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A Healthy Diet of Preemption: The Power of the FDA and the Battle Over Restricting High Fructose Corn Syrup From Food and Beverages Labeled 'Natural'

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A HEALTHY DIET OF PREEMPTION: THE POWER
OF THE FDA AND THE BATTLE OVER
RESTRICTING HIGH FRUCTOSE CORN SYRUP
FROM FOOD AND BEVERAGES LABELED
'NATURAL'

*Adam C. Schlosser**

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I. INTRODUCTION

America is unhealthy.¹ America faces an obesity epidemic.² The food consumed by Americans is making them fat.³ Americans, bombarded every single day by negative headlines like these, are becoming more and more health conscious.⁴ This newfound commitment to health is reflected in the food and beverages Americans purchase.

American consumers view food and beverage labels as the best way to establish a healthy connection between the food they purchase and their lifestyle – the most important or easiest step to improve overall health and wellness.⁵ A recent survey found thirty percent of Americans look at food and beverage labels much more than a year ago, an additional thirty-one percent read labels slightly more frequently, and forty-seven percent always examine the ingredients list.⁶ Many consumers trying to improve their overall wellness will purchase food and beverages labeled as ‘natural,’ thinking the term

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1. Jaime Huguin, *America the Unhealthy*, <http://www.cbsnews.com/stories/2004/02/26/health/main602417.shtml> (last visited Sept. 15, 2009); Mathew Reeves, *Study Finds Very Few Adults Leading Healthy Lifestyles*, Apr. 25, 2005, available at <http://news.msu.edu/story/31/>.

2. CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. OBESITY TRENDS 1985 – 2007, <http://www.cdc.gov/nccdphp/dnpa/obesity/trend/maps/index.htm> (last visited Sept. 22, 2009); *Obese Americans Now Outweigh the Merely Overweight*, REUTERS, Jan. 9, 2009, available at <http://www.reuters.com/article/domesticNews/idUSTRE50863H20090109>.

3. Paul A. Stitt, *Why Are Americans So Fat*, NOHA NEWS, Vol. XIX No. 2, 4, 4-6 (1994), available at <http://www.nutrition4health.org/nohanews/NNSp94AmericansFat.htm>.

4. See *Americans Point Fingers at Themselves for Obesity Problem; Consumers Do Not Blame Food Industry, New National Survey Reveals*, BUSINESS WIRE, Feb. 10, 2004, available at http://findarticles.com/p/articles/mi_m0EIN/is_2004_Feb_10/ai_113099519/; Adrea Miller, *Child Obesity Rates Triple*, THE WALTON TRIBUNE, Nov. 27, 2005, available at <http://www.waltontribune.com/story.lasso?ewcd=2368f1f8041ae930> (examining the growing concern over childhood obesity and providing suggestions of ways to achieve greater health).

5. See Laurie Demeritt, *What Consumers Look for on Product Labels*, NATURAL PRODUCTS INSIDER, Aug. 27, 2008, available at <http://www.naturalproductsinsider.com/articles/consumers-product-labels.html>.

6. *Id.*

indicates a healthier product.⁷ Sixty-three percent of consumers report a preference for food labeled as 'natural.'⁸ Food and beverage manufacturers also recognize the value of the word 'natural' and include the phrase on as many labels as possible to maximize profits. These factors make products labeled 'natural' one of the largest and fastest growing segments of the food and beverage industry today, accounting for billions of dollars in annual sales. Nonetheless, most consumers actually do not understand the real differences, if any, between traditional food and beverages and those bearing the term 'natural.'

The Food and Drug Administration (FDA) regulates what appears on the vast majority of food and beverage labels.⁹ Certain labeling claims, such as 'reduced fat' or 'high fiber', must meet strict requirements, while other claims, such as 'natural', do not receive such intense regulation.¹⁰ The FDA chose to place few restrictions, outside of banning artificial and synthetic ingredients and additives, on the use of the term 'natural.'¹¹

Due to the FDA's liberal definition, confusion currently exists as to what ingredients may be used in products labeled 'natural.' High fructose corn syrup (HFCS) is produced by a complex scientific manufacturing process and used as an ingredient in millions of products, many labeled 'natural.' Several consumers recently attempted to use state tort law to answer the question of whether the use of HFCS is in accord with the FDA's definition of a 'natural' product. The New Jersey District Court became the first court to issue an opinion on this question in the case *Holk v. Snapple Beverage Corporation (Holk)*.¹² The Holk court ultimately dismissed the suit

7. Karen Collins, *What a 'Natural' Label Really Means*, MSN HEALTH AND FITNESS, <http://health.msn.com/nutrition/articlepage.aspx?cp-documentid=100236030>, [hereinafter *What Natural Really Means*] (last visited Sept. 22, 2009).

8. *How Natural is Natural?*, FOOD NAVIGATOR-USA, Jan.14, 2008, available at <http://www.foodnavigator-usa.com/Financial-Industry/How-natural-is-natural>.

9. See U.S. Food and Drug Administration, Food Labeling and Nutrition Overview, [http://www.fda.gov/food/labeling Nutrition/default.htm](http://www.fda.gov/food/labeling%20Nutrition/default.htm) (last visited Sept. 22, 2009).

10. U.S. Food and Drug Administration, Food Label Helps Consumers Make Healthier Choices, <http://www.fda.gov/forconsumers/consumerupdates/ucm094536.htm> (last visited Nov. 19, 2009).

11. Claims of 'natural,' 'all natural,' and '100% natural' are used interchangeably and are not regulated differently in any manner. For the purposes of this article no changes will be recommended to this current system. All discussion will merely mention the phrase 'natural', but will apply to all of these terms.

12. *Holk v. Snapple Beverage Corp.*, 575 F.3d 329 (3d Cir. 2009). After the initial completion of this article, the United States Court of Appeals for the Third Circuit

after examining Congress' intent behind the passing of the Federal Food, Drug, and Cosmetic Act (FDCA) and then finding the Plaintiff's state tort claims impliedly preempted by the federal statute.¹³ Holk explained allowing such claims through state common law or statutes requires a court to effectively regulate in a field Congress intended the FDA to occupy exclusively and also creates obstacles to Congress' objective in creating the FDCA.¹⁴

The California Northern District Court reached the opposite conclusion in *Lockwood v. ConAgra Foods, Inc.* (Lockwood) by refusing to dismiss a similar suit, which brought state tort law claims against a manufacturer using HFCS as an ingredient on a product labeled 'natural.'¹⁵ The Lockwood court first pointed out Holk committed an error in its preemption analysis by not considering the amendments added to the FDCA by the Nutritional Labeling and Education Act (NLEA).¹⁶ The Lockwood court found the Plaintiff's claims not impliedly preempted because: Congress, by passing the NLEA, specifically contemplated and included state enforcement in conjunction with the federal regulations; the FDA declined to issue a formal regulation regarding the labeling usage of 'natural' despite several petitions and FDA-acknowledged consumer confusion; and manufacturers could comply with the FDA's existing policy on 'natural' and still follow the state laws providing the basis of the claim.¹⁷

Even though Holk failed to consider the NLEA in its analysis, the court ultimately came to the correct conclusion by finding the Plaintiff's claim preempted. By failing to dismiss its Plaintiff's claim, Lockwood misconstrued Congress' intent behind the passage of the FDCA, the NLEA, and the mandate of the FDA. If a court hears the Lockwood case, and decides HFCS cannot be used in food and bev-

overturned the initial decision of Holk. None of the reasons given by the court to overturn the original Holk decision alter any of the analysis or conclusions of this article.

13. See generally *id.*

14. *Id.* at 455-56.

15. *Lockwood v. ConAgra Foods, Inc.*, 597 F. Supp. 2d 1028, 1028 (N.D. Cal. 2009). See also *Hilt v. Arizona Beverage Co.*, 2009 WL 449190 (S.D. Cal. Feb. 4, 2009) for a substantially similar case to Lockwood. Plaintiff sued Arizona Beverage under California laws for using high fructose corn syrup in a beverage labeled 'natural' (among other claims, including certain deceptive naming claims). The Hilt court conducted a preemption analysis and denied Arizona's motion to dismiss using the same, yet less thorough, reasoning as found in Lockwood; therefore this article does not conduct any substantial analysis of the Hilt decision.

16. *Lockwood*, 597 F.Supp. 2d at 1034.

17. *Id.* at 1032-34.

verages labeled ‘natural,’ the judiciary will be overstepping its authority, ignoring long standing traditions of administrative deference, and overriding established FDA policy. The Lockwood suit, and any similar lawsuits brought in the future, should be dismissed due to issues of preemption and primary jurisdiction. Further, by using its authority, and existing legal precedents and practices, the FDA must change its current policy statement, clear up the current confusion, and issue a firm regulation banning the use of HFCS in food and beverages labeled ‘natural.’

Part II of this article discusses the typical framework for a preemption analysis and presents the findings of the Holk and Lockwood courts. Part II then moves on to explore the flaws in those analyses, illustrates several reasons why the Lockwood decision is incorrect, and concludes by demonstrating any lawsuit challenging the usage of HFCS in ‘natural’ food and beverages must be dismissed due to implied preemption or primary jurisdiction. Part III examines just how the FDA should regulate the term ‘natural’ on food and beverage labels, with particular emphasis placed on the usage of HFCS. Part III concludes by providing reasons why using HFCS as an ingredient is outside the scope of the FDA’s current policy regarding the usage of ‘natural’ and therefore manufacturers must be prohibited from using HFCS as an ingredient in food and beverages featuring the term ‘natural’ on the label.

II. FEDERAL LAW AND REGULATION PREEMPTS STATE TORT CLAIMS ATTEMPTING TO EXCLUDE HIGH FRUCTOSE CORN SYRUP FROM FOOD AND BEVERAGES LABELED ‘NATURAL’

The court system cannot be used to answer the question of whether HFCS is an acceptable ingredient in food and beverages labeled ‘natural’ because adjudication in this area is preempted by federal law or regulation. Holk, even through flawed reasoning, reached this correct conclusion. Lockwood, despite correctly pointing out Holk’s misstep, still failed in its preemption reasoning by overlooking or misconstruing key factors.

A. Traditional Preemption Analysis

The Supremacy Clause in Article VI of the United States Constitution states federal law is “the Supreme Law of the Land.”¹⁸

18. U.S. CONST. art. VI.

There is a need for the Constitution and federal laws to have the same meaning throughout every state; therefore any Congressional act will preempt a state statute,¹⁹ and the Supreme Court has held both legislative statutes and administrative regulations can preempt state law.²⁰ In all preemption analyses, courts begin by looking at Congressional intent or purpose.²¹ The deciding court must also remember historic police powers of the States²² are traditionally not to be superseded by a Federal Act unless Congress clearly manifested such a purpose.²³ The primary focus of a preemption analysis is to determine the extent to which Congress intended to replace state law with federal law.²⁴ The Supremacy Clause preempts state or local law in three circumstances: express preemption and the twin implied preemption categories of field and conflict preemption.

