THE NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD: A CHANCE TO SETTLE THE NATURAL DEBATE?

Colette McCrone[*]

INTRODUCTION

Imagine you are rushing through the store, late for a party to which you have agreed to bring the chips and dip. As you sprint through the chip aisle, you see a bag of corn chips with "All-Natural!" prominently displayed on the front. You pick it up, grab the guacamole, and head out for a night of fun. Later, you discover those corn chips were produced with a strain of corn that was genetically modified to withstand certain pesticides. Do you have a case against the chip manufacturer for misrepresenting the product with the "All-Natural!" label?

While filing suit may seem extreme, there have in fact been a number of lawsuits over scenarios similar to the one described above.[1] Genetically modified organisms, commonly called GMOs, are controversial; some hail them as a scientific miracle, capable of solving world hunger problems,[2] and others cast them as a disastrous byproduct of corporate greed, deleterious to human health and environmental sustainability.[3] However, the average American knows very little about GMOs, and even less about how they are regulated.[4] Complicating matters is the fact that the average citizen perceives "natural" to mean something very different than the definition promulgated

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[1] *See* In re Conagra Foods, Inc., 90 F. Supp. 3d 919, 939 (C.D. Cal. 2015); Rojas v. Gen. Mills, Inc., No. 12-cv-05099-WHO, 2014 U.S. Dist. LEXIS 41315, at *2 (N.D. Cal. Mar. 26, 2014); Garcia v. Kashi Co., 43 F. Supp. 3d 1359, 1368 (S.D. Fla. 2014); In re Frito-Lay N. Am., Inc., No. 12-MD-2413 (RRM)(RLM), 2013 WL 4647512, at *1–2 (E.D.N.Y. Aug. 29, 2013); *see generally* Melissa Mortazavi, *Tort as Democracy: Lessons from the Food Wars*, 57 ARIZ. L. REV. 929, 932 (2015).

[2] *See Laureates Letter Supporting Precision Agriculture (GMOs)*, SUPPORT PRECISION AGRIC. (June 29, 2016), http://supportprecisionagriculture.org/nobel-laureate-gmo-letter_rjr.html.

[3] *See About Genetically Engineered Foods*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/311/ge-foods/about-ge-foods (last visited Dec. 28, 2017).

[4] *See, e.g.*, Lee Rainie & Cary Funk, PEW RES. CTR., AMERICANS, POLITICS AND SCIENCE ISSUES 127 (2015); DELOITTE, STUDY OF ELECTRONIC OR DIGITAL LINK DISCLOSURE: A THIRD-PARTY EVALUATION OF CHALLENGES IMPACTING ACCESS TO BIOENGINEERED FOOD DISCLOSURE 63 (2017); Jimmy Kimmel Live!, *What's a GMO*, YOUTUBE (Oct. 9, 2014), https://www.youtube.com/watch?v=EzEr23XJwFY.

by regulatory agencies responsible for food labeling.[5] Litigation surrounding the use of natural labels with GMO ingredients has produced confusing and misleading results.[6] In light of this confusion, and due to increased calls for GMO labeling, Congress passed the National Bioengineered Food Disclosure Standard, the first national GMO disclosure standard, in July 2016.[7] The new measure requires manufacturers to disclose the use of GMO ingredients in the form of a symbol, text, or digital link otherwise known as a QR code.[8]

This Article explores the new law, focusing on its potential to exacerbate the confusion over the intersection of natural labels and GMO use. Because the author agrees with the criticism that the QR code option will make it difficult, and in some cases impossible, for consumers to access GMO information, this Article predicts that this new law will increase consumer confusion over the intersection of GMO use and natural labeling. It subsequently recommends that the Food and Drug Administration ("FDA") mitigate the failings of the law in order to clarify a small segment of consumer confusion. Part I gives a brief introduction to GMOs and explores the litigation around GMO-natural claims. Part II describes the current state of food regulation as it pertains to labeling, describing how both the United States Department of Agriculture ("USDA") and the FDA take part in food regulation. Part II additionally discusses the National Bioengineered Food Disclosure Standard, focusing on its strengths and weaknesses. Part III predicts that the National Bioengineered Food Disclosure Standard will not decrease consumer confusion over the intersection of natural labeling and GMOs, and in many cases, will lead to increased consumer confusion. Further, Part III recommends that the FDA exercise its authority under its enabling statute, the Food, Drug, and Cosmetic Act ("FDCA") to clarify the new law, reduce consumer confusion, and mitigate the law's failings. Relying on past case analysis of such claims as well as past FDA actions, this Part argues that the FDA should ban the use of "natural" in food labeling when a manufacturer chooses the QR code as the sole GMO disclosure method.

I. BACKGROUND: GMOS AND CURRENT CONSUMER CONFUSION

This Part provides a brief background on GMOs, outlines the debate surrounding their use, and explains how that debate has overflowed into the courts.

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[5] *See, e.g.*, *In re Conagra Foods, Inc.*, 90 F. Supp. 3d at 939; *Rojas*, 2014 U.S. Dist. LEXIS 41315, at *2; *Garcia*, 43 F. Supp. 3d at 1368; *In re Frito-Lay N. Am., Inc.*, 2013 WL 4647512, at *1–2.

[6] *See e.g.*, *In re Conagra Foods, Inc*., 90 F. Supp. 3d at 939; *Rojas*, 2014 U.S. Dist. LEXIS 41315, at *2; *Garcia*, 43 F. Supp. 3d at 1368; *In re Frito-Lay N. Am, Inc.*, 2013 WL 4647512, at *1–2. For the purposes of this article, natural labels include any use of the word "natural" on the product label, used in a way to advertise the product.

[7] *See* National Bioengineered Food Disclosure Standard, 7 U.S.C. §§ 1639–39c (Supp. 2017).

[8] *Id.* § 1639b(b)(2)(D).

A. *What Are GMOs and Why Are They So Controversial?*

GMOs are organisms whose genetic material has been altered in some way by human intervention.[9] This can be done through traditional breeding techniques[10] or other, more complicated, methods, such as recombinant DNA techniques, commonly known as gene splicing.[11] Commercially marketed GMO crops were first introduced in the mid-1990s, and their use has increased substantially since then.[12] Today, common crops such as alfalfa, canola, cotton, maize, papaya, potato, soy, squash, and sugar beets are frequently grown as GMO crops.[13] In 2015 and 2016, approximately 94 percent of all soybeans and 89 percent of corn planted was genetically modified.[14] By some estimates, 75 percent of all processed foods on supermarket shelves in the United States contained some type of GMO ingredient.[15]

The use and consumption of GMOs are controversial issues, with strong opinions on all sides. Those opposing GMOs point to alleged harmful environmental effects,[16] disastrous economic impacts on farmers,[17] and potential

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9 *GMO Facts*, NON-GMO PROJECT, http://www.nongmoproject.org/gmo-facts/ (last visited Sept. 23, 2016).

10 *Biotechnology Frequently Asked Question (FAQs)*, U.S. DEP'T OF AGRIC. (Feb. 8, 2016), http://www.usda.gov/wps/portal/usda/usda-home?navid=AGRICULTURE&contentid=BiotechnologyFAQs.xml.

11 Rita Barnett-Rose, *Judicially Modified Democracy: Court and State Pre-emption of Local GMO Regulation in Hawaii and Beyond*, 26 DUKE ENVTL. L. & POL'Y F. 71, 74 (2015); NON-GMO PROJECT, *supra* note 9.

12 *See* Stephanie Amaru, *A Natural Compromise: A Moderate Solution to the GMO & "Natural" Labeling Disputes*, 69 FOOD & DRUG L.J. 575, 575–76 (2014).

