Loyola University Chicago Law Journal

Volume 47
Issue 1 *Fall 2015*

Article 8

2015

The Lanham Act's Wonderful Complement to the FDCA: *POM Wonderful v.Coca-Cola* Enhances Protection Against Misleading Labeling Through Integrated Regulation

Jennifer Thurswell Radis

Note

The Lanham Act's Wonderful Complement to the FDCA: *POM Wonderful v. Coca-Cola* Enhances Protection Against Misleading Labeling Through Integrated Regulation

*Jennifer Thurswell Radis**

POM Wonderful sued Coca-Cola under the Lanham Act claiming that it suffered losses due to the misleading label on Coca-Cola's Minute Maid brand's Pomegranate Blueberry juice blend. Reversing the Ninth Circuit's decision in June 2014, the Supreme Court found that POM's claim was not precluded even though the label was regulated by the FDCA. In fact, the Court acknowledged the complementary nature of private enforcement with FDA regulation, as it did in Wyeth v. Levine *in 2009. This Article submits that* POM *exemplifies the Court's willingness to strengthen the Lanham Act's protections against misleading labeling, as it did the same year in* Lexmark International, Inc. v. Static Control Components, Inc. *This Article also characterizes* POM *as an endorsement of an integrated regulation scheme with private claims for commercial losses due to false or misleading labeling serving to complement FDA regulation. By combining private enforcement with FDA regulation, this Article proposes that* POM *will ultimately benefit consumers and competitors by demanding greater accuracy in food and beverage labeling.*

* B.A., University of Michigan, Ann Arbor, 1993; J.D. Candidate, Loyola University Chicago School of Law, 2016. This article is dedicated to Harrison, Phoebe, and Ruby.

INTRODUCTION

Obesity and diet-related diseases have become epidemic in the United States,[1] yet, paradoxically, American consumers regularly report

1. David Burnett, *Fast-Food Lawsuits and the Cheeseburger Bill: Critiquing Congress's Response to the Obesity Epidemic*, 14 VA. J. SOC. POL'Y & L. 357, 358 (2007) (citing OFFICE OF THE SURGEON GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., THE SURGEON GENERAL'S CALL TO ACTION TO PREVENT AND DECREASE OVERWEIGHT AND OBESITY 4–7 (2001), http://www.surgeongeneral.gov/topics/obesity/calltoaction/CalltoAction.pdf ("Obesity is a serious problem in contemporary America. . . . In 2001 the Surgeon General of the United States reported that 300,000 deaths a year can be attributed to obesity, and that obese individuals have a fifty to one hundred percent increased risk of premature death from weight-related health

an interest in making healthy eating choices.[2] Consumers frequently rely on the information provided on food and beverage labels to make dietary decisions.[3] Yet, studies have shown that consumers are often confused or misled by the labels.[4] Thus, misinformation not only influences purchasing decisions,[5] but also consumer determinations about how much of a product to eat and who will eat it are often founded on inaccurate data.[6] Therefore, truthful and clear labeling is essential for consumers to make informed choices.[7]

However, food and beverage manufacturers have an interest in marketing their products to health-conscious consumers, and thus often exaggerate or fabricate healthful qualities of their products.[8] This

---

problems.").

2. Nicole E. Negowetti, *Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority*, 2014 GOVERNANCE STUD. BROOKINGS 5–6; Jennifer L. Pomeranz, *Litigation to Address Misleading Food Label Claims and the Role of the State Attorneys General*, 26 REGENT U. L. REV. 421, 421 (2014) [hereinafter Pomeranz, *Litigation*].

3. U.S. GOV'T ACCOUNTABILITY OFF., GAO-11-102, FOOD LABELING: FDA NEEDS TO REASSESS ITS APPROACH TO PROTECTING CONSUMERS FROM FALSE OR MISLEADING CLAIMS 1 (2011) [hereinafter GAO, 2011] ("Consumers increasingly seek information on food labels to help them make healthy food choices." (footnote omitted)); *Fooled by Food Labels: 9 Deceptive Claims to Watch Out For*, CNCA HEALTH, http://www.cncahealth.com/explore/learn/nutrition-food/fooled-by-food-labels-9-deceptive-claims-to-watch-out-for#.VFajn74lofk [https://web.archive.org/web/20141125181005/http://www.cncahealth.com/explore/learn/nutrition-food/fooled-by-food-labels-9-deceptive-claims-to-watch-out-for#.VgQ7_I9Viko] (last visited Sept. 24, 2015) [hereinafter CNCA] ("The majority of Americans rely on food labels to give them an accurate picture of the nutritional content of the foods they buy for themselves and their families.").

4. Jennifer L. Pomeranz, *A Comprehensive Strategy to Overhaul FDA Authority for Misleading Food Labels*, 39 AM. J.L. & MED. 617, 621 (2013) [hereinafter Pomeranz, *Strategy*]; Jennifer L. Harris et al., *Nutrition-Related Claims on Children's Cereals: What Do They Mean to Parents and Do They Influence Willingness to Buy?*, 14 PUB. HEALTH NUTRITION 2207, 2207 (2011).

5. 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 misleading labeling encourages "consumers to choose highly processed foods and refined grains instead of fruits, vegetables and whole grains").

6. *See* Claudia L. Andre, *What's in That Guacamole? How* Bates *and the Power of Preemption Will Affect Litigation Against the Food Industry*, 15 GEO. MASON L. REV. 227, 229 (2007) ("Misleading labels could affect consumers' food choices and ultimately have an effect on consumer health."); Hayes, *supra* note 5, at 19 ("[C]ompanies are cashing in on health-conscious shoppers by creating deceptive marketing and labeling for children's food products, misleading consumers into believing they are making healthier choices.").

7. Alan D. Mathios, *The Impact of Mandatory Disclosure Laws on Product Choices: An Analysis of the Salad Dressing Market*, 43 J.L. & ECON. 651, 671 (2000) (finding that food labels have an impact on consumer food choices); Maggie LaBarbera, *Reading Food Labels - How Does It Help Buy Healthier Foods*, NOURISH INTERACTIVE (May 14, 2012), http://www.nourishinteractive.com/healthy-living/free-nutrition-articles/161-family-facts-importance-reading-food-labels ("Reading food labels will make it much easier for you to compare foods and find the foods that have the nutritional value your child needs.").

8. GAO, 2011, *supra* note 3, at 1; CNCA, *supra* note 3 ("It's no secret that food manufacturers

common practice undermines consumers' attempts to eat healthier and feed their families appropriately.[9] It also harms competing manufacturers who may lose customers when misleading labels deceive consumers and divert their sales.[10] In this context, the Lanham Act, which prohibits misleading labeling as unfair competition, provides manufacturers with a civil remedy if they suffer lost sales that are proximately caused by misleading labeling.[11]

The Food and Drug Administration ("FDA") regulates food and beverage marketing, and specifically prohibits false or misleading labeling, pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA").[12] The FDA faces significant enforcement limitations, however, due in part to insufficient funding,[13] inadequate enforcement authority,[14] and perhaps agency capture.[15] As a result, foods are regularly sold bearing false or misleading labels,[16] many of which are arguably FDA compliant.[17] For example, one of Coca-Cola's Minute

---

often stretch the regulatory limits on food packages to make their products appeal to consumers, and sometimes their claims are downright fraudulent.").

9. GAO, 2011, *supra* note 3, at 1*;* CNCA, *supra* note 3 ("[M]any food labels are incredibly misleading, leading you to think you're choosing healthy foods when you're really not.").

10. Pomeranz, *Strategy*, *supra* note 4, at 621; *see also infra* notes 389, 407–11 and accompanying text (discussing competitive marketing strategies and effects).

11. 15 U.S.C. § 1125(a)(1) (2012); Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1391 (2014). However, the Lanham Act only protects against commercial injuries and is not available to consumers. *Lexmark*, 134 S. Ct. at 1390.

12. 21 U.S.C. § 343 (2012); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-597, FOOD LABELING: FDA NEEDS TO BETTER LEVERAGE RESOURCES, IMPROVE OVERSIGHT, AND EFFECTIVELY USE AVAILABLE DATA TO HELP CONSUMERS SELECT HEALTHY FOODS 1 (2008) [hereinafter GAO, 2008]; U.S. FOOD & DRUG ADMIN., FOOD FACTS: FOOD ALLERGIES 1 (2010), http://www.fda.gov/downloads/Food/ResourcesForYou/Consumers/UCM220117.pdf ("FDA regulates the labeling of all foods, except for poultry, most meats, certain egg products, and most alcoholic beverages.").

13. Pomeranz, *Strategy*, *supra* note 4, at 619 (2013); *see infra* Part I.A (discussing FDA enforcement limitations).

14. Negowetti, *supra* note 2, at 3; *see infra* Part I.A (discussing enforcement limitations).

15. 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, 978 (2008); *see also* RICHARD J. PIERCE, JR. ET AL., ADMINISTRATIVE LAW AND PROCESS § 1.72 (2d ed. 1992) ("An agency is captured when it favors the concerns of the industry it regulates, which is well-represented by its trade groups and lawyers, over the interests of the general public, which is often unrepresented."); *see infra* Part I.A (discussing enforcement limitations).

16. *The Impact of the Nutrition Labeling and Education Act of 1990 on the Food Industry*, 47 ADMIN. L. REV. 605, 606 (1995) ("[I]n the last decade, the food industry has used [the link between diet and disease prevention] to its own advantage, flooding the market with food labels that are full of false and misleading health claims.") [hereinafter *Impact of the NLEA*]; *Regulation of Dietary Supplements: Hearing Before the Subcomm. on Agric. of the H. Comm. on Appropriations*, 103d Cong. 63–66 (1993) [hereinafter *Supplements Hearing*] (testimony of FDA commissioner, Dr. David A. Kessler).

17. Pomeranz, *Strategy*, *supra* note 4, at 618; *see infra* notes 71–73, 397 and accompanying

Maid juices was made almost entirely of apple and grape juice, but its label displayed the name "Pomegranate Blueberry" in large lettering, with the words "Flavored Blend of 5 Juices" below in much smaller type.[18] This label arguably misled consumers into thinking that the product contained substantial amounts of pomegranate and blueberry juice,[19] yet it technically conformed to FDA labeling requirements.[20]

POM Wonderful LLC ("POM"), a manufacturer of pure pomegranate juice and pomegranate juice blends,[21] sued Coca-Cola under the Lanham Act, claiming that Coca-Cola's misleading juice label diverted some of POM's market share to Coca-Cola.[22] The lower federal courts found that allowing POM's claim to proceed would undermine the FDA and its enforcement authority under the FDCA.[23] Reasoning that Congress intended to give the FDA exclusive regulatory authority over food labeling, the lower courts held that Lanham Act challenges to

---

text (discussing food labels that are misleading but not in violation of FDA regulations).

18. Brief for Petitioner at 2, POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228 (2014) (No. 12-761) [hereinafter Petitioner's Brief] ("Over 99% of the product is apple and grape juice. The amounts of pomegranate and blueberry juice it contains [are] 0.3% and 0.2% respectively."); Susan Berfield, *Pom Wins in the Supreme Court. Now it's Pom v. Coke, Round 2*, BLOOMBERG BUS. (JUNE 12, 2014), http://www.businessweek.com/articles/2014-06-12/supreme-court-rules-pom-wonderful-can-sue-Coke-over-misleading-label ("Coca-Cola's Pomegranate Blueberry juice is 99.4 percent apple and grape juice.").

19. Petitioner's Brief, *supra* note 18, at 3 ("A consumer survey . . . showed that consumers are misled in large numbers to believe that Coca-Cola's product actually has substantial amounts of pomegranate and blueberry juice."); Eric Goldman, *Previewing A "Juicy" Supreme Court Case on Food Labeling Regulation*, FORBES (Apr. 21, 2014, 3:30 AM), http://www.forbes.com/sites/ericgoldman/2014/04/21/previewing-a-juicy-supreme-court-case-on-food-labeling-regulation/ ("Pom introduced survey and other evidence that consumers over-estimated the amount of pomegranate and blueberry juice in Coca-Cola's product.").

20. Brief in Opposition to Petition at 2, POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228 (2014) (No. 12-761) (noting that FDA regulations expressly authorize Coca-Cola's label); Aimee Picchi, *In Juicy Battle with Coke, Supreme Court Sides with POM*, CBS NEWS (June 12, 2014, 11:55 AM), http://www.cbsnews.com/news/in-a-juicy-battle-with-coke-supreme-court-sides-with-pom/.

21. POM's pomegranate blueberry juice blend contains 85% pomegranate and 15% blueberry juices. *POM Blueberry*, POM WONDERFUL, http://www.pomwonderful.com/pomegranate-products/juice/blueberry/ (last visited Sept. 24, 2015); Danielle Wiener-Bronner, *Pom Wonderful Can Sue Coca-Cola for False Advertising*, WIRE (June 12, 2014, 11:38 AM), http://www.thewire.com/national/2014/06/pom-wonderful-can-sue-coca-cola-for-false-advertising/372653/.

22. Petitioner's Brief, *supra* note 18, at 3; POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2235 (2014).

23. *See* POM Wonderful LLC v. Coca-Cola Co., 679 F.3d 1170, 1178 (9th Cir. 2012) ("In concluding that POM's claim is barred, we do not hold that Coca–Cola's label is non-deceptive. . . . We are primarily guided in our decision . . . by Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling."); *False Advertising/Unfair Competition*, 26 BUS. TORTS REP. 258, 259 (2014) [hereinafter *False Advertising*].

FDA-regulated labels are barred.[24]

In June 2014, the Supreme Court reversed, finding no evidence to suggest that Congress intended the FDCA to preclude Lanham Act claims.[25] As Lanham Act suits reveal instances of misleading labeling and deter deceptive marketing practices, the Court reasoned that the two Acts actually complement each other in regulating food labels.[26] Therefore, the Court held that competitors may file Lanham Act claims challenging FDA-compliant labels as misleading.[27]

Part I of this Article provides a background of FDA regulation and illustrates the Supreme Court's acknowledgement of the complementary nature of private enforcement with FDA regulation in the 2009 case, *Wyeth v. Levine*.[28] Part I also explores the Lanham Act and the Court's willingness to strengthen the Act's protections against misleading labeling in its March 2014 decision, *Lexmark International, Inc. v. Static Control Components, Inc*.[29] Part II offers a discussion of the opinion in *POM Wonderful LLC v. Coca-Cola Co.*,[30] and Part III analyzes the decision, finding it consistent with prior holdings and an endorsement of an integrated regulation scheme between the complementary enforcement methods of the FDA and the Lanham Act.[31] Part IV discusses the expected impact of *POM* and concludes that by combining private enforcement with FDA regulation, *POM* will ultimately benefit consumers and competitors by demanding greater accuracy in food and beverage labeling.[32]

I. BACKGROUND

The nature of today's food environment is viewed as a leading cause of obesity, heart disease, diabetes, and other diet-related illnesses.[33]

---

24. *POM*, 679 F.3d at 1175–76; POM Wonderful LLC v. Coca-Cola Co., 727 F. Supp. 2d 849, 872 (C.D. Cal. 2010).

25. *POM*, 134 S. Ct. at 2233; *False Advertising*, *supra* note 23, at 259.

26. Private enforcement of the Lanham Act's prohibition against deceptive labeling reveals instances of misleading labeling and deters deceptive marketing practices. *POM*, 134 S. Ct. at 2238; *see infra* Parts II.C, III.E (discussing the complementary nature of private claims with FDA enforcement).

27. *POM*, 134 S. Ct. at 2233; *see infra* Part II (discussing the *POM* opinion).

28. *See infra* Part I.B.1 (discussing Wyeth v. Levine, 555 U.S. 555 (2009), and state law claims challenging FDA-regulated products).

29. *See infra* Part I.B.2 (discussing the Court's treatment of the Lanham Act in Lexmark International, Inc. v. Static Control Components, Inc.,134 S. Ct. 1377 (2014)).

30. *See infra* Part II (discussing the Court's decision in POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228 (2014)).

31. *See infra* Part III (analyzing the *POM* decision).

32. *See infra* Part IV (discussing the impact of the *POM* ruling).

33. William Kasapila & Sharifudin Shaarani, *Harmonisation of Food Labeling Regulations in*

While 64% of U.S. adults recognize the value of maintaining a healthy diet, more than 35% of adults suffer from obesity.[34] Experts contend that one of the causes of this disparity is the proliferation of food labels that create the misleading impression that unhealthy foods are nutritious.[35] While standardized ingredient panels and nutritional information are required on food packaging under federal regulations,[36] food manufacturers use the rest of the label as a point-of-purchase marketing device to induce consumers to purchase their goods.[37] With greater public awareness of the importance of nutrition in health and disease prevention, manufacturers have focused much of their food label marketing to appeal to this greater demand.[38]

Exploiting the demand for healthier foods, manufactures fill grocery stores with products making various nutritive claims that often fall short of representing the product's actual dietary impact.[39] For example,

---

Southeast Asia: Benefits, Challenges and Implications, 20 ASIA PAC. J. CLINICAL NUTRITION 1, 1 (2011); Pomeranz, *Litigation*, *supra* note 2, at 1.

34. Negowetti, *supra* note 2, at 5–6 ("While the Center for Disease Control (CDC) reports that more than one-third of U.S. adults (35.7%) are obese, a 2013 Healthy Eating Consumer Trend Report shows that sixty-four percent (64%) of consumers (an increase from fifty-seven percent (57%) in 2010) agree on the importance of healthy eating and nutrition." (footnote omitted)); *see also* Melissa M. Card, *America, You Are Digging Your Grave with Your Spoon—Should the FDA Tell You That on Food Labels?*, 68 FOOD & DRUG L.J. 309 (2013) ("Obesity contributes to an estimated 400,000 deaths in the United States each year.").

35. Pomeranz, *Strategy*, *supra* note 4, at 630; s*ee also* Negowetti, *supra* note 2, at 6 ("The 'American obesity paradox' . . . may be explained by the so-called 'health-halo' claims made on foods. The theory is that people tend to overestimate the healthfulness of a food based on one perceived attribute of the food . . . . With claims such as 'natural' on processed foods, consumers feel better about eating these convenience foods even though they may in fact be anything but 'natural.' Judging a food as more healthful, may lead people to eat more of that food."); Charles J. Walsh & Marc S. Klein, *From Dog Food to Prescription Drug Advertising: Litigating False Scientific Establishment Claims Under the Lanham Act*, 22 SETON HALL L. REV. 389, 398 (1992) ("While truthful information empowers consumers to maximize utility, erroneous information may lead them to make incorrect decisions.").

36. Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 343**–**l(a)(3) to (a)(4) (2012); Pomeranz, *Litigation*, *supra* note 2, at 421.

37. Pomeranz, *Litigation*, *supra* note 2, at 421–22; *cf.* Tanya Joliffe & Nicole Nichols, *The Loopholes of Food Labeling*, SPARKPEOPLE, http://www.sparkpeople.com/resource/nutrition_articles.asp?id=153 (last visited Oct. 5, 2015) ("As a consumer, your best option is to disregard the claims on the front of the package because, while they may be true, it may not tell you the whole story.").

38. Pomeranz, *Litigation*, *supra* note 2, at 422; *cf.* Joliffe & Nichols, *supra* note 37 ("No matter what the fad is—low-carb, fat-free, organic, or heart-healthy—manufacturers will try to lure you into buying their product.").

39. Tamara Duker Freuman, *When Nutrition Labels Lie*, U.S. NEWS & WORLD REP. (Aug. 21, 2012, 12:50 PM), http://health.usnews.com/health-news/blogs/eat-run/2012/08/21/whennutrition-labels-lie; *see* Margaret A. Hamburg, Comm'r, U.S. Food & Drug Admin., Remarks at the Atlantic Food Summit (Mar. 4, 2010) (transcript available at http://www.fda.gov/newsevents/speeches/ucm209924.htm) ("Recently, . . . with consumers' growing interest in eating healthy,

while federal regulations require food labels to display names that accurately describe the products,[40] foods continue to have names that do not comply with this instruction by referring to flavors rather than ingredients.[41] Kellogg's Frosted Mini-Wheats Blueberry cereal, for instance, is not made with any blueberries.[42] Not only are foods regularly marketed with confusing labels that violate federal regulations, many have labels that while technically FDA compliant, are nonetheless misleading to consumers.[43] The label on Thomas' Original Made with Whole Grains English Muffins extols "the goodness of whole grains," yet the main ingredient is processed flour that has been stripped of the bran, germ, and nutrients of whole grain.[44] As studies show that many food labels confuse or deceive consumers, health experts are calling for greater oversight of food labeling practices.[45]

---

we've seen the emergence of eye-catching claims and symbols on the front of food packages that may not provide the full picture of their products' true nutritional value.").

40. 21 C.F.R. § 102.5(a) (2015).

41. Pomeranz, *Strategy*, *supra* note 4, at 625–26; *see infra* notes 71–73 and accompanying text (discussing labels that remain misleading under FDA naming regulations).

42. *Kellogg's Frosted Mini-Wheats Blueberry Cereal*, KELLOGG'S, http://www.frostedminiwheats.com/Products/Blueberry-muffin (last visited Sept. 13, 2015); *see also* Mike Adams, *Investigation: Breakfast Cereal "Fruits" and "Berries" Are Faked; Made from Crazy Chemicals*, NAT. NEWS, http://www.naturalnews.com/fake-fruit-breakfast-cereals.html (last visited Sept. 13, 2015) ("Kellogg's Frosted Mini-Wheats Blueberry cereal . . . contains no blueberries!"). Similarly, Yoplait's Simply Go-Gurt brand "Strawberry" and "Mixed Berry" flavored yogurt tubes do not contain strawberries or any type of berries. *See Yoplait Simply Go-Gurt*, YOPLAIT, http://www.yoplait.com/products/yoplait-simply-go-gurt (last visited Sept. 24, 2015). It is not reasonable to take all food labels literally, however, and thus the maker of Captain Crunch cereal was not liable just because "Crunchberries" did not contain any real berries. *See* Sugawara v. Pepsico, Inc., No. 2:08-CV-01335-MCE-JFM, 2009 U.S. Dist. LEXIS 43127, at *8, *12 (E.D. Cal. May 21, 2009).

43. Pomeranz, *Strategy*, *supra* note 4, at 618 ("Current food labeling practices include both actual misbranding and permissible but potentially misleading claims about the healthfulness of processed foods."); Freuman, *supra* note 39 ("Nutrition Facts labels are not always factual . . . the law allows a pretty lax margin of error—up to 20 percent—for the stated value versus actual value of nutrients."); Catherine Zuckerman, *Food Fraud: Labels on What We Eat Often Mislead*, NAT'L GEOGRAPHIC (July 12, 2013), http://news.nationalgeographic.com/news/2013/07/130712-food-fraud-science-economic-adulteration-seafood-honey-juice/.

44. *Thomas' Original Made with Whole Grains English Muffins*, THOMAS' BREADS, http://www.thomasbreads.com/products/original-made-whole-grains-english-muffins (last visited Sept. 24, 2015) (listing unbleached enriched wheat flour as the main ingredient); *CSPI Urges FDA Crackdown on False & Misleading Food Labeling*, CTR. FOR SCI. PUB. INT. (Dec. 29, 2009), http://cspinet.org/new/200912291.html [hereinafter *CSPI*].

45. Pomeranz, *Litigation*, *supra* note 2, at 422; *see also* Marion Nestle & David S. Ludwig, *Front-of-Package Food Labels: Public Health or Propaganda?*, 303 J. AM. MED. ASS'N 771, 772 (2010). During Michelle Obama's "Let's Move!" campaign's fourth anniversary celebration, the First Lady stated: "As consumers and as parents, we have a right to understand what's in the food we're feeding our families because that's really the only way that we can make informed choices—by having clear, accurate information." Michelle Obama, First Lady, Office of the First Lady, Remarks at the East Room (Feb. 27, 2014) (transcript available at https://www.whiteho

Consumers should be able to rely on food label messaging to maximize their grocery budgets and prevent diet-related health problems.[46]

This Part first explores FDA oversight of food and beverage labels and examines various explanations for its regulatory inadequacies.[47] Subsequently, this Part introduces the concept of private enforcement as a supplement to agency regulation through *Wyeth v. Levine*, where a private cause of action was utilized to challenge an FDA-approved drug label under state law.[48] Finally, this Part discusses the Supreme Court's treatment of the Lanham Act in *Lexmark International, Inc. v. Static Control Components, Inc.* The Lanham Act provides a federal cause of action for those commercially injured by misleading labels; and in *Lexmark*, the Court clarified and expanded Lanham Act standing and set the stage for private claims, such as *POM Wonderful LLC v. The Coca-Cola Co*.[49]

A. FDA Background and Deficient Regulation

The Food and Drug Administration is charged with the authority and responsibility to protect consumers from misleading food and beverage labels.[50] The FDA is one of the United States' most powerful administrative agencies as it is responsible for regulating over a quarter

use.gov/the-press-office/2014/02/27/remarks-first-lady-nutrition-facts-label-announcement); *see also First Lady Promotes "Let's Move" Campaign At Miami Park*, CBS MIAMI (Feb. 25, 2014, 8:40 PM), http://miami.cbslocal.com/2014/02/25/michelle-obama-visits-miami-to-promote-fitness/.

46. *CSPI*, *supra* note 44 (quoting Ilene Ringel Heller, senior staff attorney at Center for Science in the Public Health); *see also* Gerald Masoudi & Christopher Pruitt, *The Food and Drug Administration v. the First Amendment: A Survey of Recent FDA Enforcement*, 21 HEALTH MATRIX 111, 111 (2011) ("[C]onsumers and medical providers cannot make informed decisions about regulated products without access to truthful, scientifically accurate, and balanced product information.").

47. *See infra* Part I.A (discussing FDA regulation).

