



4-1-2017

An Examination of Trans Fat Labeling: Splitting the Third & Ninth Circuit

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Recommended Citation

Jack Gainey, *An Examination of Trans Fat Labeling: Splitting the Third & Ninth Circuit*, 23 Wash. & Lee J. Civ. Rts. & Soc. Just. 461 (2017).

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An Examination of Trans Fat Labeling: Splitting the Third & Ninth Circuit

Jack Gainey*

Abstract

At first glance, consumer claims alleging misleading labeling would seem to find a simple resolution. Under 21 U.S.C. § 343, which governs misbranded food, a food product is misbranded if “its labeling is false or misleading.”¹ However, controversial interpretation of seemingly straightforward statutory language, together with evolving case law, have blurred a once clear picture. Disagreement over the federal preemption of consumer claims regarding trans fat, underscored by a dispute regarding standing, have combined to create a divergence of opinions between courts across the country.

In 2011, the United States District Court for the Northern District of California considered a class action trans fat misbranding claim alleging that a food manufacturer had deceptively labeled certain ice cream products as containing zero grams of trans fat even though the products contained partially hydrogenated oil, a source of trans fat.² The district court found that the class of consumers had standing to bring a trans fat misbranding claim.³ However, the district court ultimately dismissed the case, holding that the trans fat misbranding claims were preempted by federal law.⁴ The Ninth Circuit Court of Appeals later affirmed the district court’s dismissal on federal preemption grounds.⁵ In 2015, the Ninth Circuit returned to the issue in a

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1. 21 U.S.C. § 343(a)(1) (2017).
2. *Carrea v. Dreyer’s Grand Ice Cream, Inc.*, No. C 10-01044 JSW, 2011 WL 159380, at *1 (N.D. Cal. Jan. 10, 2011).
3. *Id.* at *2–*3.
4. *Id.* at *4.
5. *Carrea v. Dreyer’s Grand Ice Cream, Inc.*, 475 Fed. App’x 113, 115 (9th Cir. 2012).

*different case, but this time it reached the opposite conclusion, holding that claims by consumers alleging that a “No Trans Fat” label was misleading as applied to a product containing partially-hydrogenated oil were not preempted by federal law.*⁶

*The Third Circuit on the other hand, dismissed a similar consumer protection claim.*⁷ *In Young, products that contained trans fat but stated, “NO TRANS FAT, directly above a symbol of a heart to convey heart health” were found not to be misleading.*⁸ *The Third Circuit pronounced that the consumer’s claims were contradicted by both FDA regulations governing trans fats, as well as disclosures made on the product’s own packaging.*⁹ *The FDA requires that fat levels of less than 0.5 grams per serving shall be expressed as zero.*¹⁰ *Thus, the Third Circuit determined that because the product in question contained less than 0.5 grams of trans fat per serving, the manufacturer’s “claims that [their product] contains ‘NO TRANS FAT’ and ‘No Trans Fatty Acids’ [were] consistent with FDA regulations.”*¹¹

The part of the label, and the substance that courts choose to apply the FDA regulation to, drastically changes the meaning and impact of the regulation. The Ninth Circuit’s interpretation is supported by logic and a greater weight of evidence. Warning letters issued by the FDA, overturned cases relied on by the Third Circuit, and the structure and text of the regulations all reinforce the Ninth Circuit’s decision.

6. See *Reid v. Johnson & Johnson*, 780 F.3d 952, 959–63 (9th Cir. 2015) (considering whether a plaintiff’s claim that a “No Trans Fat” label was misleading as used to describe a product containing partially-hydrogenated vegetable oil, which contains trans fats, was preempted under federal law).

7. See *Young v. Johnson & Johnson*, No. CIV.A. 11-4580 JAP, 2012 WL 1372286, at *1 (D.N.J. Apr. 19, 2012) (discussing the granting of Johnson & Johnson’s motion to dismiss), *aff’d*, 525 F. App’x 179 (3d Cir. 2013).

8. *Id.*

9. *Id.*

10. 21 C.F.R. § 101.9(c)(2)(ii) (2016).

11. See *Young*, 2012 WL 1372286, at *3–*5 (explaining why Benecol’s claims were consistent with FDA regulations).

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I. Introduction

Food labeling has seen an increased level of consideration and scrutiny due to “dietary-related diseases” and consumer trends showing an increased interest in nutrition.¹² The Food and Drug Administration (FDA) currently has authority over food labeling.¹³ The FDA traces its origins to public concern over Upton Sinclair’s best-selling novel *The Jungle*, which exposed unsanitary conditions in the American meat-packing industry.¹⁴

The early twentieth century saw an unprecedented expansion in the regulation of food safety, which led to many laws aimed at protecting consumers.¹⁵ Another wave of consumer protection laws

12. See Jennifer L. Pomeranz, *Litigation to Address Misleading Food Label Claims and the Role of the State Attorneys General*, 26 REGENT U.L. REV. 421, 421 (2014) (“The increased global prevalence of diet-related diseases, such as diabetes, heart disease, and cancer, elevates the importance of truthful and accurate nutrition information in the marketplace.”).

13. See 21 U.S.C. § 343-1 (2012) (explaining national uniform nutrition labeling).

14. See generally UPTON SINCLAIR, *THE JUNGLE* (Dover 2001) (1906).

15. See generally Spencer Weber Waller et al., *Consumer Protection in the United States: An Overview*, 2011 EUR. J. OF CONS. L. 803 (2011).

were passed in the 1960's under both President Kennedy and President Johnson.¹⁶ Complex consumer protection laws now exist at both the state and federal level.¹⁷

The duty of protecting consumers is dispersed through different channels. Many states charge their attorney generals with enforcing their consumer protection laws, while consumers have the right to bring common law tort claims, statutory causes of action, and class actions.¹⁸ The Food, Drug and Cosmetic Act (FDCA) empowers the FDA to “protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled.”¹⁹ The FDA's standard for whether a food product is misbranded is if the labeling is “false or misleading in any particular.”²⁰ False and deceptive advertising claims are fertile ground for consumer protection litigation.²¹

Trans fat has become a heavily litigated issue in the realm of consumer protection. Consumers claim that manufacturers misrepresent their products by deceptively labeling trans fat.²² Courts have struggled particularly with the statutes and regulations that govern the disclosure of trans fat in food products.²³ These products are required by regulation to have a

16. *See id.* (explaining the progression of consumer protection laws).

17. *See id.* (“The result is that American consumers are protected from unsafe products, fraud, deceptive advertising, and unfair business practices through a mixture of national, state, and local governmental laws and the existence of many private rights of actions.”).

18. *See id.* (explaining the different private rights of action for consumers).

19. *What Does FDA Do?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm> (last visited Apr. 18, 2017) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

20. 21 U.S.C. § 343(a) (2012).

21. *See Pomeranz, supra* note 12, at 423 (“As a result of outdated regulations and lax enforcement, the initiation of private lawsuits has escalated.”).

22. *See Carrea v. Dreyer's Grand Ice Cream, Inc.*, No. C 10-01044 JSW, 2011 WL 159380, at *1 (N.D. Cal. Jan. 10, 2011) (“Plaintiff . . . [alleges] that the ‘0g Trans Fat’ statements displayed on the product packaging and in marketing materials are false and misleading as allegedly determined by the FDA”), *aff'd*, 475 F. App'x 113 (9th Cir. 2012); *Reid v. Johnson & Johnson*, 780 F.3d 952, 955–57 (9th Cir. 2015) (describing the underlying claim by a consumer that a “No Trans Fat” label found on a margarine product was unlawfully misleading because the product did contain trans fats).

