food label that is regulated by the FDCA.” *Id.*

146. *Id.* at 2237.

147. *Id.* at 2233.

148. *Id.*

149. *Id.* at 2235.

150. *Id.* at 2233.

151. *Id.* at 2235.

152. *Id.* at 2239.

by the FDA, POM Wonderful's Lanham Act claim was not precluded.<sup>153</sup> The Court found no textual support in either the FDCA or the Lanham Act that suggested that Congress intended to prohibit Lanham Act claims involving beverage labels.<sup>154</sup> Moreover, the Court noted that both statutes had been amended at various points and that the FDCA expressly preempts some state law claims—if Congress wanted to preclude Lanham Act claims under these circumstances, it certainly could have done so.<sup>155</sup> In addition, the statutes complement each other in that they both regulate food labeling with the goal of protecting the integrity of the marketplace, but they approach this goal from different angles.<sup>156</sup> The Court rejected the notion that the FDCA's labeling requirements are a ceiling with regard to regulation.<sup>157</sup> Although ensuring compliance with the labeling guidelines is one method of curbing industry misrepresentations, it is not the exclusive method.<sup>158</sup> The Court reasoned that Congress could have intended to place additional pressure on producers when it created a private cause of action in the Lanham Act.<sup>159</sup> Because competitors in the same industry have "detailed knowledge regarding how consumers rely upon certain sales and marketing strategies," they may be much better at ferreting out potentially misleading product labels than the FDA.<sup>160</sup> The Court found that "Lanham Act suits draw upon this market expertise by empowering private parties to sue competitors to protect their interests on a case-by-case basis."<sup>161</sup> In addition, it is not feasible for the FDA to bring enforcement actions for all problematic food and beverage labels.<sup>162</sup> If competitors were precluded from bringing Lanham Act suits, manufacturers in industries receiving less attention from the FDA could misbrand their products with impunity, which in turn could harm consumers.<sup>163</sup> Thus, the Court concluded that POM Wonderful's Lanham Act claim could proceed, even though the Minute Maid juice label was subject to regulation by the FDA.<sup>164</sup>

Several lower court decisions after *POM Wonderful LLC v. Coca-Cola Co.* discussed the preclusion doctrine in the context of other FDA-regulated products.<sup>165</sup> Not surprisingly, most of these decisions reflect a reluctance to apply the preclusion doctrine and have thus extended the holding in *POM Wonderful*

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153. *Id.* at 2241.

154. *Id.* at 2237.

155. *Id.* at 2238.

156. *Id.*

157. *Id.* at 2240.

158. *Id.* at 2238.

159. *Id.*

160. *Id.*

161. *Id.*

162. *Id.* at 2239.

163. *Id.*

164. *Id.* at 2241.

165. See, e.g., *Church & Dwight Co v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-cv-585, 2015 U.S. Dist. LEXIS 67187, at \*17 (S.D.N.Y. Mar. 24, 2015).



*LLC v. Coca-Cola Co.* beyond the food labeling context and into the drug and device context.<sup>166</sup> For example, in *Church & Dwight Co. v. SPD Precision Diagnostics, GmbH*,<sup>167</sup> the district court held that the preclusion doctrine did not bar a competitor's Lanham Act claim, despite the fact that the medical device at issue went through an extensive FDA approval process.<sup>168</sup> First, the court recognized the absence of an express provision in the FDCA precluding competing claims.<sup>169</sup> Second, the court focused on the resource constraints of the FDA and the public policy benefits of treating FDA regulation as the floor, rather than the ceiling, of acceptable manufacturer conduct.<sup>170</sup> Lanham Act claims can supplement FDA regulation, thereby ensuring a fairer, more honest marketplace.<sup>171</sup> Thus, the court concluded that FDA approval of the product was "beside the point" and did not bear on the preclusion issue.<sup>172</sup>

Other lower courts have declined to apply the preclusion doctrine where the Lanham Act claims were based on allegations that the defendant misrepresented its product as FDA-approved.<sup>173</sup> For example, the courts in *Par Sterile Products, LLC v. Fresenius Kabi USA, LLC*<sup>174</sup> and *JHP Pharmaceuticals, LLC v. Hospira,*

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166. See White, *supra* note 28, at 283-84 (discussing application of *POM Wonderful LLC v. Coca-Cola Co.*'s preclusion holding in lower court decisions).

167. 2015 U.S. Dist. LEXIS 67187.

168. *Id.* at \*29. This case involved a false advertising claim based on the defendant's representations that its pregnancy test could also give the consumer an estimate of the number of weeks of her pregnancy. *Id.* at \*4. The defendant argued that because the product's label was subject to an extensive FDA approval process, the plaintiff's Lanham Act claim was precluded. *Id.* at \*5. Although the court agreed that the pregnancy test had been subjected to an extensive FDA approval process, the court declined to apply the preclusion doctrine. *Id.* at \*29.

169. *Id.* at \*20.

170. *Id.* at \*24-28 (relying on *Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009), in finding that private lawsuits incentivize manufacturers to eliminate safety risks and also serve to compensate victims of manufacturer misconduct).

171. *Id.* at \*26.

172. *Id.* at \*25.

173. See, e.g., *Innovative Health Solutions, Inc. v. DyAnsys, Inc.*, No. 14-cv-5207, 2015 U.S. Dist. LEXIS 65431, at \*22 (N.D. Cal. May 19, 2015) (holding that a Lanham Act claim based on an alleged misrepresentation of FDA approval was not precluded).

174. No. 14-C-3349, 2015 U.S. Dist. LEXIS 32409, at \*11-12 (N.D. Ill. Mar. 17, 2015). In this case, the plaintiff manufactured an injectable vasopressin product, which was FDA-approved. *Id.* at \*2. The defendant also manufactured a vasopressin injectable, but it was not FDA-approved. *Id.* The plaintiff alleged that the defendant marketed and otherwise created the impression that its product was FDA-approved. *Id.* at \*5. The defendant argued that the plaintiff was seeking to enforce the FDCA through a Lanham Act claim; the court disagreed, finding that "the dispute is of the sort with which the Lanham Act is concerned to the extent it involves deception of consumers as to the fact of whether a product carries the imprimatur of FDA approval." *Id.* at \*11. In addition, "[a]s long as there is no allegation that [defendant] must do something that directly conflicts with the FDCA or an FDA regulation, or may not do something that the FDCA or an FDA regulation specifically requires . . . [plaintiff's] Lanham Act claim is not precluded by the FDCA." *Id.* at \*11-

*Inc.*,<sup>175</sup> reached this conclusion in reliance on the *POM Wonderful LLC v. Coca-Cola Co.*<sup>176</sup> decision. The *JHP* court focused on the public policy benefits of allowing Lanham Act claims to augment FDA regulation:

[FDA approval is] a sort of “Good Housekeeping Seal” for pharmaceuticals: it is the government’s imprimatur on a product, indicating quality, safety, and desirability . . . if a product *has* been approved, consumers may take some assurance that it has been properly tested and meets the agency’s minimum quality standards. This makes an FDA-approved product a more attractive product, whether at the wholesale, retail, or end user level. But it can also be expensive to get approval for a drug, so a company that chooses to invest in getting approval may operate at a competitive disadvantage if other companies can falsely represent to the public that their unapproved products are FDA-approved. Thus, representations that a drug is approved when it is not undermine the Lanham Act’s public policy goals both by confusing consumers and by enabling unfair competition by producers who have not bothered to get FDA approval.<sup>177</sup>

These courts were careful to place limits on their holdings, however, noting that a competitor cannot use a Lanham Act claim to pursue a private remedy for violation of the FDCA: “That is, because the FDCA does not contain a private right of action, claims that require a court to interpret, apply, or enforce the FDCA remain precluded.”<sup>178</sup> Lanham Act claims may still be barred by the doctrine of preclusion if, for example, those claims conflict with the FDA’s affirmative policy judgment or if the claims involve litigation of an FDCA violation.<sup>179</sup> One post-*POM Wonderful LLC v. Coca-Cola Co.* case, for example, found that the preclusion doctrine barred a Lanham Act suit that alleged that the defendant was required to seek FDA approval for its medical device and it failed

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175. 52 F. Supp. 3d 992 (C.D. Cal. 2014). In this case, the plaintiff manufactured an injectable epinephrine product and obtained FDA approval for its product under the brand name Adrenalin. *Id.* at 996. The defendants also manufactured injectable epinephrine products, but their products were not FDA-approved. *Id.* The plaintiff brought a Lanham Act suit alleging, among other claims, that the defendants’ advertisements misled consumers by representing that their products were approved by the FDA. *Id.* The defendants argued that this claim should have been dismissed under the doctrine of preclusion because drug regulation is within the exclusive authority of the FDA. *Id.* at 1001. The court rejected this argument. *Id.*

176. 134 S. Ct. 2228 (2014).