48. *See infra* Part I.B.1 (discussing private regulation and Wyeth v. Levine, 555 U.S. 555 (2009)). Many state law challenges to food and beverage labels are expressly preempted by the FDCA, however, which prohibits state laws that are not identical to some FDA labeling regulations. *See* 21 U.S.C. § 343–1 (2012) (prohibiting states from establishing food labeling requirements that are not identical to FDCA food labeling requirements).

49. *See infra* Part I.B.2 (discussing the Lanham Act's private cause of action and Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377 (2014)).

50. Pomeranz, *Strategy*, *supra* note 4, at 619. *See generally* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: A FOOD LABELING GUIDE (Jan. 2013), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm [hereinafter GUIDANCE FOR INDUSTRY 2013]. FDA regulation essentially began in 1906 under the Pure Food and Drugs Act, when the regulatory body was established as the "Bureau of Chemistry." The Agency's name was changed to the "Food, Drug and Insecticide Administration" in 1927 and to its current version in 1930. *About FDA, History*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm (last visited Sept. 24, 2015).

of the country's gross domestic product,[51] including more than $1 trillion in consumer goods.[52] Pursuant to the FDCA, the FDA has the authority to protect the public by acting as a marketing gatekeeper for the majority of the products it regulates,[53] setting safety, quality, and labeling requirements for those products.[54]

Congress enacted the FDCA in 1938, amid concerns about dangerous consumer products and deceptive marketing,[55] to safeguard the health

51. PREVENTING REGULATORY CAPTURE: SPECIAL INTEREST INFLUENCE AND HOW TO LIMIT IT 152 (Daniel Carpenter & David A. Moss eds., 2013); Jaimy Lee, *FDA Budget Increase Not Enough, Advocates Say*, MOD. HEALTHCARE (Mar. 4, 2014), http://www.modernhealthcare.com/article/20140304/NEWS/303049970 (quoting American Society of Health-System Pharmacists Vice President Kasey Thompson, stating, "the FDA regulates about 25 cents of every dollar of the gross domestic product"). The U.S.'s GDP in 2013 was almost 16.8 trillion dollars, and the 2014 GDP is estimated at over 17.4 trillion dollars. *Gross domestic product (GDP) of the United States 2014*, STATISTA, http://www.statista.com/statistics/263591/gross-domestic-product-gdp-of-the-united-states/ (last visited Sept. 13, 2015).

52. Gardiner Harris, *The Safety Gap*, N.Y. TIMES MAG., Oct. 31, 2008, at 46. The FDA regulates products that account for "20 cents of every dollar spent by consumers." John P. Swann, *FDA's Origin*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm (last visited Sept. 13, 2015) (adapted from A HISTORICAL GUIDE TO THE U.S. GOVERNMENT (George Kurian ed., 1998)).

53. 21 U.S.C. § 301; PREVENTING REGULATORY CAPTURE, *supra* note 51, at 152; Geoffrey M. Drake & Victoria C. Smith, *Prescription Medication Cases: The Case Against Negligent Design Claims*, DRI FOR DEF. Oct. 2012, at 16 ("Through a series of complex federal statutes and regulations, the FDA acts as a 'gatekeeper' to the United States marketplace.")

54. 21 U.S.C. § 301; *About FDA, What We Do*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last visited Sept. 24, 2015); Pomeranz, *Strategy*, *supra* note 4 at 619 (2013). The agency wields authority primarily over food, pharmaceuticals, vaccines, medical devices, cosmetics, tobacco products, and radiation-emitting products. *About FDA, What Does FDA Regulate?*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm (last visited Sept. 24, 2015); *see also* PREVENTING REGULATORY CAPTURE, *supra* note 51, at 152. The FDA regulates 80% of the nation's food supply, requires labels on packaged foods, and specifies standards to ensure that food labels display accurate information on which consumers can rely to make healthy food choices. *FDA, USDA, NOAA Statements on Food Safety*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm248257.htm (last visited Sept. 24, 2015); *see also* CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., A FOOD LABELING GUIDE: GUIDANCE FOR INDUSTRY 4 (2013). Within the FDA's Office of Foods and Veterinary Medicine, food labeling is the responsibility of the Center for Food Safety and Applied Nutrition, and its Office of Nutrition, Labeling, and Dietary Supplements publishes industry guidance for food labeling. Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938); Wyeth v. Levine, 555 U.S. 555, 566 (2009).

55. *How Did the Federal Food, Drug, and Cosmetic Act Come About?*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214416.htm (last visited Sept. 24, 2015) ("The political will to effect a change came in the early 1930s, spurred on by growing national outrage over some egregious examples of consumer products that [harmed] many people. The tipping point came in 1937, when an untested pharmaceutical killed scores of patients . . . ."). Subsequently, Congress enacted laws authorizing the FDA to regulate pesticide residue on foods in 1954, chemical additives in 1958, and color additives in 1960. Swann, *supra* note 52. Congress's first attempt at regulating food and beverage labeling came in 1906 with the Pure Food and Drugs Act, which banned misbranded and adulterated foods from interstate commerce.

and safety of the public.[56] In 1990, Congress bolstered the FDCA's misbranding provisions by enacting the Nutrition Labeling and Education Act ("NLEA") to give consumers reliable and consistent nutrition information that would reduce confusion and promote selection of healthy foods.[57] Amending the FDCA, the NLEA authorized the FDA to regulate and standardize health claims on food and beverage packaging, and required specific nutritional information disclosures on product labels.[58]

To administer the FDCA's food and beverage labeling provisions, the FDA promulgated food labeling requirements to protect the public from misbranded products.[59] Food product labels are considered commercial speech and honest labeling is protected as such by the First Amendment.[60] This constitutional protection is not extended to false

---

Pub. L. No. 59-384, 34 Stat. 768; *Wyeth*, 555 U.S. at 566. As the Act failed to encompass many hazardous products, injured consumers turned to state regulations and common law liability to fill the protection gaps. Pub. L. No. 59-384, 34 Stat. 768; *How Did the Federal Food, Drug and Cosmetic Act Come About?*, *supra*; *see also Wyeth*, 555 U.S. at 566.

56. *POM*, 134 S. Ct. at 2234; 62 Cases of Jam v. United States, 340 U.S. 593, 596 (1951) ("The purposes of this legislation [are to] . . . touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.").

57. 21 U.S.C. § 343–1; GAO, 2011, *supra* note 3, at 5 ("According to FDA documents, the primary goals of the Nutrition Labeling and Education Act of 1990 were to (1) make nutrition information available to assist consumers in selecting foods that could lead to healthier diets; (2) eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent and that consumers could rely on; (3) help consumers maintain healthy dietary practices and protect them from unfounded health claims, so a health claim used on a product would be one that consumers could rely on to give them truthful and not misleading information; and (4) encourage product innovation by developing and marketing nutritionally improved food."); *see also* Card, *supra* note 34, at 311 (citing *Overweight and Obesity*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/obesity/data/adult.html (last updated Sept. 21, 2015)) ("The goal of the law was to modify food labels to allow consumers to make healthy choices based on modern health concerns, such as obesity. Despite this goal, obesity rates dramatically increased from 1990 through 2010."). As the influence of diet on health and wellness became clear, the food industry inundated supermarkets with products touting nutritional benefits that were fraudulent and misleading. *Impact of the NLEA*, *supra* note 16, at 606; *see also Supplements Hearing*, *supra* note 16, at 63–66 (testimony of FDA commissioner, Dr. David A. Kessler).

58. 21 U.S.C. § 343; Negowetti, *supra* note 2, at 2; Pomeranz, *Litigation*, *supra* note 2, at 422–23. Despite the added nutrition disclosures, labels remained unclear, and consumers continued to be confused by food and beverage labels. Card, *supra* note 34, at 311 ("[E]ven though food labels contained essential information, this information was unintelligible from the consumer's perspective."); Jean Lyons & Martha Rumore, *Food Labeling—Then and Now*, 2 J. PHARMACY & L. 171, 180 (1994) (quoting Department of Health and Human Services Secretary, Dr. Louis W. Sullivan as stating, "[t]he grocery store has become the tower of Babel, and consumers need to be linguists, scientists, and mind readers to understand many of the labels they see").

59. GAO, 2011, *supra* note 3, at 1; *About FDA, What We Do*, *supra* note 54.

60. Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976) (holding that while commercial speech is protected, "some forms of commercial speech

and deceptive speech, and thus misleading information on product labels may be regulated.[61] Speech that is merely "potentially misleading" cannot be banned,[62] and the government can only demand that it be portrayed in a nondeceptive manner and be accompanied by disclaimers or disclosures if necessary to correct the "potentially misleading" message.[63]

Accordingly, the FDCA proscribes the misbranding of food and beverages.[64] A product is misbranded if its label is false or

---

regulation are surely permissible"); *see also* Leslie Gielow Jacobs, *Compelled Commercial Speech As Compelled Consent Speech*, 29 J.L. & POL. 517 (2014) ("Commercial speech may be subject to greater government regulation than fully protected speech because the reason that the Constitution protects it is different.").

61. Corn Prods. Ref. Co. v. Eddy, 249 U.S. 427, 431 (1919) ("[I]t is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold."); *but cf.* Michael Taylor, *How the FDA Is Picking Its Food Label Battles*, ATLANTIC (July 19, 2010, 9:00 AM), http://www.theatlantic.com/health/archive/2010/07/how-the-fda-is-picking-its-food-label-battles/59927/ (explaining that proving food labels are misleading is demanding and costly to the FDA, and thus many deceptive labels go unchallenged).

62. *See* Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999) (holding that the First Amendment does not allow the FDA to prohibit a "potentially misleading" label unless it considers whether a disclaimer would negate the claim's potentially misleading nature); *see also* Fleminger, Inc. v. U.S. Dep't of Health & Human Servs., 854 F. Supp. 2d 192, 195 (D. Conn. 2012) (applying *Pearson*); All. for Nat. Health U.S. v. Sebelius, 786 F. Supp. 2d 1, 4 (D.D.C. 2011) (applying *Pearson*).

63. Pomeranz, *Strategy*, *supra* note 4, at 624–25; *see also* Card, *supra* note 34, at 312–13 (explaining that the FDA can require food and beverage labels to display specific information, warnings, or disclaimers).

64. 21 U.S.C. § 331(a) (2012) ("The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded."). FDA regulations also govern health and nutrient content claims of food packaging, such as "low sodium" or "all natural." 21 C.F.R. §§ 101.70–.83 (2015) (health claims); *id.* §§ 101.54–.69 (nutrient content claims). While food manufactures have labeled products as "natural" with great marketing results for decades, the FDA never published a comprehensive definition of the term. BRUCE SILVERGLADE & ILENE RINGEL HELLER, CTR. FOR SCI. IN THE PUB. INTEREST, FOOD LABELING CHAOS pt. X-6 (2010). Therefore, a product such as Hunt's Tomato Sauce may claim that it is "100% Natural" when, in fact, the product is made using reconstituted industrial tomato concentrate—highly processed tomato paste and added water—and contains added citric acid. *Tomato Sauce Scam*, FOOD IDENTITY THEFT, http://foodidentitytheft.com/culprits/tomato-sauce-scam/ (last visited Sept. 24, 2015). Citric acid, often added to foods as a preservative, is typically produced as a byproduct of the mold aspergillus niger rather than culled from citrus fruits. Bethany Moncel, *What is Citric Acid?*, ABOUT FOOD, http://foodreference.about.com/od/Food-Additives/a/What-Is-Citric-Acid.html (last visited Sept. 13, 2015) ("Although citric acid is found in high concentrations in many citrus fruits, it is not economical to extract the acid from fruit for industrial use."). The FDA regulations issued in 1993 were innovative when enacted, but are now archaic and neither address current mislabeling trends nor reflect advances in nutrition science. INST. OF MED. & NAT'L RESEARCH COUNCIL, ENSURING SAFE FOOD: FROM PRODUCTION TO CONSUMPTION 87 (1998) ("There are inconsistent, uneven, and at times archaic food statutes that inhibit use of science-based decision making in activities related to food safety."). Many FDA-compliant labels remain

misleading,[65] portrays an inaccurate name or identification,[66] makes prohibited health claims,[67] or lacks the nutritional panel or other required disclosures.[68]

Under FDA regulations, food labels must prominently display a statement of the product's identity.[69] Generally, food and beverage names must correctly portray and express the fundamental nature of the food or ingredients in clear and straightforward language.[70] FDA regulations, however, effectively permit juice blends to have confusing names.[71] In fact, a juice blend that contains minuscule amounts of a particular juice may nonetheless bear the name of that juice as long as the word "blend" is used on the label to signify that the fruit in the name of the beverage is really only one of many juice ingredients.[72] For this reason, "Juicy Juice All-Natural 100% Juice Orange Tangerine," which contains mostly apple juice, is not in violation of FDA naming regulations.[73]

---

misleading, and categorically unhealthy foods enjoy a "health halo" from their deceptive package labels. Michelle I. Banker, *I Saw the Sign: The New Federal Menu-Labeling Law and Lessons from Local Experience*, 65 FOOD & DRUG L.J. 901, 919 n.153 (2010) ("[L]abels can provide a so-called health halo—biasing consumers' perception and causing them to underestimate calories in food.").

65. 21 U.S.C. § 343(a) ("A food shall be deemed to be misbranded . . . [if] its labeling is false or misleading in any particular . . . .").

66. *Id.* § 343(i) ("A food shall be deemed to be misbranded . . . [u]nless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food.").

67. 21 C.F.R. § 101.14(e) (2015).

68. 21 U.S.C. § 343(f) ("A food shall be deemed to be misbranded . . . [i]f any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.").

69. 21 C.F.R. § 101.3(a); Pomeranz, *Strategy*, *supra* note 4, at 625.

70. 21 C.F.R. § 102.5(a) ("The common or usual name of a food . . . shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients.")

71. Pomeranz, *Strategy*, *supra* note 4, at 626.

72. *See* 21 C.F.R. § 102.33(c) ("If a diluted multiple-juice beverage or blend of single-strength juices contains a juice that is named or implied on the label or labeling other than in the ingredient statement (represented juice), and also contains a juice other than the named or implied juice (nonrepresented juice), then the common or usual name for the product shall indicate that the represented juice is not the only juice present (e.g., 'Apple blend; apple juice in a blend of two other fruit juices.')").

73. *Id.* § 102.33(c); Hemi Weingarten, *Nestlé "Juicy Juice" Slammed By FDA for Misleading Consumers [Inside the Label]*, FOODUCATE (Dec. 27, 2009), http://blog.fooducate.com/2009/12/27/nestle-juicy-juice-slammed-by-fda-for-misleading-consumers-inside-the-label/; *see Orange*

As food and beverage labels do not require FDA approval prior to marketing and sale, enforcing the prohibition against misleading labels requires first identifying violations in products already in commerce.[74] Food facility inspections mainly concentrate on food safety; however, FDA inspectors are instructed to examine at least three food package labels during every inspection.[75] Food labels may also be examined during inspections of food products entering the country from a foreign nation.[76] Additionally, the FDA investigates complaints made by consumers, public interest groups, industry competitors, and others about food labels that may be in violation of FDA regulations.[77]

Many experts claim that FDA inspectors are not sufficiently trained to evaluate food labels.[78] Inspectors follow the Compliance Program Guidance Manual, which explains the standards for the nutrition panel, itemizes allergens that must be identified, and specifies the guidelines for health and nutrient content claims.[79] The manual does not include much needed instructions or direction for inspectors to identify false or deceptive food labels.[80]

When the FDA's Office of Regulatory Affairs identifies a minor labeling violation, it may send a letter to the food manufacturer to address the issue and request that it be amended.[81] For more serious violations a "warning letter" is sent to the manufacturer notifying it that enforcement proceedings may commence if the label is not corrected.[82]

Tangerine, JUICY JUICE, http://juicyjuice.com/products/juicy-juice-fruit-juice/orange-tangerine/#Ingredients (last visited Sept. 24, 2015) (listing the three main ingredients, in order by volume, as apple juice, pear juice, and grape juice).

74. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-309R, FEDERAL OVERSIGHT OF FOOD IRRADIATION 4 (2010) ("[L]abels on food products subject to FDA jurisdiction do not have to be reviewed and preapproved by FDA before marketing.").

75. GAO, 2008, *supra* note 12, at 2; Negowetti, *supra* note 2, at 2.

76. GAO, 2008, *supra* note 12, at 2; *Importing Food Products into the United States*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ (last visited Sept. 24, 2015).

77. GAO, 2008, *supra* note 12, at 2. When industry, consumer groups, or others believe that certain types of food labeling information is false or misleading, or that changes to requirements are needed for public health, or for other reasons, they may request or formally petition the FDA to issue regulations or guidance to address the problem. *Id.* at 1–2.

78. Negowetti, *supra* note 2, at 23; GAO, 2011, *supra* note 3, at 29.

79. *Compliance Program Guidance Manual (CPGM)*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/ICECI/ComplianceManuals/CompliancePrograManual/ucm2005382.htm (last visited Sept. 24, 2015); *see also* Negowetti, *supra* note 2, at 23.

80. *See* GAO, 2011, *supra* note 3, at 23 ("The FDA has not given . . . its inspectors instructions for identifying potentially false or misleading information in such claims when examining food labels as part of food facility compliance inspections."); Negowetti, *supra* note 2, at 23.

81. GAO, 2011, *supra* note 3, at 7; Pomeranz, *Strategy*, *supra* note 4, at 632.

82. During the oversight process, the FDA may also conduct a regulatory meeting with the

These warning letters, requesting voluntary compliance with FDCA requirements, are the FDA's sole method of enforcement against false or misleading labels.[83]

Unsurprisingly, the warning letters offer little motivation for companies to discontinue the effective marketing practice of enticing consumers through deceptive food labels.[84] Thus, the FDA does not have the uniform enforcement authority it needs to successfully prevent food manufacturers from marketing their products with misleading labels.[85] In 2007, the U.S. Government Accountability Office ("GAO") placed FDA enforcement of food labeling regulations on its "high-risk list of government programs that need broad-based transformation to achieve greater economy, efficiency, effectiveness, accountability, and sustainability."[86] In 2008 and 2011, the GAO reported on the ineffectiveness of the FDA's enforcement strategies and criticized FDA oversight practices.[87]

Integral to the FDA's failure to adequately address misleading food labeling practices is its inadequate funding.[88] Scholars suggest that

---

food manufacturer to rectify the food label. GAO, 2011, *supra* note 3, at 7; Pomeranz, *Strategy*, *supra* note 4, at 632.

83. Pomeranz, *Strategy*, *supra* note 4, at 632; *see also* U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL ch. 4, § 4.1, http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176870.htm (last updated June 19, 2015). More rigorous enforcement methods, such as fines and recall requests that are utilized when public safety is at risk, are not available for misleading and deceptive food labels. 21 U.S.C. § 336 (2012) ("Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning."). Congress was explicit that the non-acute health consequences of deceptive food labeling do not require seizure, injunction, or civil monetary penalties. *Id*. § 333(d) (exceptions involving misbranded food). In fact, the statute expressly prevents the FDA from imposing the more severe enforcement strategies for substantially false or misleading food and beverage labels. 21 U.S.C. § 333(d) ("No person shall be subject to the penalties of subsection (a)(1) of this section for a violation of section 331 of this title involving misbranded food if the violation exists solely because the food is misbranded under section 343(a)(2) of this title because of its advertising.").

84. Negowetti, *supra* note 2, at 3. *Contra* Brief of Dr. Michael Friedman, Former Acting Commissioner and Lead Deputy Commissioner for the United States Food and Drug Administration as Amicus Curiae in Support of Respondent at 13, POM Wonderful LLC v. The Coca-Cola Company, 134 S. Ct. 2228 (2014) (No. 12-761) ("These warning letters are not trivial matters; companies take them seriously.").

85. Negowetti, *supra* note 2, at 3; Pomeranz, *Strategy*, *supra* note 4, at 619.

86. GAO, 2011, *supra* note 3, at 8; Negowetti, *supra* note 2, at 8.

87. GAO, 2011, *supra* note 3, at 8. The GAO noted that the FDA did not track known labeling violations to ensure they were remedied or detail the violations in order to inform the public. GAO, 2008, *supra* note 12, at 26. Moreover, the FDA did not have adequate figures on the number of labels actually examined by FDA inspectors. Negowetti, *supra* note 2, at 8.

88. Pomeranz, *Strategy*, *supra* note 4, at 619; David C. Vladeck, *The FDA and Deference*

because the FDA lacks the resources to increase its enforcement capacity, it is unable to squarely meet the massive misbranding issues within the food industry.[89] Thus, some critics fault Congress, which condemns the FDA's labeling enforcement inadequacies on the one hand, while depriving it of needed funding on the other.[90]

First Amendment constraints on the regulation of commercial speech exacerbate the FDA's budgetary dilemma because proving that a label is misleading, and not merely "potentially misleading," is a significant and pricey endeavor.[91] Former FDA Deputy Commissioner Michael Taylor explained that the FDA's limited resources inhibit its ability to go up against the food industry.[92] As food safety programs are a higher priority than misbranding, Taylor stated that the FDA "must make choices."[93] This explanation for the FDA's unwillingness to address misleading food labels disappointed consumers and public health advocates, but it was welcome news to food manufacturers with little fear from the FDA when marketing food with false or misleading packaging.[94]

Lost: A Self-Inflicted Wound or the Product of A Wounded Agency? A Response to Professor O'Reilly, 93 CORNELL L. REV. 981, 983 (2008).

89. Negowetti, *supra* note 2, at 1, 2; Pomeranz, *Strategy*, *supra* note 4, at 636–37.

90. Negowetti, *supra* note 2, at 22; Vladeck, *supra* note 88, at 983.

91. Timothy D. Lytton, *Banning Front-of-Package Food Labels: First Amendment Constraints on Public Health Policy*, 14 PUB. HEALTH NUTRITION 1123, 1123 (2011); Taylor, *supra* note 61 ("[U]nder prevailing legal doctrines concerning 'commercial free speech,' the evidentiary requirements placed on FDA to prove that such claims are misleading are significant and costly to meet."); *see also id.* ("We're also conscious of the cleverness of marketing folks, who, once we prove today's claim is misleading, can readily come up with another one tomorrow. Going after them one-by-one with the legal and resource restraints we work under is a little like playing Whac-a-Mole, with one hand tied behind your back."). Thus, due in part to budgetary limitations, the FDA does not properly address food labeling violations or amend those regulations that condone misleading claims. Pomeranz, *Strategy*, *supra* note 4, at 619; *see also* Marsha N. Cohen, *Commentary: Can We Talk? About Food and Drug Regulation and the First Amendment*, 58 FOOD & DRUG L.J. 741, 742 (2003) ("It is FDA's obligation to defend vigorously the regulatory choices made by the U.S. Congress. The agency has not done nearly enough to muster its defenses.").

92. *See* Taylor, *supra* note 61 ("[Eliminating misleading labels is] a tall order, especially considering the other high-priority nutrition and food safety initiatives that compete for FDA's finite resources. We'll consider all possibilities, but, in the meantime, we call on the food industry to exercise restraint."); *see also Food Mislabeling Litigation and the Success of Preemption and First Amendment Defenses*, BLANK ROME LLP (Feb. 2013), http://www.blankrome.com/index.cfm?contentID=37&itemID=2997 (noting that First Amendment defenses have been successful in food labeling cases).

93. *See* Negowetti, *supra* note 2, at 9; Taylor, *supra* note 61.

94. Marion Nestle, *Health Claim Warriors Rally the Troops*, ATLANTIC (Aug. 4, 2010, 8:47 AM), http://www.theatlantic.com/health/archive/2010/08/health-claim-warriors-rally-the-troops/60848/; Marion Nestle, *Why the FDA Must Act on Health Claims*, FOOD POL. (Aug. 2, 2010), http://www.foodpolitics.com/2010/08/why-the-fda-must-act-on-health-claims/.

Some experts point to agency capture as the reason for the FDA's regulatory failures.[95] Federal Reserve Chairwoman Janet L. Yellen described agency capture as "when a regulatory agency advances the interests of the industry it is supposed to oversee rather than the broader public interest it should represent."[96] As food manufacturers want less labeling regulation than the goals of the FDCA seek to accomplish, "corrosive capture" results when the industry is able to drive the regulatory process to include lenient labeling rules or reduced enforcement actions.[97] In the past several decades, scholars have observed capture in the FDA's marginal enforcement practices and policy decisions, which were made to benefit the industry rather than serve its statutory mission.[98] The "revolving door" practice of shuttling industry executives to senior appointments at the FDA and back again, has been believed to generate agency action that amounted to deregulation.[99] Additionally, political pressure has been blamed as causing the FDA to take action with greater concern for political constituents than for the public welfare.[100] Even further, some scholars suggest that agency capture has contributed to the lack of deference the

95. PREVENTING REGULATORY CAPTURE, *supra* note 51, at 152 ("If ever there were a plausible prima facie case for capture, a gatekeeping regulator like the FDA would seem to provide it."); O'Reilly, *supra* note 15, at 941.

96. *See generally* Steven Harras, *Yellen: Push Bank Ethics, Curb 'Regulatory Capture,'* CONG. Q, Mar. 4, 2015, 2015 WL 897954.

97. PREVENTING REGULATORY CAPTURE, *supra* note 51, at 152; O'Reilly, *supra* note 15, at 978 ("[C]apture of the Agency's political leadership by agents of its regulated industries has been manifest in [its] visible policy shifts."); *see also Breaking News: POM's "David and Goliath" Victory over Coca-Cola*, ALLIANCE FOR NAT. HEALTH (June 17, 2014), http://www.anh-usa.org/pom-david-and-goliath-victory-over-coca-cola/ [hereinafter ALLIANCE FOR NAT. HEALTH] ("[F]ederal agencies harass small food and supplement companies on labeling and advertising, but let industry favorites ignore or stretch the same rules.").