13 *See ISAAA Brief 51-2015: Executive Summary*, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, http://www.isaaa.org/resources/publications/briefs/51/executivesummary/default.asp (last visited Sept. 23, 2016).

14 *See Recent Trends in GE Adoption*, U.S. DEP'T OF AGRIC. ECON. RES. SERV. (July 14, 2016), http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx.

15 CTR. FOR FOOD SAFETY, *supra* note 3.

16 *See Myths & Realities of GE Crops*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/311/ge-foods/myths-and-realities-of-ge-crops (last visited Dec. 20, 2016) ("Laboratory and field evidence shows that [GMO] crops can harm beneficial insects, damage soils and transfer GE genes in the environment, thereby contaminating neighboring crops and potentially creating uncontrollable weeds."); David A. Mortensen et al., *Navigating a Critical Juncture for Sustainable Weed Management*, 62 BIOSCIENCE 75, 83 (2012) (arguing that GMOs have harmed ecosystems through increased herbicide use, the emergence of herbicide resistant weeds, and a decrease in weed management).

17 *See Genetic Engineering*, FRIENDS OF THE EARTH, http://www.foe.org/projects/food-and-technology/genetic-engineering (last visited Oct. 10, 2016) (arguing that patented biotechnology has led to "corporate control" over farmers); NON-GMO PROJECT, *supra* note 9(pointing out that "companies that make GMOs now have the power to sue farmers whose fields have been contaminated with GMOs, even when it is the result of the drift of pollen from neighboring fields." (citing Carey Gillam, *Monsanto Wins Lawsuit Filed by U.S. Organic Farmers Worried About Seed Contamination*, THE HUFFINGTON POST (June 10, 2013), http://www.huffingtonpost.com/2013/06/10/monsanto-wins-lawsuit_n_3417081.html)).

health problems.[18] For these reasons, some are morally opposed to GMO consumption.[19] GMO proponents argue that there is no scientific evidence to back up critics' claims.[20] For example, a study released in 2016 by the National Academies of Science, Engineering, and Medicine declared that that GMOs are safe for consumption and have no negative impact on the environment.[21] Further, many proponents argue that GMO use can help relieve world food shortage issues, lower the price of food, and provide much-needed nutrients to the world's population.[22] For example, proponents often point to Golden Rice, a strain of rice specifically developed to provide much needed Vitamin A to the underdeveloped world,[23] and gripe that ill-placed GMO concerns have stymied Golden Rice distribution and use.[24] Finally, many point out that these two polarizing positions miss the larger point: that the risks and benefits of GMO use are varied and that current scientific data is, at best, inconclusive.[25]

Much of the controversy is centered on labeling. Similar to the debate over GMOs in general, there are strong arguments for and against labeling. Proponents of labeling argue that because studies are inconclusive, consumers should be able to choose between GMO and non-GMO products.[26] Many Americans agree: regardless of the poll cited, approval of GMO labeling regularly falls around 90 percent.[27] Opponents of mandatory GMO labeling

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18 *See* JOHN FAGAN ET AL., GMO MYTHS AND TRUTHS 128 (2d ed., 2014) (stating that "[s]tudies show that GM foods can be toxic, allergenic, or have unintended nutritional changes."); Barnett-Rose, *supra* note 11, at 75–80 (providing a summary of alleged GMO health concerns including, toxicity, allergenic, and carcinogenic concerns).

19 *See* Mortazavi, *supra* note 1, at 951.

20 *See All Things Considered: The Salt: GMOs Are Safe, But Don't Always Deliver on Promises, Top Scientists Say* (May 17, 2016), https://www.npr.org/sections/thesalt/2016/05/17/478415310/top-scientists-say-gmos-are-safe-but-dont-always-deliver-on-promises.

21 *See* Andrew Pollack, *Genetically Engineered Crops Are Safe, Analysis Finds*, N.Y. TIMES (May 17, 2016), http://www.nytimes.com/2016/05/18/business/genetically-engineered-crops-are-safe-analysis-finds.html?_r=1.

22 *See* SUPPORT PRECISION AGRIC., *supra* note 2; *Benefits of Food & AG Biotechnology*, COALITION FOR SAFE AFFORDABLE FOOD, http://coalitionforsafeaffordablefood.org/benefits-of-biotechnology/ (last visited Oct. 31, 2016).

23 *See* Ingo Potrykus, *Golden Rice and Beyond*, 125 PLANT PHYSIOLOGY 1157, 1158 (2001)*; see generally Why Golden Rice, Is There a Need for It?*, GOLDEN RICE HUMANITARIAN BOARD, http://www.goldenrice.org/Content3-Why/why.php (last visited Jan. 6, 2017).

24 *See Some Facts About Rice*, GOLDEN RICE HUMANITARIAN BOARD, http://www.goldenrice.org/Content3-Why/why4_facts.php (last visited Jan. 6, 2017).

25 For a discussion on the varied claims against GMOs, see Susan Johnson, *Genetically Modified Food: A Golden Opportunity?*, 14 SUSTAINABLE DEV. L. & POL'Y 34, 34 (2014) and Natasha Gilbert, *A Hard Look at GM Crops*, 497 NATURE 24, 24–26 (2013).

26 *See, e.g.*, *Mission Statement*, NON-GMO PROJECT, http://www.nongmoproject.org/about/mission/ (last visited Sept. 23, 2016).

27 *Why Label?*, JUST LABEL IT!, http://www.justlabelit.org/right-to-know-center/right-to-know/ (last visited Nov. 14, 2017); *About GE Food Labeling*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/about-ge-labeling (last visited Nov. 14, 2017).

counter that GMO-free labeling already exists in the form of organic labeling (organic products must be GMO-free by law to receive the organic label)[28] and through voluntary labeling programs, such as the Non-GMO Project.[29] Further, opponents argue that requiring labels will stigmatize products deemed to be safe, decreasing demand while increasing costs and decreasing use, a potentially disastrous impact for those living in underdeveloped countries,[30] as well as for those living in low-income communities in the United States.[31]

Complicating this debate is the simple fact that many Americans know very little about GMOs.[32] By one estimate, 54 percent of Americans reported knowing "very little or nothing at all about genetically modified foods."[33] This lack of knowledge extends to how GMOs are treated by U.S. regulatory agencies. This confusion and disconnect have led to increased litigation over the GMO-natural divide.

B. *History of GMO-Natural Lawsuits*

Much of the confusion centers on whether a food containing GMO ingredients can be labeled as "natural." Currently, manufacturers *can* label a

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28 Miles McEvoy, *Organic 101: Can GMOs Be Used in Organic Products?*, U.S. DEP'T OF AGRIC. (May 17, 2013), http://blogs.usda.gov/2013/05/17/organic-101-can-gmos-be-used-in-organic-products/.

29 Greg Jaffe, *What You Need to Know About Genetically Engineered Food: Myths and Facts About Health, Corruption, and Saving the World*, THE ATLANTIC (Feb. 7, 2013), http://www.theatlantic.com/health/archive/2013/02/what-you-need-to-know-about-genetically-engineered-food/272931/; *About*, NON-GMO PROJECT, http://www.nongmoproject.org/about/ (last visited Dec. 29, 2017).

30 *See* The Editors, *Labels for GMO Foods Are a Bad Idea*, SCI. AM. (Sept. 1, 2013), http://www.scientificamerican.com/article/labels-for-gmo-foods-are-a-bad-idea/. For a thorough discussion of arguments against GMO labeling, see Gary Marchant, *Counterpoint: The Case Against Mandatory Labeling of GE Food*, 28 NAT. RESOURCES & ENV'T 11, 13 (2013).

