
Naturally Misleading: FDA's Unwillingness To Define "Natural" and the Quest for GMO Transparency Through State Mandatory Labeling Initiatives

*"Today is a significant victory in the fight to know what is in the food we eat and what we feed to our families Connecticut will be the first state in the nation to pass a GMO labeling law and this sets the stage for other states to join the growing movement to give consumers more choices."*¹

I. INTRODUCTION

Consumers across the country cannot help but notice that the natural food industry has caught onto their preferences for "all natural" food.² Natural food has developed into a thirty-seven billion dollar per year industry in response to consumers' attraction to "all natural" products.³ A robust segment of the "all natural" trend are the anti-genetically modified organisms supporters.⁴

1. See Press Release, Dannel P. Malloy, Governor of Conn., Gov. Malloy and Legislative Leaders Announce Agreement on GMO Labeling Legislation (June 1, 2013), available at <http://www.governor.ct.gov/malloy/cwp/view.asp?Q=525816&>, archived at <http://perma.cc/PBC3-XXPX> (commenting in response to passing GMO labeling bill). Connecticut's Speaker of the House Brendan Sharkey stated these words in his approval of the GMO labeling legislation. See *id.*

2. See Patrick Hunt, *A Sneak Peek at This Year's Eco Pulse Insights: Survey Finds 'Grown in the USA' Surging in Popularity, Right Behind 'Natural' and 'Organic.'* SHELTON GRP. (June 23, 2011), <http://sheltongrp.com/a-sneak-peek-at-this-years-eco-pulse-insights/>, archived at <http://perma.cc/3XQU-CGC4> (reporting study results). According to a study done by the Shelton Group, a marketing and advertising agency focused on sustainability, twenty-five percent of consumers said the best description to read on a food label is "all natural" or "100 percent natural," finishing ahead of "100% organic" and "grown in the USA." *Id.*; see also Deena Shanker, *Is the 'Natural' Label 100 Percent Misleading?*, GRIST (Sept. 6, 2012), <http://grist.org/food/is-the-natural-label-100-percent-misleading/>, archived at <http://perma.cc/JCT8-CK8Z> (summarizing Shelton Group study results). A recent study reports that not only do consumers like to see the food label read "all natural," but on their last five trips to the grocery store, sixty-one percent of consumers bought a product labeled "natural" or "organic" and twenty-nine percent bought one of these products on all five trips. See *Food Labeling Poll*, GREENERCHOICES 4 (July 11, 2007), http://greenerchoices.org/pdf/Food%20Labeling%20Poll-final_rev.pdf, archived at <http://perma.cc/HJK6-ZEQU> (summarizing poll results).

3. See Correy Stephenson, *Washington Plaintiffs Suing Over 'All Natural' Claims on the Rise*, LEGALNEWS.COM (Apr. 9, 2012), <http://www.legalnews.com/detroit/1273459>, archived at <http://perma.cc/3ABS-HF82> (noting companies realize consumers believe "natural" products healthier than other products); see also Natural Foods Merchandiser, *NFM Market Overview 2012: Natural Stays on Perennial Path to Growth*, NEWHOPE360 (May 29, 2012), <http://newhope360.com/nfm-market-overview/nfm-market-overview-2012-natural-stays-perennial-path-growth>, archived at <http://perma.cc/V8QE-2DRW> (explaining growth of natural food industry).

4. See Emily Swanson, *GMO Poll Finds Huge Majority Say Foods Should Be Labeled*, HUFFINGTON POST (Mar. 4, 2013), http://www.huffingtonpost.com/2013/03/04/gmo-poll_n_2807595.html, archived at <http://perma.cc/B2YE-54BS> (identifying large group favoring GMO labeling). According to a YouGov poll,

Genetically modified organisms (GMOs) are plants or animals that are created by genetic engineering (GE)—combining deoxyribonucleic acid (DNA) from different species to create combinations that cannot occur in nature.⁵ Anti-GMO advocates believe consumers have a right to know what is in the food products they are purchasing, including whether those products contain GMOs.⁶

GMO critics are taking their concerns to the state and federal legislatures.⁷ Currently, thirty-seven states are organizing mandatory GMO labeling initiatives, including New York, Maryland, and Massachusetts.⁸ In June 2013, Connecticut and Maine were the first two states to pass GMO-labeling bills, requiring sellers and farmers of genetically modified foods to label their products as such.⁹ Additionally, consumers allege products containing GMO ingredients cannot be considered “natural” and are filing class action lawsuits against food companies who continue to label these products “natural.”¹⁰ These lawsuits can be filed with such frequency because the United States Food and Drug Administration (FDA) has not issued a formal definition of “natural.”¹¹

eighty-two percent of respondents believe that foods containing GMOs should be labeled. *See id.*

5. *See What Is GMO?*, NON-GMO PROJECT, www.nongmoproject.org/learn-more/what-is-gmo/ (last visited Oct. 25, 2013), archived at <http://perma.cc/5HJ7-KU4V> (defining GMOs).

6. *See* Neil D. Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*, 6 *DRAKE J. AGRIC. L.* 81, 96 (2001) (acknowledging consumers' right-to-know arguments as central issue); Carl R. Galant, Comment, *Labeling Limbo: Why Genetically Modified Foods Continue To Duck Mandatory Disclosure*, 42 *HOUS. L. REV.* 125, 149 (2005) (explaining consumers' right-to-know argument); Elton Robinson, *Connecticut Passes GMO Labeling Law—Sort Of*, *DELTA FARM PRESS* (June 10, 2013), <http://deltafarmpress.com/government/connecticut-passes-gmo-labeling-law-sort>, archived at <http://perma.cc/PWJ8-D4AW> (quoting Governor Malloy's comment Connecticut labeling bill ensures consumers' right to know).

7. *See Mandatory Labeling Efforts*, NON-GMO PROJECT, <http://www.nongmoproject.org/take-action/mandatory-labeling/> (last visited Mar. 8, 2014), archived at <http://perma.cc/3W8M-6NXZ> (summarizing mandatory GMO labeling efforts).

8. *See id.* (noting number of GMO initiatives in United States).

9. *See* Act of June 25, 2013, Pub. Act 13-183, 2013 Conn. Acts 777 (Reg. Sess.) (codified at scattered sections of CONN. GEN. STAT. ANN. § 21a). The Connecticut GMO labeling statute only becomes effective when four other states enact similar legislation. *Id.* at 781-82. One of the four states must border Connecticut, and the combined population of the northeastern states that enact GMO-labeling laws must total more than twenty million based on the 2010 census. *Id.*; *see also* Act of Jan. 12, 2014, ch. 436, 2013 Me. Laws 1237 (codified at ME. REV. STAT. ANN. tit. 22, §§ 2591-2596). In order for the Maine act to take effect similar legislation must be adopted in five contiguous states, including Maine. 2013 Me. Laws at 1238; *see also* Jacqueline Wattles, *Connecticut Still Alone on Passing GMO Labeling Bill*, *CTNEWSJUNKIE* (July 23, 2013), http://www.ctnewsjunkie.com/ctnj.php/archives/entry/connecticut_still_alone_on_passing_gmo_labeling_bill/, archived at <http://perma.cc/Z4D3-YPAX> (explaining Connecticut bill stipulations).

10. *See, e.g., In re Frito-Lay N. Am., Inc. All Natural Litig.*, No. 12-MD-2413(RRM)(RLM), 2013 WL 4647512, at *1 (E.D.N.Y. Aug. 29, 2013) (alleging various Frito-Lay products mislabeled “all natural” because of presence of GMOs); *Parker v. J.M. Smucker Co.*, No. C 13-0690 SC, 2013 WL 4516156, at *1 (N.D. Cal. Aug. 23, 2013) (arguing Crisco cooking oil not “all natural” because of GMO presence); *In re ConAgra Foods Inc.*, 908 F. Supp. 2d 1090, 1095 (C.D. Cal. 2012) (arguing Wesson cooking oils not “natural” because of presence of GMOs).

11. *See* Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms;

The battle for GMO transparency shows no signs of slowing down.¹² With the passage of the Connecticut and Maine GMO-labeling bills and the narrow loss of Proposition 37 in California, Massachusetts should introduce and pass its own GMO-labeling law.¹³ Legal hurdles abound with potential state and federal constitutional arguments, including the argument that a consumer's right to know what is in his or her food is not a valid reason to label food products.¹⁴ Lawmakers, however, have shown support for mandatory labeling in response to numerous advocacy groups who argue foods should be labeled to reflect consumers' concerns.¹⁵

The FDA should also define the word "natural."¹⁶ A formal definition of "natural" could provide guidance to the judicial system to help resolve the vast number of class actions currently in the court system regarding "all natural" food labels.¹⁷ Consumers would also feel more informed and food producers would have specific guidelines as to whether or not they can put the coveted "all natural" label on their food products.¹⁸

This Note will analyze the surge in GMO labeling legislation and advocate for Massachusetts to pass its own GMO labeling bill.¹⁹ It also highlights the benefits of the FDA issuing an official definition of the term "natural" as

Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993) [hereinafter Food Labeling 1993] (explaining FDA's intention not to officially define "natural"); see also C. Kinnier Lastimosa, *Consumer Lawsuits Arising from "Green" Labeling Claims*, CONSUMER & PERS. RTS. LITIG., Spring 2012, at 6 (explaining uncertainty surrounding "natural").

12. See Stephenson, *supra* note 3 (explaining reasons for increase of cases alleging false advertising with use of "all natural"); see also *Mandatory Labeling Efforts*, *supra* note 7 (noting labeling initiatives exist in number of states).

13. See 2013 Conn. Acts 777 (stating Connecticut's GMO-labeling bill); 2013 Me. Laws 1237 (stating Maine's GMO-labeling bill); see also A. Bryan Endres et al., *United States Food Law Update: Shrouded by Election-Year Politics, State Initiatives and Private Lawsuits Fill in the Gaps Created by Congressional and Agency Ossification*, 9 J. FOOD L. & POL'Y 99, 115-16 (2013) (summarizing Proposition 37). Proposition 37 was a balloting initiative that would have mandated labels for all products containing GMOs. *Id.* Voters failed to pass Proposition 37, with 48.6% voting "yes" and 51.4% voting "no." *Id.*

14. See Galant, *supra* note 6, at 149, 153-59 (summarizing constitutional arguments for GMO labeling); see also Hamilton, *supra* note 6, at 96 (explaining consumers' right-to-know argument).

15. See Endres et al., *supra* note 13, at 116-17 (noting fifty-five members of Congress signed petition demanding GMO labeling); see also Citizen Petition Before the U.S. FDA: Petition Seeking Mandatory Labeling for Genetically Engineered Foods at 13, Center for Food Safety v. Taylor (Oct. 11, 2012), available at <http://www.centerforfoodsafety.org/files/ge-labeling-petition-10-11-2011-final.pdf>, archived at <http://perma.cc/R7G7-ZF5G> [hereinafter Citizen Petition] (arguing for labeling requirement for information consumers find significant).