98. O'Reilly, *supra* note 15, pts. XII–XIII; Vladeck, *supra* note 88, at 982 ("[The FDA's 2006] policy reversal on preemption is nothing short of an effort to give the pharmaceutical and medical device industry protection from tort litigation, and . . . the Plan B debacle, which was made to appease anti-abortion groups, was an insult to the FDA's scientific process.").

99. *See* PREVENTING REGULATORY CAPTURE, *supra* note 51, at 152. For example, Michael Taylor worked as an FDA attorney early in his career; he then worked for a private law firm representing Monsanto, a major agricultural company; thereafter, he returned to the FDA in 1991, as Deputy Commissioner for Policy. Tom Philpott, *Monsanto's Man Taylor Returns to FDA in Food-Czar Role*, GRIST (July 9, 2009), http://grist.org/article/2009-07-08-monsanto-fda-taylor/. Subsequently, Taylor briefly worked at the U.S. Department of Agriculture and then went to work as Monsanto's counsel, before coming back to the FDA in 2009, as Senior Advisor to the Commissioner. *Id.*

100. O'Reilly, *supra* note 15, at 941 ("[I]n recent years, the news media has disdained the Bush Administration's political manipulation of the FDA and has questioned the Agency's scientific integrity."); Vladeck, *supra* note 88, at 982; *see also* FRAN HAWTHORNE, INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT 31 (2005) (criticizing the FDA for being a "political pawn").

courts are willing to give to administrative agencies in general, and the FDA in particular.[101]

Capture of administrative agencies is often evidenced through regulatory preemption, which may be used as an instrument of deregulation.[102] Preemption, where a federal law invalidates state and local regulatory enforcement, can be used as a method of deregulation to insulate manufacturers from the harsh penalties and strict requirements of state statutes and common law.[103] State tort law claims are banned if preempted by a federal statute or regulation, shielding defendant manufacturers from the time and expense of litigation.[104]

Critics have argued that agency capture occurs when regulatory agencies include preemption policies in new rules and regulations, without congressional sanction.[105] This was the case in 2006, when the FDA promulgated a prescription drug labeling rule that did not expressly preempt state law, but was prefaced by a preamble stating that the FDA's approval of a drug label impliedly preempted certain state law claims against the drug's manufacturer.[106]

---

101. John Duffy, *Opinion Analysis: The Triumph of the Lanham Act (and of Federal Private Rights of Action)*, SCOTUSBLOG (June 13, 2014, 5:22 PM), http://www.scotusblog.com/2014/06/opinion-analysis-the-triumph-of-the-lanham-act-and-of-federal-private-rights-of-action/; *see also* O'Reilly, *supra* note 15, at 962 ("Given that the FDA can be buffeted on both sides by those with political motives, the Judiciary may not wish to maintain deference to the FDA's scientific choices.").

102. PREVENTING REGULATORY CAPTURE, *supra* note 51, at 154; O'Reilly, *supra* note 15, at 967; *see also infra* note 111 and accompanying text (discussing CSPI's settlements for misleading labels).

103. PREVENTING REGULATORY CAPTURE, *supra* note 51, at 154; Denis Stearns, *New Obama Policy Allows States to Be Tougher on Food Safety*, FOOD POISON J. (May 21, 2009), http://www.foodpoisonjournal.com/food-poisoning-resources/new-obama-policy-allows-states-to-be-tougher-on-food-safety/#.VDF3jr4lofk.

104. O'Reilly, *supra* note 15, at 967; Thomas H. Sosnowski, *Narrowing the Field: The Case Against Implied Field Preemption of State Product Liability Law*, 88 N.Y.U. L. REV. 2286, 2287 (2013).

105. O'Reilly, *supra* note 15, at 967 ("[T]he use of implied preemption as a shield from tort liability has loomed large on the policy agenda of the Bush Administration's appointees."); Stearns, *supra* note 103.

106. Wyeth v. Levine, 555 U.S. 555, 575–76 (2009). *See generally* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006). Subsequently, in 2009 President Obama sent a presidential memorandum to the heads of executive departments and agencies instituting a policy to curtail regulatory preemption. Barack Obama, Preemption, 74 Fed. Reg. 24693 (May 20, 2009) ("[P]reemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption."). Likely in response to the preamble in the 2006 FDA drug labeling regulation, the presidential memorandum also stated that agencies should not include language in regulatory preambles that preemption is implied, if preemption is not codified in the rule. *Id.*; *see also FDA Notice Clarifies Past Federal Preemption Policy Statements*, KELLEY DRYE (Oct. 6, 2011), http://www.kelleydrye.com/

B. The Private Enforcement Alternative

The absence of effective food labeling enforcement has given attorneys the opportunity to fill the gap through litigation.[107] The FDCA does not provide a private cause of action, and consumers injured by misleading labels must turn to state tort law and consumer protection statutes to seek redress against food and beverage manufacturers.[108] Parties commercially injured by deceptive labels, on the other hand, may file suit under the Lanham Act, a federal law prohibiting unfair competition practices, including marketing products with false or misleading labels.[109]

The Center for Science in the Public Interest ("CSPI") established a litigation department in 2004 "to fill the void left by the inactive government agencies by using state and federal courts to help correct corporate misbehavior."[110] CSPI found that the possibility of bad press and the threat of costly litigation provided more effective motivation for compliance than FDA warning letters, which provide little deterrence against misleading labeling.[111] There were over 150 class actions filed against food manufacturers between 2011 and 2013,[112] none of which would have been possible had state law been preempted by the FDCA.[113]

---

publications/client_advisories/0696.

107. 15 U.S.C § 1125(a)(1) (2012); Negowetti, *supra* note 2, at 23; Pomeranz, *Strategy*, *supra* note 4, at 619.

108. Eric S. Almon, *Preemption of State Failure-to-Warn Claims After* Wyeth v. Levine*: The Regulatory Function of State Tort Law*, 45 U.S.F. L. REV. 215, 217 (2010); Pomeranz, *Strategy*, *supra* note 4, at 619.

109. 15 U.S.C. § 1125(a)(1) ("Any person who, on or in connection with any goods . . . uses in commerce any . . . false or misleading description . . . which . . . is likely to cause confusion, or to cause mistake, . . . shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act."); Pomeranz, *Strategy*, *supra* note 4, at 619.

110. Negowetti, *supra* note 2, at 7; *Litigation Project*, CTR. FOR SCI. PUB. INT., http://www.cspinet.org/litigation/ (last visited Sept. 24, 2015).

111. Negowetti, *supra* note 2, at 7; Pomeranz, *Strategy*, *supra* note 4, at 619. For example, in 2005, CSPI settled with Aunt Jemima's parent company, Pinnacle Foods, for misleadingly labeling a product as "blueberry" waffles when it contained no actual blueberries. Negowetti, *supra* note 2, at 7. Additionally, CSPI brought change to Capri Sun and 7UP labels that claimed they were "natural" despite containing high-fructose corn syrup. *Id.*

112. Negowetti, *supra* note 2, at 1; *cf.* David T. Biderman & Joren S. Bass, *Trends in Food Labeling and Nutrition Class Actions*, A.B.A. (Apr. 30, 2012), http://apps.americanbar.org/litigation/committees/classactions/articles/spring2012-0412-trends-food-labeling-nutrition-class-actions.html ("In recent years, the number of consumer class actions challenging health and nutrition marketing claims made in relation to food and drinks has expanded dramatically.").

113. PREVENTING REGULATORY CAPTURE, *supra* note 51, at 154; *see also supra* note 98 and accompanying text (discussing preemption).

1. Consumer Actions: *Wyeth v. Levine* and State Law Claims

To maintain centralized governmental regulation, federal laws preempt private state law claims.[114] Inadequate regulation, however, substantiates the need for an integrated regulation scheme that takes advantage of multiple methods of enforcement.[115] In 2009, in *Wyeth v. Levine*, the Supreme Court had the opportunity to take a deferential approach and find that the FDCA preempted the plaintiff's claim.[116]

---

114. *Cf.* John F. Easton, Recent Decision, *The United States Court of Appeals for the Fourth Circuit: RCRA Consent Order Preempts State-Law Injunction*, 54 MD. L. REV. 955, 958 (1995) ("Various reasons have been suggested to explain the necessity for federal preemption, such as the need for uniformity, the elimination of dual systems of regulation, and the realization of benefits to be derived from a centralized federal agency which can boast specialized knowledge and experience." (footnotes omitted)); Michele E. Gilman, *Presidents, Preemption, and the States*, 26 CONST. COMMENT. 339, 342 (2010) ("A centralized approach, such as that fostered by federal preemption, ensures uniformity . . . ."). The federal preemption doctrine originates in the Supremacy Clause of the U.S. Constitution, which provides that federal law is the supreme law of the land. U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and . . . shall be the supreme Law of the Land."); *see also* BLACK'S LAW DICTIONARY (9th ed. 2009) ("The principle (derived from the Supremacy Clause) that a federal law can supersede or supplant any inconsistent state law or regulation."). State laws, including common law, are thus preempted if in conflict with federal law. 81 C.J.S. *States* § 49 (2015), Westlaw (database updated July 2015); Richard C. Ausness, *Federal Preemption of State Products Liability Doctrines*, 44 S.C. L. REV. 187, 191 (1993). The Supreme Court has also reasoned that congressional intent is the "ultimate touchstone," and will generally only find preemption where Congress's purpose to supersede state law is "clear and manifest." Wyeth v. Levine, 555 U.S. 555, 579 (2009) (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); Retail Clerks v. Schermerhorn, 375 U.S. 96, 103 (1963)); Ausness, *supra*, at 192; *see also* Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) (presuming fields traditionally occupied by the states are not preempted unless it is the clear and manifest intent of Congress). *Express preemption* exists when a federal law includes explicit language that it supersedes state law. Josh Ashley, *A Bittersweet Deal for Consumers: The Unnatural Application of Preemption to High-Fructose Corn Syrup Labeling Claims*, 6 J. FOOD L. & POL'Y 235, 242 (2010); Ausness, *supra*, at 191. For example, in the NLEA, Congress included an express provision prohibiting states from enacting regulations that are of the same type but not identical to certain food labeling requirements in the FDCA. Nutrition Labeling and Education Act of 1990, § 6, 104 Stat. 2362–64; Van H. Beckwith, *Litigating Food and Beverage Labeling Cases: Some Strategies and Trends*, *in* FOOD AND DRUG LITIGATION STRATEGIES: LEADING LAWYERS ON BUILDING STRONG DEFENSES AND ADAPTING TO EVOLVING FDA REGULATIONS 3 (2013). If Congress's purpose is not explicit, the Court may find *field preemption* in an area of law where federal regulation is so all-encompassing that Congress did not leave room for state law to displace it. Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 203–04 (1983); Fid. Fed. Savings & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 154 (1982). Additionally, *implied preemption* exists where state regulation is not completely supplanted in a particular field but where state law is in conflict with federal law either because compliance with both would be impossible, or where state law presents an obstacle to the full achievement of Congress's intent. *Pac. Gas & Elec. Co.*, 461 U.S. at 203–04; Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963); Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

115. *See infra* Part IV.A (discussing alternatives to integrated regulation).

116. *See* Reply Brief for Petitioner at 3, Wyeth v. Levine, 555 U.S. 555 (2009) (No. 06-1249) ("In this situation, state tort law is undoubtedly preempted."); *see also infra* Part IV.A.1

Instead, the Court recognized the added layer of enforcement such claims provide and found that the FDCA complements, rather than preempts, state law challenges to FDA-regulated labels.[117]

In *Wyeth*, the Supreme Court clarified the federal preemption doctrine by holding that a manufacturer could be liable under state law in a claim challenging an FDA-approved drug label.[118] Additionally, because the evidence suggested that FDA regulation needed supplemental enforcement measures to protect the public in the area of drug safety,[119] and perhaps because of the diminished deference the Court was willing to give to the FDA,[120] the Court held that private enforcement would enhance public safety by providing economic motivation to manufacturers to ensure safe labeling.[121]

In *Wyeth*, the plaintiff was treated with an intravenous drug that caused gangrene and the eventual amputation of her arm.[122] After settling her medical malpractice claims, the plaintiff sued the drug manufacturer for failure to adequately label the drug regarding the risks involved with its intravenous administration.[123]

The Supreme Court granted certiorari because of the significance of the preemption issue and "the fact that the FDA has changed its position on state tort law" to endorse federal preemption.[124] Characterizing the issue as whether a label's FDA approval under the FDCA preempted challenges to that label regarding the adequacy of its warnings,[125] the

---

(discussing alternatives to integrated regulation).

117. *See infra* Part II.B.3 (discussing the Supreme Court's decision in *Wyeth*).

118. *Wyeth*, 555 U.S. at 581; Gregory M. Dickinson, *An Empirical Study of Obstacle Preemption in the Supreme Court*, 89 NEB. L. REV. 682, 683 (2011) ("With its recent decision in *Wyeth v. Levine*, . . . the Court has clarified its preemption analysis.").

119. *Wyeth*, 555 U.S. at 578–79; Marie Boyd, *Unequal Protection Under the Law: Why FDA Should Use Negotiated Rulemaking to Reform the Regulation of Generic Drugs*, 35 CARDOZO L. REV. 1525, 1544 (2014).

120. O'Reilly, *supra* note 15, at 939; Vladeck, *supra* note 88, at 982.

121. *Wyeth*, 555 U.S. at 578–79; Konrad L. Cailteux, *Pharmaceutical Litigation Is Not Dead, but Neither Is Preemption*, ANDREWS HEALTH L. LITIG. REP., Apr. 22, 2009, at 1.

122. *Wyeth*, 555 U.S. at 559. The plaintiff was treated in a hospital with an anti-nausea drug for symptoms associated with migraine headaches. *Id.* The drug, which could be administered intravenously or intramuscularly, was known to be corrosive if it entered a patient's arteries. *Id.*

123. *Id.* The defendant drug manufacturer argued that because the drug label was approved by the FDA, federal law preempted the patient's claim and moved for summary judgment. *Id.* at 560.

124. *Id.* at 563. The FDA's policy reversal recommending federal preemption has been widely recognized as protecting the pharmaceutical industry's interests, rather than the health and safety of the public. Vladeck, *supra* note 88, at 982; *see also supra* notes 102–05 and accompanying text (discussing agency capture).

125. *Wyeth*, 555 U.S. at 565; Joseph F. Petros III, *The Other War on Drugs: Federal Preemption, the FDA, and Prescription Drugs After* Wyeth v. Levine, 25 NOTRE DAME J.L. ETHICS & PUB. POL'Y 637, 637 (2011).

Court held that the FDCA did not preempt state law.[126] In fact, the Court found that state law tort claims complement the FDA's enforcement efforts by providing additional regulation and oversight.[127]

The Court also rejected the defendant's argument that requiring manufacturers to comply with state law requirements would obstruct the purposes of Congress's labeling regulations.[128] The Court explained that in all preemption cases, Congress's purpose is the "ultimate touchstone," and that there is a presumption against preemption unless that is the "clear and manifest" intent of Congress.[129] The Court ascertained Congress' purpose by reviewing the legislative history of federal drug labeling regulation.[130] Prior to 1962, the FDA was

126. *Wyeth*, 555 U.S. at 581; Charlotte J. Skar, Case Comment, Wyeth v. Levine, *129 S. Ct. 1187 (2009)*, 86 N.D. L. REV. 405, 407 (2010). In two subsequent cases in this context, the Supreme Court distinguished *Wyeth* and found state law claims preempted by the FDCA. *See* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466 (2013); PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011). In *PLIVA*, the Court was careful to distinguish *Wyeth* because unlike in *PLIVA*, it was possible for the plaintiff in *Wyeth* to comply with both the FDCA as well as state tort laws. *PLIVA*, 131 S. Ct. at 2581.

127. *Wyeth*, 555 U.S. at 581. The Court rejected the defendant's preemption arguments, reasoning that it was not impossible to both observe FDCA requirements as well as fulfill state law requirements, and that state law tort claims do not obstruct execution of the Congress's purposes in the FDCA. *Id.* In its impossibility argument, the defendant's argued that it was impossible to modify the drug's warning label to comply with state law after it had been approved by the FDA. *Id.* at 568. The Court clarified, however, that the FDCA does not characterize products as misbranded merely because the label was amended after approval. *Id.* at 570. Rather, misbranding is defined by the substance of the label, including substance that fails to adequately warn of potential risks. *Id.* The Court added that "[t]he very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to [an FDA] regulation is difficult to accept—neither Wyeth nor the United States has identified a case in which the FDA has done so." *Id.* The Court noted that FDA regulations permitted drug manufacturers to change already approved labels to include new safety information without waiting for FDA approval if it concurrently filed an additional application with the FDA. *Id.* at 568 (citing 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2015)). The Court explained that drug manufacturers have the responsibility to ensure their drug labels adequately warn users of risks. *Wyeth*, 555 U.S. at 570–71. Thus, when the defendant became aware of the risk of gangrene from intravenous administration of the drug, it had the obligation to amend the label and file the change with the FDA. *Id.* at 571. The Court acknowledged that the FDA may have subsequently rejected the change. *Id.* Without any evidence that the FDA would have disapproved a label adding additional warnings, however, the Court concluded that it was not impossible for the defendant to comply with both the FDCA and state law. *Id.* at 572–73. *But see id.* at 605–08 (Alito, J., Dissenting) (asserting that because Congress put exclusive regulation authority in the FDA, conflict preemption should prevent state courts from overruling FDA safety guidelines).

128. *Id.* at 581 (majority opinion). *But see id.* at 582–84 (Thomas, J., concurring) (noting that the decision should have rested on the interpretation of statutory text rather than agency inaction).

129. *Id.* at 579 (majority opinion) (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)). *See generally* Retail Clerks v. Schermerhorn, 375 U.S. 96, (1963).

130. *Wyeth*, 555 U.S. at 566; William Hochul III, *Enforcement in Kind: Reexamining the Preemption Doctrine In* Arizona v. United States, 87 NOTRE DAME L. REV. 2225, 2249 n.150 (2012).

required to prove harm to prevent drugs from being marketed to the public.[131] However, Congress made several amendments to the FDCA in 1962 to shift the burden to the manufacturer to prove that a drug is both safe and effective when used as described on its proposed label.[132] Within these amendments was also a preemption provision that specified that state laws would only be preempted if in "direct and positive conflict" with the FDCA.[133] Subsequently, in 1976, when Congress added an express preemption clause for medical devices, it opted not to codify such a provision for drug labeling.[134]

The Court reasoned that if Congress believed common-law labeling claims obstructed its purposes, it would have expressly preempted such claims "at some point during its 70-year history."[135] In fact, Congress's preemption of medical devices demonstrates that it was aware of escalating tort litigation, and thus declining to similarly preempt labeling claims suggests a contrary purpose.[136] Furthermore, because Congress did not furnish a private right of action to consumers under the FDCA, the Court explained that it must have concluded that injured parties would be able to find adequate relief through common-law remedies.

In addition, the Court found no merit in the defendant drug manufacturer's reliance on a 2006 FDA labeling regulation preamble that declared "the FDCA establishes both a 'floor' and a 'ceiling,' so that FDA approval of labeling . . . preempts conflicting or contrary State law."[137] The Court noted that the FDA's statement contradicts the evidence of Congress's intent.[138] Not only did the rule itself not

131. *Wyeth*, 555 U.S. at 567; *see also* FDCA, Pub. L. No. 75-717, § 505(c), 52 Stat. 1040, 1052 (1938).

132. *Wyeth*, 555 U.S. at 567; Drug Amendments of 1962, Pub. L. No. 87-781 §§ 102(d), 104(b), 76 Stat. 780, 781, 784.

133. *Wyeth*, 555 U.S. at 567.

134. *Wyeth*, 555 U.S. at 567; Medical Device Amendments of 1976, Pub. L. No. 94-295, § 521, 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k(a) (2012)).

135. *Wyeth*, 555 U.S. at 574.

136. *Id.* at 574–75 ("Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."); *see also* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 166–67 (1989) (demonstrating Congress's recognition of rising tort litigation).

137. *Wyeth*, 555 U.S. at 580 (citing Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006)). However, in his dissent, "Justice Alito rejected the Court's interpretation of the 2006 preamble as having no weight, and instead argued that the FDA's labeling decisions bear the force of law." Andrea Ahn, Wyeth v. Levine*: Moving Away from the* Geier *Trend*, 87 DENV. U. L. REV. 561, 571 (2010) (citing *Wyeth*, 555 U.S. at 623 (Alito, J. dissenting)).

138. *Wyeth*, 555 U.S. at 577 (majority opinion); *see also* David A. Kessler & David C.

contain a preemption provision, but also the proposed rule explicitly explained that the rule would not preempt state law.[139]

The Court was particularly critical of the FDA's "dramatic change in position" from its historical view of state law providing significant additional enforcement that complements FDA regulation efforts.[140] Because of the FDA's limited resources in comparison to the amount of products on the market, the Court noted that manufacturers have superior knowledge about potential risks associated with their products.[141] As state tort claims expose drug safety issues and provide manufacturers with incentives to use adequate warning labels, the FDA traditionally regarded state claims as an additional critical measure of consumer protection that complements FDA regulations.[142] Thus, the FDA's policy reversal was at odds with its historical respect for state law remedies.[143]

Clarifying that administrative agencies are without authority to preempt state law without congressional delegation, the Court indicated that "some weight" may be accorded to an agency's position.[144] Unconvinced that state law claims obstruct Congress's purposes in FDA regulation, however, the Court explained that the amount of deference given to an agency's justification for its policy rests on "thoroughness, consistency and persuasiveness."[145] Under this analysis, the Court concluded that the FDA's 2006 labeling regulation preamble did not

---

Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 463 (2008) ("The agency's practice of non-participation in litigation was in keeping with the FDA's view that its regulatory efforts could comfortably coexist with state-law damage claims by consumers injured by drugs.").

139. *Wyeth*, 555 U.S. at 577.

140. *Id.*; *see also* O'Reilly, *supra* note 15, at 968–69 (citing Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000) (codified at 21 C.F.R. pt. 201 (2015)); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (eff. June 30, 2006) (codified at 21 C.F.R. pts. 201, 314, 601) ("When the FDA initially proposed the amendments in 2000, the preamble to the proposal expressly disavowed any intent to preempt state law tort actions. But when the final rule was published in the Federal Register in January 2006, the FDA unexpectedly changed its position to favor preemption.").

141. *Wyeth*, 555 U.S. at 578–79; *see* NAT'L ACAD., INST. OF MED., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 193–94 (2007) ("The [FDA] lacks the resources needed to accomplish its large and complex mission.").

142. *Wyeth*, 555 U.S. at 578–79; *see also* Bates v. Dow Agrosciences LLC, 544 U.S. 431, 451 (2005) (noting that private claims reveal risks and deter inadequate warnings).

143. *Wyeth*, 555 U.S. at 579.

144. *Id.* at 576 (citing Geier v. Am. Honda Motor Co., 529 U.S. 861, 883 (2000)).

145. *Id.* at 577 (citing United States. v. Mead Corp., 533 U.S. 218, 234–35 (2001); Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)).

warrant deference,[146] and rejected the FDA's new position that the FDCA preempted state tort lawsuits.[147]

2. Competitor Actions: The Lanham Act and *Lexmark International v. Static Control Components*

After *Wyeth* found product labeling that comports with FDA requirements might nonetheless be the basis for state law liability claims, the question remained whether suits challenging FDA-approved labels could be asserted under federal law.[148] The Lanham Act, the principal federal trademark statute, offers a cause of action not to consumers, but to competitors who have been harmed by false or misleading product descriptions.[149] The Lanham Act provides that a party using false descriptions or representations on products marketed in commerce are civilly liable to any competitor who is injured, or who believes they will be injured, by the deceptive packaging.[150] Section 45 of the Lanham Act explains that the purpose of the Act is to protect commercial parties from unfair competition by generating liability for the use of misleading and deceptive labeling.[151] This section discusses

---

146. *Wyeth*, 555 U.S. at 577 ("In 2006, the agency finalized the rule and, without offering States or other interested parties notice or opportunity for comment, articulated a sweeping position on the FDCA's pre-emptive effect in the regulatory preamble. The agency's views on state law are inherently suspect in light of this procedural failure.").

147. *Id.* at 581 ("In short, Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling.").

148. 1 LOUIS ALTMAN & MARIA POLLACK, CALLMANN ON UNFAIR COMPETITION, TRADEMARK AND MONOPOLIES § 5:4 (4th ed. 2007).

149. 15 U.S.C. § 1125(a) (2012) ("Any person who shall . . . use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, . . . shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any person who believes that he is or is likely to be damaged by the use of any such false description or representation."); *see* Brian Morris, *Consumer Standing to Sue for False and Misleading Advertising Under Section 43(a) of the Lanham Trademark Act*, 17 MEM. ST. U. L. REV. 417, 422 (1987).

150. 15 U.S.C. § 1125(a).

151. *Id.* § 1127; *see also* Dustin Marlan, *Trademark Takings: Trademarks As Constitutional Property Under the Fifth Amendment Takings Clause*, 15 U. PA. J. CONST. L. 1581, 1606 (2013) (citing S. REP. NO. 79-1333, at 4 (1946)) (noting that congressional hearings prior to the Act's passage revealed that one of its goals was to "secure to the business community the advantages of reputation and goodwill by preventing their diversion from those who have created them to those who have not"); Staci Zaretsky, *Trademark Law and Consumer Protection Law—Deception Is A Cruel Act: "Uniform" State Deceptive Trade Practices Acts and Their Deceptive Effects on the Trademark Claims of Corporate Competitors*, 32 W. NEW ENG. L. REV. 549, 557 (2010) (quoting George Russell Thill, *The 1988 Trademark Law Revision Act: Damage Awards for False Advertising and Consumer Standing Under Section 43 (a)—Congress Drops the Ball Twice*, 6 DEPAUL BUS. L.J. 361, 377 (1994)) (explaining that Section 45 shows the goal of the Lanham

the Lanham Act's cause of action, its standing requirements, and how the Supreme Court's decision in *Lexmark* expanded Lanham Act standing.[152]

a. The Lanham Act

Section 43(a) of the Lanham Act provides a cause of action to those harmed or who believe they are "likely" to sustain harm from deceptive marketing.[153] Plaintiffs are not required to identify particular consumers that were deceived; they need only show that the false or misleading message was "disseminated sufficiently to the relevant purchasing public."[154] Pursuant to Section 43(a), a party is exposed to liability if it markets its product in interstate commerce with false or misleading labeling, made either explicitly or impliedly.[155] The marketing must actually mislead or have the potential to mislead a substantial amount of consumers into purchasing the product, thereby injuring a competitor's business.[156]

If irreparable injury is merely likely and not realized, then remedy is limited to injunctive relief.[157] Monetary damages are only available if a party can establish that it sustained actual harm that was proximately caused by the deceptive marketing.[158] This is a difficult burden to meet

---

Act "is exclusively to protect the interests of a purely commercial class against unscrupulous commercial conduct").