177. *JHP Pharm.*, 52 F. Supp. 3d at 1000.

178. *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-cv-5852015, 2015 U.S. Dist. LEXIS 67187, at \*33 (S.D.N.Y. Mar. 24, 2015).

179. *JHP Pharm.*, 52 F. Supp. 3d at 998-99.

to do so.<sup>180</sup> In *Catheter Connections v. Ivera Medical Corp.*,<sup>181</sup> the plaintiff alleged that the defendant marketed a medical device as FDA-approved when it was not.<sup>182</sup> The defendant had, however, received FDA approval for a previous version of the device.<sup>183</sup> The court determined that the plaintiff's claim did not involve a simple case of misrepresentation; rather, it involved a question of the defendant's obligation under the FDCA to seek approval for a newer version of the device.<sup>184</sup> The court concluded that it was up to the FDA to determine whether new approval was necessary.<sup>185</sup> Because the plaintiff was, in essence, seeking a private remedy for an alleged violation of the FDCA, the claim was precluded.<sup>186</sup>

*POM Wonderful LLC v. Coca-Cola Co.* and the lower court decisions relying on it offer key insights with regard to the doctrine of preclusion. First, simply because the FDA regulates a product label does not guarantee application of the preclusion defense; FDA labeling guidelines set the floor, not the ceiling, with regard to product label regulation.<sup>187</sup> Second, Lanham Act claims based on a manufacturer's misrepresentation of FDA approval are generally not precluded.<sup>188</sup> Third, it is clear that a competitor cannot use a Lanham Act claim to pursue a private remedy for violation of the FDCA.

2. *Preemption.*—Although the preclusion doctrine deals with the relationship between potentially conflicting federal statutes, the preemption doctrine focuses on state law claims that intersect with activities regulated by federal law.<sup>189</sup> The relationship between state law claims, FDA-regulated products, and the preemption doctrine has been tortured, to say the least.<sup>190</sup> These issues have been

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180. *Catheter Connections v. Ivera Med. Corp.*, No. 2:14-CV-70-TC, 2014 U.S. Dist. LEXIS 98206, at \*16 (D. Utah July 17, 2014).

181. *Id.* at \*16.

182. *Id.* at \*6.

183. *Id.*

184. *Id.* at \*15-16.

185. *Id.* at \*16-17.

186. *Id.* at \*17. The plaintiff's other claims, which focused on the "substance of [defendant's] representations in the context of the medical device market and what drives buyers' purchasing decisions," were not precluded by the FDCA as they dealt with representations in the marketplace and did not require the court to evaluate FDA policy or speculate about the FDA approval process. *Id.* at \*19-20.

187. *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-cv-5852015, 2015 U.S. Dist. LEXIS 67187, at \*33 (S.D.N.Y. Mar. 24, 2015).

188. See *JHP Pharm., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 998-99 (C.D. Cal. 2014); *Par Sterile Prods., LLC v. Fresenius Kabi USA, LLC*, No. 14-C-3349, 2015 U.S. Dist. LEXIS 32409, at \*11-12 (N.D. Ill. Mar. 17, 2015).

189. See generally James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 967 (2008) ("Preemption is a constitutional doctrine, derived from the Supremacy Clause, of power sharing between federal, state, and local governments.").

190. See generally Claudia L. Andre, *What's in that Guacamole? How Bates and the Power*

addressed by the Supreme Court multiple times in the last fifteen years and lower courts continue to struggle with the doctrine.<sup>191</sup>

Preemption in the context of food health claims is no exception. Three types of preemption have the potential to affect food products regulated by the FDA: field preemption, conflict preemption, and express preemption.<sup>192</sup> Field preemption arises where federal law has so extensively occupied the “field” that there is no room for state regulation.<sup>193</sup> Conflict preemption arises when compliance with both the federal and state law is impossible or where the state law creates an “obstacle” to accomplishment of the federal legislation’s objectives.<sup>194</sup> In addition, the NLEA contains an express preemption provision that prohibits a state from “directly or indirectly establish[ing] any requirement for the labeling of food that is not identical to” the labeling requirements imposed by the FDA.<sup>195</sup> In this context,

“[N]ot identical to” . . . means “that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that are not imposed by or contained in the applicable federal regulation or differ from those specifically imposed by or contained in the applicable federal regulation.”<sup>196</sup>

A state may, however, impose labeling requirements that match those imposed by the FDA and a consumer may bring a state law claim to enforce those requirements.<sup>197</sup> In addition, the NLEA “does not preempt any state law unless the law is ‘expressly preempted.’”<sup>198</sup> There is a strong presumption against finding preemption in this context, as states are the traditional regulators of

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*of Preemption Will Affect Litigation Against the Food Industry*, 15 GEO. MASON L. REV. 227, 234 (2007) (“However, some statutes, including the NLEA, do not have a clear, sweeping preemption provision. The result is a mishmash of conflicting judicial decisions from both state and federal courts deciding whether or not federal law preempts state law actions.”); *see also* Marcia Boumil, *FDA Approval of Drugs and Devices: Preemption of State Laws for “Parallel” Tort Claims*, 18 J. HEALTH CARE L. & POL’Y 1, 7-12 (2015) (summarizing current law on preemption and the FDCA).

191. *See generally* Boumil, *supra* note 190, at 7-12.

192. *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3d Cir. 2009).

193. *Id.* at 336.

194. *Id.* at 339.

195. *Reid v. Johnson & Johnson*, 780 F.3d 952, 959 (9th Cir. 2015) (quoting 21 U.S.C. § 343-1(a)(5) (2012)).

196. 21 C.F.R. § 100.1(c)(4) (1993).

197. *See* Winters, *supra* note 8, at 832. (“Courts have also interpreted the express preemption provision to allow for actions to be brought under state laws establishing identical requirements to the FDCA, rejecting allegations that such actions are really attempts to enforce the FDCA and thereby circumvent the FDCA’s prohibition on private actions.”).

198. *Reid*, 780 F.3d at 959 (quoting *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 337-38 (3d Cir. 2009)).

health and safety.<sup>199</sup>

Courts have found field preemption to be largely inapplicable in the food labeling context because “[i]t does not appear that Congress has regulated so comprehensively in either the food and beverage or juice fields that there is no role for the states.”<sup>200</sup> Both conflict and express preemption, however, present a closer question when they are raised as defenses to state law claims challenging food labels.<sup>201</sup> The NLEA preemption cases present a mixed bag of results, but they can be broken down into four areas. First, in areas where the FDA has clearly set forth a labeling standard and the manufacturer is in compliance with that standard, courts will likely find the state law claim barred by the preemption doctrine because it seeks to impose obligations “different” or “in addition to” those standards set forth by the FDA.<sup>202</sup> Second, in areas where the FDA has clearly set forth a labeling standard and the manufacturer is *not* in compliance with the standard, courts generally find that the state law claim is *not* preempted because the plaintiff is seeking to enforce requirements identical to those set forth by the FDA.<sup>203</sup> Third, in areas where the FDA has not *clearly* articulated a labeling standard, courts generally find that the state law claim is not preempted.<sup>204</sup> For example, the preemption argument has been largely unsuccessful when asserted in opposition to state law claims challenging foods labeled “natural.”<sup>205</sup> To date, the FDA has not defined the term “natural” or

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199. *Holk*, 575 F.3d at 334 (“Health and safety issues have traditionally fallen within the province of state regulation. This is true of the regulation of food and beverage labeling and branding.”).

200. *Id.* at 337.

201. *See* Winters, *supra* note 8, at 834.