1. Express Preemption

Express preemption occurs when a federal statute or regulation contains specific, clear language explaining when a state or local law is to be exempted. Many federal statutes merely prohibit state or local laws that are “inconsistent” with the federal statute or regulation.²⁵ This allows states to provide regulation and enforcement in accordance with the federal rule.²⁶ Some federal statutes include

19. See *Martin v. Hunter's Lessee*, 14 U.S. 304, 324-27, 340-43 (1816).

20. See *Fidelity Fed. Savings & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 151-55 (1982).

21. “Congressional intent or purpose is the ‘ultimate touchstone’ in every pre-emption analysis.” *Medtronics, Inc. v. Lohr*, 518 U.S. 470, 485-86 (1996).

22. States’ traditional police powers include the ability to define criminal law and to protect the health, safety, and welfare of their citizens. *Gonzales v. Raich*, 545 U.S. 1, 66 (2005) (Thomas, J. dissenting). See also, e.g., Lisa Kinney Helvin, *Administrative Preemption in Areas of Traditional State Authority*, 2 CHARLESTON L. REV. 617,623-25 (2008) (providing overview of when state action may be recognized as a traditional police power).

23. In all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied the court starts with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

24. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (plurality opinion).

25. See, e.g., Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343-1 (2006).

26. See, e.g., *id.*

language, known as a savings clause, indicating Congress intended to preempt some, but not all aspects of state common law.²⁷

2. Implied Preemption

The other two circumstances giving rise to preemption are considered implied preemption. Field preemption occurs when the federal regulation is so all-encompassing there is a reasonable inference Congress purposefully left no room for state supplementation.²⁸ Legal scholars identify several distinct questions relevant to a court's field preemption analysis: (1) is the area in question one in which the federal government has traditionally played a unique role; (2) has Congress manifested a clear intent in the text or legislative history that the federal law should be functioning exclusively in the field in question; (3) would allowing state and local regulations in the area actually or potentially interfere with comprehensive federal regulatory efforts; and (4) does the law serve an important traditional state or local interest?²⁹

The final type of implied preemption, conflict preemption, can occur in two instances. Conflict preemption can occur when "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" or "when compliance with both federal and state regulations is a physical impossibility."³⁰ Conflict preemption can even still exist when there is an express preemption provision and the state law in issue is not expressly preempted.³¹ The state statute is then nullified to the extent it conflicts with federal law.³² It is important to note the three categories of preemption are not rigidly distinct, and "field preemption may be understood as a species of conflict preemption: [a] state law that falls within a pre-empted field conflicts with Congress' intent (either express or plainly implied) to exclude state regulation."³³

Implied preemption analysis is typically very fact specific and courts do get some leeway in conducting their conflict and field preemption determinations. If the court "wants to avoid preemp-

27. JAMES T. O'REILLY, FEDERAL PREEMPTION OF STATE AND LOCAL LAW: LEGISLATION, REGULATION AND LITIGATION 62-63 (American Bar Association 2006).

28. *English v. General Electric Co.*, 496 U.S. 72, 79 (1990).

29. ERWIN CHEMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES 390 (Aspen Publishers, Inc. 2d ed. 2002).

30. *Chicanos Por la Causa, Inc. v. Napolitano*, 544 F.3d 976, 982 (9th Cir. 2008).

31. *Id.* at 985.

32. *English*, 496 U.S. at 79.

33. *Id.* at 79 n. 5.

tion, it can narrowly construe the federal objective and interpret the state goal as different from or consistent with the federal purpose. But if a court wants to find preemption, it can broadly view the federal purpose and preempt a vast array of state laws.³⁴ This leeway sometimes leads to inconsistent and confusing results – even with cases featuring relatively similar fact patterns. The *Holk* and *Lockwood* decisions are clear examples of this inconsistency and confusion.

B. *Holk v. Snapple Beverage Corp.*

The New Jersey District Court issued the first opinion for a suit questioning whether HFCS is allowed as an ingredient in food and beverages labeled ‘natural.’ Stacy Holk (Holk plaintiff) brought suit alleging violations of the New Jersey Consumer Fraud Act, unjust enrichment, and breach of express and implied warranties stemming from Snapple Beverage Corporation’s (Snapple) use of the phrase ‘All Natural’ to describe its products.³⁵ The Holk plaintiff purchased two bottles of Snapple’s Acai Blackberry Fruit Juice Drink, which was labeled ‘All Natural’ and contained HFCS.³⁶ The Plaintiff alleged HFCS could not be considered ‘natural’ because it does not “originate from natural sources, but instead [is] created through ‘enzymatically catalyzed chemical reactions in factories.’”³⁷ Snapple moved to dismiss the suit based on primary jurisdiction; the court dismissed the suit based on implied preemption, never reaching the primary jurisdiction issue.³⁸

In reaching its conclusion the court examined the preemption issue through the lens of the Food, Drug, and Cosmetic Act (FDCA).³⁹ The court began its analysis by noting the FDA promul-

34. CHEMERINSKY, *supra* note 29, at 398.

35. *Holk v. Snapple Beverage Corp.*, 574 F.Supp. 2d 447,448-49 (D. N.J. 2008).

36. *Id.* at 449.

37. *Id.*

38. *Id.* at 456 n. 5. Despite winning the suit, Snapple, sensing changing consumer preferences, the potential for future lawsuits, and bad publicity, recognized the victory as bittersweet. Snapple responded by continuing to label some of its beverages as ‘natural,’ but chose to replace the HFCS with sugar so as to avoid the future controversies and negative publicity. See also Jennifer Lee, *Reading the Tea Leaves, Snapple Refreshes Itself*, NEW YORK TIMES, Feb. 19, 2009, available at <http://cityroom.blogs.nytimes.com/2009/02/19/reading-the-tea-leaves-snapple-refreshes-itself/>.

39. Congress originally passed the FDCA in 1938, giving the FDA authority to regulate the safety of food, drugs, and cosmetics. See U.S. FOOD AND DRUG ADMINISTRATION, HISTORY OF THE FDA: *The 1938 Food, Drug, and Cosmetic Act*,

gated many regulations pertaining to the contents and labels of beverages.⁴⁰ The court next noted the FDA, under the authority of the FDCA, thoroughly defined both ‘artificial flavor’ and ‘natural flavor.’⁴¹ Finally, the court pointed out the FDA’s current policy regarding the term ‘natural’ is to (1) “not restrict its use, except for added color, synthetic substances, and flavors;” and (2) “that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food.”⁴²

Holk next moved onto its legal analysis of the preemption issue. The court first concluded Congress, when passing the FDCA, did not intend to expressly preempt States’ interest in protecting their consumers against deception and fraud in the sale of food and beverages; therefore, the Plaintiff’s claim survived an express preemption analysis.⁴³ Holk then examined whether the Plaintiff’s state claims were impliedly preempt. The court pointed out that even though the FDA declined to undergo a rulemaking to define ‘natural,’ it did define ‘natural flavor’ and issued a policy statement describing its stance on the use of ‘natural’ on labels.⁴⁴ Further, the FDA is obligated to follow its advisory opinions until such opinions are amended or repudiated.⁴⁵ The court highlighted the elaborate regulations already established by the FDCA in regards to beverage labeling.⁴⁶ This fact, coupled with the FDA’s policy statement describing the acceptable labeling use of ‘natural,’ led the court to

<http://www.fda.gov/aboutFDA/WhatWeDo/History/Origin/ucm054826.htm> [hereinafter HISTORY OF 1938 FDCA] (last visited Nov. 2, 2009).

40. See *Holk*, *supra* note 35, at 450. See, e.g., 21 C.F.R. § 102.33(1997) (defining what phrases can appear on beverage labels depending on the ingredients used); 21 C.F.R. § 101.30 (listing requirements for the usage of certain phrases related to the percentage juice declared on a beverages’ label).

41. *Id.* at 450. Artificial flavor is “any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof.” 21 C.F.R. § 101.22(a)(1) (2000). Natural flavor is defined as “the essential oil, oleoresin, essence or extractive, protein hydrolsate, distillate, any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from” the above list. 21 C.F.R. § 101.22(a)(3) (2000).

42. Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 58 Fed. Reg. 2302, 2407 [hereinafter *Food Labeling*] (Jan. 6, 1993).

43. *Holk*, 574 F. Supp. 2d at 454.

44. *Id.*

45. Food and Drug Administration Advisory Opinions, 21 C.F.R. § 10.85(e) (2008).

46. *Holk*, 574 F. Supp. 2d at 455.

conclude FDCA and FDA “regulations so thoroughly occupy the field of beverage labeling...it would be unreasonable [for the court] to infer Congress intended the states to supplement this area,” and deciding the Plaintiff’s claims requires the court to effectively regulate in a field Congress intended the FDA to occupy exclusively.⁴⁷ Holk concluded by noting that allowing claims through state common law or statutes creates obstacles to Congress’ objective in enacting the FDCA, providing yet another reason to preempt the Plaintiff’s claim.⁴⁸

C. Lockwood v. ConAgra Foods, Inc.

A little less than one year after the Holk decision, Margot Lockwood filed a similar suit in the California Northern District Court alleging ConAgra Foods, Inc. (ConAgra) violated California’s Unfair Competition Law by engaging in misleading conduct resulting from the use of HFCS as an ingredient in Healthy Choice pasta sauce labeled ‘all natural.’⁴⁹ ConAgra moved to dismiss on the grounds the Plaintiff’s claims were expressly preempted, or in the alternative impliedly preempted by the provisions added to the FDCA by the Nutrition Labeling and Education Act (NLEA).

Lockwood first noted Congress implemented the NLEA to “clarify and strengthen [the FDA’s] authority to require nutrition labeling on foods, and to establish circumstances under which claims may be made about the nutrients in foods.”⁵⁰ The NLEA also added an express preemption for state laws addressing certain subjects covered by the FDCA, including some new labeling requirements added by the NLEA.⁵¹ Lockwood also criticized the decision in Holk for failing to consider the changes to the FDCA caused by Congress’ implementation of the NLEA.⁵²

Lockwood also quickly shot down ConAgra’s express preemption argument. The NLEA’s express preemption contains language

47. *Id.*

48. *Id.* at 456.

49. *Lockwood v. ConAgra Foods, Inc.*, 597 F. Supp. 2d 1028, 1029 (N.D. Cal. 2009).

50. *Id.* at 1030 (citing *National Council for Improved Health v. Shalala*, 122 F. 3d 878, 880 (10th Cir. 1997)).