31 *See* Andrea Freeman, *Transparency for Food Consumers: Nutrition Labeling and Food Oppression*, 41 AM. J.L. & MED. 315, 316 (2015) (arguing that labeling laws do not help, and only hurt, low-income communities); Lindsay F. Wiley, *Health Law as Social Justice*, 24 CORNELL J.L. & PUB. POL'Y 47, 63 (2014) (pointing out that the alternative food movement, to which many GMO-labeling proponents subscribe, can be described as "elitist"); Rebecca L. Goldberg, *Administering Real Food: How the Eat-Food Movement Should – and Should Not – Approach Government Regulation*, 39 ECOLOGY L.Q. 773, 823–24 (2012) (recognizing that many of the Eat-Food Movement initiatives may not benefit low-income consumers.).

32 *See* Amaru, *supra* note 12, at 598 (noting that "most consumers do not have an accurate understanding of what genetic modification means"); *see also* Jimmy Kimmel Live!, *supra* note 4.

33 William K. Hallman et al., *Public Perceptions of Labeling Genetically Modified Foods* 3 (Rutgers School of Envtl. & Biological Sci. Working Paper No. 2013-01, 2013), http://humeco.rutgers.edu/documents_pdf/news/gmlabelingperceptions.pdf.

good containing GMOs with a "natural" label.[34] A manufacturer is only precluded from using a "natural" label if the product contains any additives or synthetic ingredients.[35] However, because this current legal definition of GMOs is not in line with many consumers' own beliefs about the use of "natural" or the use of GMOs, a substantial number of lawsuits have challenged manufacturers' use of this term.[36] Generally, these suits rely on state consumer protection laws, as well as on common-law fraud, misrepresentation, and express or implied warranty claims to argue that the inclusion of the "natural" label has caused harm.[37] Generally, the harm alleged is purely economic, with consumers arguing that they have paid more based on a misleading label or advertisement, or, that had they known of the presence of GMOs, they simply would not have purchased the product at all.[38] Many of these cases, although not all, are litigated in the Northern District of California, leading many to refer to that District as the "Food Court."[39] Outcomes, both there and in other districts, are varied; instead of settling the law, these lawsuits seem to have led to more questions than answers.

Many of these "natural" cases rely on *Williams v. Gerber Products Co*.[40] *Williams* dealt with a dispute over Gerber's Fruit Juice Snacks, which were packaged in a container that stated that the snacks were made "with real fruit juice and other all natural ingredients" and contained pictures of various fruits.[41] The consumer claimed that the labeling was misleading because the snacks did not contain any of the fruits pictured and were made with unnatural ingredients.[42] The Ninth Circuit reversed the district court's dismissal of the claim, noting that consumers could not be expected to check the back of the box to confirm any representations made on the front of the box.[43] The court specifically stated that "[w]e do not think that the FDA requires an ingredient list so that manufacturers can mislead consumers and then rely on

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34 Carey Gillam, *U.S. Foods Labeled 'Natural' Often Contain GMOs, Group Reports*, REUTERS (Oct. 7, 2014, 6:05 AM), https://www.reuters.com/article/us-usa-gmo-labeling/u-s-foods-labeled-natural-often-contain-gmos-group-reports-idUSKCN0HW0R520141007.

35 21 C.F.R. § 101.22 (2017).

36 *See* Mortazavi, *supra* note 1, at 932.

37 *See id.* at 950.

38 *Id.*; *see also* Ault v. J.M. Smucker Co., No. 13 Civ. 3409 (PAC), 2014 U.S. Dist. LEXIS 67118, at *5 (S.D.N.Y. 2014) (plaintiff alleged that the "All-Natural" representation was "material to her decision to purchase the products"); Garcia v. Kashi Co., 43 F. Supp. 3d 1359, 1368 (S.D. Fla 2014) (plaintiffs alleged that the "all natural" label induced them to purchase the product); Parker v. J.M. Smucker Co., No. C 13-0690 SC, 2013 WL 4516156, at *14 (N.D. Cal. Aug. 23, 2013) (plaintiff alleged she would not have made the purchase had she known about the presence of GMOs).

39 Paul M. Barrett, *California's Food Court: Where Lawyers Never Go Hungry*, BLOOMBERG BUSINESSWEEK (Aug. 23, 2013, 6:21 AM), http://www.bloomberg.com/news/articles/2013-08-22/californias-food-court-where-lawyers-never-go-hungry.

40 552 F.3d 934 (9th Cir. 2008).

41 *Id.* at 936.

42 *Id.*

43 *Id.* at 939.

the ingredient list to correct those misinterpretations and provide a shield for liability for the deception."[44]

Relying on this rationale, many courts have held that a "natural" representation on the front of a package would be a misrepresentation if the product contained GMOs.[45] For example, in *Rojas v. General Mills, Inc.*,[46] the court refused to grant a motion to dismiss despite the manufacturer's argument that its use of the word "natural" was in line with FDA rules.[47] The court specifically stated that the manufacturer's use of "natural"

> could easily be interpreted by consumers as a claim that all of the ingredients in the products are natural, which *appears to be false because they allegedly contain GMOs* and other synthetic ingredients. Taking these allegations as true and construing them in the light most favorable to the plaintiff, Rojas has adequately alleged that the representations on the products' labeling could plausibly deceive a reasonable consumer.[48]

And recently, the Ninth Circuit stated that "product information on a website . . . cannot override as a matter of law any misimpressions created by the label."[49] Many of these cases have resulted in substantial damage awards against the defendant manufacturers.[50] Sometimes, the defendants also agree to symbolic amends, such as switching to all non-GMO ingredients or going through a non-GMO verification process.[51]

However, not all courts agree with the *Williams* court's line of thinking, and some have held that the use of "natural" with GMO ingredients does not

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44 *Id.*

45 *E.g.*, Rojas v. Gen. Mills, Inc., No. 12-cv-05099-WHO, 2014 U.S. Dist. LEXIS 41315, at *17–18 (N.D. Cal. Mar. 26, 2014).

46 No. 12-cv-05099-WHO, 2014 U.S. Dist. LEXIS 41315 (N.D. Cal. Mar. 26, 2014).

47 *Id.* at *12. As described below, the FDA does not prevent a manufacturer from labeling a product as "natural" if the product also contains GMOs. *See* discussion *infra* Section II.B.2.

48 *Id.* at *10 (emphasis added); *see also* Ault v. J.M. Smucker Co., No. 13 Civ. 3409 (PAC), 2014 U.S. Dist. LEXIS 67118, at *3 (S.D.N.Y. May 15, 2014); In re Frito-Lay N. Am., Inc., No. 12-MD-2413, 2013 WL 4647512, at *16 (E.D.N.Y. Aug. 29, 2013) (denying a motion to dismiss because the court could not "conclude, as a matter of law, that the added context to the 'All Natural' label meets the heavy burden of 'extinguish[ing] the possibility' that a reasonable consumer could be misled into believing the products were GMO-free." (quoting Ackerman v. Coca-Cola Co., No. CV-09-0395 (JG) (RML), 2010 WL 2925955, at *16 (E.D.N.Y. July 21, 2010))); Parker v. J.M. Smucker Co., No. C 13-0690 SC, 2013 WL 4516156 at *18–19 (N.D. Cal. Aug. 23, 2013) (denying a motion to dismiss because "the Court cannot as a matter of law conclude . . . that reasonable consumers would all understand that packaged, non-organic foods may contain bioengineered ingredients.").

49 Balser v. Hain Celestial Grp., Inc., No. 14-55074, 640 F. App'x 694, 696 (9th Cir. 2016).

50 *See, e.g.*, Joe Van Acker, *Kashi to Pay $4M to Settle GMO False Ad Class Action*, LAW360 (June 8, 2012, 2:12 PM), http://www.law360.com/articles/664950/kashi-to-pay-4m-to-settle-gmo-false-ad-class-action ("Kashi Co. will pay up to $3.99 million to resolve a proposed class action accusing the company of falsely labeling products containing [GMOs] as being "all natural.").