202. *See, e.g., Pratt v. Whole Foods Mkt. Cal., Inc.*, No. 5:12-CV-05652-EJD, 2014 U.S. Dist. LEXIS 46409, at \*16 (N.D. Cal. Mar. 31, 2014) (“Courts in this district have generally found express preemption under the FDCA only when: (1) the FDA requirements with respect to a particular food label or package are clear; and (2) the product label or package at issue is in compliance with that policy, such that plaintiff necessarily seeks to enforce requirements in excess of what the FDCA, NLEA, and the implementing regulations require.”).

203. *See, e.g., Ivie v. Kraft Foods Glob., Inc.*, 961 F. Supp. 2d 1033, 1043 (N.D. Cal. 2013) (“Since California’s Sherman Laws fully adopt federal food labeling law, allowing plaintiff’s state law UCL claims to proceed based on the ‘unlawfulness’ of the nut mix label imposes no other requirement than what FDA regulations already require . . . for the purposes of preemption, plaintiff’s claim is not expressly preempted and cannot be dismissed on that basis.”).

204. *See Colby Ctr. v. Conagra Foods, Inc.*, No. 5:14-CV-05248, 2015 U.S. Dist. LEXIS 89711, at \*9-10 (W.D. Ark. July 6, 2015) (“The Court must consider whether the requirements Center seeks to impose in his state-law action are identical to the requirements in the NLEA. While § 343-1 lists specific instances where labeling is preempted, allegations regarding ‘all natural’ do not fall under these categories. The parties do not cite to, and the Court does not find, any regulation of the use of ‘natural’ on a food label. A finding of express preemption requires explicit statutory language preempting Center’s claims. Thus, with respect to Center’s claims . . . there are no federal requirements regarding the term ‘natural’ to be given preemptive effect.”).

205. Nicole E. Negowetti, *Defining Natural Foods: The Search for a Natural Law*, 26 REGENT

issued regulations regarding when use of this term is appropriate.<sup>206</sup> Thus, state law claims challenging “natural” representations are not inconsistent with existing FDA rules and are therefore not preempted.<sup>207</sup>

The fourth category of NLEA preemption cases is the most vexing. The preemption argument becomes a close call where the FDA has issued pertinent guidance or relevant rules, but arguably no regulation that is directly on point to the misrepresentation at issue.<sup>208</sup> The Benecol cases fall within this category.<sup>209</sup> In the 2015 Ninth Circuit opinion of *Reid v. Johnson & Johnson*, the plaintiff sued the manufacturer of Benecol, a vegetable oil-based spread.<sup>210</sup> Benecol’s label proclaimed that it contained “No Trans Fat.”<sup>211</sup> Benecol did, in fact, contain a very small amount of trans-fat.<sup>212</sup> The plaintiff alleged that these claims were not authorized by the FDA.<sup>213</sup> Although the FDA expressly allows manufacturers to use the terms “No Fat” and “No Saturated Fat” when their products contain less than .5 grams of fat per serving, the FDA has not expressly authorized a claim of “No Trans Fat” where the product contains less than .5 grams of trans-fat.<sup>214</sup> The court concluded that the “No Trans Fat” claim had not been authorized by the FDA; accordingly, the plaintiff’s state law claim challenging the truth of that representation was not preempted.<sup>215</sup> Benecol’s label also claimed that it contained plant stanol esters, which can lower cholesterol.<sup>216</sup> The FDA did expressly authorize a health claim regarding plant stanol esters and the reduced risk of high cholesterol.<sup>217</sup> The manufacturer conceded that its representations regarding plant stanol esters did not conform to the FDA’s authorized health claim regulation.<sup>218</sup> It argued, however, that its representations *did* conform to an FDA letter setting forth the agency’s enforcement intentions with regard to plant stanol esters health claims.<sup>219</sup> The manufacturer argued that this FDA letter “created [a] federal policy preempting state law.”<sup>220</sup> The court declined to give

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U. L. REV. 329, 334-35 (2014).

206. *Id.* at 343.

207. *Id.* at 334-35.

208. *See* *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 340-41 (3d Cir. 2009) (finding that in the absence of a formal definition of the term “natural,” the FDA’s policy statement regarding the term was not entitled to preclusive effect).

209. *See generally* *Reid v. Johnson & Johnson*, 780 F.3d 952 (9th Cir. 2015); *Young v. Johnson & Johnson*, No. 12-2475, 2013 U.S. App. LEXIS 9422 (3d Cir. May 9, 2013).

210. *Reid*, 780 F.3d at 956.

211. *Id.*

212. *Id.* at 957.

213. *Id.*

214. *Id.* at 962.

215. *Id.* at 963.

216. *Id.* at 956.

217. *Id.* at 963.

218. *Id.*

219. *Id.*

220. *Id.*

the letter preemptive effect because nothing indicated that the letter had the force of law and “the letter’s plain language [did] not authorize any health claims that conflict[ed] with the FDA’s existing plant stanol esters rule.”<sup>221</sup> Thus, the court found that the preemption doctrine did not bar the plaintiff’s plant stanol esters claim.<sup>222</sup>

The opposite result was reached in an unpublished 2013 Third Circuit opinion addressing the same product and same claims regarding Benecol’s trans-fat and plant stanol esters representations.<sup>223</sup> In *Young v. Johnson & Johnson*, the court interpreted the FDA’s nutrient content claim regulations to allow a claim of “No Trans Fat.”<sup>224</sup> Similarly, the court concluded that Benecol’s health claims based on the presence of plant stanol esters were permitted under FDA regulations.<sup>225</sup> Benecol’s representations were not misleading because they were authorized by the FDA; thus, the plaintiff’s state law claims were preempted because they sought “to impose standards that are not identical to those set forth in the regulations.”<sup>226</sup>

Preemption under the NLEA continues to be a contentious, confusing, and time-consuming issue that ties up litigants and the lower courts for a considerable portion of these cases. It is not the only defense raised to combat private litigation targeted at misleading food labels, however. As discussed below, defendants often assert the primary jurisdiction defense in concert with preemption or preclusion.<sup>227</sup>

3. *Primary Jurisdiction.*—Like preclusion and preemption, the primary jurisdiction doctrine bears on the relationship between agency enforcement and private litigation. The doctrine has been invoked in cases that involve both federal and state law claims targeted at areas regulated by the FDA.<sup>228</sup> It is confusingly titled, as its invocation does not require a court to dismiss a case because it lacks jurisdiction to hear the dispute; rather, it has been characterized as a prudential doctrine where the court, in its discretion, stays the dispute pending guidance from the agency with “primary jurisdiction” and expertise in the area:

The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency. A court’s

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221. *Id.* at 964-65.

222. *Id.* at 966.

223. *Young v. Johnson & Johnson*, No. 12-2475, 2013 U.S. App. LEXIS 9422 (3d Cir. May 9, 2013).

224. *Id.* at \*8-9.

225. *Id.* at \*9.

226. *Id.* at \*14.

227. *See, e.g., JHP Pharm., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992 (C.D. Cal. 2014).

228. *See, e.g., id.* at 1001 (discussing the primary jurisdiction doctrine in the context of Lanham Act claims challenging food labels); *Ivie v. Kraft Foods Glob., Inc.*, 961 F. Supp. 2d 1033, 1045 (N.D. Cal. 2013) (discussing the primary jurisdiction doctrine in context of state law claims challenging food labels).

invocation of the doctrine does not indicate that it lacks jurisdiction. Rather, the doctrine is a “prudential” one, under which a court determines that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch.<sup>229</sup>

Not every issue that touches on an area subject to federal regulation should be stayed pursuant to the primary jurisdiction doctrine, however. The doctrine should be invoked sparingly and applied only to those especially complex issues of agency regulation or issues of first impression.<sup>230</sup> The purpose of the primary jurisdiction doctrine is to encourage efficiency in decision-making.<sup>231</sup> Courts typically consider four factors in determining whether to apply the primary jurisdiction doctrine: “(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.”<sup>232</sup> The courts’ treatment of the primary jurisdiction doctrine in the context of FDA-regulated products has been inconsistent, but a few patterns in application of the doctrine appear to be emerging.