152. See *infra* Part I.B.2 for a discussion of *Lexmark*.

153. Johnson & Johnson v. Carter-Wallace, Inc., 631 F.2d 186, 189 (2d Cir. 1980); Daniel J. Mulcahy, *Section 43(a) of the Lanham Act: Its Development and Potential*, 3 LOY. U. CHI. L.J. 327, 327 (1972).

154. Gregory Apgar, *Prudential Standing Limitations on Lanham Act False Advertising Claims*, 76 FORDHAM L. REV. 2389, 2400 (2008) (citing ALTMAN & POLLACK, *supra* note 148, § 2.3).

155. Morris, *supra* note 149, at 424. The plaintiff will have a claim if the false message concerns the manufacturer's own product, and if it imparts a false impression about how it compares to the plaintiff's product. *Id.* at 424 n.59. Before 1988, however, Section 43(a) did not provide a cause of action for a manufacturer's false claims regarding the plaintiff's product alone. *Id.* Then, in 1988, the Trademark Law Revision Act amended Section 43(a) to include a manufacturer's false claims solely about the plaintiff's product. 15 U.S.C. § 1125(a)(1)(B); Peter S. Massaro, III, *Filtering Through A Mess: A Proposal to Reduce the Confusion Surrounding the Requirements for Standing in False Advertising Claims Brought Under Section 43(a) of the Lanham Act*, 65 WASH. & LEE L. REV. 1673, 1689 (2008).

156. Morris, *supra* note 149, at 424 n.59 ("Such deception must be material."); Walsh & Klein, *supra* note 35, at 414 ("The Lanham Act . . . does not allow an advertiser to mislead consumers with half-truths. Therefore, even if an advertisement is literally true, the plaintiff may still prevail by showing that consumers received a false impression about the product.").

157. Morris, *supra* note 149, at 424. A preliminary injunction, on the other hand, may be available upon a showing that the advertisement is false or misleading. *Id.*

158. *Id.*; *see also* Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1390 (2014).

even with the acknowledgment that inherent to all commercial damages caused by misleading representations is the intervening step of materially deceiving consumers with the false message.[159] To show proximate cause, Lanham Act plaintiffs must show that consumers were actually misled by the deceptive label in making product assessments and purchasing decisions.[160]

While the Lanham Act does not give standing to the public as consumers,[161] parties with commercial injuries have standing to invoke Lanham Act protection from, and compensation for, damages proximately caused by false or misleading product labels.[162] This is based on the prudential standing principle that claims brought pursuant to a statute must be encompassed by the "zone of interests" that Congress intended to protect with the statute.[163] Until 2014, however, the zone of interests test was inconsistently applied, and the U.S. circuit courts were split on how to determine whether a commercial plaintiff had standing to bring a claim under Section 43(a).[164] For example, the Ninth Circuit limited claims to direct competitors that suffered injury to

159. *Lexmark*, 134 S. Ct. at 1391 (citing Harold H. Huggins Realty, Inc. v. FNC, Inc., 634 F.3d 787, 800–01 (Cal. Ct. App. 2011)); *see* Morris, *supra* note 149, at 424–25.

160. *See Lexmark*, 134 S. Ct. at 1391 ("[A] plaintiff suing under § 1125(a) ordinarily must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising; and that that occurs when deception of consumers causes them to withhold trade from the plaintiff."); Walsh & Klein, *supra* note 35, at 414 ("Courts often require survey data to determine whether an advertising claim leaves a false impression in its wake.").

161. Conte Bros. Auto. v. Quaker State-Slick 50, Inc., 165 F.3d 221, 229 (3d Cir. 1998) (reasoning that the language, structure, history, and evidence of congressional intent show the focus of the Lanham Act is on "anti-competitive conduct in a commercial context"). The House Bill that later became the Trademark Law Revision Act of 1989 had a provision that granted consumers a right of action for Section 43(a) claims, but this was eliminated in the final Act. Massaro, *supra* note 155, at 1690–91.

162. POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2235 (2014); Pomeranz, *Strategy*, *supra* note 4, at 636; *see also* 15 U.S.C. § 1125(a)(1) (2012). Prudential standing requires that a party's claim rest within the zone of interests covered by the statute under which the suit is brought. *Lexmark*, 134 S. Ct. at 1386 (citing Elk Grove Unified Sch. Dist. v. Newdow, 542 U.S. 1, 12 (2004)).

163. Massaro, *supra* note 155, at 1679. The Court first articulated the zone of interests requirement in *Association of Data Processing Service Organizations, Inc. v. Camp*, 397 U.S. 150, 153 (1970). "[T]he question of standing is . . . whether the interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." *Id.*

164. Apgar, *supra* note 154, at 2403; *Deceptive Business Practices*, 23 BUS. TORTS REP. 72 (2011) ("The federal Circuits have split on the issue of standing under Section 43(a) of the Lanham Act . . . ."); *see also* Massaro, *supra* note 155, at 1680–82 (hypothesizing that lower courts inconsistently applied the zone of interests test because they could not "discern what the test [was] and when it should be applied" and because they thought it only applied "when a party [was] challenging an administrative agency's action").

reputation or sales.[165] The First and Second Circuits focused on whether a plaintiff had a "reasonable interest" that demanded protection from the false representations.[166] Other circuits used a five-factor standing test.[167] Generally, the effect of these approaches was to institute narrower standards than those required under the zone of interests test.[168]

Thus, while *Wyeth* granted access to the courts to parties challenging false or mislabeling under state laws, commercial plaintiffs bringing claims under the Lanham Act were often denied access to the courts on the basis of standing.[169] The significant incongruity among the circuits regarding how to determine Lanham Act standing created ambiguity in all courts and fostered forum shopping.[170] Furthermore, sporadic application of Lanham Act protections against false or misleading labeling left enforcement gaps where FDA regulation was ineffective or nonexistent.[171]

b. *Lexmark International, Inc. v. Static Control Components* Clarified

---

165. *Lexmark*, 134 S. Ct. at 1385; Apgar, *supra* note 154, at 2404.

166. *Lexmark*, 134 S. Ct. at 1385; Apgar, *supra* note 154, at 2409.

167. Articulated in *Conte Bros. Automotive v. Quaker State-Slick 50, Inc.*, the five factors considered in determining standing are:

> (1) The nature of the plaintiff's alleged injury: Is the injury "of a type that Congress sought to redress in providing a private remedy for violations of the [Lanham Act]"? . . . (2) The directness or indirectness of the asserted injury. . . . (3) The proximity or remoteness of the party to the alleged injurious conduct. . . . (4) The speculativeness of the damages claim. . . . (5) The risk of duplicative damages or complexity in apportioning damages.

165 F.3d 221, 233 (3d Cir. 1998) (footnotes omitted); *Lexmark*, 134 S. Ct. at 1391–92.

168. Massaro, *supra* note 155, at 1683; *see also Lexmark*, 134 S. Ct. at 1388 (explaining that the zone of interests test properly asks whether Congress authorized a plaintiff's claim because courts "cannot limit a cause of action that Congress has created merely because 'prudence' dictates" (citation omitted)).

169. Massaro, *supra* note 155, at 1679 (citing 15 U.S.C. § 1125(a) (2012)) ("[C]ourts have been able to dismiss Section 43(a) claims for lack of standing despite the fact that the text of Section 43(a) states that 'any person who believes that he or she is likely to be damaged' by an act of false advertising may bring a civil action . . . ."); *see, e.g.*, Associated Gen. Contractors of Cal. v. Cal. State Council of Carpenters, 459 U.S. 519, 535 (1983); Phx. of Broward, Inc. v. McDonald's Corp., 489 F.3d 1156, 1162 (11th Cir. 2007).

170. Massaro, *supra* note 155, at 1697; Laurie Richter, Rep*roductive Freedom: Striking A Fair Balance Between Copyright and Other Intellectual Property Protections in Cartoon Characters*, 21 ST. THOMAS L. REV. 441, 475 (2009) ("Because jurisdictions are clearly split on whether willfulness is a prerequisite for an award of profits for violations of Section 43(a) of the Lanham Act, plaintiffs have been increasingly forum shopping.").

171. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2239 (2014) ("Because the FDA acknowledges that it does not necessarily pursue enforcement measures regarding all objectionable labels, if Lanham Act claims were to be precluded then commercial interests—and indirectly the public at large—could be left with less effective protection in the food and beverage labeling realm than in many other, less regulated industries." (footnote omitted)).

Lanham Act Standing

In 2014, three months before the Supreme Court decided *POM*, the Court clarified the standing requirement under the Lanham Act in *Lexmark International Inc. v. Static Control Components*.[172] Rejecting the different circuits' variety of approaches, the Court returned to the zone of interests test that simply asks whether a plaintiff's claim falls within the Lanham Act's cause of action.[173]

Lexmark International, Inc., sold printer toner cartridges with an offer for a 20% discount to customers who agreed to return empty cartridges to the company for refurbishment.[174] The offer was printed on the package labels with a statement that unwrapping the toner cartridges would signify assent to the terms.[175] Static Control Components, a company involved in toner cartridge remanufacturing, sued Lexmark under the Lanham Act for false and misleading labeling.[176] Static Control alleged that the terms on the cartridge packaging deceived consumers into believing they were legally obligated to return empty cartridges to Lexmark after using them.[177] Static Control argued that these misleading claims proximately caused it to lose sales.[178]

---

172. *Lexmark*, 134 S. Ct. at 1390; Ronald Mann, *Opinion Analysis: Scalia Treatise on Standing Law Gives Sixth Circuit First Affirmance of the Year*, SCOTUSBLOG (Mar. 28, 2014), http://www.scotusblog.com/2014/03/argument-analysis-scalia-treatise-on-standing-law-gives-sixth-circuit-first-affirmance-of-the-year/ ("The simplest way to summarize the Court's opinion is that it pretty much rejected out of hand everything that either the parties or the courts of appeals have said with regard to the topic at hand, and most of what the Court itself previously has said."); *see also* Daniel Fisher, *Lexmark May Be Liable For Attacking Printer-Cartridge Rivals, Supreme Court Says*, FORBES (Mar. 25, 2014), http://www.forbes.com/sites/danielfisher/2014/03/25/lexmark-may-be-liable-for-attacking-printer-cartridge-rivals-supreme-court-says/ ("This decision basically forces all of the circuits to redo their tests, which is rare for the Supreme Court, since it more often picks one circuit's test and orders the rest to follow it.").

173. *Lexmark*, 134 S. Ct. at 1390; Eric Goldman, *Supreme Court Changes False Advertising Law Across the Country*, FORBES (Mar. 26, 2014, 11:49 AM), http://www.forbes.com/sites/ericgoldman/2014/03/26/supreme-court-changes-false-advertising-law-across-the-country/.

174. *Lexmark*, 134 S. Ct. at 1383. Lexmark manufactured and sold laser printers and new and refurbished toner cartridges. *Id.*

175. *Id.* Each toner cartridge had a microchip installed in it that would disable the cartridge from further use until Lexmark replaced the chip. *Id.* "Remanufacturers" refurbished Lexmark's empty cartridges and sold them in direct competition with Lexmark's new and used cartridges. *Id.* Static Control Components was not a remanufacturer, but rather produced a microchip that could be used by remanufacturers to replace Lexmark's microchip and enable the toner cartridges for refurbishment and resale. *Id.* at 1384. Lexmark sued Static Control for copyright infringement, and Static Control countersued Lexmark under the Lanham Act for false and misleading labeling. *Id.*

176. *Id.*

177. *Id.*

178. *Id.* Specifically, Static Control alleged decreased sales to the remanufacturers due to reduced demand for cartridge refurbishment. *Id.*

The Supreme Court granted certiorari to establish the proper standard for determining standing for Lanham Act plaintiffs bringing claims for false or misleading advertising.[179] The Court noted that the various forms of the prudential standing test were at odds with the Court's "reaffirmation of the principle that a federal court's obligation to hear and decide cases within its jurisdiction is virtually unflagging."[180] The Court reasserted the zone of interests test that limits suits brought under a particular statute to only those that are encompassed by the zone of interests that Congress intended to protect with the statute.[181]

The Court did not engage in extensive statutory interpretation to determine the zone of interests because Section 45 of the Lanham Act explicitly states that its purpose is to generate liability for deceptive and misleading marketing and to protect those involved in interstate commerce from unfair competition.[182] The Court reasoned that while at common law "unfair competition was a plastic concept,"[183] it was recognized as involving actual and potential damage to business reputation as well as injury to sales.[184] Therefore, the Court held that to fall within the zone of interests of a Lanham Act false advertising claim,

---

179. *Id.* at 1385. "The decision was assigned to Scalia because of his strong interests in standing and statutory interpretation . . . . In it, the conservative justice was able to sweep away the somewhat squishy doctrine of prudential standing and replace it with a directive for judges to look strictly at the text of a federal statute to determine whether a plaintiff lies within the zone of interests Congress intended." Fisher, *supra* note 172.

180. *Lexmark*, 134 S. Ct. at 1386 (citing Sprint Commc'ns, Inc. v. Jacobs, 134 S. Ct. 584, 591 (2013)). "Just as a court cannot apply its independent policy judgment to recognize a cause of action that Congress has denied, . . . it cannot limit a cause of action that Congress has created merely because 'prudence' dictates." *Id.* at 1388 (citing Alexander v. Sandoval, 532 U.S. 275, 286–87 (2001)).

181. *Id.* The standing question is therefore whether the plaintiff's suit falls within the statute's cause of action, and the test is not one of general applicability, but rather hinges on the provisions of the statute being invoked. *Id.* at 1389. The Court explained that this is not a particularly arduous test, nor does it bar a claim unless the plaintiff's interests are so minimally connected to or in conflict with Congressional purposes that "it cannot reasonably be assumed that Congress authorized that plaintiff to sue." *Id.* (footnote omitted).

182. *Lexmark*, 134 S. Ct. at 1387 (citing Steel Co. v. Citizens for Better Env't, 523 U.S. 83, 97, 113 n.2 (1998); Clarke v. Sec. Indus. Ass'n, 479 U.S. 388, 394–95 (1987)). The Court noted that the Lanham Act does not demand exhaustive use of statutory interpretation methods, however, because the statute contains an explicit statement of purpose. *Id.* at 1389 (citing 15 U.S.C. § 1127 (2012)).

183. *Id.*; Ely–Norris Safe Co. v. Mosler Safe Co., 7 F.2d 603, 604 (Cal. Ct. App. 1925).

184. *Lexmark*, 134 S. Ct. at 1389–90; *see* Edward Rogers, *Book Review*, 39 YALE L.J. 297, 299 (1929) (reviewing HARRY D. NIMS, THE LAW OF UNFAIR COMPETITION AND TRADE MARKS (3d ed. 1929)). *See generally* RESTATEMENT (THIRD) OF TORTS, ch. 35, intro. note, at 536–37 (AM. LAW INST. 1938). The Court noted that, as every Circuit that decided the question concluded, while a consumer "hoodwinked" into buying an unsatisfactory product may have suffered damages, he does not have standing to bring a claim under the Lanham Act. *Lexmark*, 134 S. Ct. at 1390.

a plaintiff must assert damages to business reputation or commercial sales.[185]

The Court noted that Static Control did not bring its claim as a wronged consumer, but rather as a party with a commercial interest harmed by a manufacturer's false marketing representations.[186] As Static Control alleged damages from Lexmark's misleading packaging to both reputation and sales, the Court concluded that it was within the Act's zone of interests.[187] Furthermore, the Court found that Static Control adequately alleged that its damages were proximately caused by the misleading terms on Lexmark's packaging after it showed that consumers were materially deceived by the misleading packaging.[188]

Eliminating prudential standing limitations beyond the zone of interests requirement left a practical national standard in place that removed uncertainty and limited forum shopping for those seeking to file Lanham Act claims.[189] No longer would a Lanham Act claim for misleading labeling be dismissed because of a particular court's notion of what constitutes standing, as long as the plaintiff's commercial injury to reputation or sales was proximately caused by a defendant's false or misleading representations.[190] This reaffirmation of the zone of

185. *Id.*; *see also* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2234 (2014).

186. *Lexmark*, 134 S. Ct. at 1393, (citing 15 U.S.C § 1127).

187. *Id.* at 1393.

188. *Id.* at 1394. The Court explained that while proximate causation is generally not found where there is an intervening causal step, the concern that other factors contributed to a plaintiff's injuries were not a problem in this case. *Id.* The Court explained that the basis for that general rule is that typically there is a "discontinuity" between the harm to the direct victim and the damage to the subsequent victim, leaving open the possibility that the latter victim's injuries may have been caused by something else. *Id.* (citing Anza v. Ideal Steel Supply Corp., 547 U.S. 451, 458–59 (2006)). Because Static Control's microchips were only sold to remanufacturers for use in refurbishing Lexmark's toner cartridges, if Lexmark's deceptive marketing diminished remanufacturers' sales, it inevitably also reduced Static Control's sales. *Lexmark*, 134 S. Ct. at 1394 ("Static Control's allegations suggest that if the remanufacturers sold 10,000 fewer refurbished cartridges because of Lexmark's false advertising, then it would follow more or less automatically that Static Control sold 10,000 fewer microchips for the same reason, without the need for any speculative . . . proceedings or intricate, uncertain inquiries." (citing *Anza*, 547 U.S. at 459–60)). Reasoning that in this unique situation the remanufacturers could not be considered "more immediate victims than Static Control," the Court found that the intervening step was not fatal to establishing proximate causation. *Id.*

189. Fisher, *supra* note 172; Julia Revzin, *Lawyers Weigh In On Supreme Court's* Lexmark *Ruling*, LAW360 (Mar. 25, 2014, 8:33 PM), http://www.law360.com/articles/521983/lawyers-weigh-in-on-supreme-court-s-lexmark-ruling ("Resolving the long-time three-way circuit split about a proper test for 'prudential standing' in Lanham Act false-advertising cases also removes the incentive to forum shop.").

190. Fisher, *supra* note 172 ("The decision [wipes] away a judicially created doctrine known as 'prudential standing' that had allowed courts to dismiss lawsuits simply because they didn't think the plaintiff had the right to sue."); Revzin, *supra n*ote 189 ("[The] ruling in *Lexmark International v. Static Control* will allow parties with commercial interests that are directly

interests test significantly liberalized Lanham Act standing in many of the circuits, and enabled the Lanham Act to properly fulfill its legislative purpose of protecting those involved in commerce from injuries attributable to false marketing practices.[191]

After *Lexmark*, while the consumer public is unable to invoke the Lanham Act's protections, the wide range of parties who do have standing to bring such claims ensures that consumers ultimately benefit from private commercial enforcement of the Lanham Act's prohibition against misleading labeling.[192] This added safeguard is necessary to combat the proliferation of misleading food and beverage labels in today's marketplace due to the FDA's enforcement limitations.[193] As a complement, in *Wyeth*, the Court's holding that state law claims did not obstruct Congress' purposes in FDA label regulation suggests that Lanham Act claims challenging FDA-regulated food and beverage labels should similarly be permitted.[194] Significantly, however, *Wyeth* involved the federal preemption doctrine, which applies to federal preemption of state laws, and did not address causes of action brought under federal statutes, such as the Lanham Act.

II. DISCUSSION

Wyeth and *Lexmark* thus set the stage for *POM Wonderful LLC v. Coca-Cola Co.*[195] In *Wyeth*, the Court opened the door for litigants by acknowledging that state law tort claims were necessary supplements to inadequate FDA regulation in the effort to promote safe and fair product labeling.[196] The Court opened the door further in *Lexmark* by rejecting

---

impacted by advertising to have an opportunity to challenge those ads and protect their commercial interest.").

191. Duffy, *supra* note 101; Revzin, *supra n*ote 189 ("Today's decision opens the door for false-advertising claims that genuinely injure a noncompetitor, but were previously precluded because of standing. Allowing case merits to decide these issues is sound and reasoned.").

192. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2234 (2014) ("Though in the end consumers also benefit from the Act's proper enforcement, the cause of action is for competitors, not consumers."); Duffy, *supra* note 101 ("[A]lthough the lawsuits might pit merely one business against another, such litigation has the potential to benefit consumers, who may find commercial statements more reliable.").

193. *See supra* Part I.A (discussing FDA enforcement limitations); *cf.* Richard E. Coe & Brynne S. Madway, *Recent Supreme Court Decision Gives Competitor False Advertising Claims Added Juice*, DRINKER BIDDLE & REATH LLP (June 17, 2014), http://www.drinkerbiddle.com/resources/publications/2014/recent-supreme-court-decision-gives-competitor-false-advertising-claims-added-juice (stating that in its opinion in *POM*, the Supreme Court implied that "federal statutes such as the Lanham Act could impose a higher standard for a label" than FDA regulations).

194. *See supra* Part I.B.1 (discussing the Court's decision in *Wyeth*).

195. *POM*, 134 S. Ct. 2228.

196. *See supra* Part I.B.1 (discussing the Court's decision in *Wyeth*).

prudential standing limitations for Lanham Act claims.[197] When *POM* stepped through the door, the center of the controversy was the intersection of the Lanham Act and the FDCA, and at issue was whether a litigant may bring a claim challenging an FDA-approved product label under the Lanham Act.[198] The opinion did not explicitly question the efficacy of the FDA's labeling regulations or the substantive merits of POM's claim, yet they were unquestionably important issues in the case.[199] In a unanimous decision written by Justice Kennedy,[200] the Court found that the Lanham Act complemented the FDCA's prohibition against misleading product labels,[201] and held that Lanham Act suits challenging FDA-compliant food and beverage labels were permitted.[202]

A. Background

POM Wonderful LLC is a private company that cultivates pomegranates and produces pomegranate juices.[203] Following highly

197. *See supra* Part I.B.2 (discussing the Court's decision in *Lexmark*).

198. *See infra* Part II (discussing the Court's decision in *POM*).

199. Even Justice Kennedy admitted that he was deceived into believing Coca-Cola's pomegranate juice blend was actually made from pomegranate juice. Transcript of Oral Argument at 28, POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228 (2014) (No. 12-761) [hereinafter Oral Argument] (covering statement of Justice Kennedy to Coca-Cola's attorney: "[I]f the statute works in the way you say it does and that Coca-Cola stands behind this label as being fair to consumers, then I think you have a very difficult case to make."). Later, Coca-Cola's attorney defended the label as not being misleading, stating, "we don't think that consumers are quite as unintelligent as POM must think they are." *Id.* at 40. Justice Kennedy quipped in reply, "Don't make me feel bad because I thought that this was pomegranate juice." *Id.* Justice Alito also asked:

> You don't think there are a lot of people who buy pomegranate juice because they think it has health benefits, and they would be very surprised to find when they bring home this bottle that's got a big picture of a pomegranate on it, and it says "pomegranate" on it, that it is—what is it—less than one half of 1 percent pomegranate juice?

Id. at 23–24.

200. The decision was 8–0, with Justice Breyer taking no part in the consideration or opinion. *POM Wonderful LLC v. The Coca Cola Company*, SCOTUSBLOG, http://www.scotusblog.com/case-files/cases/pom-wonderful-llc-v-the-coca-cola-company/ (last visited Sept. 24, 2015); Lawrence Hurley, *Update 2-U.S. Rules for POM Against Coca-Cola in Labeling Dispute*, REUTERS (June 12, 2014 2:47 PM), http://www.reuters.com/article/2014/06/12/usa-court-beverages-idUSL2N0OT0QL20140612 (last visited Sept. 24, 2014).

201. POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2233 (2014) ("Congress intended the Lanham Act and the FDCA to complement each other with respect to food and beverage labeling.").

202. *Id.* at 2233; *False Advertising*, *supra* note 23, at 258 ("A unanimous US Supreme Court has ruled that the [FDCA] does not preclude private suits for false advertising under the Lanham Act.").

203. *POM*, 134 S. Ct. at 2235; *POM Wonderful Startup Story*, FUNDABLE, http://www.fundable.com/learn/startup-stories/pom-wonderful (last visited Sept. 24, 2015).

publicized studies that extolled the benefits of antioxidants in pomegranates,[204] POM markets its products to health-minded consumers.[205] One of POM's juices, a pomegranate blueberry juice blend contains 85% pomegranate juice and 15% blueberry juice.[206]

Perhaps capitalizing on POM's success,[207] Coca-Cola developed a pomegranate juice blend under its Minute Maid label.[208] Coca-Cola's product contained 99% apple and grape juices, 0.3% pomegranate juice, and 0.2% blueberry juice.[209] Made from less expensive ingredients, Coca-Cola's pomegranate blueberry juice sold for nearly five times less than POM's.[210]

Written across two lines on the Minute Maid bottle's front label was "Pomegranate Blueberry" in all capital letters, despite the minimal amounts of these ingredients.[211] Underneath, in a greatly reduced font

---

204. Rebecca Reisner, *Keeping POM Wonderful*, BLOOMBERG BUSINESSWEEK (Jan. 6, 2009), http://www.businessweek.com/managing/content/jan2009/ca2009016_106810.htm; *see also* Marion Nestle, *The FTC vs. POM Wonderful: The Latest Round*, FOOD POL. (May 23, 2012), http://www.foodpolitics.com/2012/05/the-ftc-vs-pom-wonderful-the-latest-round/ ("POM has invested more than $35 million in research to prove that pomegranate juice has health benefits."). *But cf. id.* ("[E]veryone should be suspicious of the results of sponsored studies . . . .").