51 *Id.*

mislead consumers.[52] In *Barnes v. Campbell Soup Co.*,[53] the court relied on express regulatory approval of the label in granting a motion to dismiss.[54] Because both the USDA and the FDA had approved the label, the court reasoned the label could not be inherently misleading.[55] Similarly, in *Gedalia v. Whole Foods Market Services, Inc.*,[56] the court granted a motion to dismiss by the defendant grocery store because the plaintiffs relied on in-store signage and advertisements regarding store brands instead of individual on-package labeling.[57] Because those expressions—the only common representation being "365 EVERYDAY VALUE"—were general and would not "plausibly suggest natural ingredients" in each and every product to a "reasonable consumer," the plaintiffs could not have been misled when purchasing individual products.[58]

Courts are also split on whether FDA guidance on the use of "natural" is necessary at all. In denying a motion to stay for FDA guidance on the definition of "natural," the court in *In re Frito-Lay North America, Inc.*[59] noted that the inquiry into whether a label was misleading to a reasonable consumer was something for which "courts are eminently well suited, even well versed."[60] The court also noted that an FDA definition of "natural" might not "shed any further light on whether a reasonable consumer is deceived by the 'All Natural' food label when it contains bioengineered ingredients."[61] On the other hand, several courts have recently stayed actions in light of the FDA's November 2015 announcement to reconsider its definition of "natural".[62] These decisions demonstrate that on both substantive and procedural questions, the courts are divided.

These incompatible outcomes are problematic. Producers prefer national standards in order to lower production costs and to avoid litigation

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52 *E.g.*, Barnes v. Campbell Soup Co., No. C 12-05185 JSW, 2013 WL 5530017, at * 7 (N.D. Cal. July 25, 2013).

53 No. C 12–05185 JSW, 2013 WL 5530017 (N.D. Cal. July 25, 2013).

54 *See id.* at *1, 5.

55 *Id.* at *5.

56 53 F. Supp. 3d. 943 (S.D. Tex. 2014).

57 *Id.* at 957–58, 961.

58 *Id.* at 958.

59 No. 12-MD-2413 (RRM)(RLM), 2013 WL 4647512 (E.D.N.Y. Aug. 29, 2013).

60 *Id.* at *8.

61 *Id.* at *8; *see also* Bohac v. Gen. Mills, Inc., No. 12-cv-05280-WHO, 2013 WL 5587924, at *3 (N.D. Cal. Oct. 10, 2013) ("Determining whether a term is false or misleading is within the province of the courts."); Krzykwa v. Campbell Soup Co., 946 F. Supp. 2d 1370, 1374–75 (S.D. Fla. 2013) (declining to dismiss the claim based on the defendant's argument that the FDA had not defined the term); Briseno v. ConAgra Foods, Inc., No. CV 11-05379 MMM (AGRx), 2011 WL 13128869, at *7 (C.D. Cal. Nov. 23, 2011) ("[E]very day courts decide whether conduct is misleading." (quoting Lockwood v. Conagra Foods, Inc., 597 F. Supp. 2d 1028, 1035 (N.D. Cal. 2011))).

62 *See* Kane v. Chobani, LLC, No. 14–15670, 645 F. App'x. 593, 594 (9th Cir. 2016); In re Kind LLC "Healthy & All Natural" Litig., 209 F. Supp. 3d 689, 698 (S.D.N.Y. 2016). For a discussion regarding FDA's November 2015 announcement to reconsider its definition of "natural," see *infra* Section II.B.2

altogether.[63] By one estimate, pre-trial motions alone can cost up to $2 million.[64] Further, manufacturers are often found liable despite adherence to FDA, USDA, and other regulatory agency guidance and regulation (e.g., *Williams*, *Rojas*).[65] And it is likely that the patchwork of often-settled class-action lawsuits are not helping consumers determine what a misleading label really looks like.[66] For that reason, some producers have taken labeling into their own hands; in January 2016, Campbell's announced that it would begin labeling all products containing GMOs.[67] The company also announced that it supported national mandatory labeling laws.[68] After Campbell's announcement, ConAgra, General Mills, Kellogg's, and Mars announced their own versions of voluntary GMO labeling programs.[69]

II. REGULATORY CONTROL OF FOOD LABELING

GMOs have historically been regulated by three federal agencies: the USDA, the FDA, and the Environmental Protection Agency ("EPA").[70] While the EPA's sole responsibility is overseeing potential GMO impacts on the environment,[71] the FDA oversees human and animal consumption of

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63 *See, e.g.*, Jeff Harmening, *We Need a National Solution for GMO Labeling*, TASTE OF GEN. MILLS (Mar. 18, 2016), http://www.blog.generalmills.com/2016/03/we-need-a-national-solution-for-gmo-labeling/ (noting that General Mills desires a "national solution to GMO communications to consumers").

64 Barrett, *supra* note 39; *see also* 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*,* 417 (2010) ("The lack of resolution surrounding the definition of 'natural' is creating an atmosphere of inefficiency and uncertainty among food producers, where the only clear winners appear to be the lawyers suing or defending companies for using the term 'natural' on their products.").

65 *See, e.g.*, Williams v. Gerber Products Co., 552 F.3d 934, 940 (9th Cir. 2008); Rojas v. Gen. Mills Inc., No. 12-cv-05099-WHO, 2014 U.S. Dist. LEXIS, at *21, 26 (N.D. Cal. Oct. 9, 2013).

66 *See* Glenn G. Lammi, *Another Unappetizing Class Action Ruling from the Food Court*, FORBES (Aug. 9, 2012, 12:07 PM), http://www.forbes.com/sites/wlf/2012/08/09/another-unappetizing-class-action-ruling-from-the-food-court/2/#2cdd43465d0a.

67 Sidney Fry, *Campbell Soup Stirs the Big Food Pot: Announces GMO Labeling*, COOKING LIGHT (Jan. 8, 2016), http://simmerandboil.cookinglight.com/2016/01/08/campbell-soup-company-gmo-labeling/.

68 *Campbell Announces Support for Mandatory GMO Labeling*, CAMPBELL'S (Jan. 7, 2016), https://www.campbellsoupcompany.com/newsroom/press-releases/campbell-announces-support-for-mandatory-gmo-labeling/.

69 Derrick Broze, *ConAgra Foods and Kellogg's Join Growing Number of Companies Voluntarily Labeling GMOs*, ACTIVIST POST (Mar. 28, 2016), http://www.activistpost.com/2016/03/conagra-foods-and-kelloggs-voluntarily-labeling-gmos.html.

70 Luis Acosta, *Restrictions on Genetically Modified Organisms: United States*, LIBRARY OF CONGRESS (Mar. 2014), https://www.loc.gov/law/help/restrictions-on-gmos/usa.php.