16. See Erik Benny, Essay, "Natural" Modifications: The FDA's Need To Promulgate an Official Definition of "Natural" That Includes Genetically Modified Organisms, 80 GEO. WASH. L. REV. 1504, 1507 (2012) (arguing FDA needs to issue formal definition of "natural").

17. See *id.* at 1514 (observing lack of definition increases number of cases, putting strain on judicial system).

18. See *id.* at 1514-18 (explaining lack of definition wastes judicial resources and harms consumers and companies).

19. See *infra* notes 153-56 (describing GMO labeling initiatives); *infra* Part III.B (advocating for Massachusetts to pass GMO labeling law).

related to GMOs.²⁰ Part II will first introduce the benefits and potential downfalls of GMOs as well as how GMOs are currently regulated in the United States.²¹ Part II will then analyze consumer concerns.²² Next, Part II will discuss United States GMO regulation.²³ Additionally, Part II will describe food-labeling regulation in the United States and the FDA's role, particularly its refusal to define "natural."²⁴ Part II will further analyze recent class actions regarding "all natural" labels.²⁵ Lastly, Part II will evaluate current GMO labeling legislation and address the potential legal hurdles.²⁶ Part III argues that the FDA should issue a formal definition of the word "natural" requiring that the product does not contain GMOs; and if this does not occur, then Massachusetts should join Connecticut and Maine by passing its own GMO labeling bill.²⁷

II. HISTORY

A. The Background of GMOs

Genetic engineering creates GMOs by merging DNA from different species to create unstable combinations of genes that cannot occur in nature.²⁸ GE food is defined as food that is derived from, or contains ingredients derived from, GMOs.²⁹ In 1994, the Flavr Savr Tomato became the first GE food product to complete the FDA voluntary consultation process and be approved for sale.³⁰ Currently, a significant portion of the U.S. food supply consists of GMOs, with as much as eighty percent of conventional processed food containing GMOs.³¹

20. See *infra* Part III.A (arguing FDA must define "natural").

21. See *infra* Parts II.A.1-2.

22. See *infra* Part II.B.

23. See *infra* Part II.C.

24. See *infra* Part II.D.

25. See *infra* Part II.D.2.

26. See *infra* Parts II.E-F.

27. See *infra* Parts III.A-B.

28. See *supra* note 5 and accompanying text (defining GMOs); *GMO Facts*, NON-GMO PROJECT, <http://www.nongmoproject.org/learn-more> (last visited Nov. 9, 2013), archived at <http://perma.cc/W46K-BMWM> (explaining GMOs).

29. See Citizen Petition, *supra* note 15, at 3 (defining GE food).

30. See Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 405-07 (1998) (describing Flavr Savr tomato and its creation process); Kelly A. Leggio, Comment, *Limitations on the Consumer's Right To Know: Settling the Debate over Labeling of Genetically Modified Foods in the United States*, 38 SAN DIEGO L. REV. 893, 905 n.58 (2001) (describing Flavr Savr tomato). Flavr Savr tomatoes were genetically engineered to stay on the vine longer, have a longer shelf life, remain firm, and improve taste. See Noah & Merrill, *supra*, at 405; Leggio, *supra*, at 905 n.58.

31. See *GMO Facts*, *supra* note 28 (highlighting frequent use of GMOs in conventional processed food). In 2012, GMO crops grew on about 420 million acres of land in twenty-eight countries. See CLIVE JAMES, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, BRIEF 44: GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2012, at 1 (2012), available at <http://www.isaaa.org/resources/publications/briefs/44/executivesummary/pdf/Brief%2044%20-%20Executive%20Summary%20-%20English.pdf>, archived at <http://perma.cc/F4UN-92UD> (explaining increase in GM crop acres). Products

Supporters of GE food production point to the numerous benefits GE foods have on our world's food supply.³²

1. *Benefits of Genetically Engineered Food*

Supporters of GMOs often cite three major benefits of genetically modified foods: agricultural yield and quality is increased; the environment is improved; and more food is available to help fight against malnourishment worldwide.³³ Crops can be modified to become pesticide resistant by inserting the genetic makeup of the protein that acts as a natural insecticide into the crop to create an internalized insecticide.³⁴ This allows fewer crops to be lost to pests and increases the crop yield.³⁵ Additionally, crops can be modified to be drought and disease resistant, further increasing agricultural benefits and creating economic benefits to both biotechnology seed manufacturers and farmers.³⁶ GE crops can also have positive environmental benefits by creating less of a need to spray pesticides into the environment, which also prevents chemical run-off into water supplies.³⁷

Lastly, GE foods have been cited as a possible solution to world hunger and malnourishment.³⁸ Crops can be genetically modified to be more nutritious by inserting additional vitamins and minerals that were lacking in the original

made from corn, soybeans, canola, cottonseed, and sugar beets (known as the "Big Five") most frequently contain GMOs. See CTR. FOR FOOD SAFETY, TRUE FOOD SHOPPER'S GUIDE: HOW TO AVOID GENETICALLY ENGINEERED FOODS 3 (2013), http://www.centerforfoodsafety.org/files/shoppers-guide_final_24562.pdf, archived at <http://perma.cc/CRZ3-RM25> (recognizing at-risk ingredients).

32. See Sophia Kolehmainen, *Precaution Before Profits: An Overview of Issues in Genetically Engineered Food and Crops*, 20 VA. ENVTL. L.J. 267, 284-87 (2001) (outlining supposed benefits of GE food); Galant, *supra* note 6, at 131-33 (summarizing benefits of GE foods).

33. See Kolehmainen, *supra* note 32, at 284-87 (summarizing benefits of genetically engineered food); Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2180-90 (2004) (explaining potential benefits of genetically modified plants and animals); Galant, *supra* note 6, at 131-32 (describing popularly cited benefits of genetic engineering).

34. See Mandel, *supra* note 33, at 2180-81 (explaining increased agricultural yield and benefits).

35. See Galant, *supra* note 6, at 131-32 (noting genetic engineering technology to create pesticide resistant crops). Approximately fourteen billion dollars worth of crops are lost each year in the United States due to plant pests. See Mandel, *supra* note 33, at 2180. For example, a study of a particular herbicide-tolerant soybean allowed for a total production cost-reduction of six percent. *Id.* at 2181. Also, "Roundup Ready" crops marketed by Monsanto are able to resist the herbicide Roundup, which prevents crop damage. See Galant, *supra* note 6, at 132.

36. See Mandel, *supra* note 33, at 2181 (recognizing types of modifications to crops used to increase yield); Galant, *supra* note 6, at 131 (explaining economic benefits for seed manufacturers and farmers).

37. See Kolehmainen, *supra* note 32, at 285 (summarizing environmental benefits of genetically engineered crops); Mandel, *supra* note 33, at 2184 (explaining lack of need to spray pesticide); Galant, *supra* note 6, at 132 (noting farmers do not have to spray pesticide, which helps prevent chemicals in water supply). Farmers do not have to spray these toxins into the environment because crops are modified to have internal pesticides or be herbicide resistant. See Kolehmainen, *supra* note 32, at 285.

38. See Mandel, *supra* note 33, at 2182 (discussing how agricultural benefits reduce world hunger); Galant, *supra* note 6, at 132 (explaining social benefits of genetically modified foods).

crop.³⁹ GE foods can protect and increase world food supplies by modifying crops to have a longer shelf life, incur less damage, and expand the foods' hardiness.⁴⁰ Finally, the increased crop yield may also reflect on food prices for consumers, creating less expensive food choices.⁴¹

2. *Risks of Genetically Modified Foods*

Two categories of risks associated with the development of genetically modified plants and animals are typically cited by opponents of genetically modified foods: risks to human health and risks to environmental health.⁴² Although no known circumstances where genetically modified foods have caused disease or illness in humans exist, the main health concerns focus more on the uncertainty of genetically modified foods, effects on allergies, and effects on antibiotics.⁴³ The uncertainties of genetic engineering stem from the lack of control scientists have over the many variables used during the process and how each gene will react with another.⁴⁴

Allergenicity is also a concern because proteins that cause allergic reactions in some people are included when genes are inserted into plants, allowing the new plant to carry these allergenic proteins.⁴⁵ This outcome poses a serious risk because people who have food allergies may not be aware of the presence

39. See Mandel, *supra* note 33, at 2183 (noting process of making crops more nutritious); Galant, *supra* note 6, at 132 (explaining some genetically engineered crops more nutritious). A popular example of this process is "Golden Rice." See Kolehmainen, *supra* note 32, at 286 (addressing "Golden Rice"); Mandel, *supra* note 33, at 2183 (explaining "Golden Rice" goals). "Golden Rice" is rice that is fortified with vitamin A, which can help the approximately ten million people in the world who suffer from disease and death due to vitamin A deficiencies. See Kolehmainen, *supra* note 32, at 286; Mandel, *supra* note 33, at 2183.

40. See Mandel, *supra* note 33, at 2183 (discussing benefits of genetically engineered food on world food supply); Galant, *supra* note 6, at 132 (discussing how genetically engineered food increases world food supply).

41. See Mandel, *supra* note 33, at 2182 (observing economic benefits to consumers).

42. See Kolehmainen, *supra* note 32, at 275 (stating two main risks associated with genetically modified foods); Mandel, *supra* note 33, at 2190 (proposing risks divided into two distinct categories); Galant, *supra* note 6, at 133 (introducing risks offered in opposition of genetically modified foods).

43. See Kolehmainen, *supra* note 32, at 275-76 (noting unpredictability of genetically modified plants and animals); Mandel, *supra* note 33, at 2190 (explaining lack of confirmed case of disease and stating main concerns of genetically modified foods); Leggio, *supra* note 30, at 908 (arguing main complaint of genetically modified foods as too much uncertainty).

44. See Kolehmainen, *supra* note 32, at 276 (emphasizing unpredictability in process of genetically modifying). This unpredictability is illustrated through experiments that have unpredictable results. *Id.* at 276-77. For example, one study fed one group of rats with potatoes that were genetically modified and another group of rats with nongenetically modified potatoes. *Id.* at 276. The rats that ate the genetically modified potatoes developed suppressed immune systems and stunted growth, while the other group of rats showed no symptoms. *Id.*; see also Leggio, *supra* note 30, at 906-07 (discussing uncertainty of genetically modified food). The FDA observed that the comments it received in support of a labeling policy were concerned about the uncertainty surrounding the process of genetic engineering. See Leggio, *supra* note 30, at 906-07.