51. *Id.*

52. *Id.* at 1034. Lockwood also correctly points out if the FDA did choose to adopt formal regulations governing ‘natural’ labels for food and beverages it would do so under the NLEA. Food labeling, *supra* note 42, at 2302. The FDA, did however, reaffirm their non-restrictive policy regarding the usage of ‘natural’ during the passage of the NLEA. *Id.* at 2407.

forbidding states from passing any requirement for the labeling of food and beverages that is not already required by the FDCA.⁵³ The court explained the Plaintiff's claim as pled did not allege the pasta sauce is misbranded or otherwise not in compliance with existing FDCA labeling requirements; rather the claim alleged HFCS is not produced by a natural process and therefore the pasta sauce does not fit within the FDA's existing policy of 'natural.'⁵⁴ Since the Plaintiff's claim did not use California law to create a different labeling requirement than required by the FDCA, the NLEA's added express preemption provision did not apply.⁵⁵

Lockwood next examined whether the Plaintiff's claims were impliedly preempted.⁵⁶ Lockwood first discussed issues of field preemption and departed from the reasoning of *Holk* to find that Congress, with the passage of the NLEA, did not intend to occupy the entire field of food and beverage labeling for three reasons. First, the court pointed out the NLEA amended the FDCA to include an express preemption provision that allowed states to issue regulations identical to federal law.⁵⁷ Second, Congress granted states sovereignty to independently regulate subject matters covered by the NLEA as long as those state laws do not fall within the FDCA's express preemption provision.⁵⁸ This includes the ability for states to impose nutritional disclosure laws on local restaurants.⁵⁹ Third, the FDA, despite acknowledging consumers are sometimes misled by the use of 'natural,' merely issued a policy statement and not a formal legal requirement regarding the definition of 'natural.'⁶⁰ Lockwood then addressed whether the plaintiff's claims were impliedly preempted due to conflict preemption and held a manufacturer

53. 21 U.S.C. § 343-1 (2006).

54. *Lockwood*, 597 F. Supp 2d at 1031.

55. *Id.*

56. *Id.* at 1031-34.

57. *Id.* at 1032.

58. *Id.* at 1032-33.

59. See *New York State Restaurant Ass'n v. New York City Board of Health*, 556 F. 3d 114 (2nd Cir. 2009) (upholding city law requiring certain restaurants to disclose calorie content); Press Release, State of California, Gov. Schwarzenegger Signs Legislation Promoting Nutrition and Healthier Options (Sept. 30, 2008), available at <http://gov.ca.gov/press-release/10682> (signing legislation requiring restaurants with twenty or more locations to disclose calorie content); Lainie Rutkow, et. al., *Preemption and the Obesity Epidemic: State and Local Menu Labeling Laws and the Nutrition Labeling and Education Act*, 36 J.L. MED. & ETHICS 772, 781 (2008).

60. See *Lockwood*, 597 F. Supp. 2d at 1033-34.

could comply with the FDA's policy on the word 'natural' while still following the state law providing the basis for the claim.⁶¹

D. Flaws in the Holk and Lockwood Preemption Analysis

The Holk court erred by failing to consider how the provisions of the FDCA added by the NLEA affected their preemption analysis, but this error did not ultimately prove fatal to the court's reasoning. The Lockwood court, despite ostensibly conducting the proper analysis by using the additional NLEA provisions, still did not reach the correct conclusion in denying ConAgra's motion to dismiss. Ultimately, the Lockwood court failed to consider the proper Congressional intent and surrounding circumstances behind the passage of the FDCA and NLEA, which ultimately serve as clear signals the plaintiff's state law claims needed to be preempted by the federal regulations in question.

1. Congressional Intent Behind the Passage of the FDCA and the NLEA

Since Congressional intent or purpose is the 'ultimate touchstone' in every preemption analysis,⁶² a brief background on the FDCA and NLEA is a necessary starting ground. Congress, in response to the public uproar caused by Upton Sinclair's muckraking opus, "The Jungle," passed the Federal Food and Drugs Act (FFDA) of 1906 (and the companion Federal Meat Inspection Act) to create the Bureau of Chemistry, the direct forerunner to the modern FDA.⁶³ The FFDA, which gave the Bureau of Chemistry power to regulate in an area – public health and welfare – traditionally occupied by states, prohibited "the interstate transport of unlawful foods and drugs under penalty of seizure of the questionable products and/or prosecution of the responsible parties."⁶⁴ Congress passed the FDCA in 1938, creating the modern FDA, in order to correct the FFDA's lack of legally enforceable food standards, manufacturers' ongoing abuses in food packaging and quality, and an absence

61. *See id.* at 1034-35.

62. *Medtronics, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

63. Walter F. Janssen, *The Story of the Laws Behind the Labels*, FDA Consumer, June 1981, available at <http://www.fda.gov/aboutFDA/WhatWeDo/History/Overviews/ucm056044.htm>.

64. U.S. Food and Drug Administration, History of the FDA: The 1906 Food and Drugs Act and its Enforcement, <http://www.fda.gov/oc/history/historyoffda/section1.html> (last visited Sept. 24, 2009).

in the regulation of therapeutic medicine.⁶⁵ The FDCA granted the FDA broad authority to regulate food and beverage labeling and also prohibited the introduction, adulteration or misbranding of any food in interstate commerce.⁶⁶ The FDCA did not create a private right of action.⁶⁷ The FDA can enforce the FDCA and its regulations through administrative proceedings.⁶⁸

In 1990, Congress passed the NLEA, giving the FDA enhanced control over nutritional labeling on all food and beverages.⁶⁹ The NLEA represented an attempt by Congress to inform consumers of the scientific advances linking health and nutrition and to eradicate the American market of false and misleading label information.⁷⁰ Prior to enactment of the NLEA, Dr. Sullivan, head of the FDA, said his department favored uniform federal standards for food labels that would totally override state and local laws.⁷¹ Congress created NLEA amendments specifically to “establish the circumstances under which claims may be made about the nutrients in foods.”⁷² The NLEA aimed to provide a streamlined, comprehensive system of labeling easily understood by both consumers and manufacturers, and also amended the FDCA to allow states to bring their own rights of enforcement for violations of certain provisions.⁷³ The NLEA also strengthened the FDCA’s preemption provision by expressly forbidding any state or local laws which impose additional requirements or different standards of identity on food and beverage labels.⁷⁴

2. Express Preemption Analysis in *Holk* and *Lockwood*

Holk and *Lockwood* examined the same FDCA provisions⁷⁵ when conducting their respective express preemption analyses and reached the same correct conclusion: Congress did not intend to

65. History of the 1938 FDCA, *supra* note 39.

66. *See, e.g.*, 21 U.S.C. §§ 301, 331, 393.

67. 21 U.S.C. § 337(a) (2006).

68. 21 C.F.R. § 7.40 (2006).

69. MARION NESTLE, *FOOD POLITICS: HOW THE FOOD INDUSTRY INFLUENCES NUTRITION, AND HEALTH*, REVISED AND EXPANDED EDITION 250, 250 (2007).

70. *Dietary Supplements: Hearing Before the Subcomm. on Agriculture of the House Comm. on Appropriations*, 103rd Cong. 1st Sess. 25 (1993) (testimony of Dr. David A. Kessler, Commissioner Food and Drug Administration).

71. NESTLE, *supra* note 69, at 250.

72. *National Council for Improved Health v. Shalala*, 122 F. 3d 878, 880 (11th Cir. 1997).

73. 21 U.S.C. § 337 (2006).

74. 21 U.S.C. § 343-1 (2006).

75. *Id.*

expressly preempt the state tort law behind either *Holk*'s or *Lockwood*'s individual claim. The relevant FDCA section provides, "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce..any requirement not identical" to certain FDCA labeling requirements,⁷⁶ including requirements to prevent misbranding and false claims.⁷⁷ None of the requirements found in the FDCA, specifically attempt to define or regulate use of the term 'natural,' therefore, neither *Holk* nor *Lockwood*'s claim fell within the express preemption provision of the FDCA.⁷⁸

3. Mistakes in the *Lockwood* Implied Preemption Analysis

Holk and *Lockwood* both conducted an implied preemption analysis, but reached different conclusions. *Holk* found the FDCA's

76. *Id.* at § 343-1(a).

77. *See, e.g.*, 21 U.S.C.343(k) (2006) (providing food is misbranded "[i]f it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears label stating that fact..."); 21 U.S.C. § 343(c) (2006) (claiming a food is mislabeled if it is an imitation of another food but does not identify itself as an imitation).

78. Despite the findings of both *Holk* and *Lockwood*, it is not out of the question a court may find a substantially similar claim preempted because such a claim is in fact adding extra requirements to the FDCA, as amended by the NLEA. "The term 'requirements'... reaches beyond positive enactments, such as statutes and regulations to embrace common-law duties." *Bates v. Dow Agrosciences LLC.*, 544 U.S. 431, 443 (2005). "In contrast, an 'occurrence that merely motivates an optional decision' - such as the threat of state law damages remedy for a violation of an existing federal requirement - does not itself qualify as a requirement." *In re PepsiCo, Inc., Bottled Water Marketing and Sales Practices Litigation*, 588 F. Supp 2d 527, 532 (S.D. NY 2008) (citing *Bates*, 544 U.S. at 443). The PepsiCo court heard a consumer's claim alleging fraudulent labeling on purified bottled water. The plaintiff claimed state common law should not be preempted because the FDA specifically addressed the labeling requirements for 'purified water' - the bottled water variety in question - and chose to exempt 'purified water' from the same standards applied to the other varieties of bottled water. The court still held the claim expressly preempts by the federal regulation and the FDCA and rejected the plaintiff's claim that "state requirements are permitted as long the federal standard does not specifically address the terms..at issue". *In re PepsiCo*, 588 F. Supp. 2d at 538. This situation seems on its face similar to the FDA's position on HFCS' inclusion in food and beverages labeled 'natural.' The facts of PepsiCo may, however, be considered distinguishable because, unlike the term natural, the FDA underwent a formal rulemaking to construct labeling definitions for bottled water. The FDA specifically considered the terms to appear on 'purified water' before finally deciding to exclude 'purified water' from the final rule definitions, and also provided detailed reasons for this decision. The FDA, on the other hand, explicitly declined to issue any sort of formal rules with regard to HFCS or the phrase 'natural.'

detailed and extensive regulatory scheme combined with the FDA's implementing regulations impliedly preempted the Plaintiff's claims.⁷⁹ Lockwood, in reaching the opposite conclusion, pointed out the reasoning in *Holk* was flawed because the *Holk* court did not consider the new NLEA preemption provisions at any point in its implied preemption analysis.⁸⁰ Even with inchoate reasoning stemming from a failure to consider the added NLEA provisions, *Holk* ultimately still arrived at the correct conclusion. By failing to find the Plaintiff's claims impliedly preempt, the *Lockwood* court overlooked or misconstrued several key issues.

