
The Crusade Against Misleading Labels: Are Manufacturers the Protectors of Consumer Interests?

“Misbranding was one of the chief evils Congress sought to stop.”¹

I. INTRODUCTION

From television commercials and magazine ads to labels and packaging, food and beverage manufacturers spend a significant amount of money advertising their products.² Congress passed the Food, Drug, and Cosmetic Act (FDCA) to ensure that food and beverage manufacturers do not mislead or deceive consumers with their advertising.³ The FDCA’s purpose is to protect consumers from adulterated and misbranded food and beverages.⁴ The FDCA prohibited misbranding food and beverages using false or misleading labels to further this goal.⁵

In 1990, Congress amended the FDCA by enacting the Nutrition Labeling and Education Act (NLEA).⁶ Before the NLEA, each state passed its own labeling requirements for food and beverage manufacturers, as states saw fit.⁷ Recognizing the need for uniformity in the marketplace and the reduction of compliance costs for food and beverage manufacturers, Congress enacted the first national labeling law.⁸ To achieve these objectives, Congress included a

1. 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States, 340 U.S. 593, 596 (1951).

2. See STEVE W. MARTINEZ, U.S. DEP’T OF AGRIC., THE U.S. FOOD MARKETING SYSTEM: RECENT DEVELOPMENTS, 1997-2006 35-36 (May 2007), http://www.ers.usda.gov/media/196925/err42_1_.pdf [http://perma.cc/7VTM-S4H7] (discussing advertising expenditures of food and beverage manufacturers); see also James S. Wrona, *False Advertising and Consumer Standing Under Section 43(A) of the Lanham Act: Broad Consumer Protection Legislation or a Narrow Pro-Competitive Measure?*, 47 RUTGERS L. REV. 1085, 1087 (1995) (discussing important role of advertising in capitalistic, competitive marketplace).

3. See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399f (2012) (prohibiting adulterated and misbranded food, drugs, devices, and cosmetics).

4. See 21 U.S.C. § 341 (2012) (promulgating regulations to “promote honesty and fair dealing in the interest of consumers”); United States v. Dotterweich, 320 U.S. 277, 280 (1943) (asserting FDCA intended to protect lives and health of citizens in modern industrial society); Roseann B. Termini, *The Prevention of Misbranded Food Labeling: The Nutrition Labeling and Education Act of 1990 and Alternative Enforcement Mechanisms*, 18 OHIO N.U. L. REV. 77, 80 (1991) (asserting congressional purpose of FDCA aimed primarily at protecting consumers from misbranded food).

5. See 21 U.S.C. § 331(a)-(c) (2012) (prohibiting misbranding of any food, drug, device, tobacco product, or cosmetic).

6. See Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 343-1 (2012) (prescribing nutrition labeling requirements).

7. See Am. Bar Ass’n, *The Impact of the Nutrition Labeling and Education Act of 1990 on the Food Industry*, 47 ADMIN. L. REV. 605, 607 (1995) (discussing state label legislation before NLEA enactment).

8. See *id.* (crediting industry lobbying for uniform federal labor law as impetus for Congress enacting

preemption provision in the NLEA, which prohibited states from enacting label laws that are not identical to the federal requirements.⁹ This provision gave the federal government, specifically the Food and Drug Administration (FDA), the exclusive authority to regulate food and beverage labels.¹⁰

Congress also created an avenue for manufacturers to seek redress for competitors' false and misleading advertising by way of the Lanham Act.¹¹ This federal statute allows a competitor to assert a claim against another competitor alleging that the opponent falsely advertised their product, and the false advertising harmed their business.¹² While the Lanham Act does not allow individual consumers to bring claims, it theoretically protects their interests when a manufacturer makes a false advertising claim.¹³

In *POM Wonderful LLC v. Coca-Cola Co.*¹⁴ (*POM*), the Supreme Court determined whether compliance with FDCA label regulations precluded Lanham Act claims premised on allegations of false and misleading labeling.¹⁵ While the FDCA prohibits states from enacting its own labeling requirements, the Court had to determine whether the FDCA barred federal claims alleging misleading labeling.¹⁶ Overturning the Ninth Circuit, the Court held the FDCA does not preclude claims brought under the Lanham Act because the two federal statutes are complementary.¹⁷ The Court reasoned that despite the Lanham Act and the FDCA serving different purposes, the claims brought under the Lanham Act help to better protect the public's interests.¹⁸ In so holding, the Court is entrusting manufacturers to protect consumers' interests

NLEA).

9. See 21 U.S.C. § 343-1(a) (2012) (prohibiting states from establishing label requirements not identical to federal label requirements).

10. See *id.* (granting federal government exclusive authority over labeling by prohibiting states from enacting different requirements).

11. See Lanham Act, 15 U.S.C. § 1125(a) (2012) (creating cause of action for manufacturers injured by competitors' unfair practices, such as misleading labeling).

12. See *infra* text accompanying note 94 (explaining Lanham Act provides competitors with right to sue).

13. See *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2238 (2014) (stating claims under Lanham Act protect commercial interest and indirectly protect public from misleading labels).

14. 134 S. Ct. 2228 (2014).

15. See *id.* at 2233 (discussing POM's appeal to determine if FDCA compliance preempts Lanham Act claims).

16. See *id.* at 2235 (discussing FDCA provision preempting certain state-law claims on misbranding). In the NLEA, Congress enacted a provision that precluded states from establishing misbranding regulations that are similar, but not identical, to the FDCA's. See 21 U.S.C. § 343-1(a). The Court determined that because Congress did not enact a similar provision addressing preemption, Congress did not intend for the FDCA regulations to preempt claims under the Lanham Act. See *POM*, 134 S. Ct. at 2237.

17. See *POM*, 134 S. Ct. at 2238 (declaring Lanham Act and FDCA regulations complementary statutes protecting different interests). The Court stated that the two federal statutes complement each other because the Lanham Act protects manufacturers' commercial interests against unfair competition, while the FDCA protects public health and safety. See *id.*

18. See *id.* at 2239 (reasoning precluding Lanham Act claims would leave public vulnerable to misleading labeling).

indirectly.¹⁹

This Note begins with an outline of the history of federal food regulation in the United States.²⁰ It discusses the FDCA's origin and purpose and its subsequent amendment, the NLEA.²¹ This Note will then discuss the NLEA's preemption provision and its interplay with private litigation brought under state consumer protection laws.²² It will also examine the FDCA's interaction with private litigation brought under the Lanham Act.²³ The discussion then moves to the Supreme Court's decision in *POM*.²⁴ This Note will proffer that the Court's conclusion that the Lanham Act is a necessary complement to the FDCA reveals major gaps in the FDA's enforcement of the FDCA.²⁵ This Note will then examine the reasons for the FDA's sporadic enforcement of the FDCA.²⁶ Contrary to the Court's reasoning in *POM*, this Note will argue the Lanham Act is not a suitable complement to resolve the FDCA enforcement issues because manufacturers do not bring these suits to advocate for consumer protection, but rather to self-serve their own commercial interests.²⁷ Accordingly, this Note will offer an alternate solution aimed at protecting consumer interests, namely, consumer-initiated suits to enforce label regulations, brought under state consumer protection laws.²⁸

II. HISTORY

Prior to 1906, states were the sole regulators of food and beverage manufacturers.²⁹ States enacted food and beverage statutes, which focused primarily on trade and protecting consumers from adulterated food.³⁰ During

19. See *id.* (explaining precluding Lanham Act claims would leave public with "less effective protection" against misleading labeling).

20. See *infra* Part II (outlining historical development of current federal food legislation).

21. See *infra* Parts II.A-D (describing historical impetus and purpose of FDCA and NLEA enactment and its purpose).

22. See *infra* Parts II.E.1-3 (discussing NLEA preemption provision's scope and its role with private claims brought under state statutes).

23. See *infra* Part II.E.4 (discussing history and purpose of Lanham Act and its interplay with FDCA).

24. See *infra* Part II.F (summarizing facts, arguments, and holdings of Court's finding FDCA does not preempt Lanham Act claims).