205. Nina Totenberg, *POM Wonderful Wins a Round in Food Fight with Coca-Cola*, NPR: SALT (June 12, 2014), http://www.npr.org/blogs/thesalt/2014/06/12/321390014/pom-wonderful-wins-a-round-in-food-fight-with-coca-cola; *see* Nestle, *supra* note 204 ("The owners must believe that nobody will buy pomegranate juice and supplements for any reason other than health benefits.").

206. Totenberg, *supra* note 205; News Desk, *Supco: FDA-Approved Label Does Not Prevent False Advertising Claims*, FOOD SAFETY NEWS (June 13, 2014), http://www.foodsafetynews.com/2014/06/fda-approved-label-does-not-prevent-false-advertising-claims/#.VD8fvr4lofl.

207. *See* Michael Bobelian, *In* POM v. Coca-Cola, *Supreme Court Could Shake Up Food Labeling*, FORBES (Apr. 22, 2014, 3:06 PM), http://www.forbes.com/sites/michaelbobelian/2014/04/22/supreme-court-asked-to-referee-dispute-between-coca-cola-and-pom/ (noting that manufacturers began producing "beverages with little pomegranate juice that piggybacked on the fruit's popularity [POM] had largely developed with the introduction of its line of drinks"); Meghan Neal, *POM Sues Minute Maid For Exploiting Health Benefits Of Pomegranate*, HUFFINGTON POST, http://www.huffingtonpost.com/2010/07/15/pom-sues-minute-maid-for_n_647420.html (last updated Nov. 17, 2011, 9:02 AM)

208. *POM*, 134 S. Ct. at 2235; *Minute Maid Enhanced Pomegranate Blueberry Flavored 100% Juice Blend of 5 Juices*, MINUTE MAID, http://www.minutemaid.com/juice-drinks/pomegranate-blueberry-flavor-59-fl-oz-bottle [https://web.archive.org/web/20141108231138/http://www.minutemaid.com/juice-drinks/pomegranate-blueberry-flavor-59-fl-oz-bottle#] (last visited Sept. 24, 2015).

209. *POM*, 134 S. Ct. at 2235; Adam Liptak, *Coke Can Be Sued by Rival Over Juice Claim, Court Says*, N.Y. TIMES (June 12, 2014), http://www.nytimes.com/2014/06/13/business/supreme-court-says-coca-cola-can-be-sued-by-Pom-Wonderful.html?_r=0.

210. *POM*, 134 S. Ct. at 2235; Totenberg, *supra* note 205.

211. *POM*, 134 S. Ct. at 2235; Robert Barnes, *Supreme Court Says Coca-Cola Can Be Sued Over Juice Drink Label*, WASH. POST (June 12, 2014), http://www.washingtonpost.com/politics/supreme-court-says-coca-cola-can-be-sued-over-juice-drink-label/2014/06/12/20e42536-f240-11e3-914c-1fbd0614e2d4_story.html.

size, were the words "Flavored Blend of 5 Juices."[212] Also on the label was an artful depiction of some blueberries, grapes, and raspberries leaning against apple and pomegranate halves.[213]

POM sued Coca-Cola under the Lanham Act, seeking damages and an order barring the deceptive labeling.[214] POM alleged that Coca-Cola's misleading label caused consumers to believe the product contained mostly pomegranate and blueberry juices instead of containing less than a third of a percent of each.[215] As consumers were deceived into believing they were purchasing a comparable product at lower cost, POM claimed its sales were diverted to Coca-Cola.[216]

Coca-Cola stood by its label, arguing that its FDA approval precluded POM's suit.[217] The district court agreed with Coca-Cola and granted its motion for summary judgment.[218] Reasoning that the FDA already addressed the issues underlying POM's claim and expressly approved of Coca-Cola's label, the district court found that the FDCA precluded any challenge to the pomegranate blueberry juice blend's label or name.[219] In fact, the court explained that it was unable to find

---

212. *POM*, 134 S. Ct. at 2235; *see also id.* ("And below that phrase, in still smaller type, were the words 'from concentrate with added ingredients'—and, with a line break before the final phrase—'and other natural flavors.'"); Marion Nestle, POM v. Coca-Cola *at the Supreme Court: The Mind Boggle*s, FOOD POL. (Apr. 23, 2014), http://www.foodpolitics.com/2014/04/pom-v-coca-cola-at-the-supreme-court-the-mind-boggles/ (describing the label of Coca-Cola's product).

213. *POM*, 134 S. Ct. at 2235; Nestle, *supra* note 212.

214. First Amended Complaint for False Advertising at 11–12, POM Wonderful LLC v. Coca-Cola Co., 727 F. Supp. 2d 849, 872 (C.D. Cal. 2010) (No. CV-08-06237-SJO-FMO) [hereinafter Complaint]; *see also POM*, 134 S. Ct. at 2235.

215. *POM*, 134 S. Ct. at 2235; Petitioner's Brief, *supra* note 18, at 2; *see also* Oral Argument, *supra* note 199, at 14 (quoting POM attorney Seth P. Waxman, "What's misleading consumers here is they have no way on God's green earth of telling that the total amount of blueberry and pomegranate juice in this product can be dispensed with a single eyedropper. It amounts to a teaspoon in a half gallon.").

216. *POM*, 134 S. Ct. at 2235; John Kell, *Coca-Cola Squeezed by Supreme Court Juice Ruling*, FORTUNE (June 12, 2014, 12:06 PM), http://fortune.com/2014/06/12/coke-lawsuit-pom/ (last visited Sept. 24, 2015) ("Pom had alleged the advertising, label and name of the Minute Maid juice led to 'confusion' that caused Pom to lose sales.").

217. Brief for Respondent at 16, POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228 (2014) (No. 12-761) [hereinafter Respondent's Brief] ("The specificity of the food/juice naming and labeling provisions of the FDCA/NLEA (and FDA's regulations thereunder) relative to the broad and general language of Lanham Act § 43(a) further shows that Congress intended to preclude a Lanham Act claim in the circumstances here. FDA's regulations authorize the name and label of respondent's product in every respect challenged by petitioner."). Bobelian, *supra* note 207; Kell, *supra* note 216.

218. POM Wonderful LLC v. Coca-Cola Co., 727 F. Supp. 2d 849, 873 (C.D. Cal. 2010); *see also POM*, 134 S. Ct. at 2235.

219. *POM*, 727 F. Supp. 2d at 871–73 (C.D. Cal. 2010) ("[B]ecause [Coca-Cola's label] complies with the relevant FDA regulations . . . even if not to the liking of Pom, this Court cannot conclude that the Juice's naming and labeling is misleading, inaccurate, or outside the purview of

Coca-Cola's marketing was misleading or inaccurate because the product did not violate FDA labeling and naming regulations.[220]

The Ninth Circuit affirmed, noting that permitting Lanham Act challenges to FDA-approved labels conflicted with Congress's intention to bestow sole enforcement authority over food and beverage labeling on the FDA.[221] Further, the court deduced that the "Pomegranate Blueberry" name was permitted by FDA regulations because a "manufacturer may name a beverage using the name of a flavoring juice that is not predominant by volume."[222] According to the Ninth Circuit, as FDA regulations prohibit false or misleading labeling,[223] and the product's name was permitted, allowing POM's claim would have undermined the FDA's apparent authorization of the name as not misleading.[224]

Similarly, the court explained that because the label included the required qualifying language, "Flavored Blend of 5 Juices," and because the FDA did not specify that it could not be written in much smaller print below the larger "Pomegranate Blueberry," POM's challenge would undermine the FDA's expertise.[225] Reasoning that the FDA could have enacted further regulations if it considered size and font requirements necessary to avoid deception, the court concluded that it could not act where the FDA had not.[226]

B. Parties Commercially Injured by Misleading Labels Have Lanham Act Standing

The Supreme Court first clarified that POM had standing to bring its Lanham Act suit against Coca-Cola.[227] Noting that the Act provides a right of action for unfair competition from misleading labeling, the

---

the FDA. . . . Pom's challenge is therefore barred."); *see also POM*, 134 S. Ct. at 2235–36.

220. *POM*, 727 F. Supp. 2d 849, 872 (C.D. Cal. 2010); *see also POM*, 134 S. Ct. at 2235–36.

221. POM Wonderful LLC v. Coca-Cola Co., 679 F.3d 1170, 1175–76 (9th Cir. 2012) ("Where the FDA has not concluded that particular conduct violates the FDCA, we have even held that a Lanham Act claim may not be pursued if the claim would require litigating whether that conduct violates the FDCA.").

222. *Id.* at 1176–77 (citing 21 C.F.R. § 102.33(c), (d) (2015)).

223. *Id.* at 1175 (9th Cir. 2012) ("The FDCA . . . comprehensively regulates food and beverage labeling. It provides that a food is misbranded if its labeling is false or misleading in any particular . . . . The FDA, for its part, has promulgated regulations that address how a manufacturer may name and label its juice beverages.").

224. *Id.* at 1177 ("Despite speaking extensively to how prominently required words or statements must appear, the FDA has not (so far as we can tell) required that all words in a juice blend's name appear on the label in the same size . . . .").

225. *Id.*

226. *Id.*

227. POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2234 (2014)

Court invoked its decision in *Lexmark* to explain the zone of interests standing principle.[228] Parties that allege commercial injuries to reputation or sales proximately caused by misleading representations have standing to bring Lanham Act claims.[229] Foreshadowing its later rationale, the Court added that while consumers do not have standing to bring such actions, consumers ultimately benefit from Lanham Act claims.[230] As POM alleged that it suffered reduced sales that were caused by Coca-Cola's deceptive juice label, the Court concluded that POM had standing to bring the claim.[231]

C. Congress Did Not Intend the FDCA to Preclude Lanham Act Claims

Coca-Cola argued that because FDA regulations permitted its juice label and because Congress intended "national uniformity" in food and beverage labeling,[232] the FDCA precluded POM's Lanham Act claim.[233] Coca-Cola asserted that this congressional purpose is evident in the centralization of FDA enforcement authority in the federal government, the explicitness of the FDCA, and the express preemption of some state laws.[234] The Court disagreed, finding that none of these particulars demonstrated congressional intent or strategy to preclude Lanham Act suits.[235]

---

228. *Id.* (citing Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1390 (2014)) ("As the Court held this Term, the private remedy may be invoked only by those who allege an injury to a commercial interest in reputation or sales.").

229. *Id.*; *see also Lexmark*,134 S. Ct. at 1390.

230. *POM*, 134 S. Ct. at 2234; *see infra* Part II.B (discussing the Court's treatment of Lanham Act standing in *POM*); *see also infra* Parts III.E (discussing how integrated regulation benefits consumers), IV.A (predicting that allowing private enforcement will lead to more rigorous labeling).

231. *POM*, 134 S. Ct. at 2234 ("POM's cause of action would be straightforward enough but for Coca-Cola's contention that a separate federal statutory regime, the FDCA, allows it to use the label in question and in fact precludes the Lanham Act claim.").

232. Respondent's Brief, *supra* note 217, at 1 ("In this case, a private litigant invoking the Lanham Act seeks to disrupt the national uniformity Congress has required in the naming and labeling of food and juice products."); *POM*, 134 S. Ct. at 2239.

233. *POM*, 134 S. Ct. at 2234. The Court also clarified that the case at bar did not involve the issue of federal preemption. "In pre-emption cases, the question is whether state law is preempted by a federal statute, or in some instances, a federal agency action. This case, however, concerns the alleged preclusion of a cause of action under one federal statute by the provisions of another federal statute." *Id.* at 2236. Thus, the intricate federal preemption doctrine was not implicated. *False Advertising*, *supra* note 23, at 259; Jennifer M. Thomas, *POM's Lanham Act Claims Against Coca-Cola are Not Precluded by the FDC Act*, FDA L. BLOG (June 12, 2014), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/06/poms-lanham-act-claims-against-coca-cola-are-not-precluded-by-the-fdc-act.html.

234. Respondent's Brief, *supra* note 217, at 16; *POM*, 134 S. Ct. at 2239.

235. *POM*, 134 S. Ct. at 2239 ("[T]hese details of the FDCA do not establish an intent or design to preclude Lanham Act claims.").

Coca-Cola first argued that congressional intent is demonstrated in FDA enforcement authority resting in the federal government and not in private regulation.[236] The Court noted, however, that POM was not attempting to enforce the FDCA or FDA regulations.[237] Rather, POM sought to enforce the Lanham Act, and federal enforcement of the FDCA does not suggest congressional intent to ban private enforcement of the Lanham Act or any other federal statute.[238]

The Court emphasized that neither the Lanham Act nor the FDCA contain any express provision that bars or restricts Section 43(a) claims that challenge FDA-compliant labels.[239] Lanham Act claims are not precluded by any statutory provision,[240] and the lack of such a provision provides evidence that Congress did not intend to forbid false or misleading marketing claims challenging FDA-regulated products.[241] The Court channeled its logic from *Wyeth*, reasoning that because these statutes operated concurrently for more than seventy years, if it was Congress's purpose to foreclose Lanham Act claims, it would have enacted a preemption provision at some point.[242] Congress's refusal to amend the FDCA to preempt false or misleading labeling claims throughout that seventy-year period, even when enacting other amendments to both statutes,[243] is evidence that it was not Congress's intention that FDA oversight would be the sole means of compelling appropriate food and beverage labeling.[244]

---

236. Respondent's Brief, *supra* note 217, at 16; *POM*, 134 S. Ct. at 2239. During Oral Arguments, Coca-Cola's attorney also stated, "We're not talking about supplementing the [FDA]'s enforcement resources. We're talking about supplanting their regulatory judgment in the area." Oral Argument, *supra* note 199, at 23.

237. *POM*, 134 S. Ct. at 2239.

238. *Id.* ("The centralization of FDCA enforcement authority in the Federal Government does not indicate that Congress intended to foreclose private enforcement of other federal statutes.").

239. *Id.* at 2237 ("Beginning with the text of the two statutes, it must be observed that neither the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA.").

240. *Id.* ("[T]he FDCA, by its terms, does not preclude Lanham Act suits.").

241. *Id.* (citing Wyeth v. Levine, 555 U.S. 555, 574 (2009)) (noting that if Congress "concluded, in light of experience, that Lanham Act suits could interfere with the FDCA, it might well have enacted a provision addressing the issue").

242. *Id.* at 2239, (citing *Wyeth*, 555 U.S. at 574); *see also* Oral Argument, *supra* note 199, at 26 (quoting Justice Kagan: "There are plenty of statutes which say you can't bring State law or Federal law claims. Congress knows how to do that.").

243. *POM*, 134 S. Ct. at 2237; *see, e.g.*, Nutrition Labeling and Education Act of 1990, 104 Stat. 2353; Trademark Law Revision Act of 1988, § 132, 102 Stat. 3935, 3946 (including an amendment that added to the FDCA an express preemption provision with respect to state laws addressing food and beverage misbranding); *see also* § 6, 104 Stat. at 2362 (codified at 21 U.S.C. § 343–1 (2012)).

244. *POM*, 134 S. Ct. at 2237 (citing *Wyeth*, 555 U.S. at 575).

In addition, Coca-Cola asserted that the purpose of the preemption provision in the NLEA that was added to the FDCA in 1990 was to provide manufacturers with nationally uniform regulations rather than "a patchwork" of state requirements.[245] The NLEA's preemption clause prohibits states from establishing regulations "that are of the type but not identical to" particular FDA labeling requirements.[246] Coca-Cola argued that allowing false and misleading labeling claims under the Lanham Act would undermine the goal of the preemption provision.[247] The Court disagreed, noting that this provision only applies to some specific FDCA requirements and, even then, only applies to state law and not federal statutes.[248] The Court reasoned that preemption of some state laws does not demonstrate congressional intent to preempt federal lawsuits; instead, the Court recognized that such specificity actually suggests that it was not Congress' purpose to prohibit regulation in other forms. [249]

Furthermore, the Supreme Court questioned whether permitting Lanham Act claims would create a "disuniformity" that would conflict with congressional purposes.[250] Congress opted to grant a cause of action to parties commercially injured by false or misleading labeling to promote a uniform national policy against unfair competition.[251] Unlike state laws and regulations that could vary widely by jurisdiction, the Lanham Act's protections extend evenly to all plaintiffs within the statute's zone of interests.[252] Additionally, Congress often grants federal rights of action in fields where it expresses a need for national uniformity.[253] In fact, as the Court noted in *Wyeth*, "[t]he FDCA contemplates that federal juries will resolve most misbranding

245. Respondent's Brief, *supra* note 217, at 24; *POM*, 134 S. Ct. at 2239.

246. *POM*, 134 S. Ct. at 2238 (citing § 343–1(a)(1) to (a)(5)).

247. Respondent's Brief, *supra* note 217, at 49; *POM*, 134 S. Ct. at 2239.

248. *POM*, 134 S. Ct. at 2239 ("A significant flaw in this argument is that the pre-emption provision by its plain terms applies only to certain state-law requirements, not to federal law. . . . Coca–Cola in effect asks the Court to ignore the words 'State or political subdivision of a State' in the statute.").

249. *Id.* at 2238 ("By taking care to mandate express pre-emption of some state laws, Congress if anything indicated it did not intend the FDCA to preclude requirements arising from other sources."); *see also* Setser v. United States, 132 S. Ct. 1463, 1469–70 (2012) (applying the principle that expression of particular matters implies the exclusion of others).

250. *POM*, 134 S. Ct. at 2239.

251. *Id.* (noting that Congress chose to utilize the Lanham Act private cause of action to enforce its national policy prohibiting unfair competition).

252. *Id.* at 2240.

253. *Id.* (comparing Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 162 (1989) (noting congressional purpose to establish national uniformity in intellectual property law), with 35 U.S.C. § 281 (2012) (granting a private cause of action for patent infringement)).

claims."[254] Thus, the Court concluded that it was Congress's purpose to allow Lanham Act claims challenging FDA-regulated labels to enforce a uniform prohibition against false or misleading labeling.[255]

Coca-Cola also argued that the specificity of FDA regulations demonstrates congressional intent to preclude Lanham Act claims.[256] The Court acknowledged that FDA regulations are considerably more detailed than the Lanham Act, particularly regarding labeling requirements for juice blends.[257] Yet, the Court considered this immaterial because the FDCA and the Lanham Act have different objectives and scopes and therefore complement, rather than conflict, each other.[258] While both the FDCA and the Lanham Act prohibit false or misleading food and beverage labeling, regulations implemented by the FDA are in place to protect the consumer public.[259] Conversely, the Lanham Act protects those engaged in commerce from unfair competition.[260] The Court explained that it would be contrary to Congress's purpose to find that one federal statute precludes the exercise of another that is complementary.[261]

Furthermore, the Lanham Act and the FDCA also involve complementary remedies.[262] Lanham Act enforcement substantially

---

254. *Id.* (citing Wyeth v. Levine, 555 U.S. 555, 570 (2009)).

255. *Id.* at 2240 ("The Lanham Act itself is an example of this design: Despite Coca–Cola's protestations, the Act is uniform in extending its protection against unfair competition to the whole class it describes.").

256. Respondent's Brief, *supra* note 217, at 36; *POM*, 134 S. Ct. at 2240.

257. *POM*, 134 S. Ct. at 2240 (referring to Food Labeling; Declaration of Ingredients; Common or Usual Name for Nonstandardized Foods; Diluted Juice Beverages, 58 Fed. Reg. 2897–2926 (1993)).

258. *Id.* at 2240 ("[N]either the statutory structure nor the empirical evidence of which the Court is aware indicates there will be any difficulty in fully enforcing each statute according to its terms."); *see also id.* at 2238 (citing J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc., 534 U.S. 124, 144 (2001)) ("[W]e can plainly regard each statute as effective because of its different requirements and protections.").

259. *Id.* at 2234 (citing 62 Cases of Jam v. United States, 340 U.S. 593, 596 (1951)); FDCA, § 401, 52 Stat. 1040, 1046 (codified at 21 U.S.C. § 341 (2012)) (explaining that the FDA may promulgate regulations to "promote honesty and fair dealing in the interest of consumers").

260. *POM*, 134 S. Ct. at 2238 (citing Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1389–90 (2014)). During oral arguments, Justice Ginsburg told Coca-Cola's attorney, "[t]he law that you are relying on is supposed to be concerned with nutritional information and health claims, not a competitor losing out because of the deception." Oral Argument, *supra* note 199, at 29. Thus, Justice Ginsburg continued, "[t]he consumer is able to buy the Coca-Cola product much cheaper and the POM product costs more; the consumer thinks that they are both the same, so they'll buy the cheaper one." *Id.*

261. *POM*, 134 S. Ct. at 2238 ("Where two statutes are complementary, it would show disregard for the congressional design to hold that Congress intended one federal statute nonetheless to preclude the operation of the other." (citing J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc., 534 U.S. 124, 144 (2013))).

262. *Id.* at 2238 ("The two statutes complement each other with respect to remedies in a more

relies on competitors asserting commercial damages, whereas the FDCA provides no private cause of action and its enforcement is primarily the FDA's responsibility.[263] The Court explained that competitors have superior perspective and expertise about the sales and marketing dynamics of their industries.[264] Not only are manufacturers aware of how marketing affects consumer purchasing, but they also have an interest in discovering instances of false or misleading labeling (and may do so sooner and perhaps more accurately than FDA investigators).[265] This industry expertise is brought to bear in Lanham Act claims, through which competitors can safeguard their interests against misleading product representations.[266] The Lanham Act's monetary remedy provides added encouragement for injured parties to reveal deceptive labels and deters manufacturers from engaging in false or misleading labeling practices.[267] Because enforcement under both statutes increases protections for consumers as well as parties with commercial interests at stake, the Court concluded that permitting Lanham Act claims is consistent with congressional intent.[268]

Similarly, the Court acknowledged that because the FDA does not take action against many products that are mislabeled,[269] prohibiting Lanham Act claims like POM's may leave competitors as well as consumers exposed to such violations.[270] The FDA also does not pre-approve food and beverage labels like it does for other product labels—such as pharmaceuticals—and, therefore, barring Lanham Act claims would leave the food and beverage industry with wide regulation

---

fundamental respect."); *see* 15 U.S.C. § 1125(a) (2012) (Lanham Act cause of action).

263. *POM*, 134 S. Ct. at 2235 (citing 21 U.S.C. §§ 333(a)–337 (FDCA penalties)).

264. *POM*, 134 S. Ct. at 2238 ("Competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely upon certain sales and marketing strategies.").

265. *Id.* ("[Competitors'] awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators.").

266. *Id.* ("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."); *see* Liptak, *supra* note 209 ("[Justice Kennedy] added that competitors like Pom had the incentives and expertise to help enforce the false-advertising law.").

267. *POM*, 134 S. Ct. at 2238–39, (citing J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc., 534 U.S. 124, 144 (2013)) ("Lanham Act suits, to the extent they touch on the same subject matter as the FDCA, provide incentives for manufacturers to behave well.").

268. *Id.* at 2238–39 ("This is quite consistent with the congressional design to enact two different statutes, each with its own mechanisms to enhance the protection of competitors and consumers.").

269. *Id.* at 2239 (citing Brief for United States as Amicus Curiae at 16, POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228 (2014) (No. 12-761) [hereinafter Amicus Brief]).

270. *See id.* ("[I]f Lanham Act claims were to be precluded then commercial interests—and indirectly the public at large—could be left with less effective protection in the food and beverage labeling realm than in many other, less regulated industries.").

gaps.[271] Reasoning that Congress likely did not intend "the FDCA's protection of health and safety to result in less policing of misleading food and beverage labels than in competitive markets for other products," the Court reasoned that precluding Lanham Act challenges to food and beverage labels would conflict with congressional purposes.[272]

Additionally, it was the government's position that that Lanham Act suits are prohibited if FDCA requirements explicitly require or permit those features of a label that are challenged in the claim.[273] The government, as amicus curiae, asserted that because Coca-Cola's Pomegranate Blueberry juice blend followed FDA naming requirements, POM's challenge to the product name was precluded.[274] Conversely, because FDA regulations do not specifically address other features of the label, such as the images of the fruits and the size of the disclaimer, the government contended that those components may be challenged.[275]

The Supreme Court found no evidence that the FDA contemplated the complete range of interests that the Lanham Act encompasses.[276] In fact, the Court noted that the FDA expressly urged manufacturers to design product labels to reflect an accuracy greater than what was required by FDA regulations.[277] Additionally, the Court distinguished *POM* from *Geier v. American Honda Motor Co.*, in which a plaintiff's claim was barred as being in direct conflict with the agency's policy.[278] Noting that the FDA is without authority to administer Lanham Act provisions, the Court reasoned that POM's claim did not undermine the FDA's judgment.[279]

---

271. *See id.* ("[I]t would appear the FDA does not preapprove food and beverage labels under its regulations and instead relies on enforcement actions, warning letters, and other measures."); Amicus Brief, *supra* note 269, at 16 ("FDA does not approve juice labels . . . .").

272. *POM*, 134 S. Ct. at 2241 ("The position Coca–Cola takes in this Court that because food and beverage labeling is involved it has no Lanham Act liability here for practices that allegedly mislead and trick consumers, all to the injury of competitors, finds no support in precedent or the statutes.").

273. Amicus Brief, *supra* note 269, at 11.

274. *Id.* at 17–18; *see also POM*, 134 S. Ct. at 2240.