In reaching its decision against implied preemption, the *Lockwood* court relied heavily on the NLEA's express savings clause, which states "the [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under..." various FDCA food and beverage labeling requirements.⁸¹ Lockwood points out, because of this savings clause, Congress manifested an intent not to solely occupy the field of food and beverage nutritional labeling.⁸² The court indicated the mere presence of this savings clause precluded the option of implied preemption.⁸³ However, the Supreme Court does not give much weight to savings clauses appearing in the same statute as a preemption provision.⁸⁴ In *Geier v. American Honda Motor Co.*, the Court concluded a "savings clause foresees - it does not foreclose - the possibility a federal..standard will preempt a state common law tort action with which it conflicts."⁸⁵ The inclusion of a savings clause does nothing to alter ordinary principles of preemption, including the standard rules for finding a claim impliedly preempt.⁸⁶ Further, the main value in allowing state tort claims under a statute's savings clause is preserving tort actions with deterrent value to achieve certain safety standards.⁸⁷ Neither the *Holk* nor *Lockwood* plaintiffs maintained a concrete, actual physical injury similar to those found in other product safety liability cases where state tort claims were allowed to

79. *Holk*, 574 F. Supp. 2d at 454.

80. *Lockwood*, 597 F. Supp. 2d at 1032-33.

81. *Id.* at 1032 (citing 21 U.S.C. § 343-1 (2006)).

82. *Id.* at 1033 - 34.

83. *Id.* at 1032 - 33.

84. See Sandra Zellmer, *Preemption by Stealth*, 45 HOU. L. REV. 1659, 1660 (2009).

85. *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 870 (2000). (finding a claim preempt by "declin[ing] to give broad effect to a savings clause where doing so would upset the careful regulatory scheme established by federal law").

86. *Id.* at 870-74.

87. *Id.* at 870.

fill in the safety voids of federal regulation.⁸⁸ Moreover, the lack of clear detrimental effects from HFCS consumption obviates the need for these same state tort laws.⁸⁹

Congress did not expect to leave the entire field of food related consumer protection in the hands of the FDA, but did intend to give the FDA control of the entire field of establishing health and nutritional labeling claims on food and beverages.⁹⁰ Congress recognized state enforcement of FDA-created label standards is necessary to overcome the lack of a private remedy in the FDCA.⁹¹ Simply passing legislation - merely having it in the books - is not the same as actual enforcement; the rules need to have teeth and those teeth need to bite. Congress, and the FDA itself, freely acknowledged a lack of available resources to properly enforce all labeling regulations,⁹² so it was only natural states be given the power to create private rights of action to carry out their traditional duties of protecting their citizens. Congress intended the NLEA to add state common law tort actions to enforce the federal standards of the FDCA.⁹³ However, when litigation wields state common law as a method to supplement existing federal labeling standards, courts have repeatedly dismissed such suits. This is true, especially, when, much like Lockwood, adjudicating the case would add or alter requirements to

88. See generally *Bates v. Dow Agrosciences LLC.*, 544 U.S. 431 (2005) (holding claims alleging damages from harmful pesticides brought under state tort law are not preempted by the Federal Fungicide, Insecticide and Rodenticide Act); *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) (holding the Federal Boat Safety Act did not preempt all state law design defect damages). It is important to note, however, that neither of those statutes is as broad as the FDCA.

89. See discussion *infra* Part III.B.

90. The FDA's traditional mission statement is to develop policy and regulations for nutritional labeling and food standards within the United States. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, *About FDA: CFSAN-What We Do*, available at <http://www.cfsan.fda.gov/~dms/onplds.html>. See also Claudia L. Andre, *What's in That Guacamole? How Bates and the Power of Preemption Will Affect Litigation Against the Food Industry*, 15 GEO. MASON L. REV. 227, 251 (2007).

91. 21 U.S.C. § 337 specifically allows states to bring certain actions themselves.

92. See Mary Mosquera, *Lawmakers Say Budget Underfunds FDA*, FEDERAL COMPUTER WEEKS, Feb. 5, 2008, available at <http://fcw.com/articles/2008/02/05/lawmakers-say-budget-underfunds-fda.aspx> [hereinafter *Budget Underfunds FDA*].

93. See *Vermont Pure Holdings, LTD. v. Nestle Waters North America, Inc.*, 2006 WL 839486, 6-8 (D. Mass. 2006) (holding states can issue laws to supplement existing federal regulations pertaining to bottled water). Cf. *Mills v. Giant of Md., LLC*, 441 F. Supp 2d 104, 105 (D.D.C. 2006) (dismissing a suit attempting to use state common law to add certain warnings to labels on containers of milk).

the FDCA's and FDA's established national, uniform, food and beverage labeling scheme.⁹⁴

Lockwood also incorrectly found against implied preemption based on the power of states to regulate subject matters addressed by the NLEA, but also outside the FDCA's express preemption provision. For example, state and local governments are free to pass their own regulations governing restaurants and menu disclosures.⁹⁵ The food served in restaurants, as well as prepared food served in supermarkets or other chain eateries, is completely different than the *packaged* food and beverages regulated by the FDCA and FDA regulations. Packaged food and beverages, which are the products covered by the FDCA, will be sold throughout the United States, while the food and beverages falling under the areas left open by the NLEA amendments are purchased and consumed within a single state. This distinction is important because any federal law or regulation with the goal of creating a uniform national system preempts any state law that discriminates or places impositions on interstate commerce.⁹⁶ Allowing states or local governments to pass their own menu disclosure laws does nothing to limit interstate commerce. Allowing state tort claims to alter the usage of HFCS in one state will force manufacturers to completely change their production methods in that state, and may even expose the manufacturer to unexpected state tort liability merely from placing their product in the stream of commerce. Clearly, Congress did not intend to intentionally allow state common law supplementation if such additions would burden interstate commerce.

Lockwood also took issue with the FDA's repeated decisions not to undergo a formal rulemaking to regulate the label usage of 'natural.' The court stated this repeated inaction indicated an intent not to occupy the field. There is a fear by some courts that if the federal government fails to act, and a court holds state law preempted by this federal inaction, an area of public health or safety

94. See *Mills*, 441 F. Supp. 2d 104 (D.D.C. 2006) (dismissing a suit to place warnings on milk on the grounds the plaintiffs were trying to add requirements not required by the FDCA); *In re PepsiCo, Inc., Bottled Water Marketing and Sales Practices Litigation*, 588 F. Supp 2d 527 (S.D. NY 2008) (holding the FDCA preempted additional requirements imposed by plaintiff's state tort law claim based in an area where the FDA previously issued a rule on labeling requirements).

95. *New York State Restaurant*, *supra* note 59.

96. See Robert L. Glicksman, *Nothing is Real: Protecting the Regulatory Void Through Federal Preemption by Inaction*, 26 VA. ENVTL. L. J. 5, 20-21 (explaining the Supreme Court often uses a justification for preemption that mirrors that of the Commerce Clause).

will go unregulated.⁹⁷ This fear does not apply to the current controversy because the usage of HFCS is already regulated by the FDA. The FDA has periodically reviewed its policy and decided on maintaining the current course of action.⁹⁸ Despite, the reasoning of *Lockwood*, there is no current regulatory gap affecting the health and safety of citizens. Consumers may be confused by the meaning of the term 'natural' on food and beverages, but the FDA, not the states, is expressly charged under the FDCA and NLEA with rectifying this confusion. If a manufacturer included HFCS as an ingredient in a product labeled 'natural,' but failed to disclose HFCS on the ingredient list, a citizen can bring suit using state fraud claims, provided the state law is identical to the FDCA's misbranding or ingredient disclosure provisions.⁹⁹ Or if a manufacturer knowingly used an adulterated ingredient, a private citizen can seek damages based on state tort law.¹⁰⁰ States are still left with the power to use their state common law to enforce any violations of the FDA policy and regulation that may affect their citizens' health or safety.

Lockwood's reasoning also ignores traditional notions of administrative deference.¹⁰¹ Congress granted the FDA the power to choose when to – and by association the power not to – issue regulations creating the reasonable definition for any food or beverage. The relevant FDCA provision reads, “Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food..a reasonable definition and standard of identity, [or] a reasonable standard of quality[.]”¹⁰² The FDA used its administrative judgment to issue a policy statement on the usage of 'natural,' and then determined, based on its resource availability, to leave the policy statement in place, despite its alleged defects. This decision does not mean the FDA chose not to occupy this field,

97. *Id.* at 8.

98. Food Labeling, *supra* note 42.

99. 21 U.S.C. § 343(k) (2000).

100. *See In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1179 (Cal. 2008) (holding neither the FDCA nor the NLEA added amendments shall be interpreted to preempt food safety laws).

101. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Massachusetts v. Environmental Protection Agency*, 549 U.S. 497 (2007). *See also* Blake B. Johnson, *The Supreme Beef Case: An Opportunity to Rethink Federal Food Safety Regulation*, 16 LOY. CONSUMER L. REV. 159 (2004); Carl Tobias, *FDA Regulatory Compliance Reconsidered*, 93 CORNELL L. REV. 1003 (2008).

102. 21 C.F.R. § 341 (2001).

it merely decided its current level of occupation is proper. *Lockwood* failed in its reasoning by not respecting the FDA's decision.

Finally, *Lockwood* shot down the idea of conflict preemption by stating a manufacturer could comply with the FDA's policy on 'natural' and still comply with the state law - as postulated in the case by the plaintiff.¹⁰³ The *Lockwood* court also explained the plaintiff's interpretation is not an obstacle to the accomplishment of the objectives of the FDCA.¹⁰⁴ Both these findings represent an epic failure in reasoning. Prior to implementation of the NLEA, Congress considered the overall effect on manufacturers, including potential new costs incurred, which would result from the NLEA's passage.¹⁰⁵ Congress based its considerations solely upon new *national* federal laws, not a myriad of patchwork state labeling requirements. If state tort claims can be used to create 'natural' definitions that are different than the policy statements issued by the FDA, then it follows state tort claims can be used to alter any definitions that the FDA purposefully and strategically left some wiggle room. This system greatly hinders manufacturers' ability to know how to properly label their products. Manufacturers are then exposed to huge amounts of potential liability merely from inserting their products into the stream of commerce. These two factors completely frustrate the purpose behind the FDA's advisory system.¹⁰⁶ The purpose of the NLEA is to inform and educate, not confuse. Allowing for many distinct state common law requirements for the usage of HFCS in food and beverages labeled 'natural' frustrates this purpose. Standards can then be different in every state, leaving consumers with the responsibility of figuring out what state their 'natural' food or beverage came from, then keeping up with the labeling requirement for that state, and finally trying to figure out if HFCS could be used as an ingredient under that state's requirements.

E. Lockwood Erred by Not Applying the Primary Jurisdiction Doctrine

The primary jurisdiction doctrine also provides grounds for any court to dismiss a state tort law claim based on the use of HFCS in a

103. *Lockwood*, 597 F. Supp. 2d at 1034.

104. *Id.*

105. See generally Administrative Law Review, *The Impact of the Nutrition Labeling and Education Act of 1990 on the Food Industry*, 47 Admin. L. Rev. 605(1995) (discussing cost to manufacturers of the implementation of the NLEA and efforts of these companies to lobby Congress).