45. See Mandel, *supra* note 33, at 2190 (explaining allergenic proteins included in genetically modified foods). Researchers have found that when foreign genetic materials with allergenic traits are transferred to other genetically modified foods, the new food takes on the allergenic traits. See Galant, *supra* note 6, at 134 (describing allergenicity concern).

of GMOs in their food containing their food allergies.⁴⁶ Without labels on food products warning of genetically modified ingredients, the consumer does not have the necessary information to evaluate whether or not he or she is allergic to the product.⁴⁷ Finally, another health risk is the use of the antibiotic resistant “marker gene.”⁴⁸ The “marker gene” could be transferred to other organisms and up the food chain through genetic engineering, potentially causing resistance to antibiotics in humans.⁴⁹

Environmental risks are prevalent as well.⁵⁰ One potential environmental risk is that genetically modified plants will lead to greater uniformity and less biodiversity, which could lead to crop failures.⁵¹ Another risk is the development of “superweeds” and “superbugs” if herbicide-resistant plants cross-pollinate with weeds and pest-resistant traits infiltrate pest populations.⁵² Furthermore, the creation of genetically modified crops with internal pesticide traits allows pests to become used to this pesticide, rendering the pesticide useless.⁵³ Relatedly, if the pollen of a genetically modified plant is carried over to neighboring farmers’ crops by various environmental elements, the crops can be devastated if the farmers were committed to an organic crop field.⁵⁴ The lack of control scientists have over the genetically modified plants once these plants are released into the environment paired with the unpredictability of this technology is unnerving to opponents of genetically modified foods.⁵⁵

B. Consumer Concerns

Although scientists have not found definitive proof of negative effects on humans due to genetically modified foods, long-term studies have not been performed, leaving consumers uncertain.⁵⁶ The uncertainty surrounding

46. See Mandel, *supra* note 33, at 2192 (noting risk of allergies).

47. See *id.* (addressing risk of allergens in product); Galant, *supra* note 6, at 135 (noting danger of not knowing of allergenic traits in food). In 1996, a genetically modified soybean was developed with a foreign protein from a Brazil nut. See Kolehmainen, *supra* note 32, at 278 (discussing danger of allergens in genetically modified ingredients). Researchers tested the allergenicity of the genetically modified soybean and found that people allergic to Brazil nuts would be allergic to the soybeans. See *id.*

48. See Kolehmainen, *supra* note 32, at 277 (describing “marker gene”).

49. See *id.* (explaining “marker gene” and its effects); Mandel, *supra* note 33, at 2193 (explaining risk of antibiotic resistance); Galant, *supra* note 6, at 134 (arguing genetically modified foods can affect ability to control disease).

50. See *supra* note 42 and accompanying text (introducing environmental risks as potential risks of genetically modified foods).

51. See Mandel, *supra* note 33, at 2197 (noting risk of crop disturbances from crop uniformity).

52. See Kolehmainen, *supra* note 32, at 281 (discussing creation of super-tolerant bugs and plants); Mandel, *supra* note 33, at 2195 (explaining how genetic material moves into unintended environments creating “superweeds”); Galant, *supra* note 6, at 134 (introducing “superweeds” and “superbugs”).

53. See Mandel, *supra* note 33, at 2197-98 (noting various environmental risks).

54. See Kolehmainen, *supra* note 32, at 280 (discussing possible risks when genetically modified plants cross-pollinate).

55. See *id.* (explaining lack of control over genetically modified plants).

56. See Citizen Petition, *supra* note 15, at 9 (explaining lack of scientific proof does not settle concerns).

genetically modified foods has led to overwhelming support for labeling foods containing GMOs.⁵⁷ Currently, the United States does not have a mandatory labeling system for genetically modified foods in place like the European Union and other countries.⁵⁸ Consumers are making their dissatisfaction with GMOs known by urging states to introduce mandatory labeling bills to compensate for the lack of federal legislation.⁵⁹ Numerous nonprofits and other organizations were created with the purpose of advocating for mandatory labeling of genetically modified foods.⁶⁰ The current regulation of genetically modified foods in the United States is not meeting consumer expectations and is not placating their fear and uncertainties.⁶¹

C. GMO Regulation in the United States

Trust in the regulatory system of genetically modified foods is pivotal to the success of GMOs.⁶² The gaps in the United States GMO regulatory system, however, do not create the necessary trust, leading consumers to ask for change.⁶³ GMO regulation in the United States is dictated by the Coordinated

FDA scientists explained, “[t]he food safety of organisms derived from recombinant DNA technologies do not have the history of the safe use that has come to be associated with organisms derived by standard breeding practices.” *Id.*; see also Leggio, *supra* note 30, at 906-07 (noting no scientific data for potential risks). New Jersey Assemblywoman Linda Stender has sponsored a bill to have genetically modified foods labeled. See Linda Stender, Opinion, *On Genetically Modified Foods, Give Consumers a Choice*, NJ.COM (June 25, 2013), http://blog.nj.com/njv_guest_blog/2013/06/on_genetically_modified_foods.html, archived at <http://perma.cc/RA93-DC85>. Stender argues, “[o]rdinary Americans should not be forced to act as human guinea pigs for a real-time study on the long-term health impact of genetically engineered foods.” *Id.*

57. See *supra* note 4 and accompanying text (reporting poll results indicating support for mandatory labeling). According to a New York Times poll, ninety-three percent of respondents think food containing ingredients derived from GMOs should be identified. See Allison Kopicki, *Strong Support for Labeling Modified Foods*, N.Y. TIMES (July 27, 2013), http://www.nytimes.com/2013/07/28/science/strong-support-for-labeling-modified-foods.html?_r=0. Reacting to consumer concerns and demands for healthier products, grocery stores, including Whole Foods, are making pledges of full GMO transparency. See Walter Robb, *Whole Foods Market Commits to Full GMO Transparency*, WHOLE FOODS MARKET (Mar. 8, 2013), <http://www.wholefoodsmarket.com/blog/whole-foods-market%C2%AE-commits-full-gmo-transparency>, archived at <http://perma.cc/XF8Z-Z6RN>.

58. See *GMO Facts*, *supra* note 28 (stating no mandatory labeling in place). More than sixty countries have enacted mandatory labeling laws for GMOs. *Id.* This includes the European Union, which established regulations in 2003 to label and trace GMOs and regulate the labeling and sale of the foods derived from the GMOs. See Rebecca M. Bratspies, *Is Anyone Regulating? The Curious State of GMO Governance in the United States*, 37 VT. L. REV. 923, 952 (2013) (explaining European Union’s labeling efforts).

59. See *Mandatory Labeling Efforts*, *supra* note 7 (outlining labeling efforts). Currently, there are thirty-seven states with labeling initiatives. *Id.*

60. See *About*, NON-GMO PROJECT, <http://www.nongmoproject.org/about/> (last visited Nov. 17, 2013), archived at <http://perma.cc/8CWS-AJN> (explaining nonprofit’s mission); *About Just Label It*, JUST LABEL IT (DEC. 27, 2011), <http://justlabelit.org/about-just-label-it/>, archived at <http://perma.cc/DE33-7VL5> (explaining Just Label It’s initiatives).

61. See *supra* note 56 and accompanying text (explaining consumer uncertainty).

62. See Rebecca Bratspies, *Some Thoughts on the American Approach To Regulating Genetically Modified Organisms*, 16 KAN. J.L. & PUB. POL’Y 393, 395-96 (2007) (noting trust matters in regulatory systems).

63. See Maria Gabriela Balboa, *Legal Framework To Secure the Benefits While Controlling the Risks of*

Framework for Regulation of Biotechnology, developed in 1986.⁶⁴ The drafters emphasized that the Framework's aim is for "'sensible' regulation that would not stifle innovation," while the public continues to advocate for heavy regulation to protect the public from the new, uncertain biotechnologies.⁶⁵

The Framework divides up GMO regulation over three agencies—the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the FDA—each with complementary responsibilities.⁶⁶ The USDA is responsible for testing GMO crops.⁶⁷ The main focus of the USDA is to maintain plant health and decide whether the GMOs will be a plant pest risk when introduced into other environments.⁶⁸ The EPA is not always involved in GMO regulation, only when the new product is classified as a "biopesticide."⁶⁹ The FDA is responsible for the food uses and food safety of GMOs.⁷⁰

In 1992, the FDA determined genetically modified foods are not substantially different than nongenetically modified foods.⁷¹ This means that the FDA uses the same approval process for GMOs as it does for most other foods.⁷² GMOs are not considered food additives because of this FDA determination.⁷³ Products classified as food additives require special labeling and testing, but additional labeling and testing of GMOs is unnecessary because

Genetically Modified Foods: A Comparison of the Cartagena Protocol and Three National Approaches, 31 TEMP. J. SCI. TECH. & ENVTL. L. 255, 268 (2012) (explaining critics believe current regulatory system insufficient); see also Hamilton, *supra* note 6, at 99-100 (acknowledging uncertainty in regards to agency responsibility for certain tests).

64. See Bratspies, *supra* note 58, at 927-30 (summarizing history of GMO regulation in United States).

65. See *id.* at 929 (explaining drafters' goals of Coordinated Framework).

66. See Balboa, *supra* note 63, at 266 (explaining United States GMO tripartite regulation system).

67. See Hamilton, *supra* note 6, at 98-99 (noting USDA's responsibilities in GMO regulatory system). The USDA uses the Plant Protection Act (PPA) to perform the regulation of GMO crops. See Plant Protection Act § 402, 7 U.S.C. § 7701 (2012); see also Bratspies, *supra* note 58, at 931-32 (discussing USDA's regulatory powers over GMO crops). The PPA is a "quarantine statute" implemented to prevent plant pests, which means the USDA is concerned with whether the GMO will pose a plant pest risk. See Bratspies, *supra* note 58, at 932.

68. See Bratspies, *supra* note 62, at 411 (explaining USDA's role in GMO regulation).

69. See Hamilton, *supra* note 6, at 99 (explaining EPA's role in GMO regulation). Biopesticide is defined as "certain types of pesticides derived from such natural materials as animals, plants, bacteria, and certain minerals." *What Are Biopesticides?*, EPA, <http://www.epa.gov/pesticides/biopesticides/whatarebiopesticides.htm> (last updated Feb. 6, 2015), archived at <http://perma.cc/DRW3-639E> (providing definition of biopesticides). The EPA receives its authority to regulate pesticides and to assure products will not cause unreasonable risk to the environment from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). See Federal Insecticide, Fungicide, and Rodenticide Act §§ 2-35, 7 U.S.C. §§ 136-136y (2012); see also Bratspies, *supra* note 58, at 935 (explaining EPA's regulatory authority over GMOs).

70. See Balboa, *supra* note 63, at 267 (noting FDA's role in regulatory system); Hamilton, *supra* note 6, at 99 (explaining FDA's importance in GMO regulation).

71. See Balboa, *supra* note 63, at 267 (noting FDA uses same regulatory requirements for GMOs as it does for all other foods); Hamilton, *supra* note 6, at 99 (explaining FDA's 1992 decision claiming GMOs not substantially different from other crops).

72. See Balboa, *supra* note 63, at 267 (explaining no different regulations for GMOs than other foods); Hamilton, *supra* note 6, at 99 (acknowledging lack of special tests or labels for most GMOs).