First, courts are more likely to invoke the primary jurisdiction doctrine where it appears that the FDA will come forward with a relevant rule in the near future.<sup>233</sup> Conversely, it will not be invoked where it appears that the FDA intends to remain silent on the issue.<sup>234</sup> Simple agency interest in the subject matter of the lawsuit is an insufficient basis for invoking the primary jurisdiction doctrine.<sup>235</sup> In recent years, for example, a rash of cases have been filed

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229. *Dean v. Colgate-Palmolive Co.*, No. EDCV 15-0107, 2015 U.S. Dist. LEXIS 80150, at \*6-7 (C.D. Cal. June 17, 2015) (citations omitted).

230. *Id.* at \*11-12.

231. *Zakaria v. Gerber Prods. Co.*, No. LA CV-15-00200, 2015 U.S. Dist. LEXIS 80428, at \*15 (C.D. Cal. June 18, 2015).

232. *JHP Pharm.*, 52 F. Supp. 3d at 1001 (quoting *United States v. Gen. Dynamics Corp.*, 828 F.2d 1356, 1362 (9th Cir. 1987)).

233. *See Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 761 (9th Cir. 2015) (holding that the lower court did not err in applying the primary jurisdiction doctrine in a cosmetics labeling case because there were indications that the FDA would issue guidance on the topic in the near future); *Gisvold v. Merck & Co.*, 62 F. Supp. 3d 1198, 1204 (S.D. Cal. 2014) (applying the primary jurisdiction doctrine where an FDA-proposed rule was pending in notice and comment phase).

234. *See, e.g., Gedalia v. Whole Foods Mkt. Servs., Inc.*, 53 F. Supp. 3d 943, 950 (S.D. Tex. 2014) (“Here, deference to the FDA would likely be unfruitful due to the agency’s long-standing reluctance to officially define the term ‘natural.’”).

235. *See, e.g., Dean v. Colgate-Palmolive Co.*, No. EDCV 15-0107, 2015 U.S. Dist. LEXIS 80150, at \*16 (C.D. Cal. June 17, 2015) (finding that the primary jurisdiction doctrine did not bar plaintiff’s claims simply because the FTC had launched an investigation into the defendant’s conduct).



challenging food products alleged to be misbranded as “natural.”<sup>236</sup> Some of these actions were stayed pending FDA guidance on the definition of the term “natural.”<sup>237</sup> Given the fact that food labeling falls squarely within the jurisdiction of the FDA, these courts concluded that it would be more efficient, and lead to more consistent results, if the cases were stayed until the FDA spoke on the matter.<sup>238</sup> Other courts suspected that referring their cases to the FDA would be pointless because repeated calls to the FDA for a definition of the word “natural” had gone unanswered.<sup>239</sup> In 2014, the FDA, citing resource constraints, declined to issue a rule on the meaning of the term “natural.”<sup>240</sup> Accordingly, courts facing similar “natural” claims today have declined to invoke the primary jurisdiction doctrine because it appears unlikely that the FDA will answer the “natural” question anytime soon.<sup>241</sup> A similar rationale was applied in the food health claim context by the Ninth Circuit in the 2015 case of *Reid v. Johnson & Johnson*.<sup>242</sup> In that case, the plaintiff alleged that Benecol’s representations regarding trans-fat and plant stanol esters were misleading.<sup>243</sup> The defendant urged the court to refer the claims to the FDA pursuant to the primary jurisdiction doctrine; however, the court found no indication that the FDA was likely to issue new rules regarding trans-fat or plant stanol esters in the near future.<sup>244</sup> Thus, application of the primary jurisdiction doctrine was inappropriate.<sup>245</sup>

Second, courts are unlikely to apply the primary jurisdiction doctrine where the issue presented is not one that requires agency expertise, such as lawsuits alleging straightforward issues of product misrepresentation. For example, the

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236. See Negowetti, *supra* note 205, at 332-33.

237. See *In re Gen. Mills, Inc.*, No. CIV-A-12-249 KM, 2013 U.S. Dist. LEXIS 160702, at \*2 (D. N.J. Nov. 1, 2013) (referring the definition of “natural” to the FDA under the primary jurisdiction doctrine); *Barnes v. Campbell Soup Co.*, No. C12-05185 JSW, 2013 U.S. Dist. LEXIS 118225, at \*29 (N.D. Cal. July 25, 2013) (referring the definition of “natural” to the FDA pursuant to the primary jurisdiction doctrine); *Cox v. Gruma Corp.*, No. 12-CV-6502 YGR, 2013 U.S. Dist. LEXIS 97207, at \*6 (N.D. Cal. July 11, 2013) (staying “natural” case pursuant to the primary jurisdiction doctrine).

238. See Negowetti, *supra* note 205, at 340-41.

239. See *id.* at 338-39 (summarizing decisions that declined to refer the “natural” question to the FDA); see also *Langan v. Johnson & Johnson Consumer Cos., Inc.*, No. 3:13-cv-01480 (JAM), 2015 U.S. Dist. LEXIS 40984, at \*16 (D. Conn. Mar. 31, 2015) (“[A]pplication of the primary jurisdiction doctrine is particularly inappropriate where, as here, the relevant administrative agency has shown no interest in addressing the matter.”).

240. See Negowetti, *supra* note 205, at 343.

241. See, e.g., *Gedalia v. Whole Foods Mkt. Servs., Inc.*, 53 F. Supp. 3d 943, 950 (S.D. Tex. 2014) (refusing to apply the primary jurisdiction doctrine in light of the FDA’s repeated refusal to provide guidance on the meaning of the term “natural”).

242. 780 F.3d 952, 967 (9th Cir. 2015).

243. *Id.* at 957.

244. *Id.* at 967.

245. *Id.*

*Reid* court determined that it was well-able to rule on the merits of the plaintiff's claims, which primarily involved allegations of consumer fraud: "The issue that this case ultimately turns on is whether a reasonable consumer would be misled by [defendant's] marketing, which the district courts have reasonably concluded they are competent to address in similar cases."<sup>246</sup> Likewise, courts are reluctant to apply primary jurisdiction where the plaintiff's claims involve simple misrepresentations of FDA approval. For instance, in *Zakaria v. Gerber Products Co.*, the district court declined to stay the case pursuant to the primary jurisdiction doctrine where the crux of the plaintiff's claim was that Gerber overstated FDA approval of qualified health claims in connection with labels and advertisements for its infant formula.<sup>247</sup> The plaintiff alleged violations of various California consumer protection statutes and also asserted state law tort claims such as fraud and breach of warranty.<sup>248</sup> Gerber argued that the primary jurisdiction doctrine required the court to refrain from hearing the case since its qualified health claims were regulated by the FDA.<sup>249</sup> The court noted that the primary jurisdiction doctrine should only be applied in complex matters that Congress has clearly placed within the hands of an administrative agency.<sup>250</sup> The court declined to apply the primary jurisdiction doctrine in *Zakaria*, finding that there was nothing particularly complex about the task of evaluating whether Gerber's representations of FDA approval were misleading:

Plaintiff raises neither an issue of first impression nor a complex one. Instead, her claims turn on whether Defendant's representations concerning the health benefits of Good Start Gentle and the FDA's approval of the formula were false or misleading. To be sure in analyzing Defendant's health claims, a factfinder may be required to consider evidence about clinical studies . . . [but] [t]his is not a sufficient basis to apply the primary jurisdiction doctrine.<sup>251</sup>

Third, courts *may* apply the primary jurisdiction doctrine where the lawsuit involves allegations that the defendant has misrepresented the "safety," "effectiveness," or "legality" of a product. In *JHP Pharmaceuticals, LLC v.*

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246. *Id.*; see also *Garcia v. Kashi Co.*, 43 F. Supp. 3d 1359, 1380 (S.D. Fla. 2014) (finding that allegations of misleading product labels and consumer reliance are not "technical" areas requiring FDA expertise); *Rikos v. Procter & Gamble Co.*, 782 F. Supp. 2d 522, 530 (S.D. Ohio 2011) (declining to apply the primary jurisdiction doctrine where the claims involved allegations of misrepresentations and consumer reliance); *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1124 (N.D. Cal. 2010) (declining to apply the primary jurisdiction doctrine where plaintiffs advanced a straightforward claim of consumer deception, which was an area courts are equipped to handle).