275. Amicus Brief, *supra* note 269, at 18–19; *see also POM*, 134 S. Ct. at 2240.

276. *POM*, 134 S. Ct. at 2241 (citing Food Labeling; Declaration of Ingredients; Common or Usual Name For Nonstandardized Foods; Diluted Juice Beverages, 58 Fed. Reg. 2897, 2919–20 (1993)) (noting that while FDA rulemaking of the juice-naming regulation briefly alluded to a balancing of interests. it did not mention the Lanham Act)).

277. *POM*, 134 S. Ct. at 2241 (citing Food Labeling, 58 Fed. Reg. at 2897-01) ("[W]hile FDA is not requiring that each juice in a beverage be declared in the name of the product, it encourages such declarations.").

278. *POM*, 134 S. Ct. at 2241 (citing Geier v. Am. Honda Motor Co., 529 U.S. 861, 875 (2000)).

279. *Id.*

Furthermore, the Court noted that the government's assertion was based on the flawed presumption that the FDCA and FDA regulations represent a "ceiling" on food and beverage labeling requirements.[280] Rather, the Court clarified, Congress intended the Lanham Act to complement the FDCA in regulating food and beverage labels.[281] While administrative regulations may be enacted that bar private enforcement,[282] abolishing a recognized federal remedy merely because it covers corresponding subject matter "is a bridge too far."[283] Thus, the Court held that private Lanham Act claims challenging food and beverage labels regulated by the FDA were not prohibited.[284]

Thus, with a unanimous decision written by Justice Kennedy, the Supreme Court rejected the lower courts' conclusions that POM's Lanham Act claims conflicted with the FDCA.[285] The Court explained that nothing in the statutory text, legislative history, or structure of either the Lanham Act or the FDCA suggested congressional intent to preclude false or misleading labeling claims such as POM's.[286] Rather, the Court found that the Lanham Act complemented the FDCA's prohibition against false or misleading product labels,[287] and held that Lanham Act suits challenging FDA-compliant food and beverage labels were permitted.[288]

III. ANALYSIS

In *POM*, the Supreme Court acknowledged the FDA's enforcement limitations[289] and permitted private enforcement against false or

280. *Id.* at 2240 (citing Brief for the United States as Amicus Curiae Supporting Neither Party at 11, POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228 (2014) (No. 12-761)).

281. *Id.*

282. *Id.* at 2241 (citing Wyeth v. Levine, 555 U.S. 555, 576 (2009)).

283. *Id.* ("An agency may not reorder federal statutory rights without congressional authorization.").

284. *Id.* ("Congress did not intend the FDCA to preclude Lanham Act suits like POM's.").

285. *Id.* at 2233; *see also id.* at 2241–42 ("The judgment of the Court of Appeals for the Ninth Circuit is reversed, and the case is remanded for further proceedings consistent with this opinion.").

286. *Id.* at 2233; Thomas, *supra* note 233.

287. *POM*, 134 S. Ct. at 2233 ("Congress intended the Lanham Act and the FDCA to complement each other with respect to food and beverage labeling.").

288. *Id.*; *False Advertising*, *supra* note 23, at 258 ("A unanimous US Supreme Court has ruled that the Federal Drug and Cosmetics Act (FDCA) does not preclude private suits for false advertising under the Lanham Act.").

289. *See supra* Part II.C (discussing how Congress did not intend to preclude Lanham Act claims with the FDCA); *see also POM*, 134 S. Ct. at 2235 (noting that the FDCA does not provide a private cause of action); *id.* at 2238 (explaining that the FDA knowledge and expertise of market dynamics is inferior to that of business competitors); *id.* at 2239 (noting that the FDA does not take action against many misleading product labels); *id.* (explaining that the FDA does

misleading labeling by competitors as an additional safeguard to protect consumer as well as commercial interests.[290] This Part analyzes two alternative enforcement methods the Court could have embraced,[291] and briefly examines the decision from the perspective of the Justices during oral arguments.[292] This Part also explores the Court's reasoning and finds that it represents an approval of cooperative regulation between the federal government and private parties that is consistent with the Court's presumption against preemption in general[293] and its treatment of the preemption doctrine in *Wyeth* in particular.[294] Additionally, this Part explains that the unanimous decisions in *POM* and *Lexmark* strengthen the FDCA's and the Lanham Act's protections against false or misleading labeling by giving greater enforcement authority to private parties in the joint regulation of product labeling.[295] This Part explores how the integrated regulation will offset the functional limitations of the FDA and provide a means of redress for parties commercially injured by deceptive labeling.[296]

A. Alternative Solutions to Integrated Regulation

POM's emphasis on complementary methods of enforcement endorses an integrated scheme of regulation for food and beverage labels.[297] Yet, there are two alternative solutions that the Court could have used in its reasoning. First, some critics suggest that centralized regulation is necessary for national uniformity.[298] Second, other experts

---

not require pre-market approval of food and beverage labels).

290. *Id.* at 2238–39.

291. *See infra* Part III.A (discussing alternative solutions to integrated regulation).

292. *See infra* Part III.B (remarking on the oral arguments before the Court in *POM*).

293. *See infra* Part III.C (analyzing *POM* in the context of prior decisions).

294. *See infra* Part III.C (explaining how *POM* is consistent with *Wyeth*).

295. *See infra* Part III.D (discussing how integrated regulation is optimal for food and beverage labeling).

296. *See infra* Part III.E (discussing how the *POM* decision will benefit both the food industry as well as consumers).

297. POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2231 (2014) ("Allowing Lanham Act suits takes advantage of synergies among multiple methods of regulation."); Bryan Benedict, *What a Ruling on Juice May Mean for Craft Beer*, FOODERY (June 18, 2014), http://www.fooderybeer.com/philly-beer-blog/what-a-ruling-on-juice-may-mean-for-craft-beer ("Before this ruling, the FDA was the end all be all of decisions about regulations regarding labeling and naming of juices. The court's ruling on Pom Vs Coke shows a shift in regulation/enforcement away from the FDA and towards private entities (competitors) to help police potentially abusive marketing tactics.").

298. *See supra* Part II.C (discussing Congress's intentions for Lanham Act claims); *infra* Part III.A (discussing alternative solutions to integrated regulations); *see also* Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 970 (2002) (noting that the Court will find private claims preempted in fields with comprehensive congressional legislation that requires national regulation).

identify the advantages of, and a modern predilection for, private enforcement.[299]

As an alternative to the decision in *POM*, the Supreme Court could have been more deferential to the FDA, as the lower courts were in their treatment of Coca-Cola's compliance with FDA regulations as evidence that the label was not misleading.[300] When Congress enacted the FDCA, centralized regulation and enforcement of FDCA requirements were given to the FDA, and no private cause of action was authorized for enforcement.[301] One of the purposes of the FDCA is to bolster consumer confidence in food safety and the accuracy of food labeling; to achieve this goal, unified government oversight may be necessary.[302] In fact, courts have exercised a presumption that the FDA sufficiently protects the public interest because of its extensive regulation of product labeling.[303]

Under centralized government regulation, agencies prescribe the procedures that manufacturers must follow in order to engage in commerce.[304] Agencies promulgate regulations and prohibit violations before harm occurs,[305] whereas private enforcement claims are only

299. Noah Feldman, *Supreme Court Laps Up POM Wonderful's Case*, BLOOMBERG VIEW (June 12, 2014), http://www.bloombergview.com/articles/2014-06-12/supreme-court-laps-up-pom-wonderful-s-case; *see infra* Part IV.A (discussing how the food and beverage labeling requirements will be more rigorous as a result of the *POM* decision).

300. *See supra* Part II.A (discussing the lower courts' treatment of POM's claim); *see also* Adam M. Reich et al., *POM Wonderful LLC v. Coca Cola Company: Have the Tides Turned in the Legal Food Fight?*, PAUL HASTINGS (July 1, 2014), http://www.paulhastings.com/publications-items/details/?id=3a7fe169-2334-6428-811c-ff00004cbded ("The Court had an opportunity to take a deferential approach and construe the FDCA's failure to create a private right of action as intent for federal agencies to preempt all states laws that otherwise might address food and beverage labels, but it did not do so.").

301. Feldman, *supra* note 299; James M. Beck & John A. Valentine, *Challenging the Viability of FDCA-Based Causes of Action in the Tort Context: The Orthopedic Bone Screw Experience*, 55 FOOD & DRUG L.J. 389, 402 (2000) (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 487 (1996)) ("[T]here is no explicit private cause of action against manufacturers contained in the [FDCA], and no suggestion that the Act created an implied private right of action.").

302. Beck & Valentine, *supra* note 301; *see also* Charlotte E. Thomas, *Pom Wonderful and Consumer Class Actions Under State Law*, DUANE MORRIS (Apr. 17, 2014), http://www.duanemorris.com/articles/pom_wonderful_and_consumer_class_actions_under_state_law_5187.html ("The deference approach will acknowledge the lack of an available private action under the FDCA and will defer to the FDA's expertise in determining the propriety of food labels.").

303. Am. Home Prods. Corp. v. Johnson & Johnson, 672 F. Supp. 135, 145 (S.D.N.Y. 1987); Daniel W. Whitney, *Product Liability Issues for the Expanding OTC Drug Category*, 48 FOOD & DRUG L.J. 321, 340 (1993).

304. STEVEN SHAVELL, ECONOMIC ANALYSIS OF ACCIDENT LAW 277–79 (1987); Kyle D. Logue, *Coordinating Sanctions in Tort*, 31 CARDOZO L. REV. 2313, 2325 (2010).

305. Many labels that violate FDA regulations, however, while prohibited, remain in commerce. *See supra* Part I.A (discussing FDA enforcement limitations).

brought after an injury occurs.[306] Further, without FDA oversight, reliance on private regulation through competitor lawsuits could be risky because the industry may share a common goal in utilizing—rather than exposing—false or misleading labels.[307]

Thus, it could be argued that exclusive government regulation provides national uniformity that allows manufacturers to rely on and conform to a comprehensive set of labeling requirements.[308] Otherwise, the "disuniformity" of multiple state requirements[309] may cause significant and expensive problems for manufacturers who designed their product labels to comply with federal laws.[310]

Another issue in the absence of centralized control is that liability may not provide sufficient motivation to ensure accurate labeling because either the sales generated from the misleading labeling may exceed the cost of a settlement or because a manufacturer may be unable to compensate for the injuries it caused.[311] Under adequate

306. Logue, *supra* note 304, at 2325; *see* Steven L. Schwarcz, *Keynote Address: "Ex Ante Versus Ex Post Approaches to Financial Regulation,"* 15 CHAP. L. REV. 257, 258 (2010) ("Some commentators frame an ex ante/ex post regulatory distinction around conduct: regulation that targets bad conduct before it occurs is deemed ex ante, whereas regulation that targets bad conduct after it occurs is deemed ex post.").

307. *See* Feldman, *supra* note 299; *see also* Shi-Ling Hsu, *What Is A Tragedy of the Commons? Overfishing and the Campaign Spending Problem*, 69 ALB. L. REV. 75, 79 (2006) (quoting Garrett Hardin, *The Tragedy of the Commons*, 162 SCI. 1243, 1244 (1968)) ("[I]ndividuals acting in their own self-interest will ruin collective wealth."); Steven L. Schwarcz, *Protecting Financial Markets: Lessons from the Subprime Mortgage Meltdown*, 93 MINN. L. REV. 373, 386 (2008) ("[T]he benefits of exploiting finite capital resources accrue to individual market participants, each of whom is motivated to maximize use of the resource, whereas the costs of exploitation, which affect the real economy, are distributed among an even wider class of persons.").

308. *See* Thomas, *supra* note 302 ("[Since] the FDA has concluded that juice manufacturers may identify juice products with a nonprimary, characteristic juice, manufacturers should be permitted to do so without slicing and dicing whether features of an otherwise compliant label render it deceptive."); *see also* Elizabeth J. Cabraser, *Due Process Preempted: Stealth Preemption As A Consequence of Agency Capture*, 65 N.Y.U. ANN. SURV. AM. L. 449, 449 (2010) ("[Proponents of widespread federal preemption] emphasize the value of the national uniformity that comes with determinations by federal agencies.").

309. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2239 (2014); Margaret H. Lemos, *State Enforcement of Federal Law*, 86 N.Y.U. L. REV. 698, 703 (2011) ("[S]tate-level variation in enforcement (as in regulation) can produce inefficient and undesirable policy outcomes.").

310. Thomas, *supra* note 302 ("Indeed, it may be very difficult (and costly) for a manufacturer to embark on a national sales campaign that complies with detailed federal regulations, only to later learn that state consumer protection laws enforced privately prohibit that same labeling as deceptive.").

311. Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEGAL STUD. 357, 360–61 (1984) ("[One determinant] of the relative desirability of liability and regulation is that private parties might be incapable of paying for the full magnitude of harm done." (emphasis omitted)); *see* John J. McKinlay, *Regulation, Renegotiation, and Reform: Improving*

government regulation, the theory is that manufacturers would not be permitted to market products with false or misleading labels in interstate commerce, whereas an economic calculation of cost may actually incentivize the use of deceptive labeling.[312] The deterrent effect of liability is also reduced when the possibility that a manufacturer may not in fact be sued is included in the cost-benefit calculation.[313]

Finally, regulation and enforcement through private litigation has the potential to be an overly expensive and protracted process that will not generate the extensive changes necessary in the area of food and beverage labeling.[314] Despite many successful cases that challenged misleading labels, individual private claims have not sufficiently impacted the existing widespread use of deceptive labels.[315]

While the FDA's enforcement limitations cannot be denied, many view labeling regulation as the government's responsibility and not the responsibility of plaintiffs' lawyers.[316] Under this alternative view, greater research, inspection methods, and funding would be needed to enhance FDA enforcement efforts rather than increased dependence on litigation for regulation.[317]

The second alternative approach to regulation and enforcement is that utilized by the Lanham Act, which depends solely on private lawsuits to enforce its prohibition against misleading labeling.[318] The theory supporting this method is that because manufacturers have an interest in preventing competitors from making misleading representations on their

---

Transnational Public-Private Partnerships in the Wake of the Gulf Oil Spill, 87 IND. L.J. 1315, 1324 (2012) (noting that market-based regulatory paradigms provide incentives to violate regulations "inasmuch as the cost-benefit balance compels" one to do so).

312. Shavell, *supra* note 311, at 360–61 ("[L]iability would not furnish adequate incentives to control risk, because private parties would treat losses caused that exceed their assets as imposing liabilities only equal to their assets."). *See generally* Sébastien Rouillon, *Safety Regulation vs. Liability with Heterogeneous Probabilities of Suit*, 28 INT'L REV. L. & ECON. 133 (2008).

313. Shavell, *supra* note 311, at 363; *see* Rouillon, *supra* note 312, at 134.

314. Negowetti, *supra* note 2, at 23; Pomeranz, *Strategy*, *supra* note 4, at 635 ("Litigation costs a substantial amount of time and resources, and could be avoided by both stricter labeling regulations enforced by the FDA and by manufacturers spending initial resources ensuring their claims are compliant.").

315. Pomeranz, *Litigation*, *supra* note 2, at 424; Pomeranz, *Strategy*, *supra* note 4, at 635 ("The initiation of such lawsuits has been increasing but has not led to a global change in food labeling." (footnotes omitted)).

316. Negowetti, *supra* note 2, at 22; *see* Amicus Brief, *supra* note 269, at 3 (noting that FDA labeling regulations are not privately enforceable).

317. Negowetti, *supra* note 2, at 22; Pomeranz, *Strategy*, *supra* note 4, at 619–20.

318. Feldman, *supra* note 299; *see, e.g.*, Diana R.H. Winters, *The Magical Thinking of Food Labeling: The NLEA as a Failed Statute* 89 TUL. L. REV. 815, 867 (2015) ("The federal government should get out of the business of trying to regulate the truth of these claims and permit their mediation through the mechanisms of state law.").

packaging, the government can save valuable resources by deferring some of its costs to private parties enforcing labeling violations through litigation.[319] Additionally, private enforcement takes advantage of the greater knowledge food and beverage manufacturers possess about marketing in the industry than the government has the resources to access.[320] As manufacturers have an interest in marketing their own products effectively and are engaged in the practice, they are better able to evaluate the impact on sales of particular marketing trends and to identify incidents of deceptive labeling.[321]

Further, skepticism of agency action lends support to private party enforcement.[322] For decades, courts have expressed apprehension that agencies are not sufficiently addressing the public's concerns.[323] In response, earlier restrictions against private claims were diminished, and many statutes were enacted with provisions granting plaintiffs private rights of action to enforce agency regulations.[324] While a Lanham Act claim is brought to remedy commercial injuries, the plaintiff acts as a "vicarious avenger of the defendant's customers"[325]

---

319. Feldman, *supra* note 299; *see* also J. Maria Glover, *The Structural Role of Private Enforcement Mechanisms in Public Law*, 53 WM. & MARY L. REV. 1137, 1217 n.57 (2012) ("[B]ecause of limited resources, the FDA relies largely on voluntary compliance with the Federal Drug and Cosmetic Act once a drug has been approved.").

320. POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2238 (2014) ("The FDA, however, does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess."); *see also* Shavell, *supra* note 311, at 359 (noting the superior knowledge private parties possess regarding liability rules); Thomas, *supra* note 302 ("[I]n an era of budget cuts it may not have the means to address manufacturer-specific labeling issues or to ensure that all consumer labeling is devoid of deception. Gaps in enforcement arguably should be supplemented through private actions brought under non-FDCA theories, providing the claimant [with] standing.").

321. *POM*, 134 S. Ct. at 2238; *see also* Shavell, *supra* note 311, at 360 ("For a regulator to obtain comparable information would often require virtually continuous observation of parties' behavior, and thus would be a practical impossibility.").

322. THOMAS F. BURKE, LAWYERS, LAWSUITS, AND LEGAL RIGHTS: THE BATTLE OVER LITIGATION IN AMERICAN SOCIETY 12 (2002); *see also* Patrick Luff, *Risk Regulation and Regulatory Litigation*, 64 RUTGERS L. REV. 73, 76 (2011) ("[G]aps arise between the socially demanded and governmentally provided levels-of-risk regulation. . . . [R]egulatory litigation developed—and persists—because it fills these gaps.").

323. BURKE, *supra* note 322, at 11; *see also* Luff, *supra* note 322, at 78–79 ("[R]egulatory litigation emerged not because of greedy lawyers or plaintiffs, but rather because of unaddressed social demands for risk regulation.").

324. BURKE, *supra* note 322, at 11 ("Litigants were not only allowed to challenge the decisions of agencies but also given the right to bypass those agencies by enforcing regulatory statutes themselves as 'private attorneys general.'"); Luff, supra note 322, at 75 ("[P]remeditated regulatory litigation arose out of a legislative desire to expand the regulatory capacity of the state . . . .").

325. John Wright, Inc. v. Casper Corp., 419 F. Supp. 292, 324 n.18 (E.D. Pa. 1976); Ames Publ'g Co. v. Walker-Davis Publ'ns, Inc., 372 F. Supp. 1, 14 (E.D. Pa. 1974); Walsh & Klein,

because competitor interests in preventing unfair competition correspond to consumer interests in accurate and reliable labeling.[326] Thus, private enforcement also provides a means to ensure that agencies are acting in accordance with their statutory mandates of protecting the public interest.[327]

Any regulatory method must be considered in terms of its utility under the circumstances to which it is to be applied, and different approaches may be more or less appropriate depending on the industry that is regulated.[328] In *POM*, the Court sanctioned an integrated approach by denying that FDA regulations were a "ceiling" for food and beverage labeling requirements and allowing Lanham Act claims to operate as additional enforcement against misleading labels.[329] This approach combines the methods described above into a hybrid scheme of regulation that allows private enforcement to compensate for agency limitations.[330]

B. Justices are Consumers, Too

It was evident during oral arguments that, despite its apparent FDA compliance, the Justices viewed Coca-Cola's juice label as cheating consumers.[331] Coca-Cola's attorney argued that consumers will realize

---

supra note 35, at 412.

326. 5 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 27:26 (4th ed. 2015); Walsh & Klein, *supra* note 35, at 412 ("A competitor's interest in fair competition and the public's interest in truthful advertising are coterminous.").

327. BURKE, *supra* note 322, at 11; *see* Luff, *supra* note 322, at 83 ("[A]dministrative agencies may fail to provide the desired protections, either because of insufficient information or imperfect implementation. . . . [L]itigation steps in to fill the gap[,] . . . it coordinates individuals and exerts sufficient pressure on industry both to compensate for past injuries and to produce future behavioral changes.").

328. Logue, *supra* note 304, at 2329 ("[G]iven that different regulatory approaches have different strengths and weaknesses in different situations, the social planner who seeks to minimize overall social costs while maximizing overall social benefits should in theory design an overarching regulatory strategy that takes all of [the] various factors into account."). *See generally* SHAVELL, *supra* note 304, at 277–90 (discussing liability versus other approaches to the control of risk)

329. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2240 (2014); *see* Thomas, *supra* note 302.

330. *See supra* notes 320–21.

331. Ronald Mann, *Argument Analysis: Justices Skeptical of Coke's Right to "Cheat Consumers,"* SCOTUSBLOG (Apr. 22, 2014, 6:00 PM), http://www.scotusblog.com/2014/04/argument-analysis-justices-skeptical-of-cokes-right-to-cheat-consumers ("Several of the Justices presumably reacting to the image of the label in POM's brief, plainly took it as a given that the label Coca-Cola defends is designed to deceive."). In response to Coca-Cola's assertions during Oral Argument that permitting POM's claim would undermine congressional intent for national uniformity, Justice Kennedy asked: "Is it part of Coke's narrow position that national uniformity consists in labels that cheat the consumers like this one did?" Oral Argument, *supra* note 199, at 28. Justice Ginsburg also noted that "the POM product costs more; the consumer thinks that they

that juice blend names indicate flavor rather than ingredient content.[332] Unconvinced, Justice Alito suggested that consumers may be "very surprised" to learn that Coca-Cola's Minute Maid brand Pomegranate Blueberry juice blend "with a big picture of a pomegranate on it" contained merely 0.2% pomegranate juice.[333]

Justice Kennedy also expressed incredulity at Coca-Cola's assertion that Congress intended a statutory scheme that foreclosed liability on FDA-compliant labels "no matter how misleading or how deceptive" they are.[334] Justice Ginsburg noted that beverage labels are not a priority with the FDA's many responsibilities and limited resources.[335] She reasoned that, because FDA regulations are not under review by the Court and do not provide a private cause of action, it is hard to believe that Congress would have intended to preclude Lanham Act claims.[336]

C. POM is Consistent with Prior Decisions

In finding that Lanham Act challenges to FDA-regulated food and beverage labels are not precluded, the Supreme Court's reasoning followed the same logic it employed in *Wyeth*.[337] In both cases, the Court found that the private enforcement mechanism utilized acted as a complementary method of enforcement.[338] In *Wyeth*, where the FDA preapproved the drug label, the Court was unwilling to find the challenge preempted despite the drug's approval.[339] In *POM*, the label

---

are both the same, so they'll buy the cheaper one." *Id.* at 29. Acknowledging that the product name may be permitted under FDA regulations, Justice Sotomayor questioned Coca-Cola's attorney about why the company would be allowed to use the name in a misleading way. *Id.* at 30.

332. Oral Argument, *supra* note 199, at 23.

333. *Id.* at 23–24.

334. *Id.* at 38; *cf.* Peter Brody, *POM v. Coke May Impact Many FDA-Regulated Products*, LAW360 (May 8, 2014, 6:15 PM), http://www.law360.com/articles/534818/pom-v-Coca-Cola-may-impact-many-fda-regulated-products ("Although the procedural posture of the case involves a motion to dismiss based on a preclusion argument, the justices were not at all reluctant to comment on the merits of the case, and they expressed skepticism with Coca-Cola's argument that its product label is not misleading.").

335. Oral Argument, *supra* note 199, at 42–43; Mann, *supra* note 331.

336. Oral Argument, *supra* note 199, at 42–43; Mann, *supra* note 331.

337. Thomas, *supra* note 233; *see* Petitioner's Brief, *supra* note 18, at 16 ("The conclusion that the FDCA does not preclude application of the Lanham Act to misleading juice labels follows inexorably from this Court's holding in [*Wyeth*], that FDA's approval of a drug label does not displace state failure-to-warn suits challenging the adequacy of the warning."). POM asserted that "[f]ollowing *Wyeth*, there can be no serious argument that the provisions of the FDCA at issue in this case are in 'irreconcilable conflict' with the Lanham Act." *Id.*

338. *See supra* Part I.B.1 (for *Wyeth's* treatment) and Part II.C (for *POM's* treatment).

339. *Attys React to High Court's POM v. Coke Lanham Act Ruling*, LAW360 (June 12, 2014, 6:37 PM), http://www.law360.com/articles/547491/attys-react-to-high-court-s-pom-v-coca-cola-lanham-act-ruling [hereinafter *Attys React*]; *see supra* Part I.B.1.

on Coca-Cola's juice blend was not preapproved, and Coca-Cola could not show that the FDA examined the label and specifically approved it.[340] As the Court found no evidence of congressional intent to prohibit Lanham Act claims, finding preclusion in *POM* would have been inconsistent with the holding in *Wyeth*.[341]

In addition, the Supreme Court's advocacy of an integrated scheme of regulation echoed its sentiment from *Wyeth* that FDA regulations are a floor, rather than a ceiling, on labeling requirements.[342] In both *Wyeth* and *POM*, the Court emphasized the FDA's limited resources in comparison to its responsibilities and the need for private claims to expose and deter violations.[343] Both cases reflect the Court's growing mistrust of administrative regulation[344] through their identification of private enforcement as an important added protection that complements FDA regulation.[345]

Furthermore, in *Wyeth*, the Supreme Court was unwilling to let regulatory preemption impede the FDA's ability to achieve its purposes.[346] It therefore rejected the Agency's 2006 statement that indicated state tort claims were preempted by the FDCA.[347] Similarly, the Court rejected the government's argument in *POM* that Lanham Act claims were precluded to the extent that the FDA regulations approve

340. Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 480 n.146 (2008) (citing Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005)) ("If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.").