73. See Hamilton, *supra* note 6, at 99 (distinguishing GMOs from food additives).

GMOs are not considered additives.⁷⁴ In fact, the FDA has not conducted a safety assessment on genetically modified foods and places the responsibility on the companies who create the genetically modified crops to disclose—voluntarily and not mandatorily—any studies the companies conducted on the product.⁷⁵

The GMO regulatory system poses serious gaps and questions for consumers.⁷⁶ One of the main holes in the regulatory system is the uncertainty of agency responsibility in regard to testing because the regulatory responsibilities are dispersed across three agencies.⁷⁷ Currently, little evidence is available regarding which agencies—if any—test for the safety of human consumption of genetically modified materials.⁷⁸ This, however, can create the appearance of high regulation because three agencies could be tasked with regulating GMOs.⁷⁹ Indeed, biotechnology companies have taken advantage of this argument by using the tripartite regulatory system as a way to prove GMOs do not need more regulation.⁸⁰ The current regulatory scheme, particularly the FDA's role and determinations that genetically modified foods are not substantially different than food generated from traditional breeding mechanisms, does not enhance consumers' trust in GMOs.⁸¹ The lack of a labeling scheme, the main focus of this Note, is the most criticized by consumers.⁸²

D. Food Labeling in the United States

1. FDA's History of Food Labeling

In the United States, Congress began regulating food and beverage labeling more than a century ago.⁸³ Before the modern era of the FDA, the states

74. *See id.* (describing consequences of distinguishing GMOs from food additives).

75. *See* Citizen Petition, *supra* note 15, at 11 (commenting on FDA's lack of safety assessment and describing voluntary consultation process). The FDA will view the results from the companies and typically follow up with a letter explaining that the FDA had no further questions. *Id.*

76. *See* Bratspies, *supra* note 58, at 940 (noting negative aspects of United States GMO regulatory system).

77. *See* Hamilton, *supra* note 6, at 99-100 (discussing consequences of United States GMO tripartite regulatory system).

78. *See id.* (noting lack of agency responsibility for testing food safety in regards to human consumption).

79. *See id.* at 99 (commenting on appearance of GMOs as highly regulated).

80. *See id.* (commenting on existence of biotechnology companies taking advantage of appearance of heavy regulation).

81. *See* Bratspies, *supra* note 58, at 954-55 (suggesting overwhelming support for labeling from consumers means desire for transparency).

82. *See id.* at 954 (explaining consumers' concern and desire for labeling).

83. *See* *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 331 (3d Cir. 2009) (outlining history of food labeling in United States); Benny, *supra* note 16, at 1509 (summarizing history of FDA).

regulated and exercised control over domestically produced foods and drugs.⁸⁴ Unsurprisingly, this led to vast inconsistencies between the states in food and drug regulation.⁸⁵ Amidst the increasing visibility of the misbranding of foods and drugs, the Division of Chemistry began to investigate the possible abuses of misbranding.⁸⁶ Harvey Washington Wiley became head chemist at the Division of Chemistry in 1883 and, while there, brought many groups together to advocate for federal laws to protect the public from the misbranding of foods and drugs.⁸⁷ With this championing effort, President Theodore Roosevelt signed the Pure Food and Drugs Act, also known as the Wiley Act, into law.⁸⁸

With the passage of the Pure Food and Drugs Act, the modern era of the FDA was born.⁸⁹ The Act's purpose was to expand the FDA's authority to enforce food and drug standards, including standards prohibiting the addition of ingredients posing a health risk and standards prohibiting false or misleading labels on food and drug products.⁹⁰ Many consumers and organizations were concerned with the lack of power Congress and the FDA had over protecting consumers from unsafe food and drug products; opinions were driven by the muckraking journalists of the early twentieth century who were uncovering food and drug regulation failures.⁹¹ The FDA and consumer protection organizations advocated to Congress the need for changes in the law to mandate quality standards for foods and to prohibit false claims for foods and drugs.⁹² Public outrage was the wake-up call for Congress when one hundred

84. See John P. Swann, *FDA's Origin*, FDA, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm> (last updated June 23, 2014), archived at <http://perma.cc/M5KA-ZUDM> (introducing early history of FDA).

85. See *id.* (summarizing food regulation pre-FDA).

86. See *id.* (introducing Division of Chemistry). The Division of Chemistry was the original name of the agency we now know as the FDA. See *id.*

87. See *id.* (describing Wiley's impact).

88. See Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, repealed by Federal Food, Drug, and Cosmetic Act, ch. 675, § 902(a), 52 Stat. 1040, 1059; Robert L. Rabin, *Federal Regulation in Historical Perspective*, 38 STAN. L. REV. 1189, 1226-27 (1986) (noting Roosevelt's support for Act); Swann, *supra* note 84 (describing passage of Federal Food and Drugs Act).

89. See Morgan Anderson Helme, Note, *Genetically Modified Food Fight: The FDA Should Step Up to the Regulatory Plate So States Do Not Cross the Constitutional Line*, 98 MINN. L. REV. 356, 360 (2013) (describing modern era of FDA); Swann, *supra* note 84 (declaring 1906 beginning of modern era).

90. See Helme, *supra* note 89, at 360 (detailing purpose of Pure Food and Drugs Act); *FDA History—Part I: The 1906 Food and Drugs Act and Its Enforcement*, FDA, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm> (last updated June 18, 2009), archived at <http://perma.cc/DW68-7LFV> [hereinafter *FDA History—Part I*] (describing history of Pure Food and Drugs Act). Upton Sinclair's *The Jungle*, with its detailed descriptions of the meat packing industry, was a major influence on the passage of the Pure Food and Drugs Act. See *FDA History—Part I, supra*.

91. See, e.g., *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 331 (3d Cir. 2009) (detailing food labeling history); Benny, *supra* note 16, at 1509 (outlining FDA history); Helme, *supra* note 89, at 360 (describing frustration with Pure Food and Drugs Act).

92. See *FDA History—Part II: The 1938 Food, Drug, and Cosmetic Act*, FDA, www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm# (last updated Sept. 24, 2012), archived at <http://perma.cc/9BAU-IJ292> [hereinafter *FDA History—Part II*] (describing FDA petitions to Congress).

people were killed by a drug containing a highly toxic chemical in 1937.⁹³ President Franklin Delano Roosevelt signed the Food, Drug, and Cosmetic Act (FDCA) on June 25, 1938.⁹⁴

The purpose of the FDCA was to give the FDA the authority to regulate food safety and labeling and mandate legally enforceable food standards, which included prohibiting false or misleading labels.⁹⁵ Under the FDCA, the FDA could create food definitions and mandate nutrition labels for food products making a health or nutrition claim.⁹⁶ The regulatory structure the FDCA implemented is still in use today, although many additions and enhancements were made to it.⁹⁷ One of the major shortcomings of the FDCA was that only sixty percent of food products in the United States had detailed nutritional information disclosed.⁹⁸ Consumers and many organizations alike were calling for the opportunity to choose healthier food products and wanted food manufactures to disclose detailed nutritional labels.⁹⁹ In 1990, Congress passed the Nutrition Labeling and Education Act (NLEA).¹⁰⁰

The NLEA is an amendment to the FDCA completely overhauling nutritional labeling requirements.¹⁰¹ Some of the reforms included in the NLEA were changing the requirements for ingredient lists on food packages, requiring nutritional labeling on most food products under FDA control, and standardizing serving sizes.¹⁰² Nutritional claims, such as “low fat” and “healthy,” now have to conform to standards set by the FDA in order to appropriately use the label on food packaging and marketing.¹⁰³ According to FDA Commissioner, Doctor Margaret Hamburg, “the public health importance of food labeling as an essential means for informing consumers about proper nutrition . . . has not been substantially addressed since the FDA implemented the Nutrition Labeling and Education Act.”¹⁰⁴ Recently, the lack of FDA

93. See *id.* (detailing triggering event for Congress).

94. See Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.) (identifying 1938 Food, Drug, and Cosmetic Act).

95. See *Holk*, 575 F.3d at 331 (describing purpose of FDCA); *FDA History—Part II*, *supra* note 92 (detailing purpose of FDCA).

96. See *Holk*, 575 F.3d at 331 (describing FDA’s function under FDCA); Benny, *supra* note 16, at 1509 (outlining purpose of FDCA).

97. See Helme, *supra* note 89, at 361 (explaining present regulatory structure of FDA).

98. See Bruce Silverglade, *Using Food Labeling To Improve Diet and Health: An Examination of the U.S. Nutrition Labeling and Education Act*, CSPI INT’L., <http://www.cspinet.org/reports/codex/labeling.htm> (last visited Nov. 21, 2014), archived at <http://perma.cc/2URH-8YJS> (describing labeling system’s shortcomings).

99. See *id.* (explaining demand for detailed nutrition labels).

100. Nutrition Labeling and Education Act Amendments of 1993, Pub. L. No. 103-80, 107 Stat. 773 (codified as amended in scattered sections of 21 U.S.C.).

101. See Helme, *supra* note 89, at 361 (describing NLEA as amendment to FDCA).

102. See *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 332 (3d Cir. 2009) (outlining NLEA reforms); Benny, *supra* note 16, at 1509 (explaining NLEA reforms).

103. See Benny, *supra* note 16, at 1510 (explaining new labeling standards under NLEA).

104. Margaret A. Hamburg, Comm’r of Food & Drugs, Keynote Address at National Food Policy

involvement in emerging food labeling issues has received major attention when it comes to the popular food label, “all natural.”¹⁰⁵

2. FDA's Reluctance To Define “Natural”

The FDA has defined popular labels such as “low fat” and “light” extensively but has yet to issue a formal definition for “natural.”¹⁰⁶ “Natural” is the most widely used food label on United States food products.¹⁰⁷ United States food manufacturers are responding to consumer demands as consumers have stated their preference for “natural” foods over products not labeled as such.¹⁰⁸ The FDA stated its intention to formulate an official definition because of increasing consumer demand, the popularity of the use of the term “natural,” and the resulting confusion of the term.¹⁰⁹ Due to lack of resources and other matters the FDA deemed more important, however, the FDA refused to issue a formal definition.¹¹⁰ Currently, no formal definition exists and the FDA has no obvious intention of defining the word “natural.”¹¹¹

Instead of a formal definition, the FDA stands behind an informal definition of “natural” as guidance to United States food manufacturers.¹¹² While the FDA holds on to this informal definition, the Third Circuit recently declared the informal definition does not have the “force of law.”¹¹³ For the informal definition to be binding, the definition must be a legislative rule rather than a

Conference (Sept. 8, 2009), available at <http://www.fda.gov/NewsEvents/Speeches/ucm182061.htm>, archived at <http://perma.cc/VC99-FY9J> (noting food labeling has not changed since NLEA).

105. See *supra* note 11 and accompanying text (addressing lack of formal definition of “natural”).

106. See, e.g., Food Labeling 1993, 2407 (explaining FDA’s intention not to officially define “natural”); April L. Farris, *The “Natural” Aversion: The FDA’s Reluctance To Define a Leading Food-Industry Marketing Claim, and the Pressing Need for a Workable Rule*, 65 FOOD & DRUG L.J. 403, 403-04 (2010) (explaining FDA’s lack of official definition for “natural”); Nicole E. Negowetti, *A National “Natural” Standard for Food Labeling*, 65 ME. L. REV. 581, 582-83 (2013) (explaining lack of definition of “natural”); see also, Benny, *supra* note 16, at 1510 (explaining FDA has not used its power to define “natural”).