247. *Zakaria v. Gerber Prods. Co.*, No. LA CV 15-00200 JAK, 2015 U.S. Dist. LEXIS 80428, at \*16 (C.D. Cal. June 18, 2015).

248. *Id.* at \*3.

249. *Id.* at \*3-4.

250. *Id.* at \*15.

251. *Id.* at \*17.

*Hospira, Inc.*, for example, the plaintiff brought a Lanham Act claim alleging that the defendant's marketing of its injectable epinephrine product misled consumers by, among other things, representing that its products were safe, effective, and legal.<sup>252</sup> The court suggested that these claims could be subject to the primary jurisdiction doctrine because determinations of a product's "safety" and "effectiveness" may fall within the expertise of the FDA.<sup>253</sup> The court also suggested that representations regarding a product's compliance with applicable laws—including the FDCA—could be subject to the primary jurisdiction doctrine because the question of a product's "legality" under the FDCA is for the FDA to decide:

In short, unlike the binary factual determination of whether Defendants' products are, in fact, FDA-approved, the question of legality directly implicates the FDA's rulemaking authority. The determination of whether a drug is "new," and whether it can be lawfully marketed under the FDCA, involves complex issues of history, public safety, and administrative priorities that Congress has delegated exclusively to the FDA.<sup>254</sup>

*B. Preclusion, Primary Jurisdiction, and Potential Interagency Conflict*

Two of the jurisdictional doctrines discussed above—preclusion and primary jurisdiction—have implications not only for private actors seeking remedies for misbranded food products, but also for other agencies seeking to protect the consuming public.<sup>255</sup> As noted in Part I.A.3, the FDA and the FTC share enforcement authority with regard to representations about a food's health benefits.<sup>256</sup> Historically, the FDA has exercised jurisdiction over food labels, while the FTC has exercised jurisdiction over advertisements.<sup>257</sup> There is not always a bright line between labels and advertisements<sup>258</sup> however, and the potential for jurisdictional confusion arises when the FTC takes issue with health

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252. *JHP Pharm., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 996 (C.D. Cal. 2014).

253. *Id.* at 1003. However, the court concluded that the plaintiff had alleged no facts to suggest that the defendant's products were unsafe or ineffective; thus, the court declined to decide whether any such claims, had they been properly before the court, would have been barred by the primary jurisdiction doctrine. *Id.*

254. *Id.* at 1004.

255. See Masaitis & Woolley, *supra* note 8 (discussing application of the preclusion and primary jurisdiction doctrines to a FTC lawsuit challenging manufacturer's representations about FDA-regulated qualified health claim).

256. See *supra* Part I.A.3.

257. See *supra* Part I.A.

258. See Kim Schmid, Jenny Young & Katherine Fillmore, *Gray Zone Between FDA and FTC Nutraceutical Regulation*, L. 360 (Aug. 13, 2013), <http://www.bowmanandbrooke.com/~media/Documents/Insights/News/2013/08/Gray%20Zone%20Between%20FDA%20And%20FTC%20Nutraceutical%20Regulation.pdf> [<http://perma.cc/V5Y9-262D>] (noting blurred lines with regard to advertisements and labels in context of nutraceuticals).

claims that have been regulated, at least in part, by the FDA. Such is the case in the recently filed lawsuit of *Federal Trade Commission v. Gerber Products Co.*<sup>259</sup> Gerber has pleaded the affirmative defenses of preclusion and primary jurisdiction, arguing that the FDA is the only agency with authority to address the disputed health claims.<sup>260</sup>

The action, filed in October, 2014 in the District of New Jersey, alleged that Gerber violated the FTC Act through the “labeling, advertising, marketing, distribution, and sale” of its infant formula, Gerber Good Start Gentle.<sup>261</sup> The FTC’s complaint challenged representations made in a variety of media: television commercials, print advertisements, supermarket displays, a gold sticker affixed to the formula container, and a badge on the formula label.<sup>262</sup> Specifically, the complaint alleged that in 2005, Gerber sought FDA health claim approval for the relationship between the whey protein in its formula and a reduced risk of food allergies.<sup>263</sup> The FDA rejected this petition, finding that it was not scientifically supported.<sup>264</sup> Three years later, Gerber sought health claim approval based on “emerging clinical results” for the relationship between whey protein and atopic dermatitis.<sup>265</sup> The FDA did not authorize the health claim, but it did issue a letter permitting Gerber to make the following qualified health claim: “the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of atopic dermatitis is uncertain, because there is little scientific evidence for the relationship.”<sup>266</sup> Gerber marketed its infant formula with a gold badge affixed to the label that read, “1st and Only, Meets FDA Qualified Health Claim.”<sup>267</sup> Another sticker affixed to the formula canister boasted the relationship between its formula and a reduction in the risk of allergies: “1st & ONLY Routine Formula TO REDUCE THE RISK OF DEVELOPING ALLERGIES.”<sup>268</sup> Based on these facts, the FTC complaint made two claims.<sup>269</sup> First, it alleged that Gerber made false, misleading, or unsubstantiated claims based on its express or implied representation that “feeding Gerber Good Start Gentle formula to infants with a family history of allergies prevents or reduces the risk that they will develop allergies.”<sup>270</sup> Second, the complaint alleged that Gerber expressly or impliedly represented that its formula “qualified for or received approval for a health claim” from the FDA,

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259. See Complaint, *supra* note 13.

260. Answer, *Gerber Products Co.*, No. 2:14-cv-06771-SRC-CLW, at 6, 8 (see Gerber’s third and fourteenth affirmative defenses).

261. Complaint, *supra* note 13, at 2.

262. *Id.* at 3-6.

263. *Id.* at 7.

264. *Id.* at 7-8.

265. *Id.* at 8.

266. *Id.*

267. *Id.*

268. *Id.* at 5 (emphasis in original).

269. *Id.* at 9-10.

270. *Id.* at 9.

when, in fact, no such approval was given.<sup>271</sup>

The *Gerber* case provides a vehicle to examine the preclusion and primary jurisdiction doctrines in the context of the overlapping jurisdiction of the FTC and the FDA. The FTC is bringing an action involving—at least in part—health claims on food labels that the FDA has already regulated. As noted in Part I.A., regulation of food labels has traditionally fallen to the FDA, while regulation of food advertising has fallen to the FTC.<sup>272</sup> The FTC has expressed its willingness to defer to the FDA’s conclusions with regard to the scientific substantiation of health claims and qualified health claims.<sup>273</sup> Here, the FDA has already evaluated Gerber’s scientific evidence, denied approval for an unqualified health claim, and issued a letter of enforcement discretion with regard to a qualified health claim.<sup>274</sup> Thus, to the extent Gerber is playing fast and loose with those determinations, it is clear that the FDA has enforcement authority.

At first blush, it would appear that the FTC is out of bounds and infringing on the jurisdiction of the FDA. The FTC’s first claim is that Gerber made false, misleading, or unsubstantiated claims based on its express or implied representation that “feeding Gerber Good Start Gentle formula to infants with a family history of allergies prevents or reduces the risk that they will develop allergies.”<sup>275</sup> If the FTC’s claim will require the court to reweigh or reevaluate the FDA’s findings with regard to the qualified health claim, it is likely that the court will decline to hear the dispute under either the preclusion or primary jurisdiction doctrines.<sup>276</sup> Such a question would require the court to “interpret, apply, or enforce the FDCA”<sup>277</sup>—a circumstance that requires application of the preclusion doctrine. Such an allegation may require the court to tread on areas particularly within the FDA’s expertise and may result in a second-guessing of the FDA’s determinations, thus implicating the primary jurisdiction doctrine.

On the other hand, the FDA’s exercise of regulatory authority does not, as a matter of course, prevent other agencies from regulating similar conduct.<sup>278</sup> It is clear that the FTC has broad authority to bring actions against advertisers for unsubstantiated health claims in advertisements<sup>279</sup> and as illustrated in *POM Wonderful, LLC v. Federal Trade Commission*,<sup>280</sup> the FTC has authority to dictate the type of substantiation required to support such claims. Thus, to the extent the misrepresentations at issue in *Gerber* deal with unsupported health

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271. *Id.* at 10.

272. *See supra* Part I.A.

273. *See supra* Part I.A.3.