71 FED'N OF AM. SCIENTISTS, *U.S. Regulation of Genetically Modified Crops*, http://fas.org/biosecurity/education/dualuse-agriculture/2.-agricultural-biotechnology/us-regulation-of-genetically-

GMOs.[72] Prior to the passage of the National Bioengineered Food Disclosure Standard, the USDA focused its oversight on ensuring that GMOs would not harm agricultural products.[73] Under the new law, the USDA now additionally oversees GMO labeling of human consumable foods.[74] The FDA holds general authority over food labeling schemes, as explained below.[75]

A. *The USDA*

Generally, the USDA is tasked with promoting and protecting American agricultural interests.[76] While this includes non-food related policies, such as the administration of farm subsidies, development of rural economic plans, and conservation practices, much of the Agency's policies focus on regulating and promoting America's agricultural products.[77]

1. The USDA's General Food Regulatory Scheme

Two branches of the USDA regulate food labeling: the Food Safety and Inspection Service ("FSIS") and the Agricultural Marketing Service ("AMS"). FSIS is responsible for egg, meat, and poultry inspection and labeling.[78] AMS is responsible for organic labeling[79] and Country of Origin Labeling ("COOL").[80] Organic labeling is completely voluntary, used only by farmers and manufacturers who wish to grow, produce, and market

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engineered-crops.html (last visited Jan. 2, 2018). The EPA's role in GMO regulation is beyond the scope of this comment, as the EPA's authority controls the development of bioengineered pesticides and does not extend to labeling. For a general discussion of EPA regulation, see *EPA's Regulation of Biotechnology for Use in Pest Management*, U.S. ENVTL. PROTECTION AGENCY, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/epas-regulation-biotechnology-use-pest-management (last visited Jan. 2, 2018).

72 FED'N OF AM. SCIENTISTS, *supra* note 71.

73 This authority is understood to rest under 7 U.S.C. § 7712(a) (2012).

74 7 U.S.C. § 1639b (Supp. 2017).

75 *See* 21 U.S.C. § 343-1(a).

76 *See About the U.S. Department of Agriculture*, U.S. DEP'T OF AGRIC., http://www.usda.gov/wps/portal/usda/usdahome?navtype=MA&navid=ABOUT_USDA (last visited Nov. 8, 2017).

77 *Mission Areas*, U.S. DEP'T OF AGRIC., https://www.usda.gov/our-agency/about-usda/mission-areas (last visited Nov. 9, 2017).

78 *About FSIS*, U.S. DEP'T OF AGRIC., FOOD SAFETY & INSPECTION SERVICES, http://www.fsis.usda.gov/aboutfsis (last visited Nov. 9, 2017).

79 *Using the Organic Seal: Media, Marketing & Educational Materials*, U.S. DEP'T OF AGRIC., AGRIC. MKTG. SERV., https://www.ams.usda.gov/publications/content/using-organic-seal (last visited Nov. 9, 2017).

80 *FAQs – Country of Origin Labeling (Beef and Pork Repeal)*, U.S. DEP'T OF AGRIC. AGRIC. MKTG. SERV., https://www.ams.usda.gov/sites/default/files/media/FAQs%20-%20COOL%20Beef%20Pork%20Repeal.pdf (last visited Nov. 2, 2016).

organic products.[81] AMS is tasked with ensuring that the organic seal (which was created by the USDA) "is not used in a way that would negatively impact the value, integrity, or security of the seal as a marketing tool for certified organic products."[82] COOL labeling, a required disclosure, was partially repealed in 2015 as related to labeling of beef and pork.[83] However, COOL labeling is still required for "(i) muscle cuts of lamb and venison; (ii) ground lamb and ground venison; (iii) farm-raised fish; (iv) wild fish; (v) a perishable agricultural commodity; (vi) peanuts; and (vii) meat produced from goats; (viii) chicken, in whole and in part; (ix) ginseng; (x) pecans; and (xi) macadamia nuts."[84]

2. Historical Treatment of GMOs

Prior to the passage of the new law, the USDA rooted its authority to regulate genetically modified plants in the Plant Protection Act.[85] Specifically, the Act authorizes the USDA to "prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance" if deemed necessary to "prevent the introduction into . . . or the dissemination of a plant pest or noxious weed within the United States."[86] The Animal and Plant Health Inspection Service ("APHIS"), a branch of the USDA, implements this mandate.[87] APHIS treats all GMOs as plant pests,[88] ensuring that the introduction of a genetically modified plant is safe for agricultural use.[89] Generally, APHIS will look to whether either the original plant product that is being genetically modified or the donor species (the species

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81 *See Using the USDA Organic Seal: Media, Marketing & Educational Materials*, U.S. DEP'T OF AGRIC., https://www.ams.usda.gov/sites/default/files/media/Using%20the%20Organic%20Seal%20Factsheet.pdf (last visited Jan 2, 2017); *see also* 7 C.F.R. § 205.311 (2017).

82 U.S. DEP'T OF AGRIC., *supra* note 81; *see also Organic Labeling*, U.S. DEP'T OF AGRIC., AGRIC. MKTG. SERV., https://www.ams.usda.gov/rules-regulations/organic/labeling (last visited Nov. 8, 2017) (discussing organic labeling generally).

83 7 U.S.C. § 1638 (2012), *amended by* 7 U.S.C. § 1638 (Supp. 2017) (effective Dec. 18, 2015).

84 7 U.S.C § 1638(1)(A).

85 *See* 7 U.S.C. §§ 7701–7786 (2012); Acosta, *supra* note 70.

86 7 U.S.C. § 7712(a).

87 *Am I Regulated Under 7 CFR part 340?,* U.S. DEP'T OF AGRIC., ANIMAL & PLANT HEALTH INSPECTION SERV., https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated (last visited Nov. 8, 2017).

88 *Id.*; *see also* 7 C.F.R. § 340.1 (2017) (defining plant pest).

89 U.S. Dep't of Agric., Animal & Plant Health Inspection Serv., *Biotech Regulation Video*, YOUTUBE (Apr. 8, 2014), https://www.youtube.com/watch?v=ytzwXOaIvqQ&feature=youtu.be (explaining that "APHIS's role is to make sure that biotech products are safe for agriculture and the environment").

of plant "donating" its genetic material) is a plant pest.[90] If neither item is considered a plant pest, the "new" GMO plant receives regulatory approval and farmers can begin planting the product.[91] For example, in 2012, Del Monte Fresh Produce Company sought approval of a GMO pineapple with increased levels of lycopene.[92] The lycopene was derived from other pineapple varieties, as well as from tangerines.[93] Because neither the pineapple nor the genetic materials added to it (i.e., the genetic material pulled from other pineapple species and tangerines) was a plant pest, the new variety was approved by APHIS.[94]

3. The National Bioengineered Food Disclosure Standard

In July 2016, Congress passed the first GMO required-disclosure law, to be administered by the USDA.[95] Named the National Bioengineered Food Disclosure Standard,[96] the law was a reaction to Vermont's own GMO disclosure law passed in 2015.[97] Fearful of a balkanization of state GMO laws as other states responded to Vermont's law, Congress intended to create a national disclosure standard to which all manufacturers could adhere.[98] Signed into law by President Obama in July 2016, the law grants the USDA the authority to administer GMO labeling.[99]

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90 *See* Letter from Michael J. Firko, APHIS Deputy Administrator, to Mr. William Haun, Calyxt, Inc. (Sept. 15, 2016), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/16-090-01_air_response_signed.pdf; Letter from Michael J. Firko, APHIS Deputy Administrator, to Mr. Richard Hamilton, President and CEO of Ceres, Inc. (July 18, 2016), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/15-264-02_air_response_signed.pdf.

91 *See, e.g.*, Letter from Michael J. Firko, APHIS Deputy Administrator, to Mr. Richard Hamilton, President and CEO of Ceres, Inc. (June 3, 2016), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/15-035-01_air_response_signed.pdf) (confirming that TRSBG101B is not a regulated strain because it is not a plant pest and no organisms used as sources of its genetic material are plant pests).

92 Letter from Thomas Young, Senior Vice President of Del Monte Fresh Produce Company, Inc., to Mr. Michael C. Gregoire, APHIS Deputy Administrator (July 30, 2012), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/del_monte_inquiry_letter.pdf.