341. *See* Oral Argument, *supra* note 199, at 40–41 (quoting Justice Sotomayor: "How is Wyeth any different? The FDA here—it's even worse, this case. The FDA doesn't approve the labels. It never looks at them and says they are okay or not okay . . . how is this better than Wyeth?"); *see also supra* Part II.C (discussing the Court's finding that it was not Congress's intent to preclude Lanham Act claims).

342. POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2240 (2014); Wyeth v. Levine, 555 U.S. 555, 563 (2009).

343. *POM*, 134 S. Ct. at 2238–39; *Wyeth*, 555 U.S. at 578–79.

344. This sentiment was expressed one year earlier in *City of Arlington v. FCC*, when the three-Justice dissent described the expanding power of the administrative state as short of "tyranny" but nonetheless dangerous. 133 S. Ct. 1863, 1879 (2013) (Roberts, C.J., dissenting) ("It would be a bit much to describe the result as the very definition of tyranny, but the danger posed by the growing power of the administrative state cannot be dismissed."). *See generally* O'Reilly, *supra* note 15, at 939 (asserting that agency capture is to blame for the reduced deference the Court is willing to give FDA determinations); Vladeck, *supra* note 88, at 985 (asserting that in addition to capture, inadequate funding and functional limitations have decreased courts' respect for FDA decisions).

345. *Wyeth*, 555 U.S. at 1202; *POM* 134 S. Ct. at 2238–39.

346. *See supra* notes 140–47 and accompanying text (discussing the Court's treatment of the preemption doctrine in *Wyeth*).

347. *See supra* notes 146–47 and accompanying text (explaining the Court's application of the preemption doctrine in *Wyeth*).

the challenged labels.[348] In both cases, the Court was unwilling to give deference to the FDA's position, opting instead to approve of Lanham Act enforcement over FDA-regulated products to provide greater protection against false or misleading labeling.[349]

The Court's refusal to let regulatory preemption ban state law claims in *Wyeth* is parallel to its unwillingness to allow prudential standing limitations prohibit Lanham Act claims in *Lexmark*.[350] In *POM*, the Court refused to allow FDA regulation of food and beverages to preclude Lanham Act challenges to misleading labels.[351] Thus, the Court's recognition of the benefits and necessity of private enforcement is evidenced in all three cases.[352]

POM also reinforces the Court's general presumption against preemption, as noted in *Wyeth*.[353] In fact, *POM* continues a history of Supreme Court opinions that maintained that unless Congress's intentions are manifest, courts should not find that Congress intended to preclude remedies for injured parties.[354] For seventy years, the Lanham Act provided a private right of action for misleading marketing[355] and, without evidence of congressional intent to limit or exclude such claims, the Court was unlikely to find preclusion.[356]

---

348. *See supra* Part II.C (discussing how Congress did not intend the FDCA to preclude Lanham Act claims); *see also POM*, 134 S. Ct. at 2241; *Wyeth*, 555 U.S. at 580.

349. *POM*, 134 S. Ct. at 2241; *Wyeth*, 555 U.S. at 577.

350. *See supra* notes 137–47, 179–81 and accompanying text (discussing standing requirements).

351. *See POM*, 134 S. Ct. at 2241 (refusing to elevate the FDCA and the FDA's regulations over the private cause of action authorized by the Lanham Act); *see also supra* Part II.C (discussing how Congress did not intend the FDCA to preclude Lanham Act claims).

352. *See* Duffy, *supra* note 101 ("[*Lexmark*] swept away the 'prudential standing' limitations on the Lanham Act's private right of action (and on all other federal private causes of action) and replaced those limits with a relatively plaintiff-friendly analysis . . . . Now . . . [*POM*] has eliminated another significant hurdle for Lanham Act plaintiffs.").

353. *See supra* notes 180–81 (discussing the Court's reassertion of the zone of interests test in *Lexmark*).

354. *See* Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 605 (1991) ("[W]e start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947))); Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984) ("It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."); *see also* Sharkey, *supra* note 340, at 456 ("By way of divining congressional intent, the Court has wielded the presumption against preemption as an interpretive canon in areas traditionally occupied by the states.").

355. *See supra* Part I.B.1 (discussing the opinion in *Wyeth*); *Attys React*, *supra* note 339.

356. *See POM*, 134 S. Ct. at 2241 ("[T]he FDCA and the Lanham Act complement each other in the federal regulation of misleading labels. Congress did not intend the FDCA to preclude Lanham Act suits like POM's."); *see also* Benjamin K. Olson et al., *Pom v. Coke Will Impact Financial Services Too*, LAW360 (June 23, 2014), http://www.law360.com/articles/550279/pom-v-Coca-Cola-will-impact-financial-services-too ("In some respects, the holding in Pom is

Three months after the Court broadened the Lanham Act's protections in *Lexmark*, which clarified—and in many jurisdictions broadened—the scope of Lanham Act claims, the Court added further protections against deceptive labeling in *POM*.[357] Where *Lexmark* demonstrates that false advertising claims can be brought by indirect as well as direct competitors, *POM* emphasizes that private parties can bring Lanham Act claims challenging FDA-regulated labels.[358] As the Court removed barriers to plaintiff actions in both cases, some suggest that these two decisions will instigate a substantial increase in Lanham Act claims over false or misleading food and beverage labels.[359]

In both *POM* and *Lexmark*, however, and consistent with much of the history of the Lanham Act,[360] the Court maintained that Lanham Act claims are exclusively for commercial plaintiffs injured by unfair competition.[361] *POM* followed the standing requirement set forth in *Lexmark* by establishing that POM Wonderful had standing because it suffered commercial injuries to its sales that were proximately caused by consumers deceived by Coca-Cola's misleading labeling.[362] To the disappointment of many consumer advocates and plaintiffs' attorneys, the federal protection against misleading labeling remains unavailable to consumers.[363]

---

unsurprising. Prior to the ruling, lower courts already acknowledged that compliance with one federal consumer protection law did not necessarily grant immunity from the application of a separate federal consumer protection law.").

357. *See* Duffy, *supra* note 101; *see also supra* Part II.B (discussing *POM* and Lanham Act standing).

358. *Attys React*, *supra* note 339 ("Viewed in conjunction with the March ruling in the Lexmark case, the decision in Pom v. Coke clearly communicates that the Supreme Court is unwilling to unduly limit the ability to bring false advertising claims under the Lanham Act.").

359. David Conway, *Supreme Court Opens Door to Food and Beverage Label Challenges Under Lanham Act*, VENABLE LLP: ALL ABOUT ADVERT. L. (June 12, 2014), http://www.allaboutadvertisinglaw.com/2014/06/supreme-court-opens-door-to-food-and-beverage-label-challenges-under-lanham-act.html; *see infra* Parts IV.B–C (discussing the impact of the *POM* decision).

360. *See supra* Part I.B.2 (discussing Lanham Act standing).

361. *POM*, 134 S. Ct. at 2235; Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1395 (2014); *see supra* Part II.B (discussing the Supreme Court's treatment of Lanham Act standing in *POM*).

362. *See POM*, 134 S. Ct. at 2235; *see also supra* Part II.B (discussing Lanham Act standing).

363. Dale J. Giali & Andrea Weiss, *POM v. Coke Does Not Alter the Landscape for Food False Advertising Class Actions*, MAYER BROWN: CLASS DEF. BLOG (June 16, 2014), https://www.classdefenseblog.com/2014/06/pom-v-coke-does-not-alter-the-landscape-for-food-false-advertising-class-actions/; Jon Peritz, *Judging a Juice by its Label*, COWAN, DEBAETS, ABRAHAMS & SHEPPARD LLP: LEGAL BLOG (June 30, 2014), http://cdas.com/judging-juice-label-u-s-supreme-courts-decision-pom-wonderful-v-coca-cola-company-may-open-lid-lanham-act-liability-even-another-federal-statute-may-apply/.

D. Integrated Regulation Is Optimal for Food and Beverage Labeling

POM's emphasis on complementary methods of enforcement endorses an integrated scheme of regulation for food and beverage labels that will benefit consumers as well as competitors.[364] Legal scholars have identified a modern predilection toward private enforcement,[365] and the widespread shift away from centralized administrative agency enforcement to private enforcement through litigation has been a contentious change.[366] The *POM* decision represents approval of such an integrated approach to regulation, utilizing the Lanham Act's private enforcement mechanism to enhance FDA regulation of food and beverage labeling.[367] In fact, the Court identified the benefits of employing "multiple methods of regulation to better implement the prohibition against deceptive labeling."[368] As a result of the decision, FDA regulations merely set a "floor" for food and beverage labeling requirements, and Lanham Act claims will provide added protection against false or misleading labels.[369]

---

364. *POM*, 134 S. Ct. at 2231 ("Allowing Lanham Act suits takes advantage of synergies among multiple methods of regulation."); Bruce Horovitz, *Honesty: New Ingredient in Food Labels*, USA TODAY (June 12, 2014, 6:06 PM), http://www.usatoday.com/story/money/business/2014/06/12/food-labels-pom-wonderful-coca-cola-supreme-court/10381115/ ("'This is a really good decision for consumers—and for honest businesses,' says Steve Gardner, litigation director at the Center for Science in the Public Interest, an activist consumer group. 'This encourages honest competition.'").

365. Luff, *supra* note 322, at 74 ("For some time now, a unique phenomenon has been developing in the world of litigation—litigation has become a regulatory device as a result of courts more frequently issuing decisions with widespread regulatory effects."); Feldman, *supra* note 299.

366. David Freeman Engstrom, *Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of Qui Tam Litigation Under the False Claims Act*, 107 NW. U. L. REV. 1689, 1690 (2013); *see, e.g.*, Richard L. Revesz, *Federalism and Interstate Environmental Externalities*, 144 U. PA. L. REV. 2341, 2343 (1996) (suggesting that environmental law issues require a centralized federal response). For an examination of private enforcement of federal securities laws, see Daniela Nanau, *Analyzing Post-Market Boom Jurisprudence in the Second and Ninth Circuits: Has the Pendulum Really Swung Too Far in Favor of Plaintiffs?*, 3 CARDOZO PUB. L. POL'Y & ETHICS J. 943 (2006); and James J. Park, *The Competing Paradigms of Securities Regulation*, 57 DUKE L.J. 625 (2007). For a discussion of products liability regulation, see Sharkey, *supra* note 340, at 449.

367. Feldman, *supra* note 299; *see* Deborah R. Hensler & Thomas D. Rowe, Jr., *Beyond "It Just Ain't Worth It": Alternative Strategies for Damage Class Action Reform*, 64 L. & CONTEMP. PROBS. 137, 137 (2001) (noting that private actions can "supplement regulatory enforcement by administrative agencies that are under-funded, susceptible to capture by the subjects of their regulation, or politically constrained").

368. *POM*, 134 S. Ct. at 2239; *see* Hensler & Rowe, *supra* note 367, at 137.

369. *See POM*, 134 S. Ct. at 2240; *see* Walsh & Klein, *supra* note 35, at 411 ("Congress . . . indicated that it had adopted the Lanham Act in general, and section 43(a) in particular, to protect competitors and consumers. . . . [It] protects the public by making consumers confident that they can identify brands they prefer and can purchase those brands without being confused or misled."

1. Integrated Regulation Provides Practical Enforcement Solutions

Because the FDA does not have exclusive regulatory authority over food and beverage labeling, manufacturers now have a larger oversight function in policing misleading product labels.[370] The FDA has insufficient resources to meet its regulatory demands[371] and subordinate knowledge of marketing strategies in relation to that of food manufacturers.[372] Private enforcement will remedy the FDA's functional shortcomings by exploiting private funding, knowledge, and expertise.[373]

Among the GAO's criticisms in 2008 and 2011 was the FDA's relative stagnancy in the face of a burgeoning food industry.[374] The GAO found that while more food manufacturers were joining the industry every year, the number of inspections and enforcement actions had not kept pace and, in some markets, even decreased.[375] In the face of mounting complaints from private parties, consumer groups, and state officials regarding misbranding, the GAO's statistics caused some experts to view the FDA's inadequate enforcement as a signal that it "abdicated its responsibility" to guard against false or misleading food and beverage labels.[376] Through increased reliance on private enforcement, significant regulatory costs will be deferred to manufacturers[377] who have greater awareness of deceptive marketing

---

(emphasis omitted)).

370. Associated Press, *Supreme Court Turns on the Juice for POM-Coca-Cola Suit*, DAILY REC. (June 12, 2014), http://thedailyrecord.com/2014/06/12/supreme-court-turns-on-the-juice-for-pom-coke-suit/; *Supreme Court's Ruling in* POM Wonderful LLC v. Coca-Cola Co. *Confirms That Private Companies May Sue Competitors For False and Deceptive Food and Beverage Labels*, DOWNEY BRAND LLP (June 17, 2014), http://www.downeybrand.com/Resources/Legal-Alerts/83302/Supreme-Courts-Ruling-in-Pom-Wonderful-LLC-v-Coca-Cola-Co-Confirms-That-Private-Companies-May-Sue-Competitors-For-False-and-Deceptive-Food-and-Beverage-Labels ("[T]he Court gave this 'policing power' to private businesses and competitors because of the detailed information companies have on how consumers rely upon certain sales and marketing strategies.").

371. Glover, *supra* note 319, at 1217 n.57; *see supra* Part I.A.

372. Glover, *supra* note 319, at 1154 ("[T]he best sources of information about private wrongs are often the parties themselves, because they tend to have superior knowledge regarding the costs and benefits of given activities, the costs of reducing risks of harm, and the probability or severity of risk.").

373. *Id.* at 1155 ("Private enforcement provides, in many respects, a direct response to the functional limitations of public regulatory bodies in the enforcement of various laws.").

374. GAO, 2008, *supra* note 12, at 5; Negowetti, *supra* note 2, at 8.

375. GAO, 2008, *supra* note 12, at 5; Negowetti, *supra* note 2, at 8.

376. Bruce Silverglade, *Rebuttal to FDA Report to Congress on Agency Enforcement Actions Regarding Health-Related Claims on Food Labels*, CTR. FOR SCI. PUB. INT. (July 18, 2006), http://cspinet.org/new/pdf/fn5rep.pdf; *see* Negowetti, *supra* note 2, at 8.

377. Glover, *supra* note 319, at 1155 ("[Private enforcement] provides protections against harm based on the initiative of a few, which counters the problem of limited agency resources.");

both as culprits and victims of misleading labeling practices.[378]

2. Integrated Regulation Offers Immunity from Capture

Manufacturer oversight also safeguards against deregulation from agency capture.[379] Unlike the lower courts that expressed concern about undermining FDA authority, through *POM* the Supreme Court demonstrated that it is concerned that the FDA would not remedy the false or misleading labeling practices that abound in today's food environment.[380] The Court's skepticism about the FDA's competence contrasts with the deference given to the agency in its first century.[381] Suspicion of agency capture has likely contributed to the erosion of the Court's confidence in FDA action,[382] and thus private enforcement provides a substitute for questionable agency regulation. If the FDA permits a label to mislead consumers either because of permissive regulations or because it does not address a violation, *POM* empowers competitors to do something about it themselves.[383]

Feldman, *supra* note 299.

378. *See* Glover, *supra* note 319, at 1155 ("[T]hose who commit wrongdoing, and victims of such wrongdoing, often have superior access to relevant information."); Shavell, *supra* note 311, at 359.

379. BURKE, *supra* note 322, at 7 ("Within the national government, courts can protect policies from 'capture,' a danger that separation of powers exacerbates."); Engstrom, *supra* note 366, at 1690–91 (noting that increased private enforcement limits agency capture by the regulated industry); Glover, *supra* note 319, at 1155–56 ("Private litigation also gives individuals a 'personal role and stake in the administration of justice' and provides an avenue of redress that is more insulated from political capture than public agencies." (quoting Richard B. Stewart, *Crisis in Tort Law? The Institutional Perspective*, 54 U. CHI. L. REV. 184, 198 (1987))).

380. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2239 (2014) ("Because the FDA acknowledges that it does not necessarily pursue enforcement measures regarding all objectionable labels, . . . if Lanham Act claims were to be precluded then commercial interests—and indirectly the public at large—could be left with less effective protection in the food and beverage labeling realm than in many other, less regulated industries."); *see also supra* notes 217–26 and accompanying text (discussing the lower courts' decisions in *POM*), Part III.A (discussing alternative solutions). *See generally* Duffy, *supra* note 101.

381. Duffy, *supra* note 101 ("More than a century ago, administrative agencies were often cast in nearly heroic terms; they were thought to be wise experts who could bring intelligent, centralized regulation to remedy the abusive marketplace tactics. In yesterday's decision, however, the Court shows just how little is left of that notion."); *see also* O'Reilly, *supra* note 15, at 940 ("The judicial deference given to the Agency is usually attributed to the FDA's century-long legacy of scientific expertise.").

382. *See* O'Reilly, *supra* note 15, at 940 ("[P]olitical manipulations of the FDA (for the benefit of conservative political constituencies) may diminish the willingness of federal judges to defer to our nation's most distinguished regulatory Agency"); *see also* Vladeck, *supra* note 88, at 984 ("[R]egulatory failure, as much as regulatory capture, has wounded the Agency and will continue to undermine its credibility in court.").

383. *See* ALLIANCE FOR NAT. HEALTH, *supra* note 97 ("[T]his ruling may spark a sort of industry self-policing . . . ."); *see also supra* note 370 and accompanying text (discussing industry self-policing).

E. The Private Cause of Action Benefits Consumers and Industry

With the ability to invoke Lanham Act protection from deceptive labeling, those injured may seek redress—which is not available under the FDCA.[384] The "distinct compensatory function"[385] of Lanham Act claims for false or misleading labeling completes the regulatory scheme by providing those injured with adequate relief for injuries suffered as a result of deceptive labels.[386] It also exposes violations by allowing competitors to bring claims against manufacturers who use false or misleading labeling to market competing products.[387] In fact, the cause of action is amenable to multiple motivations because in addition to monetary relief for injury to reputation or sales, the Lanham Act provides for injunctive relief.[388] Eliminating the deceptive labels that adversely impact a company's sales will effectively reduce its product's competition.[389] For example, should POM Wonderful prevail on remand, in addition to a monetary award to compensate for the company's lost sales, the court could enjoin Coca-Cola from utilizing the deceptive label that caused consumers to believe Coca-Cola's

384. *See* ALLIANCE FOR NAT. HEALTH, *supra* note 97 ("[I]f Food Company A makes a misleading labeling claim (even if said claim is FDA-approved) which steals market share from Food Company B, Company B can now sue Company A under the Lanham Act."); Walsh & Klein, *supra* note 35, at 408 ("Short of governmental action or a competitor's agreement to abide by industry standards, an aggrieved manufacturer has only one effective remedy to combat false comparative advertising: an action under section 43(a) of the Lanham Act.").

385. *POM*, 134 S. Ct. at 2238–39; Wyeth v. Levine, 555 U.S. 555, 579 (2009).

386. Sharkey, *supra* note 340, at 479–80 ("Remedies and enforcement are key ingredients of integrated schemes of regulation, and any court's consideration of the comprehensiveness of a federal regulatory scheme must pay some attention to the remedial end."); Glover, *supra* note 319, at 1144 ("[P]rivate enforcement mechanisms should be integrated with other regulatory efforts when necessary to effectuate the complete range of remedies provided in a given scheme . . . .").

387. *POM*, 134 S. Ct. at 2238–39 (citing *Wyeth*, 555 U.S. at 579) ("By serving a distinct compensatory function that may motivate injured persons to come forward, Lanham Act suits, to the extent they touch on the same subject matter as the FDCA, provide incentives for manufacturers to behave well.").

388. *See* Ed Hafer & Jordan Lipp, *Compliance With FDA Labeling Guidelines No Defense Against Federal Unfair Competition Claims*, DAVIS, GRAHAM & STUBBS LLP (June 12, 2014), http://www.dgslaw.com/images/materials/ClientAlert-Compliance-With-FDA.html ("Lanham Act suits . . . . offer compensatory damages beyond those offered under most state laws: disgorgement of profits, injunctive relief, destruction of offending products, and even attorney fees in 'exceptional cases.'").

389. Natalie Zmuda, *Pom's Supreme Court Win Against Coca-Cola Has Major Implications for Brands*, ADVERT. AGE (June 12, 2014), http://adage.com/article/cmo-strategy/pom-s-supreme-court-win-Coca-Cola-major-implications/293689/ ("[The decision] opens up a whole new realm of possibilities for competitors to sue one another based on labeling claims. It's another tool in the arsenal of brand wars."); *see, e.g.*, Benedict, *supra* note 297 ("True craft breweries can now say to other parties that using the word 'craft' is wrong and the act of doing so is hurting other craft brands.").

product was substantially similar to POM's.[390]

The Supreme Court's decision will likely deter manufacturers from utilizing deceptive labeling.[391] Prior to *POM*, manufacturers were unlikely to ensure their labels were accurate beyond what was required by FDA regulations; the threat of liability will encourage increased label clarity.[392] When designing product labels, in addition to FDA regulations, manufacturers will now be forced to consider the likelihood of Lanham Act claims challenging the labels.[393] This will likely result in fewer instances of deceptive labeling, as manufacturers will endeavor to avoid defending against such suits.[394]

IV. IMPACT

This Part will explore the impact of the Supreme Court's decision in *POM* and the effect of litigation as a complementary method of regulation to FDA enforcement. The consumer public will reap the benefits of *POM* because food and beverage manufacturers will utilize less deceptive labeling practices to avoid the threat of litigation.[395]

---

390. *See* Complaint, *supra* note 214, at 11 ("Plaintiff prays for . . . injunctive relief prohibiting Defendants . . . from engaging in false or misleading advertising with respect to the their Pomegranate Blueberry Product and/or violating Lanham Act § 43(a), which relief includes but is not limited to removal of all false or misleading advertisements and corrective advertising to remedy the effects of Defendants' false advertising.").

391. Brent Kendall, *Supreme Court Allows False-Advertising Suit Against Coca-Cola*, WALL ST. J. (June 12, 2014, 4:03 PM), http://online.wsj.com/articles/supreme-court-allows-false-advertising-suit-against-coca-cola-1402582954 (noting that consumer groups said "private litigation by companies was a deterrent to misleading food and beverage marketing"); *see also* Logue, *supra* note 304, at 2314.

392. Meg Bohne, *A Win for Pom Is a Win for Consumers*, NOT IN MY FOOD.ORG (June 13, 2014), http://notinmyfood.org/posts/4088-a-win-for-pom-is-a-win-for-consumers ("[W]hile . . . [the] decision was made to protect the interests of POM, consumers may benefit in the end if product labeling is held to a higher, more truthful standard. And considering that there's no shortage of misleading labeling on the market right now, this could be a very good thing."); *see* Logue, *supra* note 304, at 2337 (suggesting that agency regulations only incentivize manufacturers to take minimally required action but the threat of liability promotes additional measures).

393. Giali & Weiss, *supra* note 363; Conway, *supra* note 359.

394. *See* Totenberg, *supra* note 205 ("[T]he Lanham Act is the yin to the FDA's yang, because it should 'provide incentives for manufacturers to behave well.'"); *see also* Logue, *supra* note 304, at 2319 ("A key assumption underlying the economic analysis of law generally and torts in particular is the view that individuals and firms for the most part behave rationally, that the relevant parties can and do weigh the costs and benefits of their actions and make choices that on balance tend to maximize their own expected utility.").

395. *See infra* Part IV.A. *But see* Goldman, *supra* note 19 (asserting that *POM* does not provide a clear victory to consumers). "Either consumers may pay a premium for juices that sound fancy but are really just 99%+ garden-variety juice, or consumers may pay more across-the-board as rival food and drink manufacturers find new reasons to engage in new and costly litigation armageddons." *Id.*

Where before manufacturers only had to meet the minimum requirements imposed by the FDA, they now are unable to avoid Lanham Act liability by merely asserting FDA compliance.[396] This Part also suggests that litigation is likely to increase with expanded Lanham Act standing requirements; however, proliferation should be limited by the high costs of pursuing Lanham Act claims. Finally, this Part reveals that while the primary jurisdiction doctrine may limit some claims, courts are now extending *POM*'s reasoning to consumer class actions challenging food and beverage labels under state and local laws.

A. Food and Beverage Labeling Requirements Will Be More Rigorous

A label may still be misleading even though it complies with FDA regulations, and thus labeling requirements are more rigorous under Lanham Act standards.[397] Manufacturers must now consider the general message a food or beverage label conveys as opposed to focusing on particular aspects of the label that are compliant with FDCA requirements. Therefore, while Lanham Act suits are fought between businesses, consumers are the ultimate beneficiaries because they will enjoy more reliable and accurate labels.[398] In fact, soon after the decision in *POM* was announced, attorneys and marketing experts recommended that manufacturers reexamine their product labels to determine whether they may be vulnerable to claims challenging the labels as misleading.[399] It is now more difficult for manufacturers to use words and pictures to suggest that products contain particular

396. *See* Totenberg, *supra* note 205 ("Justice Anthony Kennedy said that 'the position Coca-Cola takes in this court' is that because it complied with the Food and Drug Act's labeling requirements, it could 'mislead and trick consumers' without being subject to liability. That assertion, he said, is 'incorrect.'"); Elaine Watson, *POM v Coke at Supreme Court: Food Marketers Be Warned, if Your Labels Are FDA Compliant or Not, You're Fair Game*, FOOD NAVIGATOR-USA.COM (June 12, 2014, 5:48 PM) http://www.foodnavigator-usa.com/Regulation/POM-v-Coke-at-Supreme-Court-Food-marketers-be-warned-if-your-labels-are-FDA-compliant-or-not-you-re-fair-game ("Compliance with FDA labeling requirements becomes, in effect, a floor, and in no sense a ceiling.").