25. See *infra* Part III.A (arguing Court's decision illustrates inadequacy of current FDCA enforcement).

26. See *infra* Part III.A (outlining reasons for FDA's weak enforcement of FDCA's prohibition of misleading labels).

27. See *infra* Part III.B (rejecting Lanham Act claims as means to supplement FDCA compliance).

28. See *infra* Part III.C (noting consumer litigation better suited to further FDCA's goal of consumer protection).

29. See Termini, *supra* note 4, at 79-80 (discussing pre-federal state regulation of food and beverages). The early laws that American colonies enacted primarily served trade interests, focusing on inspections and standards of weight. See *id.*; see also Joe Dages, Comment, *Private Parties and the FFDCA: How Creative Litigants Have Circumvented Section 310 and Undermined the NLEA's Express Preemption Amendments*, 62 CATH. U. L. REV. 1061, 1063 (2013) (attributing states' historical regulation of food and beverages to constitutional grant of police powers).

30. See Termini, *supra* note 4, at 77-78 (noting many state food laws focused primarily on contaminated

this time, the federal government did not enact any national food and beverage laws, leaving states to promulgate regulations tailored to its individual needs.³¹ As the economy transitioned from an agricultural economy to an industrial economy, however, food production also industrialized to meet the demands of the growing urban population.³² With expanded interstate commerce, the United States recognized the need for a national food law.³³

A. The Pure Food and Drug Act of 1906

Due to the lack of federal laws regulating industrial food manufacturers, there were unsanitary conditions and uncontrolled uses of toxic coloring and chemical preservatives.³⁴ Because most states' food laws focused primarily on adulterated food, there were no regulations aimed at preventing food misbranding.³⁵ Recognizing the need for such regulation, Dr. Harvey Wiley, the head of the Department of Chemistry within the Department of Agriculture, campaigned for a federal pure food bill to prohibit both adulterated and misbranded food, beverages, and drugs.³⁶ Around the same time as Dr. Wiley's crusade, Upton Sinclair published *The Jungle*, a novel depicting the unsanitary and revolting conditions in a meat-packing plant.³⁷ The need for federal regulation of the food and beverage industry received national attention, further pushing Congress to pass a federal food bill.³⁸ On June 30, 1906, Congress signed the Pure Food and Drug Act (Wiley's Act) into law.³⁹

Wiley's Act prohibited manufacturing and shipping adulterated or

food rather than misbranded food). Many states, including Massachusetts and Virginia, had regulations in place aimed at protecting consumers from adulterated food. *See id.* at 78. Virginia was the first state to enact a law that attempted to curb misbranding. *See id.*

31. *See* Wallace F. Janssen, *The Story of the Laws Behind the Labels*, FDA CONSUMER (1981), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm> [http://perma.cc/KL3D-AS3S] (discussing widely varied food laws states enacted catering to individual needs).

32. *See id.* (discussing market conditions leading to necessity of federal food regulations); Termini, *supra* note 4, at 79 (crediting industrialization as significant precursor to 1906 Act).

33. *See* Janssen, *supra* note 31 (citing post Civil War expansion of interstate commerce as impetus to enacting national food law).

34. *See id.* (discussing substandard conditions and standards in food manufacturing absent federal regulation).

35. *See* Termini, *supra* note 4, at 79 (noting most states' food laws focused primarily on food adulteration, not food misbranding).

36. *See* Janssen, *supra* note 31 (discussing Wiley's campaign tactics used in rallying for national food law). Wiley garnered various women's organizations' support to call for federal food regulation. *See id.* Also, in an effort to gain public interest and awareness, Wiley assembled a volunteer "poison squad" who agreed to eat only chemically preserved foods to demonstrate its negative effect on health. *See id.*

37. *See* Claudia L. Andre, Comment, *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) (attributing promulgation of 1906 Act in part to appalling conditions described in *The Jungle*).

38. *See* Janssen, *supra* note 31 (crediting Wiley's rigorous crusade and *The Jungle* with arousing public interest in national food law).

39. *See* Pure Food and Drug Act, ch. 3915, 34 Stat. 768 (1906) (repealed 1938) (creating first federal food law in series of many enacted during twentieth century).

misbranded foods in interstate commerce.⁴⁰ Congress enacted the legislation to prevent injury to consumers resulting from false and misleading statements on food, beverages, and drugs.⁴¹ While Wiley's Act was a significant step for consumer protection from misbranded foods and beverages, it had flaws.⁴² Most notably, Wiley's Act lacked specific guidelines for compliance.⁴³ Also, it was difficult for the government to prosecute claims of fraud against manufacturers who violated Wiley's Act by misbranding their products.⁴⁴

B. The Food, Drug, and Cosmetic Act of 1938

Recognizing the shortcomings of Wiley's Act, Congress amended it several times.⁴⁵ Congress soon recognized, however, the necessity of creating an entirely new act.⁴⁶ Headed by Rexford Guy Tugwell, the Assistant Secretary of Agriculture in 1933, the FDA drafted a new bill.⁴⁷

The industry strongly opposed the initial draft (dubbed "Tugwell's Bill") as too harsh, and consumer advocacy organizations scantily praised it.⁴⁸ There

40. *See id.* (prohibiting manufacture, sale, or transportation of adulterated, misbranded, poisonous, or deleterious foods, drugs, medicines, etc.).

41. *See United States v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar*, 265 U.S. 438, 442-43 (1924) (determining Wiley's Act's purpose to prevent false, misleading, and deceptive statements, devices, or designs); *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 409 (1914) (holding congressional intent of Act to protect consumers from misrepresentations of quality and character).

42. *See* Vincent A. Kleinfeld, *Legislative History of the Federal Food, Drug, and Cosmetic Act*, 50 FOOD & DRUG L.J. 65, 66-67 (1995) (discussing shortcomings of Wiley's Act). The FDA reported that Wiley's Act failed to address fraudulent statements about foods or drugs that are not made on the product's package, but are made elsewhere. *See id.* Additionally, Wiley's Act did not set forth legal standards for foods, give the FDA authority to inspect manufacturers' warehouses, or restrict the use of poisons in drugs. *See id.*

43. *See* Janssen, *supra* note 31 (noting Wiley Act's flaw in its lack of requirements guiding manufacturers in compliance).

44. *See id.* (discussing difficulty of government in prosecuting claims under Wiley's Act). For the government to prove alleged misleading claims were fraudulent, the government needed to show that the manufacturer intended to deceive consumers. *See id.* Proving a manufacturer's intent to deceive was difficult, however, and this difficulty enabled many food manufacturers to avoid liability. *See id.*

45. *See* Kleinfeld, *supra* note 42, at 66 (outlining six amendments and supplemental enactments to 1906 Act). Congress first amended Wiley's Act with the Sherley Amendment, after the Supreme Court held that the term *misbranded* in Wiley's Act did not apply to false or misleading statements regarding the medicinal effects of drugs. *See id.* In 1913, Congress enacted the Gould Amendment, which required manufacturers to plainly mark the weight or measure of the contents of packaged food products. *See id.* The third amendment, known as the Kenyon Amendment, redefined the term *package* as used in Wiley's Act to include wrapped meats. *See id.* Prompted by the dairy industry, Congress again amended Wiley's Act to define and standardize butter. *See id.* In 1930, Congress enacted the McNary-Mapes Amendment, which granted the Secretary of Agriculture the authority to establish quality, condition, and fill standards for canned foods. *See id.* Congress added, and later amended, the Sea Food Amendment, giving the Secretary of Agriculture the authority to inspect and examine seafood and its labeling. *See id.*

46. *See id.* at 67 (discussing FDA decision to create entirely new act rather than further amending 1906 Act).

47. *See id.* at 67-68 (discussing Tugwell's role in initial sponsoring of new federal food act).

48. *See* David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 L. & CONTEMP. PROBS. 2, 8 (1939), <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1937&context=lcp> [http://perma.cc/RXM7-K74T] (discussing poor response to first draft from

were numerous successors to this initial draft, and the FDA created many amendments to compete with rival bills from trade associations.⁴⁹ Finally, after a five-year legislative battle, Congress passed the FDCA in 1938, replacing Wiley's Act.⁵⁰

The FDCA's purpose is to protect consumers from adulterated and misbranded food, drugs, and beverages.⁵¹ Congress enacted the FDCA with the intent of protecting the public's livelihood and health because modern industrialization made it difficult for the public to protect themselves.⁵² To serve this purpose, the FDCA sets forth regulations to "promote honesty and fair dealing in the interest of consumers" by protecting consumers from false and misleading statements made on food labels.⁵³

C. Misbranding Under the FDCA

Eradicating false and misleading labels was one of Congress's top priorities.⁵⁴ To this end, the FDCA prohibits misbranding food, drugs, devices, tobacco products, and cosmetics.⁵⁵ To clarify what constitutes a misleading label, the FDCA defines a label as the written, printed, or graphic materials on

industries and consumer organizations).