93 *Id.*

94 *See* Letter from Mr. Michael C. Gregoire, APHIS Deputy Administrator, to Thomas Young, Senior Vice President of Del Monte Fresh Produce Company, Inc. (Jan. 25, 2013), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/aphis_response_del_monte.pdf; *see also FDA Concludes Consultation on Pink Flesh Pineapple*, U.S. FOOD & DRUG ADMIN. (Dec. 14, 2016), http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm533075.htm.

95 National Bioengineered Food Disclosure Standard, 7 U.S.C. §§ 1639–39c (Supp. 2017).

96 *Id.*

97 Jason Daley, *Five Things to Know About the New GMO Labeling Bill*, SMITHSONIAN.COM (July 15, 2015), http://www.smithsonianmag.com/smart-news/five-things-know-about-new-gmo-labeling-bill-180959821/?no-ist.

98 *See* S. REP. NO. 114-403, at 1 (2016).

99 7 U.S.C. § 1639b.

Under the new law, the USDA is tasked with determining the level of genetically modified materials necessary for labeling, as well as any other factors that may require disclosure.[100] The Act requires disclosure in one of three forms: a textual disclosure, a symbol (which will be designed by the USDA), or an electronic or digital link.[101] The law mandates labeling when a food product is created with genetic material "modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques"[102] as well as when any product created with genetic material "could not otherwise be obtained through conventional breeding or found in nature."[103] A food product is defined by the FDCA, which defines food as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[104] Further, the law only applies to foods subject to labeling under the FDCA, the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.[105] Finally, the law preempts all other state GMO labeling regimes.[106]

Of the many criticisms directed at the Act, the allowance of the electronic or digital link is the most vigorous.[107] Commonly called a quick response, or "QR," code, the link is a small square composed of smaller black and white squares that can be scanned by a smartphone.[108] Once scanned, the smartphone user has access to a website that displays the required information.[109] The QR code operates much like a conventional barcode, with the consumer's smartphone acting as the scanner.[110] It requires that the consumer download a smartphone application ("app") capable of scanning the QR code.[111]

Many oppose the QR code option, as they believe manufacturers will use it to mask the GMO disclosure information.[112] Unlike a simple statement

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100 *Id.* § 1639b(b)(2)(B)–(C).

101 *Id.* § 1639b(b)(2)(D).

102 *Id.* § 1639(1)(A).

103 *Id.* § 1639(1)(B).

104 21 U.S.C. § 321(f) (2012); *see also* 7 U.S.C. § 1639(2).

105 *See* 7 U.S.C. § 1639a(c)(1)-(2); *see also* 21 U.S.C. §§ 301–399f (Food, Drug, and Cosmetic Act), §§ 601–695 (Federal Meat Inspection Act), §§ 451-472 (Poultry Products Inspection Act), §§ 1031–1056 (Egg Products Inspection Act).

106 7 U.S.C. § 1639i(b).

107 *See All Things Considered: The Salt*: *Congress Just Passed a GMO Bill. Nobody's Super Happy About It*, NAT'L PUB. RADIO (July 14, 2016), http://www.npr.org/sections/thesalt/2016/07/14/486060866/congress-just-passed-a-gmo-labeling-bill-nobodys-super-happy-about-it.

108 *QR code*, OXFORDDICTIONARIES.COM, https://en.oxforddictionaries.com/definition/qr_code (last visited Jan. 8, 2017).

109 *See* Rachel Swaby, *QR Code*, WIRED (Apr. 16, 2013), https://www.wired.com/2013/04/qrcode/.

110 *See id.*

111 *Id.*

112 *See, e.g.*, Jean Halloran, *5 Reasons Why QR Codes Aren't the Answer for GMO Labeling*, CONSUMERSUNION (May 18, 2016), http://consumersunion.org/2016/05/5-reasons-why-qr-codes-arent-the-answer-for-gmo-labeling/.

or symbol on the product packaging, the QR code makes finding this information much more difficult.[113] Critics claim that this is exactly what manufacturers want: if the information is harder to find, consumers are less likely to seek it out.[114] Further, critics argue that the average grocery shopper is unlikely to take the time to scan these codes.[115] As one Senator stated during floor debates, the QR code "shows a total lack of understanding about shopping in the real world," pointing out that "[t]he last thing a parent has is spare time to take out their phone and scan every product before placing it in their cart, even assuming the store has the Internet service . . . and . . . that person has a smartphone."[116] Further, critics argue that for those consumers who lack access to the internet (many rural consumers) or do not have the means to own a smartphone (low-income consumers), the QR code will provide no disclosure at all.[117]

In light of these concerns, the final Act requires the USDA to "conduct a study to identify potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods."[118] It further requires the study to focus on specific factors: "(A) The availability of wireless internet or cellular networks. (B) The availability of landline telephones in stores. (C) Challenges facing small retailers and rural retailers. (D) The efforts that retailers and other entities have taken to address potential technology and infrastructure challenges."[119] If the USDA determines that consumers will not have an adequate means to access this information, then it "shall provide additional and comparable options to access the bioengineering disclosure."[120]

In September 2017 the USDA released the study, which confirmed many of the concerns described above: while most Americans are familiar with QR codes, they also struggle to utilize them in a way that actually discloses the presence of GMO ingredients.[121] And it further confirmed that rural areas are at a disadvantage when utilizing tools that rely on internet access.[122]

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113 *Id.*

114 *See id*.; Swaby, *supra* note 109 ("For the majority of cell phone users, the experience [of using a QR code] is simply not worth the effort.").

115 *See, e.g.*, Halloran, *supra* note 112.

116 162 CONG. REC. S4,862 (daily ed. July 7, 2016) (statement of Sen. Blumenthal).

117 *See* 162 CONG. REC. H4,939 (daily ed. July 14, 2016) (statement of Rep. Lee) ("This bill will hurt the most vulnerable among us. The provision to include 'digital labeling' will withhold valuable information about GMO foods from rural, low-income and elderly Americans who are less likely to own a smart phone or have access to the internet.").

118 7 U.S.C. 1639b(c)(1) (Supp. 2017).

119 *Id.* § 1639b(c)(3).

120 *Id.* § 1639b(c)(4).

121 DELOITTE, *supra* note 3, at 35, 42

122 *Id.* at 21, 28.

To solve some of these issues, the study suggests that the USDA work to educate consumers on how to properly utilize QR codes[123] and that rural grocers and food retailers install either QR-scanning devices in store or beef up their internet service.[124] Of course, it also noted that retailers see little to no return on these types of investments, and so encouraging them to invest in these solutions could be problematic.[125]

It is unclear what options the USDA will have to address these issues or implement the study's proposed solutions. The law specifies that any language accompanying the QR code may only state: "'Scan here for more food information,' or equivalent language that only reflects technological changes."[126] And as the USDA Office of General Counsel noted in a letter to Congress, the law "does not provide any new authority to provide equipment, funding, or services to assist in accessing the electronic disclosure."[127]

Supporters point out that the QR code disclosure option offers a practical and moderate solution to the labeling debate.[128] As noted above, there are a myriad of reasons why consumers oppose GMOs (or simply want to know when and where they exist), and a physical product label will never be able to disclose enough information to satisfy all of those reasons. A QR code, however, can do just that by linking consumers to a more detailed and flexible webpage.[129] Further, because many consumers view GMOs in a negative light,[130] manufacturers worry that a label will stigmatize what are otherwise healthy foods.[131] A QR code may avoid that issue, as those who really care about accessing GMO information will utilize the QR code, while those who are indifferent to GMO information will not seek the information out.

While the QR code may have its benefits, it requires consumers to take an extra step in order to determine or confirm whether the advertised information on the front of the package aligns with their expectations. Not only does this fly in the face of *Williams*' rationale, but it is also contrary to the

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123 *Id.* at 68.

124 *Id.* at 5, 21, 66.