107. See Endres et al., *supra* note 13, at 109 (explaining popularity of “natural” food).

108. See *supra* note 2 and accompanying text (explaining consumer preference for “natural” food products).

109. See Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (proposed Nov. 27, 1991) [hereinafter Food Labeling 1991] (stating FDA’s intention to define “natural”). “Because of its widespread use, and the evidence that consumers regard many uses of this term as non-informative, the agency is considering establishing a definition for this term.” *Id.*; see also Negowetti, *supra* note 106, at 585 (noting FDA’s intention to define “natural”).

110. See Food Labeling 1993, 2407 (stating refusal to define “natural”); Benny, *supra* note 16, at 1510 (explaining FDA’s refusal to define “natural”).

111. See *supra* note 106 and accompanying text (explaining lack of FDA formal definition of “natural”).

112. See Food Labeling 1993, 2407 (stating intention to maintain informal definition). “The agency will maintain its current policy . . . not to restrict the use of the term ‘natural’” *Id.*; see also Food Labeling 1991, 60,466 (stating current informal policy). “[T]he agency has considered ‘natural’ to mean that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there.” Food Labeling 1991, 60,466.

113. See *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 342 (3d Cir. 2009) (declaring current definition of “natural” does not have force of law).

policy statement and, to determine which one it is, courts must look to whether the definition has the “force of law” or not.¹¹⁴ In *Holk v. Snapple Beverage Corp.*, the court ruled that the definition does not have the “force of law” because the FDA stated its intention to not create a formal definition, the FDA arrived at the informal policy without public input nor did it take into consideration the comments it received from the public, and the agency said there was still much to determine and consider before formally defining the word “natural.”¹¹⁵ If the court found that the informal definition of “natural” did have the “force of law” it would have preempted any state law definition of the word “natural.”¹¹⁶ Thus, enforcement of the definition cannot be compelled because the informal definition of “natural” is not binding.¹¹⁷

Although the FDA does not have a strong enforcement process for use of the word “natural” on food products, consumers and consumer advocate organizations are beginning to use the judicial system to regulate the use of the word “natural” on United States food products.¹¹⁸ Specifically, consumers are arguing products containing GMOs and genetically modified based ingredients cannot be considered “natural” and are filing lawsuits against companies who use GMOs and proclaim that the product is “natural.”¹¹⁹ Judges do not have

114. See *Chrysler Corp. v. Brown*, 441 U.S. 281, 301-02 (1979) (describing how rule may become binding or have “force of law”). “We described a substantive rule—or a ‘legislative-type rule,’—as one ‘affecting individual rights and obligations.’ This characteristic is an important touchstone for distinguishing those rules that may be ‘binding’ or have the ‘force of law.’” *Id.* at 302 (citations omitted) (quoting *Morton v. Ruiz*, 415 U.S. 199, 232, 235-36 (1974)); see also *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109 (D.C. Cir. 1993) (explaining ways to distinguish legislative from nonlegislative rules). The court can determine whether or not a certain rule has legal effect by determining

- (1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action . . . (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule.

Am. Mining Cong., 995 F.2d at 1112. If any of these factors are answered affirmatively, then the rule has legal effect. *Id.*; see also *Benny*, *supra* note 16, at 1510-11 (explaining process of legally binding statements).

115. See 575 F.3d at 341-42 (stating reasons why informal policy does not have “force of law”).

116. See *id.* at 342 (declaring current definition of “natural” does not have “force of law” to preempt state law); *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 244-45 (3d Cir. 2008) (determining federal regulations established by formal procedure preempt state law). “Courts with good reason are wary of affording preemptive force to actions taken under more informal circumstances.” See *Fellner*, 539 F.3d at 245.

117. See *Benny*, *supra* note 16, at 1511 (explaining nonbinding effect of “natural” definition). The FDA uses warning letters sent to food manufacturers to enforce its informal “natural” definition. See *Negowetti*, *supra* note 106, at 588 (describing FDA’s method of enforcing its informal “natural” definition).

118. See *Farris*, *supra* note 106, at 411 (noting increase of class actions initiated by consumers and consumer advocate organizations).

119. See, e.g., *Silber v. Barbara’s Bakery, Inc.*, 950 F. Supp. 2d 432, 435 (E.D.N.Y. 2013) (alleging defendant’s products not “all natural” because products contain GMOs); *Krzykwa v. Campbell Soup Co.*, 946 F. Supp. 2d 1370, 1371-72 (S.D. Fla. 2013) (arguing “all natural” soup line not natural because it contains GMOs); *Benny*, *supra* note 16, at 1506 (explaining plaintiffs brought suits against companies with “natural” labels containing GMOs). Many such lawsuits are filed in the Northern District of California, affectionately

the expertise to determine whether an ingredient can be considered “natural” or not, and thus, some have chosen to stay the matters in order to allow the FDA to issue an official definition.¹²⁰ In July 2013, Judge Rodgers acknowledged that no formal definition of the word “natural” exists and believes the Supreme Court would overstep the FDA’s interpretative authority if it made a decision on whether GMOs are considered natural or not.¹²¹ She, therefore, stayed a class action suit for six months to allow for the FDA to issue official guidance on the term “natural.”¹²² A formal definition of “natural” would not only provide guidance in the judicial system (preventing judicial waste) but consumers would also feel more informed and food producers would have specific guidelines as to whether or not they can put the “all natural” label on their food products.¹²³ If the FDA issues a formal definition for the term “natural,” it should provide guidance on whether GMOs are “natural” in order to clear up the emerging issue of GMO labeling.¹²⁴

E. State GMO Labeling Legislation

Proposed state legislation is increasing throughout the country and poses different legal issues and arguments.¹²⁵ Not only are concerned consumers initiating class actions to promote change in the use of the label “natural,” but they are also creating a movement by initiating and supporting state legislation to require labels on food products containing GMOs.¹²⁶ A turning point in food labeling legislation was the national visibility of California’s Proposition 37.¹²⁷

known as the Food Court, because of the “consumerfriendly legal climate and a health-conscious jury pool.” See Vanessa Blum, *A Wave of Class Actions for the ‘Food Court,’* LEGAL INTELLIGENCER, Mar. 6, 2013, at 4 (describing favorable legal atmosphere for food label lawsuits in California).

120. See *Van Atta v. Gen. Mills, Inc.*, No. 12-cv-02815-MSK-MJW, 2013 U.S. Dist. LEXIS 118137, at *9-10 (D. Colo. July 18, 2013) (recommending case stayed due to referral to FDA by Judge Rodgers); *Cox v. Gruma Corp.*, 12-CV-6502 YGR, 2013 WL 3828800, at *2 (N.D. Cal. July 11, 2013) (staying action for six months to allow FDA to issue formal definition); *Ries v. Hornell Brewing Co., Inc.*, No. 10-1139-JF (PVT), 2010 WL 2943860, at *6 (N.D. Cal. July 23, 2010) (staying action for six months allowing FDA to issue formal definition of “natural”).

121. See *Cox*, 2013 WL 3828800, at *2 (refusing to make determination whether GMOs natural or not).

122. See *id.* (holding action stayed for six months).

123. See *Benny*, *supra* note 16, at 1514 (describing consequence of FDA’s inaction).

124. See *infra* Part III.A (discussing need for “natural” definition for FDA to clear up GMO labeling issue).

125. See *infra* Part II.F (discussing constitutional hurdles to GMO labeling legislation).

126. See *supra* note 59 and accompanying text (noting number of states with proposed GMO labeling legislation).

127. See Helena Bottemiller, *With Recent Victories, Movement To Label GMOs Gains Steam*, FOOD SAFETY NEWS (June 27, 2013), <http://www.foodsafetynews.com/2013/06/movement-to-label-gmos-gaining-steam/#.UswtBf18LwK>, archived at <http://perma.cc/EZ7X-MVC9> (noting GMO labeling movement picked up steam six months after Proposition 37); Maggie Caldwell, *Maine Is Second State To Pass GMO Labeling Law*, MOTHER JONES (June 14, 2013), <http://www.motherjones.com/blue-marble/2013/06/maine-gmo-labeling>, archived at <http://perma.cc/8CFT-VW86> (describing right-to-know activists as more determined after Proposition 37 defeat).

Currently, two initiatives have been successful and two have been unsuccessful.¹²⁸ In June 2013, both Connecticut and Maine passed bills requiring food manufacturers to label their food products that contain GMOs.¹²⁹

1. Connecticut's GMO Labeling Law

In June 2013, Connecticut became the first state to pass a GMO labeling law, igniting optimism for GMO labeling advocates.¹³⁰ The law defines natural food as food “(A) that has not been treated with preservatives, antibiotics, synthetic additives, artificial flavoring or artificial coloring; and (B) that has not been processed in a manner that makes such food significantly less nutritive; and (C) . . . that has not been genetically engineered”¹³¹ It also requires “(A) . . . food intended for human consumption, and (B) seed or seed stock that is intended to produce food for human consumption, that is entirely or partially genetically-engineered . . . [to] be labeled . . . with the clear and conspicuous words: ‘Produced with Genetic Engineering.’”¹³² The law addresses two popular issues in food labeling: the definition of the term “natural,” and

128. See Act of June 25, 2013, Pub. Act 13-183, 2013 Conn. Acts 777 (Reg. Sess.) (codified at scattered sections of CONN. GEN. STAT. ANN. § 21a) (explaining Connecticut's GMO labeling bill); Act of Jan. 12, 2014, ch. 436, 2013 Me. Laws 1237 (codified at ME. REV. STAT. ANN. Tit. 22, §§ 2591-2596) (noting passage of Maine GMO labeling bill). Note that although Maine passed the GMO labeling bill in June 2013, Governor Paul LePage did not sign the bill into law until January 2014. See Steve Mistler, *LePage Signs Bill To Label Genetically Modified Food*, PORTLAND PRESS HERALD (Jan. 9, 2014), http://www.pressherald.com/2014/01/09/lepage_signs_maine_gmo_labeling_bill/, archived at <http://perma.cc/EP24-274H> (discussing Governor's bill signing). In July 2013, he noted that he would sign the bill into law when legislators reconvene after the current legislative session ends. See Stephanie L. Russ, *Does This Law Make My Butt Look Big? A Survey of Health-Related and Food Labeling Laws Food Service Franchise Systems Should Know*, 33 FRANCHISE L.J. 217, 229 (2013) (noting Maine bill not yet law); see also Steve Mistler, *LePage: I'll Sign Bill Requiring Labels for Genetically Modified Foods*, PORTLAND PRESS HERALD (July 9, 2013), <http://www.pressherald.com/politics/LePage-tells-GMO-labeling-bill-sponsors-hell-make-it-law.html>, archived at <http://perma.cc/2G67-E2AK> (confirming Governor's agreement to sign bill); Andrew Pollack, *After Loss, the Fight To Label Modified Food Continues*, N.Y. TIMES (Nov. 7, 2012), <http://www.nytimes.com/2012/11/08/business/california-bid-to-label-genetically-modified-crops.html> (describing California's Proposition 37 defeat); Stephanie Strom, *Food Companies Claim Victory Against Labeling Initiative in Washington State*, N.Y. TIMES (Nov. 6, 2013), <http://www.nytimes.com/2013/11/07/us/politics/food-companies-claim-victory-against-labeling-initiative-in-washington-state.html> (noting defeat of Washington's GMO labeling initiative).