106. 21 C.F.R. § 10.85 (2009).

'natural' food or beverage. Primary jurisdiction allows for the proper relationship between courts and administrative agencies.¹⁰⁷ Primary jurisdiction encourages more informed legal decisions through greater judicial utilization of administrative expertise, and also maintains the uniform treatment of a regulatory scheme by leaving critical decisions to the appropriate agency.¹⁰⁸ The doctrine is prudential and a court can consider whether to apply it whenever a claim originates in the courts, and "enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body."¹⁰⁹ In these situations, "the court may refer specific questions to the administrative body responsible for deciding such questions."¹¹⁰ A judge, when contemplating whether to apply the primary jurisdiction doctrine, must look towards the possibility that different courts addressing the same regulatory issue will reach different results and these results may undermine the regulatory scheme.¹¹¹ The judge also must consider whether the issue is "within the conventional experience of judges."¹¹²

Holk found the Plaintiff's claim impliedly preempted and thus never reached the issue of primary jurisdiction because the Plaintiff's claims were found impliedly preempted.¹¹³ *Lockwood* cited recent primary jurisdiction jurisprudence finding the "court [may stay] proceedings or dismiss the case without prejudice, so that the parties may seek an administrative ruling."¹¹⁴ *Lockwood* then pointed out there is no need to apply the primary jurisdiction doctrine because the FDA has repeatedly declined requests to formally define 'natural' due to lack of resources and other more pressing concerns.¹¹⁵ *Lockwood*, however, overlooked the fact the FDA has already issued a statement on the labeling use of 'natural.' Over time, manufacturers and other interested parties asked the FDA to examine that deci-

107. *U.S. v. W. Pac. R.R. Co.*, 352 U.S. 59, 63 (1956).

108. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 672 (2003) (Breyer, J. concurring).

109. *W. Pac RR*, 352 U.S. at 64.

110. *Holk v. Snapple Beverage Corp.*, 574 F.Supp. 2d 447, 452 (D.N.J. 2008).

111. For a general background on the usage of the primary jurisdiction doctrine see Aaron J. Lockwood, *The Primary Jurisdiction Doctrine: Competing Standards of Appellate Review*, 64 WASH. & LEE L. REV. 707, 732 (2007).

112. *Far E. Conference v. United States*, 342 U.S. 570, 574 (1952).

113. *Holk*, 574 F. Supp. 2d at 455 n. 5.

114. *Lockwood*, 597 F. Supp. 2d at 1034-35 (citing *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008)).

115. *Lockwood*, 597 F. Supp. 2d at 1035.

sion, and, after using its expertise on food and beverage labeling and the best use of its own resources, the FDA consistently decided the current policy of 'natural' is best left in place, without any additions or alterations. A court must not substitute its policy judgment for that of the FDA, even if the FDA's judgment results in inaction. An agency decision on how to best use its own resources must be given deference by a court.¹¹⁶ In *Cohen v. McDonalds Corp.*, a court dismissed a suit because settling the plaintiff's claim required the court to fill holes in the NLEA the federal government had declined to yet fill.¹¹⁷ That decision emphasized that a state court could not substitute its judgment for that of the FDA and any other result creates a danger of non-uniformity.¹¹⁸ It is not a court's duty – nor should it possess the power – to create or change a policy statement in an area that an agency already considered settled. For these reasons, *Lockwood's* initial determination to not apply the primary jurisdiction doctrine is incorrect.

Lockwood also found nothing involved in the Plaintiff's claim can be considered a highly technical area where the FDA has greater technical expertise than the court.¹¹⁹ The judge must merely decide whether the label claims are considered misleading under California state law, and judges decide claims about misleading labeling all the time.¹²⁰ By reaching this conclusion, *Lockwood* greatly oversimplifies the real issue at hand. No judge could decide whether the label found on the Healthy Choice Pasta Sauce is misleading without first deciding whether HFCS is considered 'natural' under the FDA's current guidance documents – a decision that cannot be accomplished without employing a highly scientific analysis.¹²¹ A judge deciding whether the complex scientific reactions used to create and refine HFCS are considered 'natural' will be conducting this highly scientific and technical analysis in an area the FDA undoubtedly possesses substantially greater experience and knowledge. The judge is essentially undertaking the job of an FDA scientist. The FDA itself asserts science is a key foundation of any decision, and its scientists

116. *Massachusetts v. Environmental Protection Agency*, 549 U.S. 497, 527 (2007) (citing *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)).

117. *Cohen v. McDonalds Corp.*, 808 N.E.2d 1, 9-10 (Ill. App. Ct. 2004).

118. *Id.* at 10.

119. *Lockwood*, 597 F. Supp. 2d at 1035.

120. *Id.*

121. *See infra* Part III.D.

are rigorously trained.¹²² A judge must defer to the expertise of the FDA and its scientists and apply the primary jurisdiction doctrine rather than reaching a decision on whether HFCS can be used as an ingredient in food and beverages labeled natural. A federal agency specializing in food and beverage labeling is better equipped to handle issues of label reform than the judiciary.

The FDA, for the previously discussed reasons of implied preemption and primary jurisdiction, possesses the power to regulate the usage of the term 'natural' on food and beverage labels. States do possess some power in this field, but this power is merely supplemental power; used to create additional means to enforce the national policy set by the FDA or regulate areas, like local restaurant nutritional disclosure requirements, purposefully left open by the FDCA. Under the FDCA, states can still protect their citizens' health and safety by allowing for common law enforcement against adulterated or misbranded food and beverages. Private citizens, however, may not use these state common law remedies to create or alter established federal definitions or regulations. The judiciary cannot use these claims to change the FDA's policy on the usage of HFCS corn syrup as an ingredient in food and beverages labeled as natural. The tort system is intended to compensate those wronged or force other wrongdoers to pay the social costs of their activities. Allowing state tort claims to alter FDA policy statements – stances relied upon for several years by manufacturers – is in effect punishing manufacturers for following federal law and allowing judges to turn thoroughly vetted, carefully crafted Congressional into confusing piecemeal. State tort claims must not be allowed to interfere with the strong federal interest in allowing a federal agency to create its own policy and regulation, especially when the duty underlying the state tort claim involves the relationship between the manufacturer and the federal agency.¹²³

III. THE FDA SHOULD PROHIBIT HIGH FRUCTOSE CORN SYRUP IN FOOD AND BEVERAGES LABELED 'NATURAL'

The FDA must create a firm, unassailable answer to the question of whether HFCS can be included as an ingredient in food and beverages brandishing the label phrase 'natural.' The 'natural' food

122. See Linda Bren, FDA Science: Protecting America's Health, FDA Consumer, March-April 2003, available at http://findarticles.com/p/articles/mi_m1370/is_2_37/ai_991480911.

123. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

and beverage market already features thousands of products, and is growing rapidly. Manufacturers have used HFCS liberally as a sweetener in almost every type of food and beverage imaginable since the mid-1970's, including those labeled 'natural,' but health and consumer advocates recently began to tout the detrimental effects of HFCS consumption on health. Consumers often purchase these 'natural' products under the belief the product conjures some sort of health benefit. The FDA, charged with regulating the vast majority of products labeled 'natural' must take action to correct consumer misconceptions and prevent unnecessary controversy – while carefully avoiding the typical pitfalls surrounding any attempt to create a new labeling regulation. Ultimately, the FDA must reach a firm regulatory conclusion that HFCS cannot be used as an ingredient on food and beverages labeled 'natural.'

A. Current Trends and FDA Regulation of the Phrase 'Natural' on Food and Beverage Labels

A consumer walking into any supermarket will find a dizzying array of products sporting labels claiming 'natural.' Recent reports have, in fact, suggested at least 55,000 products use the word natural on their label.¹²⁴ The sale of 'natural' food and beverages far outpaced the sale of food and beverages labeled 'organic,' with estimated 2008 sales of \$22.3 billion compared to \$4.9 billion, respectively.¹²⁵ The sales figures for 'natural' represent a ten percent increase over 2007 sales and a thirty-seven percent increase from 2004 sales.¹²⁶ Sales for 'natural' labeled food and beverages are predicted to continue to increase even further while sale of organic labeled food and beverages appears to be leveling off.¹²⁷

124. Brandweek.com, 'Natural' Beats 'Organic' in Food Sales, http://www.brandweek.com/bw/content_display/news-and-features/green-marketing/e31c36b1b7ff4e76c1d373280605794dc0 [hereinafter *Natural Beats Organic*] (last visited Sept. 21, 2009).

125. *Id.* Other studies do indicate different sales figures and illustrate the total amount of sales for the 'natural' and 'organic' labels can fluctuate greatly depending on the types of products included. See Food Marketing Institute, *Natural and Organic Sales* (2007), available at http://www.fmi.org/media/bg/natural_organic_foods.pdf (totaling 2006 sales of 'organic' labeled food and beverages at \$16.9 billion); see also Meredith Niles, *New Data Show 2008 Organic Sales Will Reach \$32.9 Billion*, GRIST, Sept. 11, 2008, available at <http://www.grist.org/article/the-organic-times-are-a-changin> (grouping 'natural' and 'organic' food sales together and finding 2008 combined sales projected to reach \$32.9 billion).

126. *Natural Beats Organic*, *supra* note 123.

127. *Id.*

Consumers generally perceive 'natural' food and beverages as healthier than other products, but the 'natural' label often confers no health benefits and in some cases may even be less healthy than food and beverages not bearing such a label.¹²⁸ The FDA's current policy on the use of the word 'natural' is not to restrict its use except for banning the addition of any added color, artificial or synthetic substances not normally expected to be in the food or beverage.¹²⁹ This somewhat amorphous definition means manufacturers can easily craft their products to fit within the existing labeling regulations. However, this creative process often comes at the expense of consumers - albeit, consumers being misled by their own perceptions. For example, both fat and salt are naturally occurring substances, meaning inherently unhealthy food and beverages, like potato chips, can be labeled 'natural.'¹³⁰ These 'natural' products often contain much greater amounts of fat and salt than their 'un-natural' counterparts, completely undermining one of the main reasons consumers choose to purchase the 'natural' product.¹³¹ The FDA itself admits consumers thinking 'natural' implies health benefits are confused by the term, but the FDA also explains 'natural' has a carefully considered, and currently settled regulatory meaning.¹³² Despite this confusion, the FDA has denied requests to create a formal definition citing a lack of resources and more pressing concerns in areas like food safety.¹³³

B. History and Controversy of High Fructose Corn Syrup

Adding to the confusion over the label use of 'natural' is the FDA's current stance on whether products incorporating HFCS can be labeled 'natural.' Scientists first created HFCS in 1957, and re-

128. See What Natural Really Means, *supra* note 7.

129. See 21 C.F.R. § 101.22 (1993) (created during the 1993 passage of the NLEA).

130. What Natural Really Means, *supra* note 7.

131. *Id.*

132. United States Food and Drug Administration, Food Label Helps Consumers Make Healthier Choices, <http://www.fda.gov/consumer/updates/foodlabels032708.html> (last visited Sept. 23, 2009).