23. *See Reid*, 780 F.3d at 960 (“FDA regulations specifically address trans fat. They provide that trans fat should generally be disclosed in the nutrition

straightforward statement of the number of grams of trans fat per serving.²⁴ However, that same regulation mandates “[t]rans fat content shall be indented and expressed as grams per serving to the nearest 0.5 (1/2)-gram increment If the serving contains less than 0.5 gram, the content, when declared, *shall be expressed as zero.*”²⁵ The difference in regulations governing claims inside the nutrition label, as opposed to nutrient content claims outside the label have also caused confusion.

Consumers across the country have brought class action lawsuits against manufacturers alleging their product packaging contains misrepresentations. In 2014, The Quaker Oats Company paid \$1.4 million to settle a class action lawsuit alleging that Chewy Granola Bars were “deceptively labeled” as having 0 grams of trans fat, but in fact contained the substance.²⁶ About fifty different flavors of Quaker products were involved in this class action. Quaker also agreed to injunctive relief which removed partially hydrogenated oils that contained trans fat from those products.²⁷

Courts have disagreed over whether these consumers have standing to sue.²⁸ Other courts that decided these cases on the merits, disagreed over whether these claims are preempted or not.²⁹ Some courts have denied standing, reasoning that, “apprehension about a possible future injury [is] insufficient to establish injury-in-fact”³⁰ Other courts have decided that a plaintiff’s financial loss in paying more for a supposedly healthy product can establish the injury-in-fact element of standing.³¹

label . . . ” (citing 21 C.F.R. § 101.9(c)(2) (2016))).

24. 21 C.F.R. § 101.9(c)(2)(ii) (2016).

25. *Id.* (emphasis added).

26. Rose Bouboushian, *Quaker Oats to Pay \$1.4M to Settle Class Action*, COURTHOUSE NEWS SERV. (July 31, 2014, 11:48 AM), <http://www.courthousenews.com/quaker-oats-to-pay-1-4m-to-settle-class-action/> (last visited Apr. 18, 2017) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

27. *Id.*

28. *Young v. Johnson & Johnson*, No. CIV.A. 11-4580 JAP, 2012 WL 1372286, at *3 (D.N.J. Apr. 19, 2012), *aff’d*, 525 F. App’x 179 (3d Cir. 2013).

29. *Id.*

30. *Id.*

31. *See Askin v. Quaker Oats Co.*, 818 F. Supp. 2d 1081, 1084 (N.D. Ill. 2011) (“[M]embers of the class did not suffer physical injury, but it does not mean that

On the preemption issue, some courts have decided these claims are preempted because the manufacturer statements complied with FDA regulations.³² Other courts have decided that because the FDA extends specific preemption protections to claims about fat, and those protections were specifically not extended to trans fats, it would be “incongruous” for the FDA regulations to preempt trans fat claims.³³

The Third Circuit and the Ninth Circuit have come to different conclusions on whether consumer claims regarding trans fat labeling should be preempted or allowed.³⁴ That circuit split, and other similar cases will be explored below en route to a proposed answer to the question of whether these consumer claims regarding trans fat labeling should be preempted.³⁵

Section II(a) will outline what trans fats are and the impact they have. Section II(b) offers an in depth look at the statutory background involved in these consumer protection issues. Section II(c) discusses the federal preemption of labeling regulations. Section III(a) examines how the Ninth Circuit originally decided these claims were preempted, and then recently reversed that decision. Section III(b) scrutinizes the Third Circuit’s decision that consumer claims regarding trans fat labeling should be preempted. Section III(c) analyzes how other courts outside of the Third and Ninth have dealt with similar issues. Finally, Section IV will conclude this examination with a resolution to this complex issue.

they were uninjured. The plaintiffs’ loss is financial: they paid more for the toys than they would have, had they known of the risks the beads posed to children. A financial injury creates standing.”).

32. *Carrea v. Dreyer’s Grand Ice Cream, Inc.*, No. C 10-01044 JSW, 2011 WL 159380, at *3 (N.D. Cal. Jan. 10, 2011).

33. *See, e.g., Reid v. Johnson & Johnson*, 780 F.3d 952, 962–63 (9th Cir. 2015) (explaining that interpreting FDA regulations to allow “No Trans Fat” labelling, despite a lack of scientific consensus on the dangers of trans fat, would not be consistent with other similar labelling restrictions).

34. *See generally id.*; *Young v. Johnson & Johnson*, No. CIV.A. 11-4580 JAP, 2012 WL 1372286, at *3 (D.N.J. Apr. 19, 2012) *aff’d*, 525 F. App’x 179 (3d Cir. 2013).

35. *Id.*

II. Background

A. *Trans Fat and its Impact*

Trans Fats “are formed during the partial hydrogenation of vegetable oils, a process that converts vegetable oils into semi-solid fats for use in margarines, commercial cooking and manufacturing processes.”³⁶ Food producers have increasingly used trans fat over the last fifteen years due to its cost effective nature³⁷ and long shelf life.³⁸ Trans fat has stability during deep-frying, and a “semisolid[]” consistency which, “can be customized to enhance the palatability of baked goods and sweets.”³⁹ Artificially produced trans fat makes up about two to three percent of a consumers “total calories consumed.”⁴⁰ Naturally occurring trans fat, makes up around 0.5 percent of total caloric intake for the average consumer.⁴¹ The drawback of trans fat comes from the health risks associated with the product.⁴²

Many private and government studies “suggest a link between trans fat consumption and serious, negative health effects such as heart disease, diabetes and cancer.”⁴³ One of the major heart health concerns is the increase of bad cholesterol from trans fat:

The major risk posed by trans fats is that they raise low density lipoprotein (LDL or bad) cholesterol in the blood. An elevated LDL cholesterol increases the risk of

36. See Dariush Mozaffarian et al., *Trans Fatty Acids and Cardiovascular Disease*, 354 NEW ENG. J. MED. 1601 (2006) (explaining the properties of trans fat).

37. See Christopher L. Burrell, Note, *Co-Signing Danger: Why the FDA Should Tighten Regulations on the Use of Trans Fat in Foods in Order To Limit Its Adverse Effects on the Health of Low-Income African-Americans*, 3 S. REGIONAL BLACK L. STUDENTS ASS'N L.J. 1, 1 (2009) (“Trans fat has proven to be cost effective, as it increases the shelf life of products and decreases the need for refrigeration.”).

38. *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1115 (N.D. Cal. 2010).

39. Mozaffarian, *supra* note 36, at 1601.

40. *Id.*

41. *Id.*

42. See *Chacanaca*, 752 F. Supp. 2d at 1115 (citing studies proffered by the plaintiff which support a link between consumption of trans fat and negative health consequences).

43. *Id.*

developing coronary heart disease (CHD). Trans fat also lowers HDL-C [high-density lipoprotein or good cholesterol] and impair[s] FMD [flowed-mediated vasodilation]. This suggests that [trans fats] increase the risk of CHD more than the intake of saturated fats, with similar effects on LDL cholesterol.⁴⁴

Some countries have gone as far as restricting the use of trans fat in food products.⁴⁵ As many as five European countries are on the road to banning trans fat through regulations, while many more have scaled back their consumption using self-regulatory mechanisms.⁴⁶

In 2013, the FDA made a determination that these partially hydrogenated oils were no longer generally recognized as safe for *any use in human food*.⁴⁷ The FDA only now claims that it has taken steps to remove artificial trans fat from processed food entirely, within the next three years.⁴⁸ This three year “compliance period” began in June 2015.⁴⁹ Even with these new regulations, trans fat will still make its way into our diet.⁵⁰ The FDA admits that trans fat will not be completely gone, “because [trans fat] also occurs naturally in meat and dairy products.”⁵¹ Companies can also petition the FDA for trans fat exemptions for specific uses.⁵²

44. Andrew J. VanLandingham, *The Awful Taste of Partially Hydrogenated Vegetable Oil: A Recommendation That Indiana Ban Trans Fats from Restaurants*, 6 IND. HEALTH L. REV. 325, 330 (2009) (internal quotations omitted).