129. See 2013 Conn. Acts 777 (explaining Connecticut's GMO labeling bill); 2013 Me. Laws 1237 (noting passage of Maine GMO labeling bill).

130. See 2013 Conn. Acts 777 (stating Connecticut's GMO labeling bill). Governor Malloy signed the bill into law in December 2013. See Genevieve Reilly, *Malloy Signs State GMO Labeling Law in Fairfield*, CT POST (Dec. 11, 2013), <http://www.ctpost.com/news/article/Malloy-signs-state-GMO-labeling-law-in-Fairfield-5056120.php>, archived at <http://perma.cc/ZJJ9-U9HC> (stating Governor Malloy signed bill into law); see also Stephanie Strom, *Connecticut Approves Labeling Genetically Modified Foods*, N.Y. TIMES (June 3, 2013), <http://www.nytimes.com/2013/06/04/business/connecticut-approves-qualified-genetic-labeling.html> (describing passage of Connecticut bill as “important first step”). The legislature passed the bill with 134-to-3 votes against. See Strom, *supra*.

131. See CONN. GEN. STAT. ANN. § 21a-92(17) (West 2015) (defining “Natural Food”).

132. See *id.* § 21a-92(a) (requiring labeling of genetically engineered food products).

whether or not food products containing GMOs should be labeled.¹³³ The law spurred optimism with Governor Malloy explaining, “[t]his is a beginning, and I want to be clear what it is a beginning of It is a national movement that will require (food) labeling.”¹³⁴

The law, however, is not a total victory for GMO labeling advocates.¹³⁵ The law will only take effect when the following occurs:

- (1) Four states, not including this state, enact a mandatory labeling law for genetically-engineered foods that is consistent with the provisions of this subsection, provided one such state borders Connecticut; and (2) the aggregate population of such states located in the northeast region of the United States that have enacted a mandatory labeling law for genetically-engineered foods that is consistent with this subsection exceed twenty million based on 2010 census figures¹³⁶

These stipulations are put in place in order to protect small businesses and farmers from suffering at the hands of out-of-state competitors who are not required to label genetically engineered food products.¹³⁷ When one state implements labeling laws and other states do not, businesses and industries are at a disadvantage.¹³⁸

2. Maine GMO Labeling Bill

Maine quickly followed Connecticut’s lead and passed a bill in the House of Representatives on June 11th by a vote of 141-to-4, and the next day, the bill passed the State Senate unanimously.¹³⁹ Maine’s bill is similar to Connecticut’s, requiring food or seed stock that is genetically engineered to be conspicuously labeled, “[p]roduced with Genetic Engineering.”¹⁴⁰ The Maine

133. See *id.* §§ 21a-92(17), 21a-92c(a) (describing definition of “Natural Food” and label requirement for GMO food products).

134. See Reilly, *supra* note 130 (describing bill signing ceremony).

135. See Strom, *supra* note 130 (noting law does not go into effect automatically); see also Martin Kaste, *So What Happens if the Movement To Label GMOs Succeeds?*, NPR (Oct. 16, 2013), <http://www.npr.org/blogs/thesalt/2013/10/16/235525984/so-what-happens-if-the-movement-to-label-gmos-succeeds> (stating more states need to pass similar laws for bill to take effect).

136. See CONN. GEN. STAT. ANN. § 21a-92c(a) (stating stipulations). States in the Northeast region are Maine, Vermont, New Hampshire, Massachusetts, Rhode Island, New York, New Jersey, and Pennsylvania. See *id.*

137. See Strom, *supra* note 130 (explaining reason for stipulations).

138. See *id.* (noting possible consequences if only one state enacted GMO labeling legislation).

139. See Act of Jan. 12, 2014, ch. 436, 2013 Me. Laws 1237 (codified at ME. REV. STAT. ANN. tit. 22, §§ 2591-2596) (noting passage of Maine GMO labeling bill); Matthew Stone, *Maine House Overwhelmingly Supports GMO Labeling Requirement*, BANGOR DAILY NEWS (June 11, 2013), <http://bangordailynews.com/2013/06/11/politics/maine-house-overwhelmingly-supports-gmo-labeling-requirement/>, archived at <http://perm.a.cc/XD6G-QBZN> (announcing Maine House of Representative vote tally for GMO labeling bill).

140. See ME. REV. STAT. ANN. tit. 22, § 2593(1) (2015) (requiring labeling).

bill, however, does not define the term “natural” as does the Connecticut law.¹⁴¹ Similar stipulations present in the Connecticut law are also included in the Maine bill’s text.¹⁴² GMO labeling advocates are optimistic the bill and law will go into effect following the example of other northeastern states.¹⁴³

3. *Unsuccessful GMO Labeling Initiatives*

GMO labeling initiatives, however, have faced notable setbacks. Proposed GMO labeling laws left up to popular vote have not fared well, despite the minor successes of lobbying efforts in certain state legislatures.¹⁴⁴ On November 6, 2012, California voters voted against Proposition 37 with fifty-one percent of voters opposing the bill and forty-nine percent voting in favor of it.¹⁴⁵ If passed, Proposition 37 would have required the labeling of genetically modified foods and prohibited those food products from being labeled “natural.”¹⁴⁶ Substantial donations from large biotechnology and food lobbyists played a significant part in the Proposition’s demise.¹⁴⁷ Lobbyists from biotechnology firms feel as though mandatory labeling laws are unnecessary because there is no evidence GMOs pose a health risk and mandatory labels will make consumers believe products that do contain GMOs

141. See CONN. GEN. STAT. ANN. § 21a-92(17) (West 2015) (defining word “Natural Food”); ME. REV. STAT. ANN. tit. 22, § 2592 (providing Act definitions, absent is “natural”).

142. See 2013 Me. Law 1237, 1238 (stating stipulations). The law will only go into effect when four other states pass legislation similar to the Maine labeling. See *id.*

143. See Jenny Hopkinson, *Vermont, Northeastern States Eye GMO Labeling in 2014—Specialty Crops Fight for Space in Farm Bill*, POLITICO (Dec. 23, 2013), <http://www.politico.com/morningagriculture/1213/morningagriculture12567.html>, archived at <http://perma.cc/2VSB-MPUK> (explaining Vermont poised for GMO labeling bill in 2014).

144. See TEXT OF PROPOSED LAWS 110-13 (2012), available at <http://vig.cdn.sos.ca.gov/2012/general/pdf/text-proposed-laws-v2.pdf#nameddest=prop37>, archived at <http://perma.cc/EEY7-2LKJ> (stating Proposition 37); Initiative Measure No. 522 (Wash. 2012), available at http://sos.wa.gov/_assets/elections/initiatives/FinalText_285.pdf, archived at <http://perma.cc/UYSS-NZDP> (stating Initiative 522).

145. See DEBRA BOWEN, CAL. SEC’Y OF STATE STATEMENT OF VOTE: NOVEMBER 6, 2012, GENERAL ELECTION 13 (2012), available at <https://www.sos.ca.gov/elections/sov/2012-general/sov-complete.pdf>, archived at <http://perma.cc/YPY6-G356> (stating poll results for Proposition 37).

146. See TEXT OF PROPOSED LAWS, *supra* note 144, at 110-13 (explaining requirement of labeling genetically engineered food).

The purpose of this measure is to create and enforce the fundamental right of the people of California to be fully informed about whether the food they purchase and eat is genetically engineered and not misbranded as natural so that they can choose for themselves whether to purchase and eat such foods.

Id. at 111.

147. See Pollack, *supra* note 128 (commenting on funds spent in Proposition 37 campaign). Food and biotech companies spent forty-six million dollars to defeat the bill, while supporters of Proposition 37 raised \$9.2 million. *Id.* The “Big Six” lobbyists, who continuously pour money in to defeat GMO labeling initiatives, are Bayer, Dow, DuPont, Syngenta, Monsanto, and BASF. See Caldwell, *supra* note 127 (describing “Big Six”).

are unhealthier than food products that do not contain GMOs.¹⁴⁸

In Washington state Initiative 522 was also presented to voters in November 2013, containing similar provisions as California's Proposition 37 such as requiring labeling of genetically modified food products.¹⁴⁹ Also similar to California, the biotechnology and food industries donated twenty-two million dollars into the campaign, while GMO labeling supporters only raised \$7.8 million.¹⁵⁰ The biotechnology and food lobbyists used advertisements to inform consumers that a "yes" vote for the initiative would make food prices rise for consumers and there is no scientific-based evidence that genetically engineered foods pose a health risk.¹⁵¹ Despite these two high-profile setbacks, GMO labeling advocates remain determined and have focused their energies on passing state legislation.¹⁵² The Non-GMO Project reported that since Proposition 37's defeat, certification for food products that are GMO free have increased four-fold.¹⁵³

Currently, Massachusetts's elected officials have introduced five pieces of legislation that concern GMO labeling.¹⁵⁴ The five pieces of legislation were assigned to two different committees: the Joint Committee on Public Health and the Joint Committee on Environment, Natural Resources and Agriculture.¹⁵⁵ Two of these bills are modeled after California's Proposition 37 and prohibit genetically engineered products from being labeled "natural."¹⁵⁶ If Massachusetts passes a GMO labeling law, Connecticut and Maine are one

148. See Bottemiller, *supra* note 127 (stating Grocery Manufacturers Association's argument against labeling); Caldwell, *supra* note 127 (explaining biotechnology's apprehension to labeling laws); Pollack, *supra* note 128 (describing big food and biotechnology companies' argument against labeling).

149. See Initiative Measure No. 552 (discussing initiative's labeling requirements).

150. See Jenny Hopkinson, *Washington GMO Labeling Initiative Losing, but Not Done*, POLITICO (Nov. 6, 2013), <http://www.politico.com/story/2013/11/washington-state-gmo-labeling-initiative-2013-elections-99442.html>, archived at <http://perma.cc/9E95-EPYM> (stating donation amounts for GMO labeling campaign). Initiative 522 is the highest grossing ballot initiative campaign in Washington history. *Id.*

151. See *id.* (explaining lobbyists' strategy).

152. See Caldwell, *supra* note 127 (noting twenty-six state legislatures have introduced GMO labeling bills).

153. See Bottemiller, *supra* note 127 (noting Non-GMO Project's success in light of Proposition 37's defeat). The Non-GMO Project offers the only independent verification for nonGMO food products in North America. See *Product Verification*, NON-GMO PROJECT, <http://www.nongmoproject.org/product-verification/> (last visited Nov. 22, 2014), archived at <http://perma.cc/6VRL-2WCS>.