133. See Lorraine Heller, 'Natural' Will Remain Undefined Says FDA, FOOD NAVIGATOR-USA, Jan. 4, 2008, available at <http://www.foodnavigator-usa.com/Financial-Industry/Natural-will-remain-undefined-says-FDA>; see also Lorraine Heller, HFCS is Not 'Natural', Says FDA, FOOD NAVIGATOR-USA, Apr. 2, 2008, available at <http://www.foodnavigator-usa.com/Financial-Industry/HFCS-is-not-natural-says-FDA> [hereinafter *HFCS Not Natural*] (mentioning petitions from Sara Lee and the Sugar Refiners).

fined the manufacturing process to reach its present day efficiency in the 1970's.¹³⁴ HFCS, aided by exceptionally favorable government policy, quickly became the sweetener of choice for American food and beverage manufacturers.¹³⁵ HFCS provides certain advantages to food and beverage manufacturers: it is sweeter and easier to mix than sugar; acts as a preservative and can extend product shelf life; and is more economical to purchase and transport.¹³⁶ More and more products began to take advantage of these benefits and the average American's yearly HFCS consumption increased every year until a 1998 peak of about sixty pounds per person.¹³⁷ Today, Americans consume more HFCS than almost any other country, amounting to about forty-two pounds per person per year.¹³⁸ One in ten products ingested by Americans contains HFCS as an ingredient; including foods as unexpected as hamburger buns and 'healthy' granola bars.¹³⁹

Doctors, scientists, and dieticians recently began linking HFCS with America's ever-increasing obesity and health problems.¹⁴⁰ Regu-

134. High Fructose Corn Syrup, <http://www.oukoshers.org/index.php/common/article/2489> (last visited Nov. 19, 2009); Linda Joyce Forristal, *The Murky World of High-Fructose Corn Syrup*, WISE TRADITIONS IN FOOD, FARMING, AND THE HEALING ARTS (Fall 2001), available at <http://www.westonaprice.org/motherlinda/cornsyrup.html> [hereinafter *Murky World*].

135. Archer Daniels Midland (ADM), one of the pioneering producers of HFCS, and also one of America's largest corn producers, was arguably one of the most politically connected companies in the 1970's and 1980's. Then CEO Dwayne Andreas was considered a good friend of Ronald Reagan. Soon after taking office, then president Reagan instituted a harsh sugar import quota, which greatly increased the price of sugar and forced major soft drink manufacturers to switch to HFCS as a sweetener. Today ADM controls about one-third of the domestic HFCS market, which brings ADM about \$529 million in yearly profit. See Tom Philpott, *The Story Behind the Corn Industry's Annoying Ad Blitz*, GRIST, Oct. 17, 2008 <http://www.grist.org/article/the-bitter-with-the-sweet/> [hereinafter *Ad Blitz*] (last visited Nov. 19, 2009).

136. *Murky World*, *supra* note 134; Guess What's Lurking in Your Food, <http://www.highfructosecornsyrup.org/2009/02/guess-whats-lurking-in-your-food.html> (last visited Nov. 19, 2009) (explaining when coke switched to HFCS in 1983 it is estimated they saved \$750 million).

137. *Ad Blitz*, *supra* note 135.

138. Karen Gaudette, *Is High-Fructose Corn Syrup Making Us Fat?*, SEATTLE TIMES, Feb. 7, 2007, available at http://seattletimes.nwsourc.com/html/foodwine/2003559833_syrup07.html.

139. *Ad Blitz*, *supra* note 135; Dr. Lonnie Lowry, *Thank You for Guzzling Corn Syrup*, TMUSCLE, http://www.tmuscle.com/free_online_article/sports_body_training_performance_nutrition/thank_you_for_guzzling_corn_syrup [hereinafter *Guzzling Corn Syrup*] (last visited Nov. 19, 2009).

140. See generally George A. Bray et al., *Consumption of High-Fructose Corn Syrup in Beverages May Play a Role in the Epidemic of Obesity*, 79 AM. J. CLINICAL NUTRITION

larly consuming products containing high amounts of HFCS can be a cause of type two diabetes, high blood pressure, and coronary artery disease.¹⁴¹ Studies also show high amounts of ingested HFCS can lead to leptin resistance.¹⁴² Leptin is a hormone that helps the body regulate hunger and energy expenditure.¹⁴³ When a body becomes resistant to leptin, rapid weight gain and obesity quickly follow.¹⁴⁴ Increased fructose consumption also leads to disruption of cell functioning and aging.¹⁴⁵ Some critics point out the widespread use of HFCS may be damaging to the environment as well as consumers' health.¹⁴⁶

The supposed deleterious health effects and laboratory origins of HFCS have led many to argue food and beverages using HFCS as an ingredient should not be allowed to use the word 'natural' on the label.¹⁴⁷ The Center for Science in the Public Interest (CSPI) fired the first salvo in the natural war against HFCS, threatening suit against manufacturers Kraft and Cadbury Schweppes. CSPI alleged fraud because Kraft and Cadbury Schweppes labeled their respective beverages, Capri Sun, and 7Up, as 'natural' despite ingredients prominently featuring, among other seemingly synthetic ingredi-

537, 537-43 (2004), available at <http://www.ajcn.org/cgi/content/full/79/4/537> [hereinafter *Consumption of HFCS*]; Carolyn Poirot, *High-Fructose Corn Syrup Fueling Obesity Epidemic, Doctors Say*, SEATTLE TIMES, Dec. 4, 2005, available at http://seattletimes.nwsourc.com/html/health/2002658491_healthsyryp04.html; but cf. Daniel Engber, *Dark Sugar: The Decline and Fall of High-Fructose Corn Syrup*, SLATE, April 28, 2009, available at <http://www.slate.com/id/2216796/> (noting the perceived detrimental effects of a diet containing large amounts of HFCS, but also finding those claims lacking hard evidence and nothing indicates HFCS is any more detrimental to health than normal sugar); *Ad Blitz*, *supra* note 135 (noting almost all studies on HFCS appear to be somewhat flawed based on the fact sources of funding typically come from biased sources like the Corn Refiners or the Sugar Refiners).

141. Katherine Zeratsky, *High-Fructose Corn Syrup: What are the Concerns?*, Nutrition and Healthy Eating, <http://www.mayoclinic.com/health/high-fructose-corn-syrup/an01588> (last visited Sept. 18, 2009).

142. *Consumption of HFCS*, *supra* note 139 at 538; Christine Gulifoy, *Fructose Sets Table for Weight Gain Without Warning*, GENETIC ENGINEERING AND BIOTECHNOLOGY NEWS, Oct. 16, 2008, available at <http://www.genengnews.com/news/bnitem.aspx?name=43618189> [hereinafter *Fructose Sets Table*].

143. *Fructose Sets Table*, *supra* note 141.

144. *Id.*

145. *Guzzling Corn Syrup*, *supra* note 138.

146. Eviana Hartman, *High-Fructose Corn Syrup: Not So Sweet for the Planet*, THE WASHINGTON POST, Mar. 9, 2008, available at <http://www.washingtonpost.com/wp-dyn/content/article/2008/03/06/AR2008030603294.html>.

147. HFSC Not Natural, *supra* note 132.

ents, HFCS.¹⁴⁸ Both companies recognized the potential negative publicity and damages were not worth the potential new sales created from the usage of the phrase 'natural,' and quickly agreed to remove the word 'natural' from their respective beverages' labels before the suits could move beyond the initial stages.¹⁴⁹

The Corn Refiners Association (CRA) recently began to push back against the negativity, launching an eighteen month campaign, costing between \$20-30 million, and targeting moms.¹⁵⁰ The campaign included a very intensive Internet presence.¹⁵¹ HFCS has also begun to garner some very unlikely defenders. Marion Nestle, a nutritionist and author of several food policy books and articles, says HFCS is undeserving of all the scrutiny.¹⁵² She says HFCS causes a similar effect on the human body as sugar, and a more likely culprit causing the decrease in American health is the widespread consumption of sweeteners in general.¹⁵³ CSPI recently stated, although

148. Press Release, Center for Science in the Public Interest, Kraft is Sued for Falsely Calling Capri Sun Drink "All Natural," Jan. 8, 2007, available at <http://www.cspinet.org/new/200701081.html>; Press Release, Center for Science in the Public Interest, CSPI to Sue Cadbury Schweppes Over "All Natural" 7UP, May 11, 2006, available at <http://www.cspinet.org/new/200605111.html>.

149. Meg Marco, *Capri Sun: High-Fructose Corn Syrup No Longer "Natural"*, THE CONSUMERIST, Jan. 23, 2007, available at <http://consumerist.com/consumer/capri-sun/highfructose-corn-syrup-no-longer-natural-230839.php>; Jessica Fraser, *7UP Drops "All Natural" Claim After CSPI Threatens Lawsuit*, NATURAL NEWS, Jan. 17, 2007, available at <http://www.naturalnews.com/021443.html>; see also *supra* note 38 and accompanying text.

150. *Ad Blitz*, *supra* note 135. The ads featured on www.sweetsurprise.com depict several outdoor scenarios. In several ads a child is offered an ice pop or fruit drink containing HFCS and their mother objects, with as much gusto as if their child was offered drugs. The snack offering mother then launches into a speech about how HFCS comes from corn so it is 'natural,' safe, and no more harmful than sugar. Newly informed, the first mother then gladly gives their child the HFCS-laden snack.

151. See The Facts about High Fructose Corn Syrup, www.sweetsurprise.com (last visited Sept. 27, 2009). The President of the Corn Refiners Association, charged with damage control duty, left the very first reader comment for an article slightly critical of HFCA. See *Ad Blitz*, *supra* note 135. Also, when entering a search on Google for high fructose corn syrup the featured advertisement at the top of the page is for www.sweetsurprise.com. See Google, High Fructose Corn Syrup, http://www.google.com/search?sourceid=navclient&aq=1h&oeq=high+f&ie=UTF-8&rlz=1T4GGIH_enUS264US265&q=high+fructose+corn+syrup (last visited Sept. 27, 2009).

152. See Lisa McLaughlin, *Is High-Fructose Corn Syrup Really Good for You?*, TIME, Sept. 17, 2008, available at <http://www.time.com/time/health/article/0,8599,1841910,00.html> [hereinafter *Is HFCS Good for You?*].