45. See *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1115 (N.D. Cal. 2010) (accepting plaintiff’s assertion that certain nations throughout the world have restricted or banned the use of products with trans fat).

46. See *Europe Leads the World in Eliminating Trans Fat*, WORLD HEALTH ORG., <http://www.euro.who.int/en/media-centre/sections/press-releases/2014/europe-leads-the-world-in-eliminating-trans-fats> (last visited Apr. 18, 2017) (“Denmark, Austria, Hungary, Iceland, Norway and Switzerland have set similar limits that virtually ban trans fats from food products, but consumption remains high where no policies are in place”) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

47. *FDA Cuts Trans Fat in Processed Foods*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm372915.htm> (last visited Apr. 18, 2017) (on file with the Washington and Lee Journal of Civil Rights and Social Justice) (emphasis added).

48. *Id.*

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.*

Trans fat bans on local levels have had a positive health impact.⁵³ In 2007, New York City forced restaurants to stop using partially hydrogenated oils.⁵⁴ A study in 2012 examined lunch receipts, collected from fast-food chains before and after the ban went into effect, and trans fat consumption dropped by 2.5 grams per meal.⁵⁵

From a policy standpoint, it has been argued that poor African-Americans are impacted at a greater rate by trans fat “because African-Americans are more likely than other populations to rely on cheaper food produced through unhealthy processing methods.”⁵⁶ One example of how poor African-Americans are more vulnerable to unhealthy food can be seen in the disbursement of fast-food restaurants in lower-income neighborhoods.⁵⁷ This bears “a direct correlation to higher incidence of obesity.”⁵⁸ Trans fat also impacts this community disproportionately in the following ways:

Conditions such as hypertension, diabetes, and high cholesterol are widespread in the African-American community and are made worse by trans fat. When coupled with the fact that poor African-Americans may not understand nutrition labels, cannot afford higher priced products, and may live in fast food dominated neighborhoods, it becomes clear that they are particularly vulnerable to the effects of trans fat. Thus, greater measures are needed to better protect them as consumers.⁵⁹

53. See Amanda MacMillan, *NYC's Fat Ban Paying Off*, CNN (July 16, 2012), <http://www.cnn.com/2012/07/16/health/nyc-fat-ban-paying-off> (last visited Apr. 18, 2017) (concluding that the reduced consumption due to the restrictions on trans fat is increasing the health of its citizens) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

54. *Id.*

55. *Id.*

56. Burrell, *supra* note 37.

57. See *id.* at 12 (describing a 2005 study that showed that 72% of the restaurants in South Los Angeles were fast food restaurants compared to only 41% of restaurants in West Los Angeles, a more affluent neighborhood (citing ANNIE PARK ET AL., CMTY. HEALTH COUNCILS, SOUTH LOS ANGELES HEALTH EQUITY SCORECARD (2008))).

58. See *id.* (noting, from the same 2005 data, that 30% of South Los Angeles residents were obese compared to only 19.1% in the greater metropolitan area and only 14.1% in West Los Angeles).

59. *Id.*

B. Statutes & Regulations Involved in Trans Fat Labeling

The Nutrition Labeling Education Act (NLEA), which amended the FDCA, was signed into law by President George H.W. Bush and allowed for greater regulation of nutritional claims.⁶⁰ The NLEA authorized the FDA to require ingredient disclosure.⁶¹ Legislative history informs us that there were two distinct reasons for the NLEA. The first was to “establish uniform national standards for the nutritional claims and the required nutrient information displayed on food labels.”⁶² Second, the NLEA sought to ensure that any state law “requirement for nutrition labeling of foods that is not identical to the requirements” of the NLEA is preempted.⁶³

21 U.S.C. § 343 governs misbranded food.⁶⁴ Under § 343(a)(1), a food product will be misbranded if “its labeling is false or misleading.”⁶⁵ Together § 343(q) and § 343(r) “regulate the information that goes into the ‘nutrition box’ section on all packaged products [as well as] nutrient content claims that appear elsewhere on the label.”⁶⁶ There is an important distinction between nutrient content claims and information that is declared on the nutrition label.⁶⁷ “Information that is required or permitted to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject” to the same requirements.⁶⁸ When the information in the nutrition label is placed elsewhere on the item, it then becomes a nutrient content claim, which is subject to a different set of regulations.⁶⁹ The cases involved in the circuit split center mostly around

60. Pomeranz, *supra* note 12, at 422.

61. *See id.* at 422–23 (explaining how the NLEA expanded the scope of the FDCA in relation to misleading labeling claims).

62. *See* H.R. Rep. No. 101-538, at 12 (1990) (explaining the reasons the NLEA was authorized).

63. *Id.* at 8.

64. 21 U.S.C. § 343 (2012).

65. 21 U.S.C. § 343(a)(1) (2012).

66. Chacanaca v. Quaker Oats Co., 752 F. Supp. 2d 1111, 1117 (N.D. Cal. 2010).

67. 21 C.F.R. § 101.13(c) (2016).

68. *Id.*

69. *Id.*

nutrient content claims that appear outside of the nutritional label.⁷⁰

An express nutrient content claim is a claim that makes a “direct statement about the level (or range) of a nutrient in the food, e.g., ‘low sodium’ or ‘contains 100 calories.’”⁷¹ An implied nutrient content claim indirectly describes the contents of a product and can occur in one of two ways.⁷² The first is when a claim “[d]escribes the food or an ingredient therein in a manner that suggests that a nutrient is *absent* or *present* in a certain amount (e.g., ‘high in oat bran’).”⁷³ The second way is when a claim “[s]uggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., ‘*healthy*, contains 3 grams (g) of fat’).”⁷⁴

Federal regulations state these nutrient content claims cannot be made on a products label, unless they are in accordance with governing regulations.⁷⁵ For example, a nutrient content claim cannot be two times the size of the product’s statement of identity.⁷⁶ A product’s statement of identity is the common or usual name for the product, such as “milk” on a milk carton.⁷⁷ See Figure 1 below for an example of Benecol’s nutrient content claim.⁷⁸ On the bottom left of the front of the label there is a symbol of a heart, and the words, “NO TRANS FAT” are placed above the heart.⁷⁹

70. See *Young v. Johnson & Johnson*, 525 F. App’x 179, 180–81 (3d Cir. 2013) (describing two claims made outside of the nutrition box).

71. 21 C.F.R. § 101.13(a)–(b) (2016).

72. See *id.* § 101.13(b) (“A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under 101.9 or under 101.36 . . . may not be made on the label or in labeling of the food. . .”).

73. *Id.*

74. *Id.* (emphasis added).

75. *Id.*

76. See *id.* § 101.13(f) (“A nutrient content claim shall be in type size no larger than two times the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.”).