154. See *Mass State GMO Labeling Legislation*, MA RIGHT TO KNOW GMOS, <http://marighttoknow.com/home/legislative-support/ma-legislation/#H2093> (last visited Jan. 20, 2014), archived at <http://perma.cc/K6VB-3BZU> (explaining current proposed bills in Massachusetts Legislature); see also H. 2037, 188th Gen. Ct. (Mass. 2013); H. 808, 188th Gen. Ct. (Mass. 2013) (stating text of GMO labeling bill); H. 1936, 188th Gen. Ct. (Mass. 2013) (stating text of GMO labeling bill); H. 813, 188th Gen. Ct. (Mass. 2013) (describing GMO labeling bill); H. 2093, 188th Gen. Ct. (Mass. 2013) (describing proposed GMO labeling bill).

155. See *Mass State GMO Labeling Legislation*, *supra* note 154 (describing status of proposed bills, as of Jan. 20, 2014).

156. See H. 2037 (stating GMOs not natural); H. 1936 (stating GMOs improperly labeled "natural"); see also *TEXT OF PROPOSED LAWS*, *supra* note 144, at 110-13 (defining Proposition 37).

state closer to putting the laws pending in those states into effect.¹⁵⁷

F. Potential Constitutional Arguments That Threaten State GMO Labeling Legislation

Constitutional hurdles threaten the success of state GMO labeling legislation.¹⁵⁸ Two prominent constitutional threats are the freedom of free interstate trade under the Commerce Clause and commercial free speech under the First Amendment.¹⁵⁹ The Commerce Clause of the U.S. Constitution limits state action impacting interstate trade.¹⁶⁰ States have the police power to regulate and protect citizens' health and welfare.¹⁶¹ Thus, a state that passes GMO labeling legislation will have to argue how the state is protecting the health and welfare of its citizens in order to withstand constitutional challenges.¹⁶² Arguing the GMO labeling legislation is implemented to protect the health and welfare of its citizens, however, will be an uphill battle because the FDA does not currently acknowledge a difference between genetically modified and nongenetically modified food.¹⁶³

A potential First Amendment argument against state GMO labeling legislation is that mandating GMO labels makes manufacturers speak commercially against their will.¹⁶⁴ A similar argument and issue was presented in *International Dairy Foods Ass'n v. Amestoy*.¹⁶⁵ In *Amestoy*, dairy manufacturers brought an action challenging the constitutionality of a Vermont law requiring dairy manufacturers to label products that were derived from

157. See Sacha Pfeiffer & Lynn Jolicoeur, *Mass. Considers GMO Labeling Laws*, WBUR (June 19, 2013), <http://www.wbur.org/2013/06/19/massachusetts-gmo-labels>, archived at <http://perma.cc/93HZ-2QKG> (explaining Massachusetts' potential effect on other states' GMO labeling legislation).

158. See Galant, *supra* note 6, at 154-55 (explaining constitutional hurdles to legislative attempts); Helme, *supra* note 89, at 370 (exploring constitutional threats of state GMO laws).

159. See U.S. CONST. amend. I (proclaiming right to free speech); U.S. CONST. art. I, § 8, cl. 3 (granting Congress right to regulate commerce with foreign nations as well as among states). The Commerce Clause has been interpreted to give Congress the power to regulate three areas under the Commerce Clause: "Congress may regulate the use of the channels of interstate commerce;" "Congress is empowered to regulate and protect the instrumentalities of interstate commerce, or persons or things in interstate commerce, even though the threat may come only from intrastate activities;" and, "Congress' commerce authority includes the power to regulate those activities having a substantial relation to interstate commerce." *United States v. Lopez*, 514 U.S. 549, 558-59 (1995); see also Galant, *supra* note 6, at 154-55 (introducing potential constitutional threats to state GMO labeling legislation); Helme, *supra* note 89, at 367-68 (describing modern analysis of Commerce Clause).

160. See U.S. CONST. art. I, § 8, cl. 3 (stating Commerce Clause); Galant, *supra* note 6, at 157 (noting Commerce Clause imposes limitations on state action).

161. See Helme, *supra* note 89, at 371 (summarizing state's police power).

162. See Galant, *supra* note 6, at 158 (noting requirement of valid state interest for legislation).

163. See *id.* (noting difficulty of arguing constitutionality of GMO labeling legislation).

164. See *id.* at 155 (examining First Amendment challenges).

165. 92 F.3d 67 (2d Cir. 1996); see also Galant, *supra* note 6, at 156-57 (summarizing *Amestoy*); Matthew Rich, Note, *The Debate Over Genetically Modified Crops in the United States: Reassessment of Notions of Harm, Difference, and Choice*, 54 CASE W. RES. L. REV. 889, 904-05 (2004) (noting *Amestoy* similar to GMO labeling issue).

cows treated with a synthetic growth hormone.¹⁶⁶ The dairy manufacturers argued the mandatory labeling statute was a violation of their First Amendment Right to commercial free speech.¹⁶⁷

The court used a four-part test established in *Central Hudson Gas & Electric Corp. v. Public Service Commission*¹⁶⁸ to analyze the dairy manufacturers' right not to speak in the commercial context.¹⁶⁹ The court found that the state failed to establish the second prong of the test, because Vermont did not claim that public welfare or safety concerns prompted the passage of the statute but that strong consumer interest and the consumers' right-to-know encouraged legislators to act.¹⁷⁰ The court further established "consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement . . . in a commercial context."¹⁷¹ Judge Leval, however, in a dissenting opinion, proclaimed if Vermont put forth the evidence of health issues it sought to prevent through labeling, a different outcome might have occurred.¹⁷² Despite this, the majority's holding that consumer interest does not qualify as a substantial state interest has significant implications on GMO right-to-know campaigns and legislation.¹⁷³

III. ANALYSIS

A. FDA Must Define the Word "Natural" and the Definition Should Not Include Genetically Modified Food Products

The ambiguity and lack of a definition of the word "natural" has not only frustrated consumers, but has also clogged the judicial system with cases judges do not have the necessary expertise to decide because they do not know what is considered "natural" and what is not.¹⁷⁴ Particularly, when it comes to

166. See *Amestoy*, 92 F.3d at 69 (introducing facts of case). The synthetic growth hormone is meant to increase milk production. *Id.*

167. See *id.* at 70 (explaining dairy manufacturers' argument).

168. 447 U.S. 557 (1980).

169. See *id.* at 566 (establishing four-part test); see also *Amestoy*, 92 F.3d at 72 (noting four-part test). The four-part test the *Amestoy* court used to determine whether a government restriction on commercial free speech is allowed was: "(1) whether the expression concerns lawful activity and is not misleading; (2) whether the government's interest is substantial; (3) whether the labeling law directly serves the asserted interest; and (4) whether the labeling law is no more extensive than necessary." 92 F.3d at 72; see also Galant, *supra* note 6, at 156-57 (summarizing *Amestoy* analysis).

170. See *Amestoy*, 92 F.3d at 73 (holding government restriction of commercial free speech not valid under second prong).

171. See *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1996) (holding consumer interest not substantial state interest).

172. See *id.* at 76-77, 81 (Leval, J., dissenting) (noting different outcome if proper evidence put forth).

173. See Rich, *supra* note 165, at 906 (explaining implications of *Amestoy* decision for GMO labeling movement).

174. See Benny, *supra* note 16, at 1516 (explaining lack of ability of judges to attempt to define "natural").

genetically modified foods, there needs to be a clear consensus whether or not such foods can be considered “natural.”¹⁷⁵ The FDA has the delegated authority to prevent misbranding and misleading food labels through the NLEA, which was enacted to prevent the very problem that is occurring now: consumers being misled by the label “natural.”¹⁷⁶ The FDA must use this delegated authority to officially define “natural” because it is the agency with the necessary expertise, authority, and resources to clear up the problematic ambiguity on one of the most popular food labels in the United States.¹⁷⁷ The natural food industry is far too large and the label “natural” is far too popular for the FDA to ignore its delegated authority and not define the term.¹⁷⁸

The FDA not only should use its delegated authority to define “natural,” but the definition should not include GMOs.¹⁷⁹ Consumers agree GMOs are not considered natural and are frequently misled when food products labeled “natural” contain GMOs, as evidenced by the number of lawsuits initiated by consumers against food manufacturers that use the label natural with GMOs.¹⁸⁰ Merging DNA of different species to create combinations of genes not occurring in nature creates GMOs.¹⁸¹ By definition, therefore, GMOs are not natural.¹⁸² The informal definition that the FDA currently uses for guidance defines “natural” as a food product that does not include anything artificial or synthetic that would not normally be expected to be included in the product.¹⁸³ GMOs certainly qualify as an ingredient not normally expected to be included in a food product, evidenced by the fact that consumers have felt misled by the label “natural,” when in fact, the food product contains GMOs.¹⁸⁴

175. See, e.g., *In re Frito-Lay N. Am., Inc. All Natural Litig.*, No. 12-MD-2413(RRM)(RLM), 2013 WL 4647512, at *1 (E.D.N.Y. Aug. 29, 2013) (alleging various Frito-Lay products mislabeled “all natural” because of presence of GMOs); *Parker v. J.M. Smucker Co.*, No. C 13-0690 SC, 2013 WL 4516156, at *1 (N.D. Cal. Aug. 23, 2013) (arguing Crisco cooking oil not “all natural” because of GMO presence); *In re ConAgra Foods Inc.*, 908 F. Supp. 2d 1090, 1095 (C.D. Cal. 2012) (arguing Wesson cooking oils not “natural” because of presence of GMOs).

176. See Nutrition Labeling and Education Act Amendments of 1993, Pub. L. No. 103-80, 107 Stat. 773 (codified as amended in scattered sections of 21 U.S.C.) (outlining FDA’s role in misbranding of food); Benny, *supra* note 16, at 1515 (describing FDA’s role under NLEA).

177. See Farris, *supra* note 106, at 420 (noting FDA has expertise to define “natural” while courts do not); Benny, *supra* note 16, at 1515 (emphasizing FDA’s role in defining “natural”).

178. See Farris, *supra* note 106, at 423 (noting natural food industry too large to have such ambiguity); *supra* notes 3-4 and accompanying text (discussing popularity of natural food industry and label “natural”).

179. See, e.g., *In re Frito-Lay N. Am., Inc. All Natural Litig.*, 2013 WL 4647512, at *1 (alleging various Frito-Lay products mislabeled “all natural” because of presence of GMOs); *Parker*, 2013 WL 4516156, at *1 (arguing Crisco cooking oil not “all natural” because of GMO presence); *In re ConAgra Foods Inc.*, 908 F. Supp. 2d at 1095 (arguing Wesson cooking oils not “natural” because of presence of GMOs).