274. Complaint, *supra* note 13, at 7-8.

275. *Id.* at 4.

276. *See supra* Parts II.A.1, II.A.3.

277. *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-cv-5852015, 2015 U.S. Dist. LEXIS 67187, at \*3 (S.D.N.Y. Mar. 24, 2015).

278. *See Childs*, *supra* note 135, at 2413-14 (discussing the FDA and the FTC’s shared jurisdiction with regard to food labeling and advertising).

279. *Id.*

280. 777 F.3d 478, 498 (D.C. Cir. 2015).

claims in advertisements—particularly those claims that are far afield from the qualified health claims the FDA evaluated and regulated—the FTC’s authority to do so is indisputable. Moreover, the more the FTC’s complaint is characterized as an action based on Gerber’s misrepresentations of the scope of FDA approval for its health claims, the more likely the case will survive preclusion and primary jurisdiction challenges.<sup>281</sup> Indeed, the FTC expressly pleaded such a count in its complaint.<sup>282</sup> Courts have held that a claim based on a misrepresentation of FDA approval is not barred by either the preclusion or primary jurisdiction doctrine.<sup>283</sup> Questions of the existence of FDA approval are simple enough for the court to answer, requiring no special agency expertise.<sup>284</sup>

Given courts’ recent reluctance to apply the doctrines of preclusion and primary jurisdiction in the context of food products,<sup>285</sup> it seems likely that the FTC will be allowed to pursue its claims, despite the fact that its claims involve two areas traditionally within the jurisdiction of the FDA: qualified health claims and product labels. Regardless, the defendant has pleaded these defenses<sup>286</sup> and if the parties do not settle their dispute, the court will have to answer these jurisdictional questions. Such a battle will undoubtedly be costly and divert the FTC’s resources away from the merits of the dispute. As discussed below, a good deal of time, energy, and expense is wasted on these jurisdictional challenges in both the private litigation and interagency contexts. Reform is needed.

### III. ANALYSIS AND POLICY RECOMMENDATIONS

As outlined in Part I, representations about a food’s health benefits can be affected by four overlapping forces: (1) regulation by the FDA of product labels; (2) enforcement actions by the FTC with regard to advertisements; (3) Lanham Act claims by competitors; and (4) state law claims by consumers.<sup>287</sup> The convergence of these forces leads to two separate jurisdictional questions. The first question, discussed in Part III.A, involves the appropriate balance between federal regulation of health claims and private actions seeking redress for misleading health claims. The jurisdictional doctrines of preclusion, preemption, and primary jurisdiction operate as burdensome roadblocks to private enforcement and they serve only to drain judicial resources and delay resolution of disputes on the merits. To remedy this problem, the NLEA’s express preemption provision should be repealed<sup>288</sup> and the FDCA should be amended to allow expressly private actions for violations of the NLEA.

The second jurisdictional question, discussed in Part III.B, involves the

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281. *See supra* Parts II.A.1, II.A.3.

282. Complaint, *supra* note 13, at 10.

283. *See supra* Parts II.A.1; II.A.3.

284. *See id.*

285. *See id.*

286. Answer, *supra* note 260, at 6, 8.

287. *See supra* Part I.

288. *See* Winters, *supra* note 8, at 861-62 (concluding that the NLEA is a “failed statute” and urging the repeal of portions of the NLEA, including its express preemption provision).

interagency overlap between the FDA and the FTC with regard to food health claim regulation. Health claims on a product label can overlap with health claims in an advertisement and the doctrines of preclusion and primary jurisdiction can be used to bar FTC enforcement actions in this area.<sup>289</sup> Congress should clarify the roles of the two agencies with regard to the regulation of food health claims to neutralize the effects of the preclusion and primary jurisdiction doctrines.

#### *A. Agency Enforcement Versus Private Litigation*

The inefficiencies of the FDA and its inability to regulate food labels effectively have been well documented by commentators.<sup>290</sup> Although some commentators suggest that the best way to handle the problem is to provide more funding so that the FDA can do its job better,<sup>291</sup> others propose a complete overhaul of the FDA's food labeling scheme.<sup>292</sup> Still others suggest that the FDA is so hopelessly broken that it cannot be trusted with such a task: "charging the FDA with the task of creating and policing a uniform [front of package] labeling system, when it cannot maintain its current regulatory obligations, seems unsound."<sup>293</sup> Commentators in the latter camp suggest that self-regulation of the food industry is the most effective way to prevent consumer deception: "[S]elf-regulation, which does not solely involve the bureaucracy of government rulemaking and enforcement, tends to be more efficient, which ultimately benefits the consumer with lower prices and potentially superior goods or services."<sup>294</sup> As neither additional funding, a comprehensive overhaul of the FDA's labeling system, nor sweeping self-regulation is immediately forthcoming,<sup>295</sup> litigation has stepped in to fill the regulatory void left by the

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289. See *supra* Part II.B.

290. See, e.g., Heinzerling, *supra* note 5, at 15 ("How does the government ensure compliance with the laws . . . especially with so many firms and products to oversee? The answer is simple: it does not. The ratio of enforcement-related activity . . . to the universe of potential enforcement targets is vanishingly small.").

291. See Negowetti, *supra* note 4, at 22 ("Policing labeling violations is the responsibility of the FDA, not plaintiffs' attorneys. To properly fulfill its statutory mission, the FDA will require an increased budget and the political will to monitor the marketplace.").

292. See Pomeranz, *supra* note 3, at 620 ("Specifically, the FDA needs the authority to seek civil penalties, prohibit claims proven to be deceptive, and compel companies to turn over their substantiation documents when new claims are proffered. With increased resources and authority, the FDA can meet current public health challenges and adequately ensure that labels are clear and consumers are properly informed and protected.").

293. Black, *supra* note 35, at 13.

294. *Id.* at 14.

295. See Kathryn E. Hayes, *Front-of-Package Nutrition Claims: Trustworthy Facts or Deceptive Marketing? Closing the Loopholes in Labeling*, 19 CARDOZO J.L. & GENDER 545, 547 (2013) (noting that self-regulation is ineffective because "manufacturers and retailers are more concerned with their bottom line than the greater public health"); see also Heinzerling, *supra* note 5, at 22 ("Congress has shown no interest in increasing the funds of the agencies charged with regulating food; indeed, in the Food Safety Modernization Act passed in 2010, Congress gave FDA

FDA.

If the goal is to keep manufacturers honest about their health claims, there is no doubt that litigation is an effective mechanism for doing so. Even if such suits are unsuccessful, the litigation costs alone are often sufficient to deter manufacturer misconduct. Commentators have noted the importance of private lawsuits in shaping food manufacturers' behavior<sup>296</sup> and they suggest that these lawsuits act as a complement to self-regulation in the industry.<sup>297</sup> Food manufacturers pay attention to lawsuits and work to avoid them: "to circumvent litigation, consumer satisfaction and careful attention to labeling continues to be the top priority."<sup>298</sup> Nothing gets a manufacturer's attention faster than a Lanham Act suit from a competitor or a consumer class action. As the Supreme Court noted in *POM Wonderful LLC v. Coca-Cola Co.*, competitors are often much more in tune with the advertisements, labels, and marketing strategies of others in their industry than regulators are.<sup>299</sup> Thus, businesses are excellent at sniffing out the misrepresentations of their competitors and they are well positioned to call out those manufacturers who step out of bounds. In addition, they have an incentive to pursue these claims that the FDA does not—the prospect of gaining competitive advantage. A plaintiff in a Lanham Act suit can obtain injunctive relief and damages for the commercial loss suffered as a result of the defendant's misrepresentation.<sup>300</sup>

Likewise, consumers are well positioned to bring actions challenging misleading health claims. As the end users of a product, they are the ones who have shelled out good money for a product that makes promises, and they are the ones harmed when that product does not deliver. Again, consumers have incentives to pursue these claims that the FDA lacks—money damages for the lost benefit of the bargain. Moreover, there is a benefit to having food labeling issues decided at the local level rather than the federal level. As Indiana University Robert H. McKinney School of Law Professor Diana Winters noted, "state law, both positive enactments and common law requirements, can be tailored in response to the interests of the state's populace . . . Public

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an enormous set of new responsibilities without providing any appreciable new funding to meet them.").