397. Conway, *supra* note 359; *see also* Part IV.A (discussing alternative solutions to integrated regulation); *supra* note 305 and accompanying text (discussing centralized government regulation).

398. Duffy, *supra* note 101; *see supra* note 216 and accompanying text (discussing consumer deception).

399. *See, e.g.*, Megan Galey, *The Food Fight Continues: POM Wonderful's Lanham Act Claim Not Barred by Food Labeling Regulations*, HUSCH BLACKWELL: FOOD & AG. L. INSIGHTS (June 17, 2014), http://www.foodandaglawinsights.com/2014/06/the-food-fight-continues-pom-wonderfuls-lanham-act-claim-not-barred-by-food-labeling-regulations/; David Ter Molen, *The Supreme Court's Lesson on Labeling*, FOOD PROCESSING, FREEBORN & PETERS (June 24, 2014), http://www.foodprocessing.com/articles/2014/the-supreme-courts-lesson-on-labeling/.

ingredients when they in fact do not.[400]

In effect, the decision acknowledges the distinction between "the legality" and "the fraud" of deceptive labeling.[401] Before *POM*, compliance immunized a manufacturer from liability for those aspects of its product's label that were authorized by FDA regulations.[402] FDA compliance will no longer offer a safe harbor from liability if a product's label is deceptive, despite FDA regulations that appear to permit the misleading representation.[403] Thus, while POM Wonderful still has the burden to prove Coca-Cola's label was deceptive, because FDA compliance is a floor and not a ceiling, POM will have its day in court.[404]

B. Competitor Claims May Increase

POM may generate a significant increase in litigation for deceptive labeling, particularly considering the expanded Lanham Act standing requirements from *Lexmark*.[405] Essentially, *POM* eliminates the barrier shielding manufacturers utilizing misleading labels from competitors' lawsuits.[406] The decision also has the potential to be used strategically

---

400. Horovitz, *supra* note 364 (quoting New York University Professor of Nutrition Marion Nestle).

401. Jennifer Kaplan, *Supreme Court Hears Misleading Advertising Case POM v. Coca-Cola*, EAT DRINK BETTER, http://eatdrinkbetter.com/2014/04/22/supreme-court-pom-v-coca-cola/ (last visited Sept. 24, 2015).

402. Ter Molen, *supra* note 399.

403. POM Wonderful LLC. v. Coca-Cola Co. *Sound Preclusion Jurisprudence or Pandora's Juice Box?*, MCGUIREWOODS (June 17, 2014), http://www.mcguirewoods.com/Client-Resources/Alerts/2014/6/POM-Wonderful-LLC-v-Coca-Cola-Co.aspx ("[F]or food and beverage companies, even the strictest compliance with FDA-promulgated rules and regulations is no longer a safe harbor against Lanham Act suits by competitors.").

404. Kaplan, *supra* note 401; Michael Palmisciano, *Reversing Ninth Circuit, Supreme Court Allows POM Wonderful to Sue Coca-Cola Under Lanham Act*, SULLIVAN & WORCESTER: TRENDING TRADEMARKS (June 13, 2014), http://www.trendingtrademarks.com/2014/06/13/reversing-ninth-circuit-supreme-court-allows-pom-wonderful-to-sue-coca-cola-under-lanham-act/. *Pom Wonderful v. Coca-Cola Co.* is scheduled for trial in March 2016. Michael Doyle, *POM Wonderful Plays Offense and Defense in Legal Fights*, MCCLATCHY DC (July 1, 2015), http://www.mcclatchydc.com/news/crime/article26002537.html.

405. Duffy, *supra* note 101; Palmisciano, *supra* note 404 ("[C]ommentators have speculated that as a result of this opinion, litigation involving misleading product labeling will increase, because companies can no longer claim a safe harbor from those suits simply because the [FDA] authorized their labels."). *But see* Hank Schultz, *Experts Advise Supplement Companies to Carefully Review Labels in Wake of* POM *Ruling*, NUTRA INGREDIENTS-USA.COM (June 17, 2014, 5:54 PM), http://www.nutraingredients-usa.com/Regulation/Experts-advise-supplement-companies-to-carefully-review-labels-in-wake-of-POM-ruling ("While this potentially opens the door for more lawsuits, I don't foresee an onslaught of competitor-based litigation." (emphasis omitted)).

406. Galey, *supra* note 399 ("The likely result is a proliferation of Lanham Act claims amongst competitors in the food industry."); Ter Molen, *supra* note 399; *see also* Hafer & Lipp,

against competitors.[407] For example, companies may bring Lanham Act suits against rival manufacturers to enlarge their market share.[408] Successful product manufacturers may also bring claims against new companies entering their markets to prevent losing any of their market share.[409] While Lanham Act claims are likely to multiply, the cost of bringing and defending these suits will limit their proliferation.[410] Additionally, the difficult evidentiary requirements will somewhat constrain the litigant pool to companies with relatively deeper pockets.[411]

C. Consumer Actions May Increase

While *POM* grants commercial plaintiffs access to courts to challenge misleading labels, consumers remain unable to bring Lanham Act claims.[412] *POM* focuses on two federal statutes—the FDCA and the Lanham Act—and does not directly address consumer protection class action litigation brought under state law.[413] As the Supreme Court acknowledged, however, the public will indirectly benefit from its decision in *POM* because while manufacturers can still hide behind FDA compliance where preemption of state law is explicit, they are

---

supra note 388 ("Lanham Act suits now have none of the pre-emption hurdles that affect state law suits related to food labeling.").

407. Reich et al., *supra* note 300; *see also* Elaine Watson, *Big Win for Coke at Supreme Court Could Really Upset Apple Cart, Says Attorney*, FOODNAVIGATOR-USA.COM (April 18, 2014, 8:54 PM), http://www.foodnavigator-usa.com/Regulation/Big-win-for-Coke-at-Supreme-Court-could-really-upset-apple-cart-says-attorney ("A decision for POM will increase the universe of claims available in competitor suits . . . ." (emphasis omitted)).

408. Reich et al., *supra* note 300; *see also* Berfield, *supra* note 18 ("The decision will now make claims on packaging and labeling additional fodder for competitive challenges, which will likely lead to an increase in brand wars . . . .").

409. Reich et al., *supra* note 300.

410. John Gotaskie, *Little Noticed POM Wonderful Decision Could Result in New Mislabeling Lawsuits*, FOX ROTHSCHILD LLP: FRANCHISE L. UPDATE (July 27, 2014) http://franchiselaw.foxrothschild.com/2014/07/articles/legal-decisions/little-noticed-pom-wonderful-decision-could-result-in-many-new-mislabelinglawsuits ("Nonetheless, new Lanham Act lawsuits based on alleged mislabeling and misadvertising of food and beverages are likely to proliferate. And, as anyone who has been involved in such suits can attest, they are costly to defend."); Schultz, *supra* note 405 ("Lanham Act cases don't occur that often generally because they are so expensive and because it is so hard to prove damages . . . ." (emphasis omitted)).

411. Schultz, *supra* note 405.

412. Giali & Weiss, *supra* note 363; *see also supra* note 251 and accompanying text.

413. *Supreme Court Unanimously Reverses Ninth Circuit's Decision in* POM Wonderful v. Coca-Cola, ROPES & GRAY (June 13, 2014), https://www.ropesgray.com/news-and-insights/Insights/2014/June/Supreme-Court-Unanimously-Reverses-Ninth-Circuits-Decision-in-POM-Wonderful-v-Coca-Cola.aspx ("[W]ith respect to consumer class actions under state law challenging food and beverage labels, the Court's opinion said nothing to suggest that such claims, if not expressly preempted, are otherwise precluded."); Giali & Weiss, *supra* note 363.

now exposed to liability under the Lanham Act.[414] This was nevertheless a disappointment for consumer advocacy groups who are unable to invoke Lanham Act protection against misleading labeling.[415]

The NLEA's preemption provision bars challenges to food and beverage labels for violations of state labeling laws that are not identical to the FDCA requirements.[416] Thus, some practitioners initially responded to *POM* with assurances to the food industry that the decision would not expand the scope of consumer actions challenging false or misleading labels because congressional design in the preemption provision is manifest.[417] In fact, the Fourth Circuit affirmed the dismissal of one consumer food and beverage labeling challenge brought in the wake of *POM* because its state law claims were expressly preempted by federal law.[418]

Another limitation on consumer claims is the primary jurisdiction doctrine,[419] which is a prudential doctrine that gives courts the authority

414. Conway, *supra* note 359; *see supra* Parts IV.B–C.

415. Peritz, *supra* note 363. *But cf. For Whom is* POM Wonderful*?*, ARNOLD & PORTER LLP (June 30, 2014), http://www.consumeradvertisinglawblog.com/lanham_act/ ("The big question is how big a win this decision will be for the consumer class action plaintiff's bar.").

416. *See* 21 U.S.C. § 343–1 (2012) (prohibiting states from establishing food labeling requirements that are not identical to FDCA food labeling requirements); *supra* note 246 and accompanying text; *see also* Peritz, *supra* note 363 ("Consumers' concerns are exacerbated by the fact the Congress has, in the FDCA, explicitly preempted state statutes that address food and beverage misbranding."); Thomas, *supra* note 233 ("[T]he Court in POM expressly denies any intended impact on issues of federal-state preemption . . . ."). In *POM*, the Court considered the specificity of this preemption provision in the NLEA as evidence against congressional intent to preclude Lanham Act claims. *See supra* Part II.C (discussing the *POM* decision).

417. *See, e.g.*, Giali & Weiss, *supra* note 363 ("[T]he *POM v. Coca-Cola* decision, while effecting a dramatic change in competitor actions, should have little impact on consumer class actions."); *see also* Conway, *supra* note 359 ("Advertisers should take comfort in knowing the limits of the Supreme Court's decision. The Court's holding applies only to Lanham Act challenges between competitors, and the current law regarding FDCA express preemption of state law consumer claims should remain intact."). *But see Attys React*, *supra* note 339 ("This decision proves that competitors can be successful at challenging their rivals and we can expect more vigorous litigation between competitors, as well as more class actions arising from consumer product labeling issues.").

418. *See* Nemphos v. Nestle Waters N. Am., Inc., 775 F.3d 616, 625 (4th Cir. 2015) (finding misleading marketing and failure to warn claims about the dangers associated with fluoridated water preempted by the FDCA and the NLEA).

419. *See* Kimberly Culp, *The Ninth Circuit Reaffirms the Application of the Primary Jurisdiction Doctrine to FCDA / Lanham Claims in the Post-*Pom Wonderful *Era*, LEXOLOGY (June 2, 2015), http://www.lexology.com/library/detail.aspx?g=92652f4f-2077-4c82-a4f3-fc725e764216 ("Notwithstanding the Supreme Court's holding in *POM Wonderful*, district courts may still apply the primary jurisdiction doctrine to determine whether to stay or dismiss a case."); *see also* Astiana v. Hain Celestial Grp., Inc., 783 F.3d 753, 760 (9th Cir. 2015) (citing Clark v. Time Warner Cable, 523 F.3d 1110 (9th Cir. 2008)) ("Primary jurisdiction is a prudential doctrine that permits courts to determine that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority

to stay or dismiss complaints without prejudice when the central issue requires agency expertise for resolution.[420] Despite the general decline in deference that courts are willing to offer to FDA actions, in *Saubers v. Kashi*, a U.S. district court in California dismissed a consumer class action a few months after *POM* on the basis of the primary jurisdiction doctrine.[421] The central issue in *Saubers* involved the labels on more than seventy-five Kashi products that listed "evaporated cane juice" rather than sugar on the ingredient labels.[422] Evaporated cane juice is actually sugar cane syrup.[423] In 2009, the FDA issued nonbinding industry guidelines stating that the common names of "sugar" or "cane syrup" should be used, rather than "evaporated cane juice," which "falsely suggests that sweeteners are juice."[424] Having never reached a final decision on the issue, in March 2014, the FDA submitted a notice requesting further comments about the use of the phrase.[425]

In *Saubers*, the court reasoned that FDA expertise was required to determine the propriety of utilizing "evaporated cane juice" on food ingredient labels.[426] Reasoning that the reopened notice and comment period would provide courts necessary guidance and allow for uniform enforcement of FDA requirements, the court dismissed the case without

---

over the relevant industry rather than by the judicial branch.").

420. Saubers v. Kashi Co., 39 F. Supp. 3d 1108, 1111 (S.D. Cal. 2014) ("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.").

421. *See Saubers*, 39 F. Supp. 3d at 1113. *But see* Ibarrola v. Kind LLC, No. 13 C 50377, 2014 WL 3509790, at *6 (N.D. Ill. July 14, 2014) (noting that the Supreme Court called the doctrine of primary jurisdiction into question in *POM*).

422. *Saubers*, 39 F. Supp. 3d at 1110.

423. David Schultz, *Evaporated Cane Juice: Sugar in Disguise?*, NPR: SALT (Oct. 18, 2012), http://www.npr.org/blogs/thesalt/2012/10/18/163098211/evaporated-cane-juice-sugar-in-disguise ("'All sugar is evaporated cane juice,' Judy Sanchez, a spokesperson for the U.S. Sugar Corp., says. 'They just use that for a natural-sounding name for a product.'"); Marion Nestle, *Evaporated Cane Juice: Sugar by Any Other Name . . .*, FOOD POL. (Apr. 8, 2014), http://www.foodpolitics.com/2014/04/evaporated-cane-juice-sugar-by-any-other-name/.

424. *Draft Guidance for Industry: Ingredients Declared as Evaporated Cane Juice; Draft Guidance*, U.S. FOOD & DRUG ADMIN. (Oct. 2009), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm181491.htm; *Ibarrola*, 2014 WL 3509790, at *2.

425. Draft Guidance for Industry on Ingredients Declared as Evaporated Cane Juice; Reopening of Comment Period; Request for Comments, Data, and Information, 79 Fed. Reg. 12507 (Mar. 5, 2014) ("The [FDA] is reopening the comment period for the draft guidance for industry entitled 'Ingredients Declared as Evaporated Cane Juice.' . . . We have not reached a final decision on the common or usual name for this ingredient and are reopening the comment period to request further comments.").

426. *Saubers*, 39 F. Supp. 3d at 1112 ("[A] determination as to the propriety of using the term "evaporated cane juice" in food labeling involves highly technical considerations, such as how evaporated cane juice is produced, the differences between evaporated cane juice and other sweeteners, and the ingredient's characterizing properties.").

prejudice.[427] Distinguishing *POM*, the court clarified that *POM* did not mention the primary jurisdiction doctrine and that dismissals without prejudice do not necessarily prevent plaintiffs' claims.[428]

Although the primary jurisdiction doctrine may somewhat limit the number of consumer actions, it has more often been rejected with courts turning to *POM*'s reasoning to find that state law consumer actions challenging misleading food and beverage labels are permitted.[429] Many practitioners predict that consumer litigation will proliferate with plaintiffs' attorneys arguing that state labeling laws complement FDCA regulation and enforcement and thus should not be preempted.[430] In fact, several courts have applied *POM*'s reasoning in finding that many state law challenges to misleading food and beverage labels are not preempted by the NLEA or FDA regulations.[431]

In *Ibarrola v. Kind*, the U.S. District Court for the Northern District of Illinois came to the opposite conclusion than the court in *Saubers* when it applied *POM*'s reasoning to a class action brought pursuant to a state consumer protection statute.[432] In *Ibarrola*, the plaintiff challenged the label on Kind's Vanilla Blueberry Clusters, which states the product contains "no refined sugars," yet lists "evaporated cane

427. *Id.* ("Allowing the FDA to resolve this matter in the first instance would permit the Court to benefit from the agency's technical expertise and would also provide for uniformity in administration of the agency's food labeling requirements.").

428. *Id.* at 1113 ("Because dismissal on the basis of primary jurisdiction is without prejudice and does not necessarily preclude any claims brought by a plaintiff, *POM Wonderful*'s reasoning does not support Plaintiffs.").

429. *See, e.g.*, Reid v. Johnson & Johnson, 780 F.3d 952, 959 (9th Cir. 2015); Sciortino v. Pepsico, Inc., No. C-14-0478 EMC, 2015 WL 3544522, at *19 (N.D. Cal. June 5, 2015); Reynolds v. Wal-Mart Stores, Inc., No. 4:14CV381-MW/CAS, 2015 WL 1879615, at *9 (N.D. Fla. Apr. 23, 2015).

430. Peritz, *supra* note 363; *see also* Michelle Gillette & Joshua Foust, *U.S. Supreme Court: Pom's Mislabeling Suit Against Coca-Cola Not Precluded by FDA Regulations*, CONSUMER PROD. MATTERS (June 13, 2014), http://www.consumerproductmatters.com/2014/06/supreme-court-finds-poms-mislabeling-claims-against-coke-not-precluded-by-fda-regs/ ("Going forward, expect creative plaintiff-side attorneys to stretch *Pom Wonderful* to argue against the preemption of food labeling claims under state law, despite the important limits on the decision's reach . . . .").

431. *See, e.g.*, Ibarrola v. Kind, LLC, No. 13 C 50377, 2014 WL 3509790, at *6 (N.D. Ill. July 14, 2014) (applying *POM* to class action brought against food manufacturer for misleading labeling under state consumer protection statute); Garcia v. Kashi Co., No. 12-21678-CIV, 2014 WL 4392163, at *7 (S.D. Fla. Sept. 5, 2014) (finding consumers challenge to cereal label not preempted by the FDCA); *see also* notes 436–55 and accompanying text (discussing consumer claims found permitted under *POM*'s reasoning).

432. *Ibarrola*, 2014 WL 3509790, at *1. The claim was brought under the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILL. COMP. STAT. 505/1 (2007), as well as Illinois common law. *Id.*

juice" as an ingredient.[433]

Kind argued that the court should stay the action under the doctrine of primary jurisdiction until the FDA makes its determination on the issue, in order to promote national uniformity and avoid "infringing on the FDA's jurisdiction."[434] Noting "the Supreme Court recently called this rationale into question in *POM Wonderful LLC v. Coca–Cola Co.*," the court refused to consider Kind's argument.[435] The court explained that in *POM*, the Supreme Court held that FDCA-regulated food and beverage labels were not "off limits" to Lanham Act claims, and many aspects of the Illinois statute are comparable to the Lanham Act.[436]

The Ninth Circuit came to a similar conclusion in *Reid v. Johnson & Johnson* when it held that a consumer class action against a food manufacturer was not preempted by the NLEA.[437] The defendants, Johnson & Johnson and McNeil Nutritionals, LLC manufacture Benecol, a spread that they market as a healthy alternative to butter and margarine.[438] The plaintiff filed a false advertising lawsuit under California law[439] challenging Benecol's label because while it proclaims the spread contains "No Trans Fats," the product does in fact contain trans fat.[440] The plaintiff also challenged various health claims on the packaging, such as "Proven to Reduce Cholesterol," as false and misleading.[441]

The court found that the label was in violation of FDA regulations

433. *Id.* at *1–2.

434. *Ibarrola*, 2014 WL 3509790, at *5; *cf.* Paula K. Knippa, *Primary Jurisdiction Doctrine and the Circumforaneous Litigant*, 85 TEX. L. REV. 1289 (2007) ("The doctrine of primary jurisdiction is a judicially created doctrine designed to determine the proper allocation of decisionmaking authority between courts and administrative agencies."); Thomas, *supra* note 302 ("Although not specifically so identified, the Ninth Circuit's rationale is close to the 'primary jurisdiction doctrine,' although that doctrine typically stays or dismisses litigation pending an agency decision rather than providing an outright bar of claims.").

435. *Ibarrola*, WL 3509790, at *6. This directly contradicts what some experts forecasted would tend to keep consumer actions in check. *See* Reich et al., *supra* note 300 (predicting that "the FDA's continued promulgation of draft and final food labeling guidance, which buoys class action defendants' primary jurisdiction and preemption arguments" would discourage class proponents).

436. *Ibarrola*, 2014 WL 3509790, at *6 n.4 ("The Lanham Act is similar to the ICFA in many respects."). The court dismissed the case with leave to amend the complaint, however, because the plaintiff failed to adequately allege that she was deceived or that any injury was sustained. *Id.* at *6.

437. Reid v. Johnson & Johnson, 780 F.3d 952, 959 (9th Cir. 2015).

438. *Id.* at 955.

439. California's Unfair Competition Law, CAL. BUS. & PROF. CODE §§ 17200–10 (West 2015); False Advertising Law, CAL. BUS. & PROF. CODE §§ 17500–09 (West 2015); Consumer Legal Remedies Act, CAL. CIV. CODE §§ 1750–84 (West 2015).

440. *Reid*, 780 F.3d at 955.

441. *Id.* at 957.

because its "No Trans Fats" claim was false or misleading.[442] Citing *POM*, the court reasoned that the NLEA does not preempt claims brought under state laws that are identical to FDA regulations,[443] and therefore the plaintiff's challenge to the "No Trans Fat" wording was not preempted.[444] The court also rejected the defendants' argument that the case should be dismissed under the primary jurisdiction doctrine because the substantive issues—whether the labels were misleading—did not require additional FDA review.[445]

Regarding the challenged health claims, the defendants argued that an FDA letter issued in 2003 indicated that the FDA was considering limiting enforcement of the relevant regulations,[446] thus creating a federal policy that preempted state law.[447] The court rejected the defendant's argument, reasoning that the letter did not carry the force of law to have preemptive effect.[448] In another example of courts declining to give deference to FDA actions, the court added that it was wary of permitting the FDA to issue letters that authorize health claims because such actions are not normally subject to judicial review.[449] In fact, the court cautioned that restricting challenges and, in turn, judicial review of FDA enforcement actions would not promote Congress's purpose in the FDCA of protecting the public health and safety.[450]

Several other consumer claims challenging food and beverage labels

---

442. 21 C.F.R. § 101.13(i)(3) (2015); *Reid*, 780 F.3d at 962 ("A nutrient content claim fails if it is 'false or misleading in *any* respect.' Because Benecol contains *some* trans fat (between 0 and 0.5 grams per serving), its "No Trans Fat" claim is misleading in at least one respect." (citation omitted)).

443. 21 U.S.C. § 343–1(a)(5) (2012); *Reid*, 780 F.3d, at 959, (citing POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2238 (2014)).

444. *Reid*, 780 F.3d at 963. In so holding, the Ninth Circuit overturned the district court's holding that "No Trans Fat" was not misleading because partially hydrogenated vegetable oil was listed as an ingredient and reasonable consumers would infer that the product contained trans fat. *Id.* The court rejected this reasoning, finding nothing to suggest that consumers would understand that partially hydrogenated vegetable oil contains trans fat. *Id.*

445. *Reid*, 780, F.3d at 966–67 ("The issue that this case ultimately turns on is whether a reasonable consumer would be misled by McNeil's marketing, which the district courts have reasonably concluded they are competent to address in similar cases.").

446. *Reid*, 780 F.3d at 952; *see also* 21 C.F.R. § 101.83(c)(2)(iii)(B)–(D).

447. *Reid*, 780 F.3d at 963.

448. *Id.* at 965 ("The FDA's equivocal language regarding its intention to foreclose its own ability to enforce noncompliance with existing rules is a good indication that it did not intend to foreclose state law challenges to health claims that do not comply with existing rules.").

449. *Id.* (citing 5 U.S.C. § 701(a)(2) (2012)) ("[A]gency decisions not to take enforcement action are usually committed to agency discretion by law and thus generally not subject to judicial review under the Administrative Procedure Act.").

450. *Reid*, 780 F.3d at 965–66 (citing POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2238 (2014)).

survived dismissal utilizing *POM* reasoning as well.[451] These decisions not only illustrate that *POM* extends to comparable state consumer protection laws, but they also signal that FDA determinations will no longer receive regular deference from the lower courts.[452]

CONCLUSION

After the decision in *POM*, Coca-Cola issued a statement that said it was "committed to clear labeling that fully complies with FDA regulations."[453] This statement misses the mark because compliance with FDA regulations does not necessarily mean the label is accurate. In fact, because labels may be misleading despite adherence to FDA regulations, those injured by deceptive labeling are not able to seek redress except through Lanham Act claims. *POM* ensures that parties commercially injured by misleading food and beverage labels are not left without an adequate remedy. In addition, the integrated regulation of food and beverage labels will improve label clarity and accuracy because Lanham Act suits will fill the regulatory gaps left by inadequate FDA regulation. In an era where diet-related diseases are rising along with consumer awareness, accurate labeling is imperative and *POM* is a step in the right direction.

451. *See*, *e.g.*, Sciortino v. Pepsico, Inc., No. C-14-0478 EMC, 2015 WL 3544522 (N.D. Cal. June 5, 2015) (allowing challenge to beverage label that failed to provide warning of carcinogenic ingredient); Reynolds v. Wal-Mart Stores, Inc., No. 4:14CV381-MW/CAS, 2015 WL 1879615 (N.D. Fla. Apr. 23, 2015) (allowing challenge to "100% Cranberry Pomegranate Flavored Juice Blend" that contained mostly apple and grape juices). *But see* Nemphos v. Nestle Waters N. Am., Inc., 775 F.3d 616 (4th Cir. 2015) (finding that state law challenge to fluoride warning label was not identical to FDA requirements and thus preempted by the NLEA).

452. Anthony Pavel & Kathleen Garvey, POM Wonderful *Decision Expands into New Territory*, MORGAN LEWIS (Oct. 21, 2014), https://blogs.morganlewis.com/welldone/2014/pom-wonderful-decision-expands-into-new-territory/ ("*POM Wonderful* might stand for the proposition that courts do not need the FDA's 'expertise' to determine whether a plaintiff has a claim."); Reich et al., *supra* note 300.

453. Brandi, *POM Victorious Over Coke in Ruling from Supreme Court*, CARE2 (June 14, 2014, 3:30 PM), http://www.care2.com/greenliving/pom-victorious-over-coke-in-ruling-from-supreme-court.html.