49. See Kleinfeld, *supra* note 42 (outlining subsequent amendments and bills introduced to Congress).

50. See *id.* (examining legislative history and ensuing legislative battle to pass FDCA). The first draft of the bill did not receive the congressional support it needed to pass and various consumer groups criticized it for not affording adequate protection to consumers. *See id.* at 74. Despite numerous amendments and successor bills, important issues remained, including whether the Federal Trade Commission or the FDA would regulate advertising and whether the Wiley's Act misbranding provision (which prohibited labeling that was false or misleading) should be changed to prohibit only labeling that was materially misleading. *See id.* at 91. Finally, the tragic Elixir Sulfanilamide disaster in 1937—where about 100 people died after ingesting improperly prepared, poisonous medicine—prompted Congress to make compromises to pass a bill. *See id.* at 92-93; *see also* Legislation, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/default.htm> (last updated July 2, 2015) [<http://perma.cc/9FQT-KQ4U>] (citing toxic elixir disaster as impetus for passage of FDCA).

51. United States v. Dotterweich, 320 U.S. 277, 280 (1943) (stating congressional purpose of FDCA to protect lives and health of public); Termini, *supra* note 4, at 80 (stating FDCA purpose of consumer protection against misbranded food).

52. See *Dotterweich*, 320 U.S. at 280 (stating FDCA aimed at protecting public health in modern society).

53. Food, Drug, and Cosmetic Act, 21 U.S.C. §341 (2014); *see also* 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States, 340 U.S. 593, 596 (1951) (asserting main congressional purpose of FDCA aimed at stopping misbranding); Kordel v. United States, 335 U.S. 345, 349 (1948) (holding FDCA protects consumers who are unable to protect themselves).

54. *62 Cases, More or Less, Each Containing Six Jars of Jam*, 340 U.S. at 596 (stating "misbranding was one of . . . chief evils Congress sought to stop.").

55. See 21 U.S.C. § 331(a)-(c) (2012) (prohibiting adulterated and misbranded food, drugs, devices, cosmetics, or tobacco products). A misbranded food is defined in the FDCA as one with a false or misleading label. See 21 U.S.C. § 343 (2012); *see also* Termini, *supra* note 4, at 82 (discussing relevant factors for allegedly misleading label). When confronted with an allegedly misleading label, the FDA will consider both the label's representations (which can be either suggested or made by words or design) and the failure to reveal material facts relating to the label's representations. *See id.*

a product's container.⁵⁶ In determining whether a label is misleading—and thus if food is misbranded—the FDCA considers the representations made or suggested by statements, words, designs, or devices and the degree to which the label fails to disclose material facts.⁵⁷ To implement these FDCA provisions, Congress vested the FDA with authority to enforce these requirements.⁵⁸ The FDA then promulgated many label regulations under its duty to enforce.⁵⁹

D. The Nutrition Labeling and Education Act of 1990

Since the FDCA's enactment in 1938, there were numerous scientific and research advancements relating to the role of diet in health and disease prevention.⁶⁰ Food manufacturers began using this progression to their economic advantage by labeling their food and beverages with misleading and false health claims.⁶¹ Recognizing the need to protect consumers from these misleading dietary and health claims, Congress amended the FDCA with the enactment of the NLEA.⁶² With the NLEA, Congress sought to strengthen the FDA's authority to require nutrition labeling and set forth requirements for nutrient claims on labels.⁶³ The NLEA required detailed nutrition labels on all food and beverages, standardized the definitions of nutrient content claims, altered the requirements for packages' ingredient labels, created uniform serving sizes for labels, and limited the types of health claims manufacturers could make.⁶⁴

In addition to streamlining and reforming the nutritional labeling requirements, the NLEA added an express preemption provision to the FDCA.⁶⁵ Prior to the NLEA's enactment, each state had its own different

56. See 21 U.S.C. § 321(k) (2012) (setting forth definition of label). A label is a written, printed, or graphic display on the container of a food or beverage product. *Id.*

57. 21 U.S.C. § 321(n) (2012).

58. See 21 U.S.C. § 341 (2012) (granting FDA authority to promulgate regulations and prescribe standards and definitions); see also *What Does FDA Regulate?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm> (last updated Dec. 28, 2015) [<http://perma.cc/N64C-8CHZ>] (discussing breadth of FDA's regulatory authority).

59. See 21 C.F.R. §§ 101.1-101.108 (2015) (setting forth various food labeling regulations).

60. See Am. Bar Ass'n, *supra* note 7, at 606 (citing scientific developments linking diet with disease prevention as impetus for NLEA enactment).

61. See Termini, *supra* note 4, at 90 (discussing food and beverage manufacturers' marketing using health claims aimed at disease prevention).

62. See 21 U.S.C. § 343-1 (2012) (amending FDCA with additional nutritional labeling requirements and clarifying federal authority over food labeling).

63. See H.R. REP. NO. 101-538, at 3337 (1990); Andre, *supra* note 37, at 232 (discussing Congress's focus on improving nutritional information on labels); Termini, *supra* note 4, at 88-89 (reiterating congressional purpose as set forth in NLEA House Report). The NLEA enactment required that food and beverage manufacturers place the well-known Nutrition Facts box on their product. See 21 U.S.C. § 343(q)(1)(A)-(D) (2012).

64. See Am. Bar Ass'n, *supra* note 7, at 606 (stating five major amendments NLEA brought to FDCA).

65. See 21 U.S.C. § 343-1(a) (2012) (prohibiting states from establishing labeling standards different than federal regulations).

labeling laws, which made compliance costly and difficult for manufacturers.⁶⁶ As a result, the food and beverage industry strongly lobbied for a federal food labeling law that would apply nationally and preempt all state labeling laws.⁶⁷

E. The FDCA and Preemption

1. Preemption Generally

Preemption is a doctrine established in the Supremacy Clause of the Constitution, which provides that if a state law conflicts with a federal law, the federal law prevails.⁶⁸ A federal law can preempt a state law through express preemption, field preemption, or conflict preemption.⁶⁹ Express preemption of a state law occurs when a federal statute explicitly states that it preempts the state law.⁷⁰ Where Congress's regulation of a field is so extensive that it leads to an inference that Congress intended the federal law to preempt state law, field preemption is implied.⁷¹ The final type of preemption, conflict preemption, occurs when the state law conflicts with the federal law, such that it is impossible to comply with both laws.⁷²

When a statute contains an express preemption provision, a court must determine the scope of the statute's preemption.⁷³ In making this

66. See Am. Bar Ass'n, *supra* note 7, at 607 (citing industry lobbying efforts to end high cost of complying with fifty different state laws); Andre, *supra* note 37, at 233 (discussing costs of complying with fifty state laws, many more stringent than federal laws).

67. See Am. Bar Ass'n, *supra* note 7, at 608 (discussing food and beverage industry's strong lobbying efforts for preemption provision in NLEA). The industry's lobbying efforts were successful because they received a preemption provision in the NLEA. *See id.* The provision, however, was not as broad as desired because, in certain circumstances, the FDA could allow states to bring enforcement actions and promulgate their own regulations. *See id.* at 608-09; cf. Emily J. Schaffer, *Is the Fox Guarding the Henhouse? Who Makes the Rules in American Nutrition Policy?*, 57 FOOD & DRUG L.J. 371, 371-72 (2002) (discussing government's role in balancing food industry's interests with public's interest).

68. See U.S. CONST. art. VI, cl. 2 (establishing federal law as supreme law of land and preempts state law). Pursuant to the Supremacy Clause, the Constitution, federal laws, and treaties take precedence over state laws, including state constitutions. *See id.*

69. See *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 767 (11th Cir. 1998) (asserting three ways Congress can preempt state law through federal laws and regulations).

70. See *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (noting Congress can explicitly say in statute federal law preempts state law).