77. See 21 C.F.R. § 101.3 (2016) (providing information on food packaging labels).

78. *Benecol 55% Vegetable Oil Spread*, GIANT EAGLE, <http://www.gianteagle.com/300450839183.aspx> (last visited Apr. 18, 2017) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

79. *Id.*



Figure 1⁸⁰

C. Federal Preemption of Trans Fat Labeling Regulations

Federal preemption of state laws dates back to the early history of the United States.⁸¹ Federal laws reign supreme over those of the states in certain situations due to the Supremacy

80. *Id.*

81. See *M'Culloch v. Maryland*, 17 U.S. 316, 427 (1819) (“It is of the very essence of supremacy, to remove all obstacles to its action within its own sphere, and so to modify every power vested in subordinate governments, as to exempt its own operations from their own influence.”).

Clause.⁸² Preemption occurs when, “(1) Congress enacts a statute that explicitly preempts state law; (2) state law actually conflicts with federal law; or (3) federal law occupies a legislative field to such an extent that it is reasonable to conclude that Congress left no room for state regulation in that field.”⁸³ In areas of traditional state regulation there is a presumption against preemption unless Congress has clearly manifested its intent to do so.⁸⁴

The reason federal preemption is a recurring issue in these cases is because of the way that Congress amended the FDCA.⁸⁵ The NLEA added a preemption provision to the FDCA which expressly preempts “state laws addressing certain subjects [including labeling requirements] that are ‘not identical to’ various standards set forth by the FDCA”⁸⁶ Federal preemption is an affirmative defense in these cases.⁸⁷ The Defendants attempt to show that “an FDCA regulation [or NLEA amendment] governs the labeling claim.”⁸⁸

However, claims will not be preempted if the regulation is not found to govern trans fat.⁸⁹ In *Reid*, the Ninth Circuit said to this point, “[i]t would be incongruous to have the same rule for both ‘No Fat’ . . . and ‘No Trans Fat’ claims, as the former is expressly permitted while the latter is not due to a lack of scientific consensus about the dangers of trans fat.”⁹⁰

82. U.S. CONST. art. VI, cl. 2.

83. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

84. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (“Congress added the remainder of the provision is evidence of its intent to draw a distinction between state labeling requirements that are pre-empted and those that are not.”).

85. *See Lam v. Gen. Mills, Inc.*, 859 F. Supp. 2d 1097, 1102 (N.D. Cal. 2012) (discussing the FDCA and the NLEA).

86. *Id.*

87. *See Trazo v. Nestle USA, Inc.*, No. 5:12-CV-2272 PSG, 2013 WL 4083218, at *6 (N.D. Cal. Aug. 9, 2013) (“It is imperative to note, however, that preemption is an affirmative defense, not an element of Plaintiffs’ claims”), *reconsideration granted*, No. 5:12-CV-02272-PSG, 2015 WL 4196973 (N.D. Cal. July 10, 2015).

88. *Id.*

89. *See generally Reid v. Johnson & Johnson*, 780 F.3d 952, 963 (9th Cir. 2015).

90. *See id.* (“Thus, the FDA’s reading of section 101.13(i)(3)—that the regulation does not authorize ‘No Trans Fat’ claims—makes the most sense of the overall labeling regime”).

III. Analysis of the Circuit Split between the Ninth and Third Circuit

A. Ninth Circuit Decisions

In 2012, *Carrea v. Dreyer's Grand Ice Cream, Inc.*⁹¹ was decided by the Ninth Circuit.⁹² *Carrea* involved a consumer protection claim surrounding a manufacturer's product that stated it contained "0 g Trans Fat."⁹³ Importantly, a "premium price" was charged for the product, above that of similar products.⁹⁴ The Plaintiff claimed he was only willing to pay that premium price because he believed the higher priced products were better than other frozen dessert products due to the alleged misrepresentations.⁹⁵

The District Court decided these allegations satisfied the injury-in-fact requirement necessary to pursue claims under California's Unfair Competition Law (UCL),⁹⁶ False Advertising Law (FAL),⁹⁷ and the California Consumer Legal Remedies Act (CLRA).⁹⁸ The UCL states that: "unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising . . ."⁹⁹ The FAL states it is unlawful to make any statement "which [is] untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading . . . with the intent not to sell that personal

91. 475 F. App'x 113 (9th Cir. 2012).

92. *Id.*

93. See *Carrea v. Dreyer's Grand Ice Cream, Inc.*, No. C 10-01044 JSW, 2011 WL 159380, at *2 (N.D. Cal. Jan. 10, 2011) (describing the allegation that Defendant charges a premium price for its ice cream products based on "misrepresentations that they contain original ingredients and zero grams of trans fat.").

94. *Id.*

95. See *id.* (explaining Plaintiff's argument that Defendant charged a premium price based on a misrepresentation, satisfying an injury in fact requirement showing grounds for possible standing).

96. CAL. BUS. & PROF. CODE § 17200 (West 2016).

97. CAL. BUS. & PROF. CODE § 17500 (West 2016).

98. CAL. CIV. CODE § 1750 (West 2016).

99. CAL. BUS. & PROF. CODE § 17200 (West 2016).

property or those services . . . as so advertised.”¹⁰⁰ The CLRA includes a list of twenty plus proscribed practices, one of which is “[u]sing deceptive representations”.¹⁰¹

The Defendant in *Carrea* challenged the claims made under state law on the premise that they impose requirements that are “not identical to’ the requirements set forth in regulations promulgated by the Food and Drug Administration . . . and are therefore expressly preempted pursuant to the Federal Food, Drug and Cosmetic Act . . . as amended by the Nutrition Labeling and Education Act”¹⁰² The regulation at issue expressly requires that “if the serving contains less than 0.5 gram, the content, when declared, shall be expressed as zero.”¹⁰³ The Defendant reasoned that “a statement about the amount or percentage of a nutrient [is permitted] if [t]he statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect”¹⁰⁴

District Judge Jeffrey S. White, who wrote the opinion in *Carrea*, first discussed recent decisions that involved preemption due to the federal regulatory statute.¹⁰⁵ Specifically he focused on *Chacanaca*, which involved the labeling of granola bars that contained “0 Grams Trans Fat” statements.¹⁰⁶ Judge White was building a foundation to ultimately declare Carrea’s claims were preempted and reminded the parties that “[i]n *Chacanaca*, the Court determined that [federal regulations *did*] preempt . . . state or local governments from imposing any requirement on nutrient content claims . . . *not* identical to the requirement of section 343(r).”¹⁰⁷ Title 21 U.S.C. § 343(r) governs nutrient content claims that manufacturers choose to include on a “food label or package,

100. CAL. BUS. & PROF. CODE § 17500 (West 2016).

101. CAL. CIV. CODE § 1770 (West 2016); CAL. CIV. CODE § 1750 (West 2016).

102. *Carrea v. Dreyer’s Grand Ice Cream, Inc.*, No. C 10-01044 JSW, 2011 WL 159380, at *3 (N.D. Cal. Jan. 10, 2011).

103. 21 C.F.R. § 101.9(c)(2) (2016).

104. *Carrea*, 2011 WL 159380, at *3 (internal quotations omitted).

105. *See id.* (“Several recent District Court decisions have held that claims based on statements concerning nutrient content, or using terms that the FA has defined or permitted, are preempted by the federal statute.”).

106. *See id.* at *4 (explaining that the court in *Chacanaca* preempted any state or local government from imposing nutrient content claims requirements made by food purveyors).