180. See Benny, *supra* note 16, at 1506 (noting number of lawsuits due to GMOs in foods labeled “natural”).

181. See *supra* note 5 and accompanying text (defining GMOs).

182. See *supra* note 5 and accompanying text.

183. See Food Labeling: 1991, 56 Fed. Reg. 60,466 (defining FDA’s informal definition).

184. See, e.g., *In re Frito-Lay N. Am., Inc. All Natural Litig.*, No. 12-MD-2413(RRM)(RLM), 2013 WL 4647512, at *1 (E.D.N.Y. Aug. 29, 2013); *Parker v. J.M. Smucker Co.*, No. C 13-0690 SC, 2013 WL 4516156,

Notably, in both passed and proposed state legislation, food manufacturers cannot label their product “natural” if the product contains GMOs.¹⁸⁵ If the FDA issued a formal definition of the word “natural” that does not include GMOs in the official definition, consumers would be more informed of GMO-free options because the labels “natural” and “organic” would not include food products with GMOs.¹⁸⁶ This is the more ideal alternative because if the FDA used its delegated authority to define “natural,” there would not be constitutional arguments used to defeat a definition of “natural” that can be used against GMO labeling legislation.¹⁸⁷ Also, if GMOs are not included in the formal definition of “natural,” many of the lawsuits will disappear as the labels will no longer be misleading.¹⁸⁸ If the FDA continues to decline to formally define “natural,” state GMO labeling legislation should be passed in order to give as much transparency to consumers as possible.¹⁸⁹

B. State GMO Labeling Legislation May Withstand Constitutional Arguments Due to New Research

With GMO labeling activists ramping up their efforts in most states, GMO labeling legislation seems to be a more attractive alternative than federal legislation or waiting for a formal definition from the FDA.¹⁹⁰ A serious threat to state GMO labeling legislation is constitutional arguments made by groups opposed to the legislation whose goal is to defeat the bill through the court system.¹⁹¹ Many GMO labeling activists argue that consumers have a right to know what is in their food.¹⁹² *Amestoy*, a case that many find to be an analogous case to GMO labeling legislation, emphasized consumer interest is not enough to rise to a substantial state interest to defeat First Amendment claims.¹⁹³ The dissenting opinion by Judge Leval, however, provides some

at *1 (N.D. Cal. Aug. 23, 2013); *In re ConAgra Foods Inc.*, 908 F. Supp. 2d 1090, 1095 (C.D. Cal. 2012); see also *supra* note 4 and accompanying text (asserting consumer support for GMO labeling).

185. See Act of June 25, 2013, Pub. Act 13-183, 2013 Conn. Acts 777 (Reg. Sess.) (codified at scattered sections of CONN. GEN. STAT. ANN. § 21a) (stating stipulations); H. 2037, 188th Gen. Ct. (Mass. 2013) (stating GMOs not natural); H. 1936, 188th Gen. Ct. (Mass. 2013) (stating GMOs cannot be labeled “natural”).

186. See *supra* note 6 and accompanying text (explaining consumers’ right-to-know position).

187. See *supra* notes 158-61 and accompanying text (summarizing various constitutional arguments against GMO state legislation).

188. See, e.g., *In re Frito-Lay N. Am., Inc. All Natural Litig.*, 2013 WL 4647512, at *1 (asserting products not “natural” because of presence of GMOs); *Parker*, 2013 WL 4516156, at *1 (arguing Crisco cooking oil not “all natural” because of GMO presence); *In re ConAgra Foods Inc.*, 908 F. Supp. 2d at 1095 (arguing Wesson cooking oils not natural because of presence of GMOs); cf. Benny, *supra* note 16, at 1506 (noting amount of lawsuits due to “natural” ambiguity).

189. See *supra* notes 12-15 and accompanying text (focusing on battle for GMO transparency).

190. See *supra* note 59 and accompanying text (discussing popularity of GMO labeling initiatives).

191. See *supra* notes 158-61 and accompanying (introducing constitutional arguments against state GMO labeling legislation).

192. See *supra* note 6 and accompanying text (summarizing consumers’ right-to-know argument).

193. See *Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1996) (holding consumer curiosity does not rise to substantial state interest); Rich, *supra* note 165, at 905-06 (comparing *Amestoy* to state GMO

encouragement to the groups who argue that the labeling laws are constitutional.¹⁹⁴ Judge Leval makes statements that are very applicable to the GMO labeling initiatives and provide encouragement that judges could potentially see GMOs in foods as a threat to the public welfare.¹⁹⁵ He states:

[T]he majority suggests that, because the FDA has not found health risks in this new procedure, health worries could not be considered “real” or “cognizable.” I find this proposition alarming and dangerous; at the very least, it is extraordinarily unrealistic. Genetic and biotechnological manipulation of basic food products is new and controversial. Although I have no reason to doubt that the FDA’s studies of rBST have been thorough, they could not cover *long-term* effects of rBST on humans.¹⁹⁶

GMO labeling activists have developed a substantial amount of evidence against the safety of GMOs; if they present the evidence in a compelling and organized fashion, as Judge Leval suggests, judges may be persuaded that GMOs in food products are a substantial state interest.¹⁹⁷

Although GMO labeling activists have gathered sizeable evidence to combat First Amendment constitutional claims, they still must face the Commerce Clause hurdle.¹⁹⁸ The Commerce Clause gives food manufacturers the right to free interstate trade, but state GMO labeling laws have the potential to hinder food manufacturers’ ability to trade in states with these laws.¹⁹⁹ This threat, however, may be lessened by the trend of state GMO labeling laws, which create stipulations before bills can take effect.²⁰⁰ In order to protect food manufacturers and farmers from market competition and to protect their ability to freely send their products interstate, the stipulation prohibits the bills from taking effect until a certain number of surrounding states bordering the original state enact similar legislation.²⁰¹ As long as other states that enact similar

legislation).

194. See *Amestoy*, 92 F.3d at 76 (Leval, J., dissenting) (providing encouragement to Vermont legislators to provide evidence).

195. See *id.* (noting with proper evidence Vermont could have succeeded).

196. See *id.* (citation omitted).

197. See *id.* at 81 (stating potential GMO safety risks and providing encouragement for GMO labeling success); Rich, *supra* note 165, at 905-06 (explaining dissent provides encouragement for GMO labeling success).

198. See *supra* notes 159-60 and accompanying text (introducing Commerce Clause threat to state GMO labeling legislation).

199. See Galant, *supra* note 6, at 157 (commenting on how state GMO labeling legislation may inhibit interstate trade).

200. See Act of June 25, 2013, Pub. Act 13-183, 2013 Conn. Acts 777 (Reg. Sess.) (codified at scattered sections of CONN. GEN. STAT. ANN. § 21a) (stating stipulations); H. 2037, 188th Gen. Ct. (Mass. 2013) (declaring GMOs not natural); H. 1936, 188th Gen. Ct. (Mass. 2013) (stating GMOs improperly labeled “natural”).

201. See Strom, *supra* note 130 (explaining reason for stipulations); Wattles, *supra* note 9 (explaining

legislation also include a comparable stipulation to help minimize the effect on interstate trade, the Commerce Clause threat may be reduced.²⁰² To protect the legislation from a Commerce Clause challenge, GMO activists should be prepared to present the same in-depth evidence of health threats as used to protect against a First Amendment challenge in order to prove there is a substantial state interest that the legislation is supposed to protect.²⁰³

With GMO labeling activists well equipped to argue for the constitutional validity of state GMO labeling legislation, Massachusetts should pass its own GMO labeling bill to further the effort for GMO transparency.²⁰⁴ Massachusetts is in a critical location because Maine and Connecticut became the first two states to pass GMO labeling legislation in the United States, establishing New England as the leading region to champion mandatory GMO labeling.²⁰⁵ If Massachusetts passes mandatory GMO labeling legislation, Maine and Connecticut bill criteria are one step closer to fulfillment.²⁰⁶ Though Massachusetts has five bills currently proposed addressing food labeling, all versions passed should include a provision prohibiting food products that contain GMOs from being labeled “natural.”²⁰⁷ Currently, two proposed bills include a definition of “natural.”²⁰⁸ This alternative will further the goal of GMO transparency and provide more clarity to consumers until the FDA defines “natural.”²⁰⁹

IV. CONCLUSION

There is no question that the natural food industry is here to stay. But what does the “natural” label mean? This is a question posed by many consumers who are concerned with ambiguity of the “natural” label. These consumers are taking their concerns to different venues, including the judiciary and legislatures. The natural food industry is far too enormous to have such ambiguity. The FDA must use its authority to establish a formal definition of

reason for stipulation).

202. See 2013 Conn. Acts 777 (stating stipulations); Act of Jan. 12, 2014, ch. 436, 2013 Me. Laws 1237 (codified at ME. REV. STAT. tit. 22, §§ 2591-2596) (stating stipulation).

203. See *supra* notes 42-49, 51-54 and accompanying text (summarizing evidence of potential health risks).

204. See H. 2037; H. 808, 188th Gen. Ct. (Mass. 2013); H. 1936; H. 2093, 188th Gen. Ct. (Mass. 2013); H. 813, 188th Gen. Ct. (Mass. 2013).

205. See Caldwell, *supra* note 127 (stating Maine as second state to follow suit after court’s GMO labeling bill); Strom, *supra* note 130 (noting Connecticut first state to pass GMO labeling legislation).

206. See Act of June 25, 2013, Pub. Act 13-183, 2013 Conn. Acts 777 (Reg. Sess.) (codified at scattered sections of CONN. GEN. STAT. ANN. § 21a) (stating stipulations in order to take effect); 2013 Me. Laws 1237 (explaining need to satisfy stipulations before bill takes effect).

207. See *Mass State GMO Labeling Legislation*, *supra* note 154 (explaining current proposed Massachusetts legislation).

208. See H. 2037, 188th Gen. Ct. (Mass. 2013) (stating GMOs not natural); H. 1936, 188th Gen. Ct. (Mass. 2013) (stating GMOs improperly labeled “natural”).

209. See *supra* note 59 and accompanying text (discussing popularity of GMO labeling initiatives).

the word “natural” to give clarity to not only the natural food industry but to consumers. Furthermore, GMOs should not be included in the formal definition of “natural.”

Connecticut and Maine are trailblazers for the GMO labeling movement. They enacted the first GMO labeling bills in the country, providing hope to consumers and advocates who believe they have the right to know what is in their food. There have been several potential constitutional arguments against state GMO labeling laws. With new research and evidence, GMO labeling advocates are in a prime position to defeat these constitutional arguments and maintain the constitutionality of the labeling laws. The current stipulations in the Connecticut and Maine bills, however, prevent the bills from taking effect. Thus, Massachusetts must pass its own GMO labeling bill to ensure consumers have a right to know what is in their food. Massachusetts is in the best position to advance the GMO labeling movement and should take advantage of the opportunity. There is only one acceptable response to consumer demand: Pass a GMO labeling bill.

Julie M. Muller