71. See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (finding field preemption where Congress's extensive regulation in field supports inference of intended preemption). A court will find field preemption if the federal regulatory scheme in a particular field is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Id.*

72. See *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 204 (1983) (holding conflict preemption occurs when state and federal law conflict rendering compliance with both impossible).

73. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (interpreting express preemption provision in Medical Device Amendment). When interpreting an express preemption provision, a court does not need to look outside the statutory language to determine the intent to preempt state laws. *See id.* at 484. In interpreting the scope of preemption, however, the court should consider the context of the preemption provision. *See id.* at 484-85. A presumption against preemption and congressional intent guide this interpretation. *See id.* at 485-

determination, courts look to the act's legislative history because Congress's purpose is the ultimate test in every preemption case.⁷⁴ Additionally, courts must apply a presumption against preemption, especially in areas within traditional state regulation.⁷⁵

2. FDCA Preemption Provision

The NLEA contains an express preemption provision that prohibits states from enacting label regulations and requirements that are not identical to the FDCA requirements.⁷⁶ Per the preemption provision, state labeling laws will be preempted if they set forth requirements that are "affirmatively different than the federal requirements."⁷⁷ The NLEA's preemption provision, however, is not wholly preclusive; individual plaintiffs can bring civil suits if the state labeling law imposes requirements identical to the federal requirements.⁷⁸

Additionally, the NLEA preemption provision contains an exemption that allows states, subject to the FDA's approval, to promulgate food and beverage labeling laws in certain circumstances.⁷⁹ Although the FDCA contains an express preemption provision, the provision is not entirely clear and comprehensive.⁸⁰ Accordingly, there were numerous cases where courts had to

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74. See *Retail Clerks Int'l Ass'n, Local 1625, AFL-CIO v. Schermerhorn*, 375 U.S. 96, 103 (1963) (discussing conflict between federal and state law); see also *Medtronic*, 518 U.S. at 485 (using "purpose of Congress . . . ultimate touchstone" language to guide in FDCA preemption analysis); *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (analyzing FDCA preemption provision by looking to congressional purpose).

75. See *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (holding courts have duty during preemption analysis to disfavor preemption); *Cipollone*, 505 U.S. at 516 (applying presumption against preemption of state police power regulations); *Taylor v. Gen. Motors Corp.*, 875 F.2d 816, 823 (11th Cir. 1989) (asserting presumption against express preemption when subject matter falls within states' rights).

76. See 21 U.S.C. § 343-1(a) (2012) (creating provision wherein federal label laws preempt state label laws). The NLEA prohibits states from directly or indirectly establishing food label requirements that are not identical to the FDCA's food label requirements. See *id.*

77. Jennifer L. Pomeranz, *Litigation To Address Misleading Food Label Claims and the Role of the State Attorneys General*, 26 REGENT U.L. REV. 421, 429 (2014) (noting preclusion of state label laws "affirmatively different" than federal requirements) [hereinafter *Litigation To Address Misleading Food Label Claims*]; Termini, *supra* note 4, at 102 (stating preclusion of state regulations conflicting with certain enumerated FDCA sections, but not all). But see Termini, *supra* note 4, at 104-05 (asserting state action still encouraged to complement federal enforcement of regulations).

78. See Am. Bar Ass'n, *supra* note 7, at 608 (noting NLEA does not preempt state's right to civil enforcement if approved by FDA); *Litigation To Address Misleading Food Label Claims*, *supra* note 77, at 429 (discussing plaintiffs' right to bring enforcement lawsuit when state law identical to federal law); see also James Springer, Note, *The Success of the Citizen Suit: Protecting Consumers from Inaccurate Food Labeling by Amending the Federal Food, Drug, and Cosmetic Act*, 68 FOOD & DRUG L.J. 401, 405-06 (2013) (discussing three ways private individuals can bring suit for misleading food and beverage labels).

79. See 21 U.S.C. § 343-1(b) (2012) (exempting states from preemption provision in certain circumstances). The exemption provides that the FDA may exempt a state requirement from Section 343-1(a) if: it would not cause a food to violate a federal requirement, it would not "unduly burden interstate commerce," and it addresses a need for regulation that the federal law does not address. *Id.*

80. See Andre, *supra* note 37, at 234 (discussing NLEA's lack of clear and expansive preemption as compared to other federal preemption statutes).

determine whether the FDCA preempted claims brought under state consumer protection laws.⁸¹

3. FDCA Interplay with State Consumer Protection Laws

Congress vested the FDA with authority to enforce the FDCA labeling requirements and bring suits against any violators.⁸² The FDA, however, does not have the resources to police all cases of food misbranding adequately.⁸³ Further, the FDCA does not allow for a private right of action to enforce the regulations.⁸⁴ Nonetheless, consumers and advocacy groups found ways to bring lawsuits to combat manufacturers' misleading labeling.⁸⁵

Groups typically bring these lawsuits under state consumer protection laws designed to protect consumers from unfair and deceptive business practices.⁸⁶ While the FDCA prohibits states from enacting label regulations that are not identical to the federal regulations, it permits state regulations that *are* identical.⁸⁷ In states with regulations identical to the FDCA's, private parties

81. See, e.g., *Wyeth v. Levine*, 555 U.S. 555, 563 (2009) (determining whether FDA drug labeling requirements preempt state law product liability claims); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485-86 (1996) (determining whether state law claim preempted for defective device design); *Holk v. Snapple Beverage Co.*, 575 F.3d 329, 335 (3d Cir. 2009) (deciding whether FDCA preempted lawsuit brought under state consumer fraud law alleging misleading beverage label); *In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1173 (Cal. 2008) (deciding whether FDCA preempted action under California's Food, Drug, and Cosmetic Law).

82. See 21 U.S.C. § 337(a) (2012) (stating United States brings proceedings to enforce FDCA regulations and punish violations).

83. See Jennifer L. Pomeranz, *A Comprehensive Strategy To Overhaul FDA Authority for Misleading Food Labels*, 39 AM. J.L. & MED. 617, 619 (2013) [hereinafter *A Comprehensive Strategy*] (discussing FDA's difficulty in sufficiently addressing misleading labels and enforcing violations); see also Alexander Gaffney, *FDA Funding Set To Increase in 2014 After Year of Cutbacks*, REG. AFF. PROFS. SOC'Y (June 6, 2013), <http://www.raps.org/regulatoryDetail.aspx?id=8625> [http://perma.cc/N3Z3-NVHJ] (noting persistent underfunding of FDA below both historical and needed levels).

84. See 21 U.S.C. § 337 (2012) (granting United States, not private individuals, authority to bring claims under FDCA).

85. See Andre, *supra* note 37, at 234-35 (discussing consumer claims against food manufacturers under state laws); Michael J. O'Flaherty, *Consumer Litigation: A Growing Enforcement Concern for Food Labeling*, 2012 WL 4971932, at *2 (2012) (examining growing trend of consumer litigation alleging misleading labeling brought under state laws); *Litigation To Address Misleading Food Label Claims*, *supra* note 77, at 429 (discussing private parties' attempts at litigating to deal with inadequate, misleading, or false labels); see also Stephen P. Teret, *Litigating for the Public's Health*, 76 AM. J. PUB. HEALTH 1027, 1027 (1986), <http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.76.8.1027> [https://perma.cc/K3C3-BEZT] (discussing success of consumer-based litigation in advocating for public's health and safety).

86. See O'Flaherty, *supra* note 85, at *2 (noting consumer-initiated litigation brought under state laws prohibiting fraudulent business practices or misleading advertising); Nicole E. Negowetti, *Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority*, BROOKINGS (June 2014), http://www.brookings.edu/~/media/research/files/papers/2014/06/26-food-labeling-litigation/negowetti_food-labeling-litigation.pdf [http://perma.cc/XB2G-2YX7] (discussing role of consumers and consumer protection groups in policing misleading food and beverage labels).