296. See Thompson, *supra* note 130, at 895 ("Class action lawsuits are currently, in the absence of an FDA rule, the best solution to define 'natural' and protect consumers against misleading 'natural' claims."); see also Andre, *supra* note 190, at 252 ("Thus, even though the NLEA is focused on protecting the consumer, it recognizes that it cannot do so in a comprehensive manner and that states should be allowed to fill in the gaps only if they so desire. Supporters of narrow preemption argue that instead of viewing state lawsuits as a burden on manufacturers, it should be framed as allowing states to provide their citizens with the ability to redress their harm.").

297. See Negowetti, *supra* note 205, at 356. ("The threat of a class action lawsuit or dilution of the [natural] term's impact on consumers could prompt food producers or retailers to create a uniform standard for the industry.").

298. Black, *supra* note 35, at 26.

299. *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2238 (2014).

300. 15 U.S.C. §§ 1116-1117 (2012).



participation in shaping [food] policy may be more prevalent in the enactment of state law than in federal regulation.”<sup>301</sup>

If private litigation is an effective way to fill the regulatory void left by lax FDA enforcement, then the jurisdictional doctrines of preclusion, preemption, and primary jurisdiction need to get out of the way. It is clear that these defenses are losing steam after the Supreme Court’s decision in *POM Wonderful LLC v. Coca-Cola Co.*; they will continue to be an uphill battle for defendants.<sup>302</sup> Courts recognize the inability of the FDA to police food health claims and they are taking matters into their own hands.<sup>303</sup> Thus, the trend is to allow more lawsuits to proceed rather than fewer. This trend, however, will likely not prevent manufacturers from asserting these defenses and using valuable court and party resources, thereby delaying judgment on the merits.<sup>304</sup>

Congress should recognize this trend and act accordingly.<sup>305</sup> Repealing the NLEA’s express preemption provision would limit the manufacturer’s ability to plead the preemption defense except in those truly meritorious circumstances of conflict preemption (i.e., where it is impossible for the manufacturer to comply with both the federal and the state requirements), thereby allowing courts and parties to spend more time on the merits of consumer claims. Such an act would preserve the federal government’s ability to set the NLEA’s regulations as the floor of acceptable manufacturer conduct, but it would also allow states to impose additional health claim labeling requirements where appropriate to protect consumers.

In addition, the NLEA should be amended to provide consumers with a private right of action for violation of its labeling requirements.<sup>306</sup> Such an action would allow consumers who reside in states without robust consumer protection laws to have a direct route to challenge health claims that violate the NLEA. Allowing a private right of action under the NLEA would also do much to take the defenses of preclusion and primary jurisdiction out of play in Lanham Act suits. In the wake of *POM Wonderful LLC v. Coca-Cola Co.*,<sup>307</sup> food

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301. Winters, *supra* note 8, at 860.

302. *See supra* Part II.

303. *See generally* Winters, *supra* note 8.

304. *See id.* at 848 (“Food manufacturer defendants in food labeling cases brought under state law almost always argue that these suits should not go forward because these issues are covered under federal law.”).

305. *Id.* at 861. Winters suggested that the NLEA’s express preemption provision and its provisions regarding health and nutrient content claims should be scrapped altogether, thus effectively allowing state law to define the contours of food health claim regulation. *Id.* She argued that the “NLEA’s confusing mandates—resulting in inconsistent judicial decisions on whether or not the Act preempts actions under state law—have negatively impacted the potential for actions under state law to affect the food labeling landscape.” *Id.* at 836.

306. *See* Heinzerling, *supra* note 5, at 23. (“Congress should authorize citizen suits for violations of the federal laws aimed at ensuring the integrity of verbal representations about our food.”).

307. 134 S. Ct. 2228 (2014).

manufacturers in future Lanham Act cases will undoubtedly invoke the preclusion doctrine after distinguishing the facts of the *POM Wonderful* decision and arguing that the allegations in the lawsuit *sub judice* are simply masquerading as attempts to “interpret, apply, or enforce the FDCA.”<sup>308</sup> Expressly allowing a private cause of action under the NLEA would eliminate this argument, thus allowing Lanham Act claims to proceed on the merits.

The downside of eliminating the NLEA’s preemption provision and expressly allowing private enforcement of FDA labeling regulations is that manufacturers could be subject to inconsistent regulation.<sup>309</sup> Courts in different jurisdictions could have varying interpretations of the NLEA,<sup>310</sup> food labels could be subject to additional regulations beyond NLEA’s mandates in different states. Although this appears to be a significant hurdle, it is no different than a myriad of other legal risks a nationwide manufacturer faces with regard to many aspects of its business. For instance, the legal standards involved in the resolution of tort claims vary from state to state—some states follow comparative fault; others follow contributory negligence.<sup>311</sup> States have different formulations for the determination of a design defect in product liability cases.<sup>312</sup> In addition, employment laws differ from state to state; employers must comply with these state laws as well as federal requirements.<sup>313</sup> Title VII, for example, does not contain an express preemption provision; rather it contains a savings clause that allows states to impose more stringent anti-discrimination regulations than those required by federal law.<sup>314</sup> Thus, Title VII sets the floor—not the ceiling—of acceptable employer conduct. Manufacturers have found ways to survive and thrive in the face of potentially inconsistent regulation in these areas; there is no reason to believe they will be unable to adapt in the food-labeling context.

Another objection to allowing private litigation to augment the NLEA is that

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308. *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-cv-5852015, 2015 U.S. Dist. LEXIS 67187, at \*3 (S.D.N.Y. Mar. 24, 2015).

309. *See* Winters, *supra* note 8, at 865-66. Winters discussed this criticism and noted that manufacturers are already subject to inconsistent results with regard to health claim regulation because courts are filling in the gaps where the FDA has failed to set forth clear guidelines.

310. *See id.*

311. *See* Donald G. Gifford & Christopher J. Robinette, *Apportioning Liability in Maryland Tort Cases: Time to End Contributory Negligence and Joint and Several Liability*, 73 MD. L. REV. 701, 707 (2014) (discussing varying approaches to the comparative fault and contributory negligence doctrines).

312. *See* Jason M. Solomon, *Juries, Social Norms, and Civil Justice*, 65 ALA. L. REV. 1125, 1198 (2014) (discussing the differences between the consumer expectation test and the risk utility test).

313. *See id.* at 1200.

314. 42 U.S.C. § 2000e-7 (2012) (“Nothing in this subchapter shall be deemed to exempt or relieve any person from any liability, duty, penalty, or punishment provided by any present or future law of any State or political subdivision of a State, other than any such law which purports to require or permit the doing of any act which would be an unlawful employment practice under this subchapter.”).

the benefit of agency expertise would be lost if NLEA violations were litigated by private parties in court rather than decided by experts at the FDA. The idea that the FDA is the only entity qualified to address issues of the scientific foundation for health claims is largely unfounded.<sup>315</sup> Courts and juries hear disputes daily that require them to evaluate scientific evidence. Toxic tort, environmental, medical malpractice, and product liability claims all involve large amounts of expert testimony and complicated scientific issues. Juries handle complex scientific matters every day; they are equally competent to decide matters of scientific importance in the context of food.

As illustrated above, private litigation can fill the regulatory gap left by lax FDA enforcement of the NLEA. Courts in a post-*Pom Wonderful LLC v. Coca Cola Co.* world have been reluctant to apply the doctrines of preclusion, preemption, and primary jurisdiction to bar private litigation, but these doctrines continue to be asserted and vigorously litigated by defendants.<sup>316</sup> To allow courts to spend more time on the merits and less time on burdensome jurisdictional motion practice, the NLEA's express preemption provision should be repealed and consumers should have a private right of action to enforce the FDA's food health claim regulations. These measures would lessen the impact of the jurisdictional doctrines discussed herein and expressly recognize the roles of the competitor and the consumer in shaping food-labeling policy.