107. *Id.* (internal citations omitted) (emphasis added).

that is, a claim that expressly or by implication . . . characterizes the relationship of any nutrient required by [section 343(q)(1) or (2)] to be in the label.”¹⁰⁸ An accompanying regulation provides that “[i]f such information is declared [outside of the nutrition label] . . . *it is a nutrient content claim and is subject to the requirements for nutrient content claims.*”¹⁰⁹At the District Court level in *Carrea*, the *Chacanaca* preemption reasoning cited by Judge White above won the day.¹¹⁰

In 2012, the Ninth Circuit affirmed the judgment of the district court in *Carrea*.¹¹¹ The court found that the Plaintiff’s claims regarding the “0g Trans Fat” statement were expressly preempted by the FDCA as amended by the NLEA.¹¹² The Court decided that the statement was “an express nutrient content claim that the [FDA] not only permits . . . but further instructs should mirror the Nutrition Facts panel.”¹¹³

On March 13, 2015, the Ninth Circuit, in *Reid v. Johnson & Johnson*,¹¹⁴ reversed a district court decision and ruled that a class action group of consumers were *not* preempted by the NLEA in their claims that the manufacturer’s vegetable oil based spread contained misrepresentations in violation of California’s unfair competition law, false advertising law, and consumer legal remedies act.¹¹⁵ This decision in March 2015 created the circuit split between the Ninth and Third Circuit. The history of *Reid* is important to understanding how the Ninth Circuit changed its opinion on the preemption of these claims.¹¹⁶

108. *Id.* (internal citations omitted).

109. *Id.* at *4 (internal citations omitted) (emphasis added).

110. *See Carrea v. Dreyer’s Grand Ice Cream, Inc.*, No. C 10-01044 JSW, 2011 WL 159380, at *4 (N.D. Cal. Jan. 10, 2011) (“Adopting the reasoning of *Chacanaca*, the Court concludes that the ‘0g Trans Fat’ statement on Defendant’s Drumsticks packaging, outside the Nutrition Facts box, is a nutrient content claim subject to the express preemption provision of the NLEA.”).

111. *Carrea v. Dreyer’s Grand Ice Cream, Inc.*, 475 F. App’x 113, 115 (9th Cir. 2012).

112. *Id.*

113. *Id.* (internal citations omitted).

114. 780 F.3d 952 (9th Cir. 2015).

115. *Id.* at 963.

116. *See Reid v. Johnson & Johnson*, No. 11CV1310 L BLM, 2012 WL 4108114, at *1 (S.D. Cal. Sept. 18, 2012) (discussing the defendant’s product and the reason for plaintiff’s claim).

The defendants in *Reid*, Johnson & Johnson, and its subsidiary, McNeil Nutritionals, LLC, manufacture a product called Benecol.¹¹⁷ Benecol's website claims "Our spreads are ideal substitutes for traditional butter and margarines."¹¹⁸ The vegetable-oil-based spread has the following statements on its labels: "Proven to Reduce Cholesterol; No Trans Fat; No Trans Fatty Acids."¹¹⁹ The Plaintiff contended that these claims were false because Benecol actually contains small amounts of trans fat.¹²⁰ The Plaintiff also claimed the product was misbranded because it contained unauthorized nutrient content claims.¹²¹

The District Court reasoned that the Plaintiff was merely seeking to distinguish, "No Trans Fat" and "No Trans Fatty Acids" on the Benecol packaging from "0g trans fat" or "0 grams trans fat" seen in *Carrea*, where the consumers' claims were dismissed.¹²² The District Court did not agree that this distinction should result in a different outcome than *Carrea*, calling it unreasonable and thus finding the trans fat claims expressly preempted by the NLEA.¹²³

On appeal, the Ninth Circuit approached the question in *Reid* by establishing the determination of the Plaintiff's "No Trans Fat" claim would turn on whether the statement is authorized by FDA regulations governing express nutrient claims.¹²⁴ The court first determined that the trans fat statements on the Benecol packaging were express claims because they were direct statements about the

117. *Id.*

118. See *Our Food Range*, BENECOL, <http://www.benecol.ie/web/benecol.ie/our-food-range/spreads> (last visited Apr. 18, 2017) (detailing the variety of spreads available as alternatives to butter or margarine) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

119. *Reid*, 2012 WL 4108114, at *1.

120. *Id.*

121. *Id.*

122. See *id.* at *10 ("[P]laintiff is attempting to distinguish '0g trans fat' or '0 grams trans fat', which the FDA permits under 21 C.F.R. § 101.13(i)(3), with Defendants' labeled Benecol's trans fat content, 'No Trans Fat' and 'No Trans Fatty Acids', thereby avoiding express preemption.").

123. See *id.* ("Accordingly, the Court finds that Plaintiff's trans fat claims are expressly preempted by the NLEA.").

124. See *Reid v. Johnson & Johnson*, 780 F.3d 952, 962 (9th Cir. 2015) ("The preemption analysis of the 'No Trans Fat' claim turns on whether the statement is authorized by FDA regulations.").

amount of trans fat in the product.¹²⁵ The court reasoned that FDA regulations would only allow express claims that “do not in any way implicitly characterize the level of the nutrient in the food and [are] not false or misleading in any respect.”¹²⁶

In deciding if these claims were authorized and thus preempted, the court turned its focus to warning letters issued by the FDA.¹²⁷ Specifically, the court examined the guidance that the FDA has given on whether a “No Trans Fat” nutrient content claim is allowed when products actually contain small amounts of trans fat.¹²⁸ The first letter stated, “No Trans Fat’ is ‘an unauthorized nutrient content claim.’”¹²⁹ Next, the court noted that a second letter from the FDA specifically stated “trans fat-free” is an “unauthorized nutrient content claim.”¹³⁰

Regarding the binding impact of those letters, the court noted they are only one of many enforcement measures the FDA uses to police labels, but ultimately are merely informal and advisory.¹³¹ The FDA uses these letters to try and obtain voluntary changes from manufactures, with what it considers to be violations of the FDCA or NLEA.¹³² The Ninth Circuit further stated that these letters or agency interpretations, whether informal or not, should be controlling unless they are clearly erroneous.¹³³ Following that principle, and believing the letters were not clearly erroneous, the Ninth Circuit chose to defer to the FDA’s interpretation that the claims on the packaging were not allowed and thus the Plaintiff’s claims were not preempted.¹³⁴ An additional reason for the Ninth Circuit’s decision on the preemption issue was that, “[a] nutrient

125. *Id.*

126. *Id.*

127. *See id.* (“The FDA has provided guidance about whether a ‘No Trans Fat’ nutrient content claim is permissible for products containing small amounts of trans fat.”).

128. *Id.*

129. *Id.*

130. *Id.*

131. *Id.* at 962 n.5.

132. *Id.*

133. *See Auer v. Robbins*, 519 U.S. 452, 461 (1997) (explaining how the court gives deference to the Secretary of Labor’s interpretation unless it is deemed clearly erroneous).

134. *Reid v. Johnson & Johnson*, 780 F.3d 952, 962–63 (9th Cir. 2015).