87. See Negowetti, *supra* note 86, at 11 (noting FDCA allows states to create causes of action for violations identical to federal requirements); *Litigation To Address Misleading Food Label Claims*, *supra* note 77, at 437 (acknowledging state consumer protection act claims allowed when statute identical to FDCA requirements). Private party claims brought under consumer protection laws generally fall into two categories:

can indirectly enforce the FDCA regulations by bringing suits against manufacturers for violating the state regulations.⁸⁸

4. FDCA Interplay with the Lanham Act

In addition to consumer-based litigation, manufacturers can also initiate litigation regarding misleading food and beverage labels through Section 43 of the Lanham Act.⁸⁹ Congress enacted Section 43 in 1946, in response to the need for a remedy for unfair competition.⁹⁰ Prior to its passage, there was no relief for competitors injured by a manufacturer's false advertising.⁹¹ The Lanham Act created a private cause of action for when a competitor's misrepresentation harmed another's sales or reputation.⁹² Only commercial competitors with an economic interest may bring a claim under the Lanham Act.⁹³ Section 43 allows a manufacturer to bring suit against a competitor who uses "any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, . . . which . . . misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities."⁹⁴

Many food, beverage, and drug manufacturers brought claims under the Lanham Act to combat their competitors' false labeling.⁹⁵ Commercial

if the claim is not something the FDCA regulates or if there is a state law identical to the FDCA regulations. *See Negowetti, supra* note 86, at 10. If the state adopted identical labeling requirements and there is a violation of those requirements, a private party may bring a claim under a separate state statute, such as a false advertising, consumer protection, or unfair trade practices statute. *See id.* at 11.

88. *See Dages, supra* note 29, at 1078-79 (acknowledging misleading labeling suits under consumer protection statutes creates indirect private FDCA enforcement).

89. *See A Comprehensive Strategy, supra* note 83, at 635 (discussing manufacturers' use of Lanham Act to combat competitors' misleading claims); *Litigation To Address Misleading Food Label Claims, supra* note 77, at 432-33 (discussing manufacturer-initiated food labeling litigation under Lanham Act).

90. *See Thomas W. Edman, Note, Lies, Damn Lies, and Misleading Advertising: The Role of Consumer Surveys in the Wake of Mead Johnson v. Abbott Labs*, 43 WM. & MARY L. REV. 417, 421-22 (2001) (summarizing history and purpose of 1946 enactment of Lanham Act).

91. *See id.* (noting no common law remedy for injured competitors existed for false advertising). The 1920 Trademark Act provided a cause of action against misleading and false advertising, but the plaintiff had to prove the competitor intended to deceive consumers. *See id.*

92. *See* 15 U.S.C. § 1125(a) (2012) (creating cause of action for private parties injured by competitor's misleading advertising).

93. *See Litigation To Address Misleading Food Label Claims, supra* note 77, at 76-77 (noting only commercial competitors, not consumers, have right to bring claim under Lanham Act).

94. 15 U.S.C. § 1125 (2012) (explaining Section 43 claims).

95. *See, e.g.*, Photomedex, Inc., v. Irwin, 601 F.3d 919, 922-23 (9th Cir. 2010) (hearing medical device manufacturer's Lanham Act claim against competitor for misleading advertising); Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1137-38 (4th Cir. 1993) (discussing drug manufacturer's 43(a) claim against generic manufacturer for false representation of FDA approval); POM Wonderful LLC v. Ocean Spray Cranberries, Inc., 642 F. Supp. 2d 1112, 1116-17 (C.D. Cal. 2009) (discussing beverage manufacturer's Lanham Act against competitor for misleading label); Grove Fresh Distrib., Inc. v. Flavor Fresh Foods, Inc., 720 F. Supp. 714, 715-16 (N.D. Ill. 1989) (describing juice manufacturer's Lanham Act claim against competitor's misleading orange juice

manufacturers who believe a competitor's misleading representations damaged their reputation or sales can bring a Lanham Act claim seeking money damages or injunctive relief.⁹⁶ Lanham Act claims, however, can pose an issue for litigants and courts as the Lanham Act and the FDCA have overlapping jurisdiction in areas like product labeling.⁹⁷ Thus, defendant manufacturers often argue the FDCA and the FDA's regulation of labeling bar Lanham Act claims brought against them.⁹⁸

Traditionally, courts recognized that the FDCA does bar certain Lanham Act claims.⁹⁹ Congress entrusted the FDA with the sole authority to interpret and enforce the FDCA, so courts barred claims that would require them to determine how the FDA would interpret and enforce its own regulations preemptively.¹⁰⁰ If courts allowed those types of claims to proceed, they would wrongfully usurp the FDA's interpretive and enforcement power.¹⁰¹ Courts also bar private litigants from using Lanham Act claims that would undermine the FDA's authority by imposing additional labeling requirements, different than those the FDCA promulgated.¹⁰² Courts recognize, however, that overlapping jurisdiction between the FDCA and the Lanham Act alone will not necessarily bar Section 43 claims.¹⁰³ When a court can decide a Lanham Act claim without requiring the court to make a determination within the purview

label).

96. See *Litigation To Address Misleading Food Label Claims*, *supra* note 77, at 432-33 (discussing aggrieved manufacturer's cause of action and remedies under Lanham Act).

97. See Theodore H. Davis Jr. & Jaclyn T. Shanks, POM Wonderful LLC v. Coca-Cola Co.: *The Supreme Court Juices Up Section 43(a) of the Lanham Act*, 7 LANDSLIDE 1, 2 (2014), http://www.americanbar.org/content/dam/aba/publications/landslide/2014_september_october/ABA_LAND_v007n01_pom_wonderful_llc_v_cocacola_co_the_supreme_court_juices_up_section_43a_of_the_lanham_act.authcheckdam.pdf [http://perma.cc/SJD9-ZBJW] (discussing complicated case law surrounding Lanham Act's intersection with FDCA misbranding regulations).

98. See, e.g., POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2233 (2014) (discussing defendant's argument FDCA bars Lanham Act claim); *Photomedex*, 601 F.3d at 923 (discussing defendant medical device manufacturer's affirmative defense of FDA's exclusive control of FDCA enforcement); *Ocean Spray Cranberries*, 642 F. Supp. 2d at 1117 (analyzing defendant's motion to dismiss Lanham Act claim because barred by FDCA).

99. See Davis & Shanks, *supra* note 97, at 3 (discussing notable cases where courts held FDCA bars Lanham Act claims). Here, preemption issues do not govern the issue of whether the FDCA bars Lanham Act claims because preemption applies when there is a federal statute and a state statute at issue and the Lanham Act and the FDCA are two federal statutes. See *POM*, 134 S. Ct. at 2236.

100. See *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) (holding courts should not "determine preemptively" how FDA will interpret and enforce regulations).

101. See *Photomedex*, 601 F.3d at 928 (refusing Lanham Act claim when claim requires court to make interpretations and determinations within FDA's purview); *Sandoz Pharm.*, 902 F.2d at 231 (rejecting plaintiff's claim because it would require court to encroach upon FDA's regulatory responsibilities).

102. See *Sandoz Pharms.*, 902 F.2d at 231 (noting Lanham Act cannot indirectly create regulations or interpretations FDCA does not directly create).

103. See *Mut. Pharm. Co. v. Ivax Pharm., Inc.*, 459 F. Supp. 2d 925, 935 (C.D. Cal. 2006) (holding FDA authority in area does not bar all Lanham Act claims). The court in *Mutual Pharmaceuticals* held that the fact that a matter relates to a subject area within the FDA's purview is not enough to bar a Lanham Act claim, as long as it does not require the court to preemptively interpret or enforce FDA regulations. *Id.*

of the FDA's authority, the claim is usually allowed.¹⁰⁴

F. POM v. Coca-Cola: A Shift in the Interplay between the FDCA and the Lanham Act

In *POM v. Coca-Cola*, pomegranate-beverage manufacturer POM brought suit against Coca-Cola, their primary competitor, under the Lanham Act.¹⁰⁵ POM alleged that the name, label, advertising, and marketing of Coca-Cola's Minute Maid beverage misled consumers, thus injuring POM's sales.¹⁰⁶ Coca-Cola argued that the FDCA precluded POM's claim because the litigation concerned a misleading or false label and thus is precluded because the FDCA regulates beverage labeling.¹⁰⁷

The district court granted Coca-Cola's motion for summary judgment regarding the claims about the beverage's name and label.¹⁰⁸ The court reasoned that the FDA already promulgated labeling requirements for beverages and the label at issue complied with them.¹⁰⁹ Since the FDCA already spoke on the issue, the court held that allowing POM to bring suit would challenge the FDA's authority to regulate labeling.¹¹⁰

On appeal, the Ninth Circuit affirmed the district court's decision.¹¹¹ The

104. See *Summit Tech., Inc. v. High-Line Med. Instruments, Co.*, 933 F. Supp. 918, 933 (C.D. Cal. 1996) (noting claims allowed where court can make determination without authoritatively interpreting and applying regulations); *Mut. Pharm. Co.*, 459 F. Supp. 2d at 938 (allowing Lanham Act claims when court does not have to interpret or enforce FDA regulation). Therefore, the Act does not bar claims where a court only has to verify compliance with a requirement already interpreted and approved by the FDA. See *Mut. Pharm. Co.*, 459 F. Supp. 2d at 939. The Lanham Act also permits claims where the plaintiff alleges the defendant falsely represented FDA compliance because those claims can be verified without requiring a FDA determination of the truth of the matter. See *id.* at 935.