125 *Id.* at 67.

126 7 U.S.C. 1639b(d) (Supp. 2017).

127 Letter from Jeffrey M. Priesto, General Counsel, U.S. Dep't of Agric., to Rep. Michael Conaway (July 8, 2016), http://www.agri-pulse.com/Uploaded/USDA-OGC-conaway-response-letter-GMO.pdf.

128 *See* 162 CONG. REC. S4,855 (daily ed. July 7, 2016) (statement of Sen. Heitkamp); 162 CONG. REC. H4,934 (daily ed. July 14, 2016) (statement of Rep. Conway).

129 *See* Sarah Zhang, *QR Codes for GMO Labeling Could Actually Be a Great Idea.*, WIRED (July 14, 2016, 1:27 PM), https://www.wired.com/2016/07/qr-codes-gmo-labeling-actually-great-idea/.

130 *See* PEW RES. CTR, *supra* note 4, at 127.

131 *See* KENT D. MESSER ET AL., COUNCIL FOR AGRIC. SCI. & TECH., PROCESS LABELING OF FOOD: CONSUMER BEHAVIOR, THE AGRICULTURAL SECTOR, AND POLICY RECOMMENDATIONS 9 (2015); *see generally* Michelle Ye Hee Lee, *Would GMO Labeling Requirement Cost $500 More in Groceries Per Family a Year?*, WASH. POST (Apr. 6, 2015), https://www.washingtonpost.com/news/fact-checker/wp/2015/04/06/would-gmo-labeling-requirement-cost-500-more-in-groceries-per-family-a-year/; ALISON VAN EENENNAAM ET AL., COUNCIL FOR AGRIC. SCI. & TECH., THE POTENTIAL IMPACTS OF MANDATORY LABELING FOR GENETICALLY ENGINEERED FOOD IN THE UNITED STATES 9 (2014).

FDA's stance on food-product labeling. Further, the Act itself constricts the USDA's ability to respond to these failings. Because using a QR code can hide information that Congress has deemed important to disclose, the FDA should use its own broad authority to limit the use of natural advertising when the QR code is utilized. The basis for this authority is discussed below.

B. *The FDA's Authority over Food Labeling*

The FDA oversees the nation's "health."[132] According to its mission statement, the FDA is responsible for "ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices," as well as regulating "our nation's food supply, cosmetics, and products that emit radiation."[133]

1. The FDA's Broad Authority over Food Labeling

The FDA is responsible for the bulk of American food labeling.[134] The Agency draws its primary authority to regulate labeling from the FDCA, originally enacted in 1938.[135] 21 U.S.C. § 343 specifically relates to "misbranded" food, and states that a food shall be deemed misbranded if it includes a "false or misleading label."[136] Historically, the FDA has treated "misleading" as any label that is inaccurate or untruthful.[137] In setting labeling requirements, the FDA relies primarily on section 701(a) of the FDCA, which grants the Secretary the authority to "promulgate regulations for the *efficient enforcement* of this chapter."[138]

The Agency has used this language to exercise broad authority over both rulemaking and jurisdiction,[139] and this broad decisionmaking authority was affirmed by a 1973 Supreme Court decision known as the *Hynson Quartet*.[140]

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132 *What We Do*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/ (last visited Jan. 2, 2018).

133 *Id.*

134 *See generally Packaging, Labeling, Transporting, Storing*, N.D STATE UNIV., https://www.ag.ndsu.edu/foodlaw/processingsector/packaging-labeling (last visited Nov. 12, 2017).

135 *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–99g (2012).

136 *Id.* § 343(a).

137 *See FDA: Foods Must Contain What Label Says*, U.S. FOOD & DRUG ADMIN. (Feb. 4, 2013), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm337628.htm.

138 21 U.S.C. § 371(a) (emphasis added).

139 *See* Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 50 FOOD & DRUG L.J. 101, 102 (1995) (arguing that the FDCA acts more like a constitution, "establish[ing] a set of fundamental objectives."); *see also* Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 HARV. L. REV. 467, 558 (2002).

140 The *Hynson Quartet* are *USV Pharm. Corp. v. Weinberger*, 412 U.S. 655 (1973); *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645 (1973); *CIBA Corp. v. Weinberger*, 412 U.S. 640 (1973); and

There, the Court upheld the Agency's decision to bar administrative hearings when it determined that it was impossible for the respondent company to bring sufficient evidence to defend its claim.[141] This decision foreshadowed a predisposition by courts to treat FDA decisions with deference, primarily due to the Agency's special scientific expertise.[142]

With this authority, the FDA has promulgated extremely specific requirements for food labeling. These requirements can include, but are not limited to, the size and placement of certain required information, the placement of certain disclosures in conjunction with other statements, and prohibitions against "intervening material."[143] For example, manufacturers are required to place food-identity and quantity information on the principle display panel ("PDP"), which is the panel first seen by consumers on store shelves.[144] If manufacturers opt not to place other required information on the PDP, such as the manufacturer's name and address, they must place it to the right of the PDP, which is referred to as the information panel.[145] Required information cannot be placed anywhere else on the packaging, and that information cannot be interrupted by "intervening material."[146] If the manufacturer lists anything that is not required, it is considered intervening material.[147] These strict and specific requirements are in addition to any required disclosures about a product's nutrition, calorie content, and allergen information,[148] and they reflect the FDA's goal to ensure that food products are "honestly labeled."[149]

An example of this labeling specificity is seen in an August 2015 FDA warning letter to Hampton Creek, producer of "Just Mayo," an egg-less brand of mayonnaise.[150] To be legally considered mayonnaise, the product must contain eggs.[151] Due to the picture of an egg on the front of the label, the FDA

Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973). Brett M. Paben, *Lack of Interest in Consumer Interests: FDA's Narrow Perspective on Food Labeling and Label Statements Undermines a Century of Agency Leadership*, 13 RUTGERS J.L. & PUB. POL'Y 174, 198, 198 n.177 (2015).

141 *See* James O'Reilly, *Jurisdiction to Decide an Agency's Own Jurisdiction: The Forgotten Tale of the Hynson Quartet*, 58 ADMIN. L. REV. 829, 835–36 (2006).

142 Paben, *supra* note 140, at 200.

143 GUIDANCE FOR INDUSTRY: A FOOD LABELING GUIDE, U.S. FOOD & DRUG ADMIN. 5–6 (Jan. 2013), https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM265446.pdf.

144 *Id.* at 5.

145 *Id.*

146 *Id.* at 5–6.

147 *Id.* at 6.

148 *Id.* at 20, 25.

149 *FDA Basics: Food*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/Transparency/Basics/ucm195786.htm (last visited Nov. 12, 2017).

150 Beth Kowitt, *The Mayo Wars Just Ended*, FORTUNE (Dec. 14, 2015), http://fortune.com/2015/12/17/hampton-creek-just-mayo-fda/.