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.”¹³⁵

The structure and language of FDA labeling regulations reinforce the Ninth Circuit’s conclusion that the Plaintiff’s claims should not be preempted.¹³⁶ The FDA expressly allows “‘No Fat’ and ‘No Saturated Fat’ claims for products that contain less than 0.5 grams of fat or saturated fat per serving.” On the other hand, “‘No Trans Fat’ claims were given the opposite treatment, and not authorized due to a lack of scientific information.”¹³⁷

The Ninth Circuit reasoned “if section 101.13(i)(3) authorizes ‘No Fat’ and ‘No Saturated Fat’ claims for products with small amounts of fat or saturated fat, then why would the FDA go to the trouble of promulgating a separate regulation expressly allowing these claims?”¹³⁸ The Defendant’s interpretation would make several regulations redundant.¹³⁹ It would be inconsistent logic by the FDA to have the same regulation for Fat and Trans Fat claims because fat claims are expressly permitted, while trans fat claims are not permitted due to the lack of a consensus about potential dangers of trans fat.¹⁴⁰ “Thus, the FDA’s reading of section 101.13(i)(3)—that the regulation does not authorize ‘No Trans Fat’ [statements]—makes the most sense of the overall labeling regime”¹⁴¹ Accordingly, the claims should not be preempted.

The Ninth Circuit rejected several of the Defendant’s arguments in *Reid*. The first theory rejected was that the “No Trans Fat” statement outside of the nutritional label is the equivalent of the 0 grams of trans fat per serving statement *inside* the nutritional label.¹⁴² The second theory was that the FDA allows for reasonable synonyms of authorized nutrient content claims to

135. *Id.* at 962.

136. *See id.* (“The structure of FDA labeling regulations bolsters this conclusion.”).

137. *Id.*

138. *Id.* at 963.

139. *Id.*

140. *Id.* at 962–63.

141. *See id.* at 963 (explaining this would give meaning to 21 C.F.R. § 101.62(b)-(c) (2016)).

142. *Id.*

be placed on the label, as long as they are not misleading.¹⁴³ The Defendant argued that the “No Trans Fat” claim was a reasonable synonym.¹⁴⁴ The court refuted that argument by calling attention to the fact that claims “like Benecol’s ‘0 grams trans fat per serving’ claim [on the nutrition label], are not nutrient content claims and thus are not covered by [the] synonym rule.”¹⁴⁵ The fact that Benecol must state that it contains “0 grams of trans fat per serving on its nutrition label makes no difference here” because the nutrient content claims are at issue, not the nutritional label.¹⁴⁶

B. Third Circuit Decisions

In 2013, the Third Circuit in *Young* decided consumer class action claims regarding trans fat nutrient content claims in Benecol were preempted.¹⁴⁷ *Young* involved the same product that was later at issue in the *Reid* case. At the District Court level in *Young* the Plaintiff claimed that Benecol’s “No Trans Fatty Acids” representations outside of the label were false and misleading as the product contains small amounts of trans fat.¹⁴⁸ The Plaintiff filed a complaint that included: violations of the New Jersey Consumer Fraud Act, breach of express warranties, breach of the implied covenant of merchantability, and unjust enrichment.¹⁴⁹ Johnson & Johnson’s motion to dismiss was granted by the District Court.¹⁵⁰

143. See 21 C.F.R. § 101.13(b)(4) (2016) (“Reasonable variations in the spelling of the terms defined in part 101 and their synonyms are permitted provided these variations are not misleading.”).

144. See *Reid v. Johnson & Johnson*, 780 F.3d 952, 962–63 (9th Cir. 2015) (discussing how a reasonable consumer would read the nutrient content claim).

145. *Id.* at 963.

146. See *id.* (explaining that required nutrition label claims can differ from nutrient content claims).

147. See *Young v. Johnson & Johnson*, 525 F. App’x 179, 183–85 (3d Cir. 2013) (stating that Young’s theories of liability were preempted and properly dismissed).

148. See *id.* at 181 (listing the five-count complaint allegations).

149. *Id.*

150. See *id.* (stating that the District Court concluded that Young lacked standing and Young’s claims were preempted).

The two issues on which the court decided the motion to dismiss were standing and preemption.¹⁵¹ In order to satisfy the constitutional minimum of standing, three elements must be established by the plaintiff.¹⁵² First, the plaintiff must have suffered an “injury in fact.”¹⁵³ Injury in fact is defined as an invasion of a legally protected interest which is “concrete and particularized” and “actual or imminent,” not “conjectural or hypothetical.”¹⁵⁴ The second element is a causal connection between the injury in fact and the conduct complained of.¹⁵⁵ Last, the injury must be “likely, as opposed to merely speculative” that the injury will be redressed by a decision in favor of the plaintiff.¹⁵⁶

In *Young* the Plaintiff did not claim that he suffered any adverse health problems from Benecol.¹⁵⁷ In fact, Plaintiff did not claim that he consumed the product, but did claim he purchased the product regularly over a “five-year period” of time.¹⁵⁸ Plaintiff’s injury in fact was not satisfied in the eyes of the court because it was determined to be an “apprehension about possible future injury.”¹⁵⁹ For these reasons, the District Court determined the Plaintiff lacked standing as injury-in-fact was not “adequately pled.”¹⁶⁰

Another important factor in the eyes of the District Court was that Benecol’s packaging did contain a disclosure regarding partially hydrogenated oils and trans fat.¹⁶¹ Thus, the substance of Plaintiff’s complaint, which stated that Benecol’s health claims were “false and misleading,” were arguably disclosed to him. The disclosure stated in part, a small amount of “partially

151. *Id.*

152. *See* Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992) (listing how courts have defined the requirement for establishing standing).

153. *See id.* at 560 (citing Allen v. Wright, 468 U.S. 737, 757 (1984)).

154. *Id.*

155. *Id.*

156. *Id.*

157. *See* Young v. Johnson & Johnson, No. CIV.A. 11-4580 JAP, 2012 WL 1372286, at *2–*5 (D.N.J. Apr. 19, 2012) (stating that adverse health conditions may help demonstrate an injury-in-fact).

158. *Id.*

159. *Id.*

160. Young v. Johnson & Johnson, 525 F. App’x 179, 181 (3d Cir. 2013).

161. *See* Young, 2012 WL 1372286, at *4 (discussing the importance of disclosure while analyzing the injury-in-fact claim element).

hydrogenated oils are used in Benecol As a result, Benecol Spreads, contain an extremely low level of trans fat. The FDA allows foods containing less than 0.5 grams of trans fat/serving to be labeled 0 grams trans fat, since this is considered an insignificant amount.”¹⁶² With regards to the preemption issue, the District Court concluded quickly that Plaintiff’s claims regarding Benecol’s statements were expressly preempted because they sought to impose requirements that were “*inconsistent*” with federal law.¹⁶³

On appeal, the Court of Appeals granted Young’s standing as “tenuous” but decided to fully consider the case.¹⁶⁴ On the merits, Young’s claims against Johnson & Johnson, were again determined to be expressly preempted by the Food, Drug and Cosmetic Act as amended by the Nutrition Labeling and Education Act.¹⁶⁵ “The NLEA expressly preempts any state-imposed requirement for nutrition labeling of food, or with respect to nutritional or health-related claims, ‘that [are] not identical to the requirement’ set forth in the relevant provisions of the Act.”¹⁶⁶ Young did not challenge that principle, but instead claimed his state law causes of action regarding Johnson & Johnson’s alleged misrepresentations are not preempted because they are identical to those set forth in the NLEA.¹⁶⁷

Young maintained that “although the regulations authorize Benecol to claim that it contains ‘0g of Trans Fat Per Serving,’ they do not expressly permit a claim of ‘NO TRANS FAT’ for the product as a whole.”¹⁶⁸ Young made the distinction in his opening brief that he “seeks to prohibit false and misleading nutrient content claims regarding *trans* fat content *per product*. Prohibition of such

162. *Id.* at *8.

163. *Id.* at *15.