105. See *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2234 (2014) (discussing grounds on which POM brought suit against Coca-Cola).

106. See *id.* at 2235 (discussing Coca-Cola's alleged misleading and deceptive label prompting POM to bring suit). Coca-Cola, through their Minute Maid brand, marketed a pomegranate blueberry drink to compete with POM's well-known pomegranate-blueberry beverage. See *id.* Coca-Cola's beverage, however, only contained 0.3% pomegranate juice and 0.2% blueberry juice. See *id.* POM brought suit alleging that Coca-Cola's beverage's label "tricks and deceives consumers" by prominently displaying the words *pomegranate-blueberry* with a picture of a pomegranate on the label. See *id.* For the less favorable claims, such as "flavored blend of 5 juices" and "from concentrate with added ingredients," Coca-Cola used a significantly smaller type. *Id.*

107. See *id.* at 2239 (discussing Coca-Cola's argument for Lanham claim preclusion based on congressional intent for labeling uniformity).

108. See *POM Wonderful LLC v. Coca-Cola Co.*, 727 F. Supp. 2d 849, 852 (C.D. Cal. 2010) (granting Coca-Cola's motion for summary judgment in part), *aff'd in part, vacated in part*, 679 F.3d 1170 (9th Cir. 2012), *rev'd*, 134 S. Ct. 2228 (2014).

109. See *id.* at 871-73 (noting FDA spoke on permissible names and labels for beverages, and Coca-Cola's beverage complies).

110. See *id.* at 871 (quoting court's previous order that determined POM's claim challenged FDA's labeling regulations for multiple-juice beverage).

111. See *POM Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1179 (9th Cir. 2012) (affirming district court's summary judgment precluding POM's claim as to beverage's name and label), *rev'd*, 134 S. Ct. 2228 (2014).

Ninth Circuit held that the FDCA barred POM's claims because Coca-Cola's label comports with the FDCA requirements.¹¹² The court further explained that if a court found Coca-Cola's beverage's name or labeling misleading or deceptive, it would conflict with FDA regulations and undermine the FDA's determination that the product's name is not misleading.¹¹³ The Ninth Circuit noted, however, that it is not holding the label is nondeceptive, but rather it is deferring to the FDA.¹¹⁴

The Supreme Court granted certiorari on the issue and reversed.¹¹⁵ To start, the Court noted this case was not a preemption case because there were two federal statutes at play.¹¹⁶ Thus, the Court clarified that the case was one of statutory interpretation.¹¹⁷ The Court interpreted the statutory language of the Lanham Act and the FDCA, holding neither the Lanham Act nor the FDCA expressly prohibits or restricts Lanham Act claims that challenge FDCA-regulated labels.¹¹⁸ The Court also cited the coexistence of the Lanham Act and the FDCA for over seventy years without an amendment to preclude Lanham Act claims as evidence of its intent to permit Lanham Act claims.¹¹⁹ Arguing Congress intended the FDCA and the Lanham Act to be complementary, the Court noted that although both deal with food and beverage labels, each statute has its own scope and purpose.¹²⁰ The FDCA protects the public's health and safety while the Lanham Act protects commercial interests against false advertising and trademark infringement.¹²¹

Coca-Cola also argued that allowing Lanham Act claims would undermine

112. *See id.* at 1176-77 (holding beverage's name complied with FDA regulations regarding names for blended juice beverages). The court cited the FDA statute allowing a blended juice to be named after any juice it contains. *See id.* As Coca-Cola's beverage did contain pomegranate and blueberry juices (albeit negligible amounts), it complied in naming its beverage *Pomegranate Blueberry*. *See id.*

113. *Id.* at 1177 (holding POM's challenge to FDCA-compliant beverage's name and label undermines FDA authority).

114. *See id.* (noting ruling does not imply beverage's name and label as nondeceptive). The court held that it is the FDA's role to impose additional labeling requirements, not POM. *See id.* The court reasoned that had the FDA found Coca-Cola's label misleading, they would have taken that position because the FDA is careful and thorough in the misleading labeling realm. *See id.*

115. *See POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2233 (2014) (reversing lower court's rulings).

116. *See id.* at 2236 (noting POM presents preclusion issue not preemption because two federal statutes involved). The Court noted, however, its preemption principles "are instructive insofar as they are designed to assess the interaction of laws that bear on the same subject." *Id.*

117. *See id.* (stating Court will apply traditional statutory interpretation principles).

118. *See id.* at 2237.

119. *See POM*, 134 S. Ct. at 2237 (citing coexistence of Lanham Act and FDCA without preemption amendment as evidence of no preclusion). The Court argued that because Congress amended the FDCA to add a state-preemption provision in 1990, by reverse implication, Congress does not intend the FDCA to bar Lanham Act claims. *See id.* The Court also implied Lanham Act claims may be in a better position than the FDA to police and enforce labeling requirements. *See id.*

120. *See POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2238 (2014) (arguing preclusion would undermine congressional intent for Lanham Act and FDCA to complement each other).

121. *See id.* (noting differences between two federal statutes' purposes).

the congressional intent of the NLEA preemption provision: a uniform national label law to make compliance with label requirements easier and less costly for manufacturers to meet.¹²² The Court, however, disagreed and held the variations produced by Lanham Act labeling claims would not be as extensive as the inconsistency resulting from fifty different state laws.¹²³ In holding that the FDCA does not preclude Lanham Act claims, the Court concluded that FDCA regulations are not a ceiling on food and beverage labeling regulation.¹²⁴

III. ANALYSIS

In overturning the Ninth Circuit, the Court's decision in *POM* altered the landscape for both food and beverage manufacturers and consumers.¹²⁵ Further, the decision's implications create unrest and uncertainty in the industry.¹²⁶ The uncertainty stems from how far *POM* will extend and whether the Court's specific language limits the decision to the food and beverage labeling context, or if it can affect other industries where two federal statutes apply.¹²⁷ Although most speculate *POM* will lead to more litigation over misleading labeling, the decision's effect on manufacturers is unclear.¹²⁸

Despite *POM*'s uncertainty, it is hailed as a victory for consumers.¹²⁹ In holding that compliance with FDCA regulations does not shelter manufacturers from misleading labeling litigation, FDCA regulations now act as a floor for manufacturers, not a ceiling.¹³⁰ As a result, the Court and legal scholars believe manufacturers will likely be more conservative in advertising and labeling because the threat of a Lanham Act claim will make manufacturers

122. See *id.* at 2239 (addressing Coca-Cola arguing Lanham Act claims undermine congressional goal of label law uniformity).

123. See *id.* at 2239-40 (holding Lanham claims not contrary to congressional goal of national uniform label law).

124. See *POM*, 134 S. Ct. at 2240 (disagreeing with government on FDCA regulations as ceiling on food and beverage labeling regulation); see also Mary LaFrance, *LaFrance on Federal False Advertising Claims Arising from FDA-Compliant Labels: POM Wonderful LLC v. Coca-Cola Co.*, 2014 EMERGING ISSUES 7211 (2014) (noting post-*POM*, manufacturers should view FDCA regulations as floor, not ceiling).