#### *B. Resolution of Interagency Jurisdictional Issues*

Not only have jurisdictional doctrines been raised to foil the attempts of private litigants who seek redress for misleading health claims, but they have also been raised in an effort to block enforcement actions by another regulatory agency, the FTC.<sup>317</sup> The traditional division of labor between the FTC and the FDA with regard to such claims is that the FTC has enforcement authority over advertisements while the FDA has authority over labels.<sup>318</sup> But as *Federal Trade Commission v. Gerber Products Co.* illustrates, the line between a label and an advertisement is not always easy to define, particularly where the FDA has engaged in some regulatory activity with regard to the health claim at issue.<sup>319</sup> Defendants in FTC enforcement actions that address misleading health claims can thus raise the arguments of preclusion and primary jurisdiction in an effort to force the case back into the lap of the FDA, an agency that is unlikely to pursue it.<sup>320</sup>

Removing the express preemption provision in the NLEA and expressly

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315. See Winters, *supra* note 8, at 859 ("This perception, that the expertise of the FDA in the matters under its jurisdiction is primary and superior, is long-standing and provides the basis for judicial deference arguments, as well as the justification for regulation. Here, however, the perception is wrong.").

316. See *supra* Part II.A.

317. See *supra* Part II.B.

318. See *supra* Part I.A.

319. See *supra* Part II.B.

320. *Id.*

allowing a private right of action for NLEA violations would lend support to the argument that neither the preclusion nor primary jurisdiction doctrine bars the FTC's enforcement actions in this context. Such legislative action would evidence Congress' intent to open areas traditionally within the FDA's exclusive authority to other enforcement mechanisms, including enforcement by another agency. Regardless, Congress should more clearly define the respective roles of these agencies with regard to representations about a food's health benefits. This action would lessen the impact of costly jurisdictional battles that serve only to drain the resources of the FTC.

### *C. Industry Guidance*

Over the past decade, consumers have seen a large increase in the volume and verbiage of food health claims and this trend does not seem to be going away at any point in the near future. As a result, companies that want to make food health claims on their product labels or in advertisements need to consider (1) how to act in the best interest of their consumers and (2) how to provide reliable information to consumers while minimizing the risk of litigation. Each of these issues is discussed below.

*1. Consumer Welfare.*—The food and beverage industry should first and foremost be concerned about the effects of food health claims on consumer health and decision-making. Prior research on the marketing of foods and beverages has shown that consumers generally benefit from increased health information on product packages and in advertisements.<sup>321</sup> Specifically, consumers use the information provided in health claims to make decisions about what is going to be the healthiest food for themselves as well as their family members. Consumers use this information to determine what types and quantities of nutrients are in their food and to understand the effects of these foods on their health. For example, someone who has diabetes needs to know how many carbohydrates are in a food product; an individual who has high cholesterol might want to know how much fat is in a food product. Marketing research also shows that consumers get confused by excess verbiage in qualified health claims and might not have the necessary knowledge to be able to interpret the intention behind the health claim.<sup>322</sup> Given the fact that consumers rely on these

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321. See generally My Bui et al., *Front-of-Package Product Labels: Influences of Varying Nutritional Food Labels on Parental Decisions*, 22 J. PROD. & BRAND MGMT. 352, 353 (2013); Lara Spiteri Cornish, *It's Good for Me: It Has Added Fibre! An Exploration of the Role of Different Categories of Functional Foods in Consumer Diets*, 11 J. CONSUMER BEHAV. 292, 296 (2012); Karen Russo France & Paula Fitzgerald Bone, *Conveying Level of Science: Tests of Iconic and Comparative Formats*, 20 MKT. LETTERS 385, 395 (2009); John C. Kozup et al., *Making Healthful Food Choices: The Influence of Health Claims and Nutrition Information on Consumers' Evaluations of Packaged Food Products and Restaurant Menu Items*, 67 J. MKT. 19, 25 (2003); Gail M. Zank & Elyria Kemp, *Examining Consumers' Perceptions of the Health Benefits of Products with Fiber Claims*, 43 J. CONSUMER AFF. 333, 343 (2012).

322. See generally Sophie Heike & Charles R. Taylor, *A Critical Review of Literature on Nutrition Labeling*, 46 J. CONSUMER AFF. 120, 133-34 (2012); Jeremy Kees et al., *Regulating*

representations to make decisions about what and how much to eat and the fact that they tend to be confused by complex health claims, the food and beverage industry should be concerned by how consumers interpret and use such information.

2. *Implications for the Food and Beverage Industry.*—The legal rulings and regulations discussed in the majority of this Article have a significant effect on how information can and should be communicated to consumers. The NLEA mandates that consumers be apprised of the nutritional content of food and beverages.<sup>323</sup> In addition, FDA regulations and FTC oversight bear on the way health claims should to be worded on a product package and in an advertisement.<sup>324</sup> To make all of this as clear as possible to the consumer, producers should carefully consider the claims that they make on products labels, promotions, and advertisements. Food producers making front-of-package claims, which are regulated primarily by the FDA, should keep the claims relatively simple. This could be accomplished in two ways, either by making straightforward nutrient-content claims or by making only those authorized health claims that have been expressly approved by the FDA. In both cases, the language associated with the claim is kept to a minimum, which is usually beneficial for marketers trying to manage the aesthetics of a product package. Adhering to the FDA-approved language for authorized health claims and nutrient-content claims will reduce the likelihood of a consumer class action or an enforcement action by the FTC.<sup>325</sup> With regard to qualified health claims, the FDA requires disclaimers that discuss the scientific certainty of the claim.<sup>326</sup> These disclaimers are often lengthy and cannot reasonably fit on a product label.<sup>327</sup> Manufacturers should resist the temptation to “summarize” these qualifiers in order to fit them onto a product label.<sup>328</sup> Departing from the FDA’s recommended disclaimer language opens the manufacturer to consumer lawsuits and FTC scrutiny. For example, it is Gerber’s alleged mischaracterization of FDA approval of its qualified health claim that is the subject of the lawsuit filed by the FTC.<sup>329</sup>

In other sorts of promotional tools, such as advertisements, marketers find more room to include the disclaiming language of a qualified health claim. As such, members of the food and beverage industry should consider saving qualified health claims for their advertising campaigns, where they have space to include a discussion of the scientific certainty of the claim. Under these circumstances, manufacturers should use the exact, verbatim language

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*Front-of-Package Nutrition Information Disclosures: A Test of Industry Self-Regulation vs. Other Popular Options*, 48 J. CONSUMER AFF. 147 (2014).

323. See *supra* Part I.A.1.

324. See *supra* Part I.A.

325. See Masaitis & Woolley, *supra* note 8.

326. See *id.*

327. See *id.*

328. See *id.*

329. See *supra* Part II.B.

recommended by the FDA in its letter of enforcement discretion.<sup>330</sup> Consumers are accustomed to hearing or reading warning and disclaimer language during advertisements in a variety of health-related product categories (e.g., pharmaceuticals, health behavior change programs and products, etc.); accordingly, they will likely not be surprised to hear disclaiming language accompanying health claims in the food and beverage context. In short, manufacturers can deal fairly with consumers and avoid litigation if they ensure that the representations about their products conform to FDA guidelines and are supported by solid scientific research.<sup>331</sup>

#### CONCLUSION

It is clear that the FDA lacks the resources and manpower to monitor every health claim asserted by every food producer. Although lawsuits filed by competitors, consumers, and the FTC can lessen the FDA's burden, the doctrines of preclusion, preemption, and primary jurisdiction create unnecessary roadblocks to these claims. Parties spend too much time litigating these threshold jurisdictional questions, time that would be better spent on the merits of the underlying claims. Congress should remove these barriers to private enforcement by eliminating the NLEA's express preemption provision and creating a private right of action for NLEA violations. In addition, Congress should clarify the roles of the FTC and the FDA with regard to food health claims. Such a clarification would answer the jurisdictional objections posed by defendants in FTC enforcement actions. Finally, manufacturers seeking to avoid litigation and to act in the best interest of their customers should carefully follow FDA guidelines and make only those health representations that are supported by solid scientific evidence.

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330. See Masaitis & Woolley, *supra* note 8.

331. See Berman, *supra* note 111, at 102 (“[When making] disease-related claims in advertising, firms should be prepared to show FTC staff that their studies are valid and the results are legitimate . . . . Accordingly, advertisers should keep records relating to studies protocols, instructions to and communications with participants, statistical analyses of test data, and any materials relating to sponsorship of their human clinical studies.”).