153. See *id.*; see also Melanie Warner, *A Sweetener with a Bad Rap*, NEW YORK TIMES, July 2, 2006, available at <http://www.nytimes.com/2006/07/02/business/>

it strongly maintains HFCS cannot be included in foods and beverages labeled 'natural', HFCS and sugar appear to be nutritionally similar.¹⁵⁴

Two recent statements by the FDA did nothing but add to the confusion. A website specializing in food and beverage issues submitted a request, through a FDA process which allows manufacturers with doubts on the usage of certain ingredients to request guidance, asking whether, under the current definitions, HFCS could be considered natural.¹⁵⁵ The FDA responded by stating the typical process used to produce HFCS "would not be consistent with our... policy regarding the use of the term 'natural.'"¹⁵⁶ This statement caused an immediate reaction from the powerful CRA.¹⁵⁷ Based on a different HFCS production process submitted by the Archer Daniels Midland Company (ADM), a prominent and outspoken CRA member, the FDA promptly (within three months) backtracked and reverted to its original stance that HFCS production fit under the current definition of 'natural.'¹⁵⁸

C. Methods for the FDA to Create More Stringent Requirements for the Appearance of 'Natural' on a Label

The recent lawsuits, coupled with widespread consumer confusion – acknowledged by even the FDA itself – indicate the FDA must meet its statutory mandate by taking action to settle the current controversy surrounding the use of HFCS as an ingredient in food and beverages labeled 'natural.' Congress passed the NLEA with the goal of educating consumers about misleading labels and also informing Americans about the connection between their health and the foods and beverages they purchase.¹⁵⁹ Creating easy to understand labels is a duty Congress clearly intended for the FDA. The

yourmoney/02syrup.html. *But see Guzzling Corn Syrup, supra* note 139 (explaining HFCS is metabolized differently than sugar).

154. *See Is HFCS Good for You?, supra* note 152.

155. *HFCS Not Natural, supra* note 133.

156. *Id.*

157. Laura Crowley, *HFCS is Natural, Says FDA in a Letter*, Food Navigator-USA, July 8, 2008, available at <http://www.foodnavigator-usa.com/Financial-Industry/HFCS-is-natural-says-FDA-in-a-letter> [hereinafter *HFCS is Natural*].

158. *Id.* *See also* Letter from Geraldine A. June, Supervisor FDA Product Evaluation and Labeling Team, to Audrae Erickson, President Corn Refiners Association, July 8, 2008, available at <http://www.corn.org/FDAdecision7-7-08.pdf> [hereinafter *HFCS Letter*].

159. *National Council for Improved Health v. Shalala*, 122 F.3d 878, 880 (10th Cir. 1997).

FDA also recognizes this important responsibility toward consumers, as Barbara Schneeman, Ph.D., Director of the FDA's Office of Nutrition, Labeling, and Dietary Supplements, recently explained, "the food label is one of the most valuable tools consumers have."¹⁶⁰ The FDA is also required to provide manufacturers with guidance to ensure food and beverage production practices fall within federal requirements.¹⁶¹ The FDA, by not crafting a firm answer to whether HFCS can be used as an ingredient in food and beverages labeled 'natural' is failing both of these tasks. However, a careful consideration of the optimal dedication of agency resources is necessary before the FDA chooses the best path to rectify this shortcoming.

The FDA previously attempted to stringently regulate 'natural' during the passage and implementation of the NLEA before ultimately settling on the current policy due to resource limitations.¹⁶² The FDA regulates an unfathomably large amount of products, which account for about \$1 trillion in consumer spending every year, or twenty-five cents of every consumer dollar spent in America.¹⁶³ Despite this wide swath of responsibility, the FDA is fre-

160. U.S. Food and Drug Administration, *Food Label Helps Consumers Make Healthier Choices*, <http://www.fda.gov/forconsumers/consumerupdates/ucm094536.htm> (last visited Sept. 27, 2009).

161. 21 C.F.R. § 10.85 (2009).

162. Food Labeling, *supra* note 42. See Proposed Trade Regulation Rule; explanation of Proceeding and Analysis: Statement of Issues; Opportunity to Submit Data, Views or Arguments, 39 Fed. Reg. 39,842, 39,844 (proposed Nov. 11, 1974) (to be codified at 16 C.F.R. pt. 437). Proposed Trade Regulation Rule 40 Fed. Reg. 23,086, 23,090 (proposed May 28, 1975) (to be codified at 16 C.F.R. pt. 437). Final Notice Regarding Proposed Trade Regulation Rule, 41 Fed. Reg. 8,980, 8,982 (Mar. 2, 1976) (to be codified at 16 C.F.R. pt. 437). The FTC ultimately terminated the rulemaking in 1983 because of the difficulty in defining 'natural' in manner that would be meaningful to a consumer in the wide variety of situations that manufacturers use the term 'natural.' See Termination of Proposed Trade Regulation; Rule on Food Advertising, 48 Fed. Reg. 23,270 (proposed May 24, 1983) (to be codified at 16 C.F.R. 437) (explaining consumers do not expect the same thing from 'natural' apples that they do from 'natural' ice cream). The FTC ultimately concluded to concentrate their resources on "more serious consumer protection problems. *Id.*

163. Jane E. Henney, M.D., Comm's of Food and Drugs, U.S. Food and Drug Admin., Remarks at the Ass'n of Am. Medical Colleges Council of Teaching Hospitals Spring Meeting (May 11, 2000) (transcript available at <http://www.fda.gov/NewsEvents/Speeches/ucm054216.htm>). See also Nicole Gavotte and Duane Stafford, *Obama Budget Boosts Food-Safety with Record FDA Hike* (update2), bloomberg.com, May 7, 2009, <http://www.bloomberg.com/apps/news?pid=20601202&sid=aqJqIXskQm4A> (last visited Sep. 26, 2009).

quently described as “chronically underfunded.”¹⁶⁴ Members of Congress referred to recent FDA budget as “grossly inadequate” to meet the extensive demands placed upon the agency.¹⁶⁵ The FDA 2009 budget saw only a \$130 million increase from 2008; all of this new money is already earmarked for issues of food protection, medical device safety, and administrative costs.¹⁶⁶ President Obama has indicated renewed commitment to the FDA.¹⁶⁷ However, President Obama and Congress dedicated no money in the American and Reinvestment Act specifically to the FDA.¹⁶⁸ Further, the majority of this newfound presidential commitment revolves around a renewed vigor to strengthen America’s food safety, especially in light of the recent tainted peanut and pistachio- fueled salmonella scares.¹⁶⁹ Despite these limitations, the FDA cannot continue with the current weak and waffling policy on HFCS. The FDA must follow the Congressional intent behind the passage of the NLEA and remove the ambiguity surrounding whether HFCS can be considered a ‘natural’ ingredient.

Both Sara Lee Corporation and the Sugar Refiners of America recently petitioned the FDA to harmonize its definition of natural with that of the USDA in order to maintain consistency across federal agencies regarding the usage of ‘natural.’¹⁷⁰ The USDA cur-

164. Mary Mosquera, *Lawmakers Say Budget Underfunds FDA*, FEDERAL COMPUTER WEEK, Feb. 5, 2008, available at <http://fcw.com/articles/2008/02/05/lawmakers-say-budget-underfunds-fda.aspx>.

165. *Id.*; see also Lisa Richwine, *Obama Picks FDA Chief, Starts Food Safety Panel*, REUTERS, March 14, 2009, available at <http://www.reuters.com/article/idUSTRE52D0KJ20090314> [hereinafter *Obama Picks FDA Chief*].

166. U.S. Food and Drug Admin., 2009 FDA Budget Summary Fact Sheet (2009), <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/2009FDABudgetSummary/ucm111422.htm> (last visited Nov. 23, 2009).

167. See Jeremy P. Jacobs, *Obama Vows to Improve the FDA*, THE HILL, March 14, 2009, <http://thehill.com/leading-the-news/obama-vows-to-improve-the-fda-2009-03-14.html> [hereinafter *Obama Vows to Improve the FDA*] (last visited Sept. 26, 2009). See also *Obama Picks FDA Chief*, *supra* note 165.

168. See American Recovery and Reinvestment Act of 2009, H-R-1, 111th Cong. (2009) (enacted), available at http://www.whitehouse.gov/the_press_office/ARRA_public_review.

169. See *Obama Vows to Improve the FDA*, *supra* note 167; *Obama Picks FDA Chief*, *supra* note 165.

170. See A. Bryan Endres, *United States Food Law Update: Labeling Controversies, Biotechnology Litigation, and the Safety of Imported Food*, 3 J. FOOD L. & POL’Y 253, 269-270 (2007); Sara Lee Corp., Citizen Petition Requesting FDA to Develop Requirements for the Use of the Term “Natural” Consistent with the USDA’s Food Safety and Inspection Service (Apr. 9, 2007), available at www.fda.gov/ohrms/dockets/dockets/07p0147/07p-0147-ack0001-vol1.pdf; *HFCS Not Natural*, *supra* note 132.

rently regulates 'natural' labeling claims on meat and poultry.¹⁷¹ These policies are substantially similar to the FDA policy, but impose an additional requirement that meat or poultry be 'minimally processed.'¹⁷² However, the USDA regulates a significantly smaller variety of products than the FDA. In fact, very few USDA products even feature multiple ingredients,¹⁷³ and almost no USDA product uses HFCS as an ingredient, so the FDA cannot easily use the USDA's 'natural' definition to solve the current problem.¹⁷⁴

A rulemaking procedure to define 'natural,' however, is not the answer either because any agency attempting to formulate a standard regulatory definition for a broad category of food conjures upon itself an enormous crunch of agency resources – both monetary and personnel.¹⁷⁵ The USDA encountered this problem first hand when it attempted to create formal regulations for the label usage of 'organic.' Congress first charged the USDA with creating a set of organic farming standards with the passage of the Organic Foods Production Act as part of the 1990 Farm Bill.¹⁷⁶ The USDA's initial attempt to craft a definition was met with the most comments of any regulation in USDA history: over 275,000.¹⁷⁷ More than ten years passed before the USDA issued a final rule in 2002.¹⁷⁸ Both 'organic' and 'natural' have similar markets and are used on millions

171. USDA Food Safety and Inspection Service, Meat and Poultry Labeling Terms, http://www.fsis.usda.gov/Fact_Sheets/Meat_&_Poultry_Labeling_Terms/index.asp (last visited Sept. 27, 2009).

172. *Id.*

173. *See id.* (listing the different USDA label requirements for meat and poultry).

174. The USDA is currently in the midst of a rulemaking to remove specific ingredients from the definition of 'natural' and the FDA may eventually be able to use this rulemaking as a loose template for an alternative method to regulate HFCS without having to undertake a massive full blown 'natural' definition. *See* Product Labeling Definition of the Term "Natural", 71 Fed. Reg. 233, 70, 504-04 (Dec. 5, 2008), available at <http://www.thefederalregister.com/d.p/2006-12-05-06-9546>.