125. See LaFrance, *supra* note 124 (discussing changed environment for food and beverage manufacturers).

126. See Davis & Shanks, *supra* note 97, at 9 (noting uncertainty of long-term implications of Court's decision).

127. See *id.* (arguing Court's references to food and beverage labels means decision will not apply outside context); see also LaFrance, *supra* note 124 (discussing unlikelihood *POM* will apply to drugs, as Court only addressed food and beverage labels).

128. See Davis & Shanks, *supra* note 97, at 9 (discussing increase in Lanham Act challenges to labels as likely effect of *POM*); see also LaFrance, *supra* note 124 (noting potential flood of litigation, given deceptive labeling tactics many manufacturers employ).

129. See *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2239 (2014) (determining public better protected regarding food and beverage labeling with Lanham Act claims allowed); LaFrance, *supra* note 124 (characterizing *POM* decision as producing beneficial results for consumers).

130. See *supra* note 124 and accompanying text (discussing rejection of government's argument on FDCA regulations as ceiling on food and beverage labeling).

consider whether their label is misleading to consumers.¹³¹ *POM*, however, will not protect consumers to the extent currently lauded.¹³² Further, the Court's implicit reliance on Lanham Act suits to complement and supplement FDCA enforcement, reveals a great problem in misleading label regulation.¹³³

A. POM Decision Sheds Light on Regulatory Gaps in Food and Beverage Label Enforcement

The Court's decision in *POM* alludes to the gaps and inadequacies in the current regulation of misleading labels, namely the enforcement measures the FDA employs, that the FDA does not require preapproval of labels, and that the FDA does not bring enforcement actions against all misleading labels.¹³⁴ The Court notes that if Lanham Act claims were barred from the food and beverage labeling context, the public would be left with less effective protection.¹³⁵ In *POM*, the Court inadvertently acknowledged that the FDA's regulation of food and beverage labeling is inadequate, and another means of enforcement is needed to protect consumers.¹³⁶ Entrusting manufacturers to fill this enforcement void through the Lanham Act is, however, insufficient.¹³⁷

An examination of the FDA reveals one of the main reasons for the enforcement gap: lack of financial resources.¹³⁸ The scope of the FDA's regulatory authority is broad.¹³⁹ It is responsible for overseeing over 100 statutes and over \$1 trillion worth of products a year, including food, drugs, cosmetics, and tobacco.¹⁴⁰ The FDA's resources, however, do not match the breadth of its responsibilities.¹⁴¹ Congress continuously underfunds the FDA, and the recent budget sequestration reduced the FDA's budget by about \$280

131. See *POM*, 134 S. Ct. at 2238-39 (discussing incentives Lanham Act suits provide for manufacturers to "behave well" with their products labeling).

132. See *infra* Part III.B (discussing flaw in Court holding Lanham Act suits protect consumers).

133. See *infra* Part III.B (noting *POM* decision illuminated deficiencies in food and beverage regulation).

134. See *POM* Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2239 (2014) (implying FDA's warning letters and enforcement actions insufficient at policing misleading labels).

135. See *id.* at 2239 (implying importance of Lanham Act claims as supplement to FDA enforcement).

136. See *id.* (holding precluding Lanham Act claims would result in "less effective protection" for food and beverages).

137. See *infra* Part III.B (discussing Court's error in holding Lanham Act as complementary to FDCA in protecting consumers).

138. See *A Comprehensive Strategy*, *supra* note 83, at 636-37 (citing FDA's insufficient funding as principal reason for inadequate labeling enforcement); Termini, *supra* note 4, at 103 (attributing inconsistent and irregular enforcement of FDCA regulations to inadequate budget and staff size); Springer, *supra* note 78, at 412 (discussing FDA's fiscal constraints in enforcing food and beverage labeling).

139. See *What Does FDA Regulate?*, *supra* note 58 (discussing breadth of FDA's regulatory authority).

140. See Springer, *supra* note 78, at 409 (discussing wide range of obligations FDA responsible for overseeing); *Legislation*, *supra* note 50 (quantifying economic value of products FDA responsible for regulating).

141. See generally *A Comprehensive Strategy*, *supra* note 83 (discussing FDA's chronic underfunding of FDA and its impact on FDA's enforcement capabilities).

million.¹⁴² Due to its scant resources, the FDA cannot police food and beverage labels as vigorously as it does prescription drug and medical device labeling, areas where the FDA requires preapproval of all labels.¹⁴³

Linked to the FDA's budgetary challenges are the inadequate enforcement measures the FDA employs.¹⁴⁴ Currently, the FDA's enforcement regime is one of voluntary compliance.¹⁴⁵ The FDA's main enforcement tool is the issuance of a "Warning Letter," where the FDA notifies the manufacturer that it is violating the FDCA and urges compliance.¹⁴⁶ This voluntary method of enforcing the FDCA, however, is ineffective at curtailing manufacturers' use of misleading labels.¹⁴⁷ Given the financial constraints, the FDA does not issue Warning Letters to many violators.¹⁴⁸

While Congress slightly increased the FDA's budget in recent years, it is still below desired levels.¹⁴⁹ Given the perpetual lack of financial resources allocated to the FDA and the unlikelihood that it will receive substantial budget increases, a better means of enforcing food and beverage labeling requirements, as discussed below, is needed.¹⁵⁰

B. Lanham Act Claims Do Not Fill in FDCA's Regulatory Gaps

The Court in *POM* held that the Lanham Act serves as a complement to the FDCA, suggesting it can fill in the FDCA enforcement gaps and indirectly protect the interests of consumers.¹⁵¹ The Lanham Act, however, is an unfair competition statute primarily aimed at protecting manufacturers' commercial

142. See Gaffney, *supra* note 83 (noting budget cuts leading to historically low levels of funding for FDA); see also Springer, *supra* note 78, at 413 (describing FDA's difficulty in meeting statutory obligations because of staff cutbacks and underfunding).

143. See *A Comprehensive Strategy*, *supra* note 83, at 636-37 (noting food and beverage label budget received lowest 2013 budget allocations of all FDA programs).

144. See *id.* at 637 (asserting FDA's primary enforcement tool does not effectively compel manufacturers to comply with labeling regulations).

145. See Negowetti, *supra* note 86, at 3 (stating enforcement measure used to achieve voluntary compliance with FDCA regulations).

146. See *A Comprehensive Strategy*, *supra* note 83, at 632 (citing Warning Letter as FDA's main enforcement tool). The FDA does not have the authority to impose civil penalties against manufacturers for false or misleading food and beverage labels, although the FDA does have this authority in other areas that it regulates. See *id.* at 631. The FDA can pursue civil penalties through the Food Safety Modernization Act if a food is misbranded but only when the misbranding relates to missing allergen information. See *id.*

147. See *A Comprehensive Strategy*, *supra* note 83, at 637 (asserting FDA Warning Letters ineffective at compelling manufacturers into compliance); Negowetti, *supra* note 86, at 9 (arguing issuing Warning Letters will not eliminate misleading labels).

148. See *A Comprehensive Strategy*, *supra* note 83, at 637 (noting insufficient budget prevents FDA from issuing Warning Letters to every manufacturer who violates FDCA).

149. See Gaffney, *supra* note 83 (discussing historically low level of FDA funding in recent years).

150. See *A Comprehensive Strategy*, *supra* note 83, at 637 (observing necessity of increased resources to address food labeling enforcement issues).

151. See *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2238-39 (2014) (holding Lanham Act claims indirectly protect "public at large" from misleading food and beverage labels).

interests.¹⁵² Manufacturers' interests typically do not align with those of consumers.¹⁵³ When manufacturers file suit against a competitor for the competitor's misleading labeling, it is, principally, to protect the manufacturer's economic interest, not to advocate for consumer interests.¹⁵⁴ Although the Court ultimately held that manufacturers' Lanham Act claims are effective at protecting "the public at large," it acknowledged that manufacturers' Lanham Act claims only *indirectly* protect consumers.¹⁵⁵

While Lanham Act claims can eliminate some misleading food and beverage labels, these claims do not make a significant impact on food and beverage labeling.¹⁵⁶ For example, manufacturers cannot bring Lanham Act claims against every case of misleading labeling; rather, manufacturers can only bring claims when they suffered an economic injury.¹⁵⁷ Also, manufacturers might not bring Lanham Act claims out of fear that a competitor will retaliate against the manufacturer with allegations of misleading and deceptive tactics.¹⁵⁸ In *POM*, the Court wrongly relies on manufacturers to indirectly protect consumer interests through the Lanham Act because a manufacturer bringing a Lanham Act suit is not doing so as a benevolent advocate for consumers.¹⁵⁹

C. Recommended Solution To Remedy the Regulatory Gap

The Court in *POM* attempted to remedy the regulatory gap within the food and beverage labeling environment by allowing Lanham Act suits.¹⁶⁰ Lanham

152. See *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990) (holding Lanham Act's primary purpose to protect commercial interest); Edman, *supra* note 90, at 421 (discussing purpose of Lanham Act as providing competitors remedy to unfair competition problems). Section 43 specifically excluded consumers misled by a manufacturer's deceptive practices, implying consumer protection was not the legislation's purpose. See Edman, *supra* note 90, at 421.