164. *See Young*, 525 F. App’x at 182 n.4 (stating that Young’s specific facts allowed the Court to review the merits).

165. *Id.* at 181.

166. *Id.* at 181–82.

167. *See id.* at 182 (arguing that the claims are identical to the NLEA, Young asserts that his product contains no trans fats and the product has been proven to reduce cholesterol).

168. *Id.* at 182.

statements is not inconsistent with the FDA's regulation allowing nutrient content claims about *trans fat per serving*.”¹⁶⁹

To further understand Young's argument, below is a brief overview of the FDA's own opinion on nutrient content claims per product versus per serving. First the FDA says that the distinction between nutrient content claims per product and per serving is necessary to understand and use the nutrition label correctly.¹⁷⁰ The FDA website explains the relationship between a serving size and the whole package.¹⁷¹ The explanation states, “[t]he size of the serving on the food package influences the number of calories and all the nutrient amounts listed on the top part of the label.”¹⁷² Seeking to emphasize the distinction between a serving size in the entire product, the FDA website goes on to say: “Pay attention to the serving size, especially how many servings there are in the food package. Then ask yourself, ‘How many servings am I consuming?’ (e.g., 1/2 serving, 1 serving, or more).”¹⁷³ The FDA also provides a sample label on the website.¹⁷⁴ The accompanying description states, “[i]n the sample label, one serving of macaroni and cheese equals one cup. If you ate the whole package, you would eat two cups. That doubles the calories and other nutrient numbers, including the %Daily Values as shown in the sample label.”¹⁷⁵ While that example used calories, the logic would remain true for trans fat. Again, Young claims he sought to prohibit misleading manufacturer statements pertaining to per product representations, not trans fat statements per serving, which may or may not be permitted by the FDA.

169. See *id.* (citing Brief for Appellant, Opening Br. at 25).

170. See *How To Understand and Use the Nutrition Facts Label*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm274593.htm> (last visited Apr. 18, 2017) (explaining that various factors help determine the Nutrient Content label) (on file with the Washington and Lee Journal of Civil Rights and Social Justice).

171. See *id.* (discussing how serving size labels attempt to help consumers understand how serving sizes and whole package sizes differ).

172. *Id.*

173. *Id.*

174. See *id.* (displaying a sample Nutrition Facts label and explaining how consumers can properly analyze these Nutrition labels).

175. *Id.* (emphasis in original).

See Figure 2 below for an example of a sample nutrition label with a red circle around where Trans Fat would have been indicated on these products. That number would then be multiplied by the number of servings, this product has thirty-two servings.

Nutrition Facts		
Serving Size 1 Tbsp (14g)		
Servings Per Container about 32		
Amount Per Serving		
Calories 100	Calories from Fat 100	
% Daily Value*		
Total Fat 11g		17%
Saturated Fat 2.5g		12%
Trans Fat 2.5g		
Cholesterol 0mg		0%
Sodium 105mg		4%
Total Carbohydrate 0g		0%
Dietary Fiber 0g		0%
Sugars 0g		

Figure 2¹⁷⁶

Before rebutting Young’s allegations regarding per product claims, the Court of Appeals did admit that the FDA has recognized the potential for a consumer to misinterpret that a product is “free” of a nutrient such as trans fat, when a nutrient content claim of 0 grams per *serving* is made.¹⁷⁷ In 1993, the FDA

176. See *FDA Cuts Trans Fat in Processed Foods*, *supra* note 47.

(“A variety of processed foods—including frozen, canned and baked goods—contain *trans* fat. The amount per serving is listed on the Nutrition Facts label The inclusion of partially hydrogenated oil in the list of ingredients is another indication [of] *trans* fat.”).

177. See *Young v. Johnson & Johnson*, 525 F. App’x 179, 183 (3d Cir. 2013) (stating that the requirement for disclosure may produce a potential for discrepancy) (emphasis added).

admitted that “[s]uch declarations could be confusing to consumers, and this consequence is unintended. ‘Free’ claims are different than claims such as ‘low,’ which do not create an expectation in consumers’ minds that the food bearing the claim will possess a [specific] amount of the nutrient in question.”¹⁷⁸ In an attempt to clear up this “misleading and confusing” labeling the FDA decided that “the determination of whether a product is free of a nutrient be based on the value of the nutrient . . . per labeled serving.”¹⁷⁹ The court stated this decision was made in the interest of “clarity and consistency” and because of that decision “FDA regulations therefore authorize nutrient content claims based on per serving amounts, even if those claims are not entirely accurate on a per product basis.”¹⁸⁰

In support of this per serving position, the court examined three regulations governing other substances which authorize nutrient content claims that a food is “free” of a specific nutrient when it contains low levels.¹⁸¹ They include the authorization of nutrient content claims that a food is calorie free when it contains less than 5 calories per serving, claims that that a food is sodium free if it contains less than 5 milligrams of sodium per serving and claims that a food contains no fat or no saturated fat if it contains less than 0.5 grams per serving.¹⁸² Therefore, the court reasoned, “the ‘NO TRANS FAT’ claim on the Benecol label is not ‘misleading’ as that term is used in [the regulation] and is authorized . . . even if a ‘no trans fat’ claim is not expressly contemplated by the regulations.”¹⁸³

In reaching the above decision the Third Circuit cited three cases which had reached a similar conclusion. All three of those cases were mentioned above, *Carrea*, *Chacanaca*, and *Reid*.¹⁸⁴ Interestingly the Third Circuit in *Young* cited the *Reid* decision from the lower court which was ultimately overturned in favor of

178. See Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 58 Fed. Reg. 44020, 44025 (Aug. 18, 1993) (discussing the unintended confusion from these declarations).

179. *Id.*

180. *Young*, 525 F. App’x at 183.

181. *Id.*

182. *Id.*

183. *Id.*

184. *Id.*

the Plaintiff, and it was decided his claims were not preempted, which brings the reasoning of the Third Circuit into question.¹⁸⁵ Two other cases relied on by the Third Circuit, *Carrea and Chacanaca*, were also Ninth Circuit cases decided before the 2015 *Reid* case which determined claims were not preempted. Nonetheless, the court concluded “[n]utrient content claim regulations promulgated under the NLEA thus authorize the Trans Fat Claims, based on the per serving amount of trans fats that the product contains.”¹⁸⁶ The Court further reasoned “[b]ecause Young seeks to bar that disclosure under state law, in effect enforcing state law requirements that are not identical to the NLEA, his action is expressly preempted as it relates to those claims.”¹⁸⁷

C. Other Decisions Involving Trans Fat Misrepresentation

The facts in the below cases do not exactly parallel those of the circuit split above, but the analysis sheds light on what might happen if these courts were to face an issue more similar to the circuit split.

United States District Court, N.D. Illinois, Eastern Division

Consumers claimed that The Quaker Oats Company lured consumers into buying their products by “touting them as being (among other things) ‘wholesome’ and ‘heart healthy,’ when in reality the products contain unhealthy trans fats.”¹⁸⁸ Plaintiff claimed that these products were misleading because its packaging and marketing campaigns both state the product contains 0 grams of trans fat.¹⁸⁹ The product actually contained up to 5 grams of trans fat per box.¹⁹⁰ The central issue in this decision was whether the consumers had established standing.¹⁹¹ The court held that the

185. *Id.*

186. *Id.*

187. *Id.*

188. *Id.* at 1083.

189. *Id.* at 1083.