175. *See generally* Lisa Schultz Bressman, *Procedures as Politics in Administrative Law*, 107 COLUM. L. REV. 1749 (2007) (describing traditional procedures and obstacles an agency faces when undergoing a rulemaking); Mark Seidenfeld, *A Table of Requirements for Federal Administrative Rulemaking*, 27 FLA. ST. U. L. REV. 533, 36-37 (2000) (summarizing the exact requirements every agency must fulfill during a rulemaking).

176. Organic Foods Production Act of 1990, Pub. L. 101-624, (codified at 7 USC § 6501-6522 2000).

177. Michelle T. Friedland, *You Call That Organic? – The USDA's Misleading Food Regulations*, 13 N.Y.U. ENVTL. L.J. 379, 383 (2005).

178. USDA Economic Research Service, Final Organic Rule Governs Marketing and Production, <http://www.ers.usda.gov/features/organic/> (last visited Sept. 27, 2009).

of products, so the FDA can reasonably infer from the USDA's tribulations what an attempt to define the term 'natural' might cost. The FDA, currently spread thin due to a lack of resources, and charged by the new administration with shifting their mission and majority of new resources heavily towards food safety, cannot afford to waste twelve years of precious resources and personnel on formally defining 'natural.'¹⁷⁹ Undertaking a formal – or even informal notice and comment – rulemaking to define the usage of every food and beverage labeled 'natural' will exacerbate the current resource problems frequently cited by the FDA.¹⁸⁰

The FDA also cannot merely issue another advisory opinion or guidance document on whether HFCS is 'natural.' The FDA flip-flopped their stance twice in a matter of months, weakening the current policy and creating uncertainty.¹⁸¹ Manufacturers need the FDA to take a reliable stance to avoid multi-million dollar lawsuits despite acting in good faith and ostensibly following FDA regulations.

179. Due to the massively growing 'natural' label food market and the potential for controversy and confusion surrounding the meaning of 'natural' the FDA will eventually need to find resources to create a formal rule for natural, and this may very well happen in the near future if the current administration keeps its promise to continue to raise FDA funding. Creating a formal definition of 'natural' is even more important with the recent focus on using the legislative process to quell America's growing obesity problem placing an emphasis the connection between food and health and leading towards the creation of ideas like New York's potential new 'obesity tax' on soda. See David Leonhardt, *Soda Tax a Tempting Target*, NEW YORK TIMES, May 19, 2009, available at http://www.nytimes.com/2009/05/20/business/economy/20leonhardt.html?_r=2&ref=business. See also generally Benjamin Montgomery, *The American Obesity Epidemic: Why the U.S. Government Must Attack the Critical Problems of Overweight and Obesity Through Legislation*, 4 J. HEALTH & BIOMEDICAL L. 375 (2008) (putting forth various suggestion on how government can use legislation to curb obesity and other self-induced health problems); David G. Yosifon, *Legal Theoretic Inadequacy and Obesity Epidemic Analysis*, 15 GEO. MASON L. REV. 681 (2008) (explaining the effects of laws on human behaviors, with particular attention paid to the affect on obesity creating habits).

180. See Seidenfeld, *supra* note 175.

181. In response to a 2006 petition by the Sugar Refiners Association the FDA cites their longstanding policy on the usage of HFCS in natural. See Letter from Audrae Erickson, President, Corn Refiners Association, to FDA Dockets Management Branch (Nov. 14, 2006), available at <http://www.fda.gov/ohrms/DOCKETS/dockets/06p0094/06p-0094-c000004-vol1.pdf>. The FDA reversed this longtime stance with a guidance letter written in April 2008 explaining HFCS may not be considered natural. See *HFSC Not Natural*, *supra* note 132. But then, after a meeting with an Archer Daniels Midland executive, the FDA quickly reversed back to their original position within a few months. See *HFCS is Natural*, *supra* note 157; *HFCS Letter*, *supra* note 158.

Some scholars also criticize the FDA for using guidance documents to create “de facto rules” that avoid procedural safeguards.¹⁸²

The FDA need not undergo a complex and lengthy rulemaking process to create a formal definition of ‘natural’ to solve this HFCS controversy, but can still provide an optimal solution by conducting an informal notice and comment rulemaking to determine whether HFCS is considered synthetic or artificial, regardless of the process used for creation. Finding HFCS synthetic precludes it from being used as an ingredient in products labeled ‘natural’ and avoids the need to create a regulatory definition for the entire class of ‘natural’ products. Determining whether HFCS is synthetic is also more of a marketing issue for labeling usage and can then avoid the loaded question of whether the consumption of HFCS is truly detrimental to ones’ health. This means many comments can be avoided, greatly truncating the notice and comment process. Choosing this small-scale regulation path will ultimately prove optimal because it is the quickest and most budget conscious method to provide a firm answer and obviate the potential for ample controversy in a hot topic area that the FDA is mandated to govern.

D. The FDA Needs to Create a Regulation Banning the Use of High Fructose Corn Syrup in Food and Beverages Labeled ‘Natural’

Any decision the FDA makes on the usage of HFCS must take into account both the scientific origins of HFCS as well as consumers’ expectations for a ‘natural’ product. The FDA’s current policy on ‘natural’ is not based on a traditional dictionary definition of the words natural and synthetic,¹⁸³ but the majority of Americans nevertheless think food and beverages labeled ‘natural’ are healthier products, or at the very least do not contain ingredients formulated through a multiple-step laboratory process.¹⁸⁴ Not only is HFCS not found in nature, but the HFCS production uses chemical processes and laboratory created enzymes, or as described in *Holk*: “enzymatically catalyzed chemical reactions in factories.”¹⁸⁵

182. Lars Noah, *The Little Agency that Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 905 (2008).

183. *Food Labeling*, *supra* note 42. Even dictionaries have a hard time defining ‘natural.’ Dictionary.com lists 38 separate definitions, <http://dictionary.reference.com/browse/natural?qsrc=2888> (last visited Mar. 30, 2010), and Merriam Webster lists 15 <http://www.merriam-webster.com/dictionary/natural> (last visited Mar. 30, 2010).

184. See *What Natural Really Means*, *supra* note 7.

185. *Holk v. Snapple Beverage Corp.*, 574 F.Supp. 2d 447, 449 (D. N.J. 2008).

The modern HFCS production method starts with the fructose found in corn.¹⁸⁶ HFCS manufactures begin the production process by treating cornstarch with a purified enzyme, alpha-amylase, producing shorter chains of sugar called polysaccharides.¹⁸⁷ Then another enzyme, glucoamylase, breaks the polysaccharides down even further, into glucose. A third enzyme, glucose-isomerase is then used to convert the glucose into a mixture of about forty-two percent fructose and between fifty and fifty-two percent glucose, with some other sugars mixed in. Glucose-isomerase is expensive, so unlike the first two enzymes which are simply added to the mixture, glucose-isomerase is packed into columns with a synthetic fixing agent, and the sugar mixture is passed over it. The glucose-isomerase is reused until it loses its activity. Two other steps, involving a liquid chromatography and back-blending are used to convert the forty-two percent fructose mixture into industry standard HFCS.

CRA argues none of these 'synthetic fixing agents' actually comes into contact with the soon-to-be HFCS, and the artificial agents are washed away before the end product is created.¹⁸⁸ The mere presence, and requirement, of these artificial fixing agents, is however, mocking the FDA's current policy on 'natural.' Clearly a synthetic ingredient is being added and included in the food, but HFCS escapes scrutiny by removing or washing the synthetic ingredient from the end product.¹⁸⁹ The FDA needs to close this washing process loop hole.

The FDA also admits HFCS can be created from different processes, one method falling within the current 'natural' usage policy and other methods falling outside that policy.¹⁹⁰ The FDA does not have the resources to determine which process a manufacture used to create the HFCS that ultimately ends up in food or beverages labeled natural.¹⁹¹ If the FDA itself cannot easily identify whether a particular HFCS production process is the process falling within the 'natural' definition, consumers stand little or no chance. Therefore, in order to live up to the Congressional mandates of the FDCA and

186. *Murky World*, *supra* note 134.

187. *Holk*, 574 F. Supp. 2d at 450; *Murky World*, *supra* note 134.

188. *HFCS Letter*, *supra* note 158.

189. *See id.*

190. *See id.*

191. *See* FDA, Guide to Inspection of Manufacturers of Miscellaneous Food Products - Volume II, http://www.fda.gov/ora/Inspect_ref/igs/foodsp2a.html (last visited Sept. 16, 2009) (listing FDA inspection techniques and requirements); *see also Obama Picks FDA Chief*, *supra* note 165 (explaining the FDA only possesses the resources to inspect 7,000 out of approximately 150,000 food-processing plants).

NLEA, based on the science behind the production of HFCS, and consumer perceptions, the FDA must undertake a rulemaking, and after considering all the evidence, issue formal regulations declaring HFCS 'synthetic' or artificial and ineligible for use in food and beverages labeled 'natural.'

V. CONCLUSION

Americans today are facing a health crisis and are turning to the food they eat to rectify this problem. These same Americans are increasingly using food and beverage labels as a means to achieve their goals of improved health. Consumers put great stock in the supposed health benefits of food and beverages labeled 'natural' without knowing the true contents of these same 'natural' products. The FDA, however, has a statutory mandate to educate consumers about the relation between the food they purchase and its label, and also protect against misleading labeling. Congress also gave the FDA the express power to create, and also modify, federally standardized labeling requirements. Well-settled standardized labels benefit both consumers and manufacturers alike. Nonetheless, the administrative world is not perfect, and the FDA must make tough choices on how to best achieve its mandates and still balance the often competing interests of manufacturers and consumers.

Consumers, frustrated with the results of this balancing act, recently attempted to use state tort law to challenge the FDA's flimsy definition of 'natural.' These suits ignore the FDA's carefully considered policy choices relating to the phrase 'natural,' as well as Congress' intention to give the FDA the sole power to make these choices. Holk, properly recognizing the ultimate preemptory power of both FDA regulations and the FDCA, dismissed the claim by its plaintiff. Lockwood failed to realize the myriad of reasons why its plaintiff's claim should be dismissed due to implied preemption. Congressional intent through the passage of the FDCA and NLEA, combined with the FDA's regulations and policy statements on the use of the term 'natural' - even if considered by some to be inadequate or inconsistent - preempts state laws. Judges should also not attempt to color in potential gray areas involving the definition of 'natural' and the usage of HFCS. They should instead defer to agency expertise and apply the doctrine of primary jurisdiction. In the future, similar suits should be dismissed for these preemptory reasons, and in the alternative due to the doctrine of primary jurisdiction.

A tempest of controversy is brewing around the usage of HFCS, and many parties are claiming HFCS just is not 'natural.' The FDA needs to flex its ultimate decision making muscle and create a firm regulation pertaining to the usage of HFCS. The FDA can quell any controversy or confusion by finding HFCS synthetic and thus not allowed in food and beverages wishing to use the labeling term 'natural.' In the end, the word corn is truly the only part of High Fructose Corn Syrup that fits any definition of 'natural.'