153. See *A Comprehensive Strategy*, *supra* note 83, at 636 (arguing Lanham Act claims not aimed at protecting public from false and misleading labels); *Litigation To Address Misleading Food Label Claims*, *supra* note 77, at 430 (contrasting manufacturer claims against consumer claims, noting former not initiated to protect consumers); see also Schaffer, *supra* note 67, at 371-72 (asserting food industry interests conflict with consumer and public interests).

154. See *Sandoz Pharm. Corp.*, 902 F.2d at 230 (holding Lanham Act aimed at protecting commercial interests).

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

156. See *A Comprehensive Strategy*, *supra* note 83, at 636 (noting Lanham Act claims do not impact manufacturers' misleading labeling tactics).

157. See 15 U.S.C. § 1125(a) (2012) (creating cause of action for private parties injured by competitor's misleading advertising); see also *A Comprehensive Strategy*, *supra* note 83, at 636 (noting labels misleading consumers not subject to Lanham Act, unless competitor financially injured).

158. See *LaFrance*, *supra* note 124 (discussing reluctance in bringing Lanham Act claims for fear of competitors retaliating). Since many food and beverage manufacturers employ questionable labeling practices, they are afraid to bring Lanham Act claims against competitors, knowing they could expose themselves to a similar suit. See *id.* "As long as puffery remains the norm, many food and beverage manufacturers will find that they live in the proverbial glass house." *Id.*

159. *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990) (quoting *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987)).

160. See *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2238 (2014) (holding Lanham Act as

Act suits are not, however, a viable solution to filling this regulatory void because corporate self-interest drives litigation and not consumer protection or advocacy.¹⁶¹ Some legal scholars argue Congress should include a provision into the FDCA allowing private citizens to bring suits against manufacturers who use false and misleading advertising.¹⁶² Today, the FDCA provides only indirect means for private consumers or consumer advocacy organizations to seek redress from manufacturers who used false or misleading labels.¹⁶³

The FDCA's preemption provision only precludes states from enacting labeling requirements that are affirmatively different from those in the FDCA.¹⁶⁴ Accordingly, the FDCA does not preclude states from enacting labeling requirements identical to those in the FDCA.¹⁶⁵ In states with labeling requirements identical to FDCA requirements, consumers can bring suits for violating the state's labeling requirements under the state's consumer protection statute.¹⁶⁶ Critics argue that this circumvents the NLEA's preemption provision and undermines the FDA's authority.¹⁶⁷ This criticism lacks merit, however, because an express reading of the preemption provision shows Congress only precluded state labeling statutes that are not identical and if they so desired, Congress could have expressly precluded all state labeling statutes.¹⁶⁸

Currently, a few states, most notably California, took advantage of this and enacted regulations identical to those in the FDCA.¹⁶⁹ This private litigation puts consumer protection in the hands of the public and advocacy organizations rather than in manufacturers' control, who bring suits primarily for their own

necessary complement to FDCA in protecting consumer interests).

161. See *supra* Part III.B (delineating reasons Lanham Act suits do not advocate for consumer protection).

162. See Springer, *supra* note 78 (suggesting adding provision to FDCA allowing citizens to bring suits for label violations).

163. See *supra* note 78 and accompanying text (discussing NLEA's preemption provision as not entirely preclusive of private action). The provision prohibits states from establishing a food label requirement that is not identical to the FDCA label requirements; it does not, however, prohibit states from establishing food label requirements identical to the FDCA's label requirements. See 21 U.S.C. § 343-1(a) (2012).

164. See Negowetti, *supra* note 86, at 11 (describing NLEA's preemption provision as permitting claims based on state laws identical to federal requirements).

165. See *Litigation To Address Misleading Food Label Claims*, *supra* note 77, at 429 (noting states may enact labeling requirements identical to FDCA requirements).

166. See Dages, *supra* note 29, at 1079-80 (discussing private party suits brought in states with labeling requirements identical to FDCA requirements); Negowetti, *supra* note 86, at 11 (describing ways to bring private misleading label lawsuits).

167. See Dages, *supra* note 29 (arguing private litigation through state consumer protection statutes undercuts FDCA preemption provision).

168. See 21 U.S.C. § 343-1(a) (2012) (prohibiting only not identical state labeling requirements and allowing identical ones).

169. See Negowetti, *supra* note 86, at 1 (discussing high volume of misleading labeling lawsuits in California district court, dubbing it "Food Court"). California enacted the Sherman Law, which adopts the FDCA's labeling requirements. See *id.* at 11. Through the state's Unfair Competition Law, Consumer Legal Remedies Act, or False Advertising Law, private parties can bring suits against manufacturers who violated the Sherman Law's labeling requirements. See *id.*

commercial and economic interests.¹⁷⁰ Moreover, these lawsuits have successfully eliminated cases of false and misleading labels because the threat of lawsuit and negative publicity incentivizes manufacturers to halt their deceptive practices.¹⁷¹ The enforcement regime of private litigation is a suitable complement to FDCA enforcement because it better aligns with the FDA's goal of protecting the public.¹⁷²

IV. CONCLUSION

Currently, there is a void in the enforcement of the FDCA against manufacturers' use of false and misleading labels. Congress granted the FDA exclusive authority over FDCA enforcement but has not bestowed the agency with the budget necessary to adequately police violations. Recognizing the need to remedy these enforcement gaps, the Court in *POM* held that the FDCA does not preclude Lanham Act claims and the Lanham Act complements the FDCA. The Lanham Act, however, is not an appropriate means of resolving the inadequate enforcement of the FDCA. Manufacturers' interests do not align with consumers' interests and claims brought under the Lanham Act for misleading labels have had little impact in eradicating manufacturers' deceptive tactics.

A better approach to resolving the FDCA enforcement issues is through consumer-initiated litigation. Consumers and advocacy groups can bring private suits against manufacturers for violating state labeling requirements that are identical to the FDCA. These lawsuits have successfully thwarted manufacturers' use of false and misleading labels. Additionally, the purpose of consumer-initiated lawsuits better aligns with the FDCA's purpose of protecting the public.

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170. See *supra* notes 153-154 and accompanying text (acknowledging manufacturers bring Lanham Act claims to serve their own commercial interests); see also Negowetti, *supra* note 86, at 7-9 (providing history of private litigation by consumers and advocacy groups against violating manufacturers). The nonprofit consumer advocacy group, Center for Science in the Public Interest, is actively involved in policing manufacturers who employ deceptive practices, such as the use of false and misleading labels on food and beverages. See Negowetti, *supra* note 86, at 7. The group uncovered numerous violations and succeeded in its goal of protecting consumers from false and misleading labels. See *id.* Consumer advocacy groups, unlike manufacturers under the Lanham Act, can bring suit against violators for the purposes of protecting consumer rights and the public health. See *Litigation To Address Misleading Food Label Claims*, *supra* note 77, at 428 (noting advocacy groups often bring lawsuits for purpose of filling enforcement gaps and protecting public).

171. See Negowetti, *supra* note 86, at 7-9 (discussing nonprofit consumer advocacy groups' many victories against manufacturers using misleading labels); see also Teret, *supra* note 85, at 1027 (noting private litigation successful tool in protecting public health in areas of inadequate regulation). The threat of large settlements and damage verdicts causes manufacturers to be more cautious. See Teret, *supra* note 85, at 1027.

172. See Negowetti, *supra* note 86, at 7-9 (discussing consumer advocacy groups' success at filling enforcement gaps by threatening suit against violating manufacturers).