190. *Id.*

191. *Id.*

injury-in-fact requirement was established because the consumers paid more for these products than they would have, had they known they were being subjected to health risks.¹⁹²

Quaker argued that because the consumers were not physically harmed by the allegedly misleading product, they lacked standing.¹⁹³ The court decided to follow a recent Seventh Circuit decision, which stated that a lack of a physical harm to the consumers does not mean that they lack standing, as financial injury can create standing. “The plaintiffs’ loss is financial: they paid more for the [the product] than they would have, had they known of the risks [product] posed to [them].”¹⁹⁴ The court determined the consumers’ claims were supportable due to the allegedly misleading product packaging regarding the absence of trans fat.¹⁹⁵

Immediate Consumption

Products that were ready for immediate consumption also created diverging opinions about whether claims were supportable. McDonald’s publishes the fat and calorie contents of its products; this information is available in store and on the company’s website.¹⁹⁶ Prior to February 8, 2006, McDonald’s stated that its large fries contained six grams of trans fat.¹⁹⁷ On February 8, 2006, McDonald’s changed its position and stated that the large fries actually contained eight grams of trans fat.¹⁹⁸ Plaintiff consumers in *Reyes* maintained that they knew about the McDonald’s representations prior to February 8, and claimed they would have modified their McDonald’s fries consumption had they known the correct information.¹⁹⁹ In order to state a claim under the Illinois Consumer Fraud and Deceptive Practices Act, the

192. *Id.*

193. *Id.* at 1084.

194. *See id.* (quoting *In re Aqua Dots Prod. Liab. Litig.*, 654 F.3d 748, 751 (7th Cir. 2011)).

195. *Id.*

196. *See Reyes v. McDonald’s Corp.*, No. 06 C 1604, 2006 WL 3253579, at *1 (N.D. Ill. Nov. 8, 2006) (describing the ways that McDonald’s made nutrition information available to the public).

197. *Id.*

198. *Id.*

199. *Id.*

Plaintiffs must allege that “(1) McDonald's is engaged in a deceptive act or practice; (2) McDonald's intended that Plaintiffs would rely on the deception; (3) the deception occurred in the course of conduct involving trade and commerce; (4) Plaintiffs were injured; and (5) conduct proximately caused Plaintiffs' injury.”²⁰⁰ In *Reyes* the court ultimately determined that the Plaintiffs had pled the elements sufficiently enough to survive a motion to dismiss.²⁰¹

In 2007, the United States District Court for the District of Columbia dismissed a physician's action against Yum! Brands, Inc. where the physician claimed that KFC failed to reveal its use of trans fat, holding that the physician did not state a claim supported under any legal theory.²⁰² The physician stated in his complaint that “KFC's use of partially hydrogenated oil is ‘unnecessary,’ because healthier oils were available. KFC advertises on its website that KFC products are part of a nutritionally healthy lifestyle. The advertisements do not reveal the use of trans fats.”²⁰³ Additionally, the Plaintiff stated that because of the FDA's warnings about trans fat in 2004 and 2005, he was trying to avoid trans fat, but KFC did not display any warning about its food containing trans fat.²⁰⁴ In its examination of Plaintiff's allegations, the court found the Plaintiff did not allege that he had suffered any immediate ill effects, nor any other kind of injury from the food he consumed.²⁰⁵ After finding that the Plaintiff failed to allege any kind of injury, the court determined that Plaintiff lacked standing in this action.²⁰⁶ The court stated that the Plaintiff did plead economic injury but “[did] not specify what ‘economic injury’ he has suffered, and none is evident from the facts presented, even under the most charitable reading of the complaint.”²⁰⁷

200. *Id.*

201. *Id.* at *2.

202. *Hoyte v. Yum! Brands, Inc.*, 489 F. Supp. 2d 24, 26 (D.D.C. 2007).

203. *Id.* at 26.

204. *Id.*

205. *Id.*

206. *Id.*

207. *Id.* at 28.

The Court's statement about a possible economic injury is significant in that it suggests it may grant standing if the same scenario was brought before it again.²⁰⁸ If this Plaintiff were to claim that he paid a higher price for KFC over other fast foods, the outcome may have been different.

IV. Conclusion

There are four compelling reasons why the Ninth Circuit's interpretation is the correct one. First, the warning letters issued by the FDA plainly state that "No Trans Fat" is an unauthorized nutrient content claim. The letters are not binding, but the Ninth Circuit determined they were not clearly erroneous, and thus history dictates they should be followed. Second, the cases relied on by the Third Circuit in *Young* bring the foundation of their analysis into question. The Third Circuit cited three Ninth Circuit cases for the proposition that claims should be preempted. One of the cases the Third Circuit relied on was the lower court's decision in *Reid*, which was overturned in 2015, stating claims are not preempted. The other two cases, *Carrea and Chacanaca*, were decided before the 2015 *Reid* decision. In fact, The Quaker Oats Company paid \$1.4 million to settle the formerly named *Chacanaca* class action in 2014.²⁰⁹ Third, the structure of FDA labeling regulations show that the Defendant's interpretation would make several regulations redundant. As mentioned above, it would be inconsistent for the FDA to use the same regulation for Fat and Trans Fat claims because those two substances have been given drastically different treatment. The reason these substances have been given different treatment is because of a lack of scientific information on trans fat.

Fourth, the Third Circuit mistakenly strays from the simplicity that 21 U.S.C. § 343(a)(1) offers.²¹⁰ Section 343(a)(1) states that a food product will be misbranded if its labeling is false

208. *Id.*

209. *See* In re Quaker Oats Labeling Litig., No. C 10-0502 RS, 2012 WL 1034532, at *1 (N.D. Cal. Mar. 28, 2012) ("In light of the consolidation, and the withdrawal of named plaintiff Robert Chacanaca, plaintiffs' unopposed request to change the caption of this action to the form set out above is granted.").

210. 21 U.S.C. § 343(a)(1) (2012).

or misleading in any respect. Using that straightforward guideline, Benecol's nutrient content claim of "No Trans Fat" is undoubtedly misleading because it contains trans fat. The Third Circuit cites calories, sodium, and fat as examples of substances where authorization was given to make nutrient content claims that a food is "free" of a substance, when it in fact does contain small amounts of it. What the Third Circuit fails to recognize is that trans fat is substantially worse for human health than those products, and has historically been treated differently than them. The FDA in 2013 made a determination that partially hydrogenated oils and trans fat were no longer generally recognized as safe for *any* use in human food.²¹¹ A substance given that distinction should not be treated the same as calories or fat.²¹² The Ninth Circuit's decision in *Reid* that nutrient content claims such as "No Trans Fat" were not authorized, and thus claims are *not* preempted under federal law, is the correct interpretation.

211. *FDA Cuts Trans Fat in Processed Foods*, *supra* note 47.

212. Compare Michael F. Jacobson, *Finally Letting FDA Be FDA*, THE HILL: CONGRESS BLOG (Feb. 25, 2016, 4:00 PM), <http://thehill.com/blogs/congress-blog/healthcare/270755-finally-letting-fda-be-fda> (last visited Apr. 18, 2017) ("Researchers at the Harvard School of Public Health estimated that trans fat [caused] upwards of 50,000 deaths per year [between 1990 and 2000]") (on file with the Washington and Lee Journal of Civil Rights and Social Justice), with *Choosing Healthy Fats*, HELPGUIDE, <http://www.helpguide.org/articles/healthy-eating/choosing-healthy-fats.htm> (last visited Apr. 18, 2017) ("Unsaturated fats are considered 'good' fats and are encouraged as part of a healthy diet") (on file with the Washington and Lee Journal of Civil Rights and Social Justice).