151 21 C.F.R. § 169.140(a), (c) (2017) (stating that mayonnaise must contain "egg yolk-containing ingredients").

believed the product label was misleading.[152] In addition, the FDA believed the use of "Just" in the product name "suggest[ed] that [the products] are 'all mayonnaise' or 'nothing but' mayonnaise," which was inaccurate because the product contained no eggs.[153] Ultimately, Hampton Creek was allowed to keep the name, but it had to make the "egg-free" disclosure larger and more prominent and was required to explain that "just" did not refer to regular mayonnaise, but instead to "justice and fairness."[154] This type of letter and outcome is illustrative of the FDA's emphasis on regulating food labels so that consumers are well informed or, at the very least, not misled after a quick glance at the label.[155]

More recently, the FDA has taken steps to ensure that standardized labels will convey the information deemed necessary after a quick, cursory glance. In May 2016, the Agency unveiled a new Nutrition Facts Label, the standard calorie and ingredient label required on all manufactured and packaged foods.[156] Most notably, the label must disclose added sugars, a larger font for calories, and more realistic serving size suggestions.[157] For example, in recognizing that the average consumer rarely consumes only a half-cup of ice cream, the serving size for ice cream has been changed to two-thirds of a cup.[158] Similarly, the FDA now requires products that are generally consumed in one sitting to be labeled as one serving, instead of the previous two to three servings that many manufacturers listed.[159] For example, prior to the change, a can of soup would include the nutrition information for one serving, and a note that there were two to three servings in that can.[160] Now, the label will reflect the nutrition information as if a consumer were to consume the entire

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152 Letter from William A. Correll, Jr., Office of Compliance Director, Public Health Serv., Food & Drug Admin., to Joshua Tetrick, Founder and Chief Executive Officer, Hampton Creek Foods, Inc. (Aug. 12, 2015), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm458824.htm.

153 *Id.*

154 Stephanie Strom, *F.D.A. Allows Maker of Just Mayo to Keep Product's Name*, N.Y. TIMES (Dec. 17, 2015), http://www.nytimes.com/2015/12/18/business/fda-allows-maker-of-just-mayo-to-keep-products-name.html.

155 *See generally FDA: Foods Must Contain What Label Says*, U.S. FOOD & DRUG ADMIN. (Feb. 4, 2013), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm337628.htm; *How to Understand and Use the Nutrition Facts Label*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm274593.htm (last visited Jan. 3, 2018).

156 Robert M. Califf & Susan Mayne, *Unveiling the New Nutrition Facts Label*, U.S. FOOD & DRUG ADMIN. (May 20, 2016), http://blogs.fda.gov/fdavoice/index.php/2016/05/unveiling-the-new-nutrition-facts-label/.

157 *Changes to the Nutrition Facts Label*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm#highlights (last visited Jan. 3, 2018).

158 *Food Serving Sizes Get a Reality Check*, U.S. FOOD & DRUG ADMIN. (Aug. 18, 2016), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm386203.htm.

159 U.S. FOOD & DRUG ADMIN., *supra* note 157.

160 *Id.*

can in one sitting.[161] And for products that are larger than one serving, but are often consumed in one sitting, such as a can of soda, or a candy bar, the manufacturer will be required to list both the nutrient and calorie information for one serving *and* for the entire package.[162] These changes are intended to "make it easier for consumers to make informed choices about what they're eating."[163] They also reflect the FDA's belief that labels should serve as an easy and convenient way for consumers to gather as much information as possible about the product they intend to purchase.[164]

2. The FDA's Treatment of "Natural"

The FDA has never officially defined "natural."[165] Generally, the Agency states that doing so is too difficult or that the Agency has higher priorities.[166] However, the FDA's policy is that manufacturers may only use a "natural" label when "nothing artificial or synthetic . . . has been included in, or has been added to, a food that would not normally be expected to be in the food."[167] For example, color additives preclude a "natural" label, as color additives are considered "synthetic."[168] In 2015, the FDA sent a warning letter to Wonder Natural Foods Corp. requesting that the company remove the "natural" wording on the front of a label where the product contained added color.[169] That letter specifically explained that "any added color is artificially coloring a food," thus precluding a natural label.[170]

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161 *Id.*

162 *Id.*

163 Califf & Mayne, *supra* note 156.

164 *Id.*

165 *See "Natural" on Food Labeling*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm (last visited Jan. 3, 2018).

166 *See generally* Statement of Policy: Foods Derived from New Plant Varieties**,** 57 Fed. Reg. 22,984, 22,991 (May 29, 1992); Greg Ryan, *FDA Won't Define 'Natural' Food Despite Judges' Pleas*, LAW360 (Jan. 7, 2014, 8:17 PM), http://www.law360.com/articles/499387/fda-won-t-define-natural-food-despite-judges-pleas.

167 Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2,302, 2,407 (Jan. 6, 1993) (codified at 21 C.F.R. § 101.22).

168 *Id.*; U.S. FOOD & DRUG ADMIN., *supra* note 165.

169 Letter from William A. Correll, Jr., Office of Compliance Director, Public Health Serv., Food & Drug Admin., to Stuart Lasdon, owner, Wonder Nat. Foods Corp. (July 13, 2015), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm460910.htm; *see also* Letter from Michael D. Roosevelt, Office of Compliance Acting Director, Public Health Serv., Food & Drug Admin., to Alex Dzieduszycki, CEO and President, Alexia Foods, Inc. (Nov. 16, 2011), http://wayback.archive-it.org/7993/20161023100513/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm281118.htm.

170 *See* Letter from Correll, *supra* note 169.

GMOs are not considered "artificial or synthetic" because the FDA does not consider their creation "synthetic."[171] Even though many GMOs are created through complicated DNA splicing procedures or other genetic engineering methods, the genetic material included in (or eliminated from) the GMO product is natural in the sense that it does not include any man-made ingredients.[172] Nothing "artificial" is added to the final GMO product, even if the final product is a combination of genetic material that would not otherwise breed or combine in nature.[173] However, the FDA will require additional labeling when there are "compositional differences" in the end product and the conventional one.[174] For example, if a manufacturer were to use a genetic technique that produced a soybean oil containing a higher level of oleic acid than is usually present in conventional soybean oil,[175] the manufacturer would be required to label the product as "high oleic soybean oil" instead of just "soybean oil."[176] While the FDA will issue warning letters based on this definition of "natural,"[177] many in the industry complain of random and unpredictable application of these regulations, and call for greater clarity on the issue.[178] Due to these complaints, the FDA announced in November 2015 that it was considering changing its definition of "natural."[179] In addition to manufacturer complaints, the FDA cited several citizen petitions requesting a formal definition, as well as continued court pressure and increased litigation, as an impetus for formally defining natural.[180]

3. The FDA's Shared Regulatory Space

Because the FDA is presumed to have authority over all food labeling under the FDCA,[181] its regulations often overlap with regulatory schemes

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171 *What Is the Meaning of 'Natural' on the Label of Food?*, U.S. FOOD & DRUG ADMIN. (Mar. 4, 2016), http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214868.htm.

172 *See generally* Chelsea Powell, *How to Make a GMO*, HARV. U.: SCIENCE IN THE NEWS (Aug. 9, 2015), http://sitn.hms.harvard.edu/flash/2015/how-to-make-a-gmo/.

173 U.S. FOOD & DRUG ADMIN., *supra* note 165.

174 *Labeling of Foods Derived from Genetically Engineered Plants*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/ingredientspackaginglabeling/geplants/ucm346858.htm (last visited Jan. 3, 2018).

175 Here, a conventional product is one that is produced with no genetic techniques.

176 U.S. FOOD & DRUG ADMIN., *supra* note 174.

177 *See* Letter from Correll, *supra* note 169; Letter from Roosevelt, *supra* note 169.

178 *See* Elaine Watson, *FDA Revises Warning Letter Over HFCS and 100% Natural Claims to 'Avoid Any Confusion,'* FOODNAVIGATOR-USA.COM (July 10, 2015), http://www.foodnavigator-usa.com/Regulation/FDA-to-revise-warning-letter-over-HFCS-and-all-natural-claims; U.S. FOOD & DRUG ADMIN., *supra* note 165.

179 U.S. FOOD & DRUG ADMIN., *supra* note 165.

180 *Id.*

181 *See* 21 U.S.C. § 371(a) (2012).

attributed to other agencies. Prior to the passage of the new law, GMO regulation was an obvious example of this.[182]

The FDA often relies on its broad directive to assert authority over areas controlled by other agencies. For example, after years of disagreement over who held authority over alcoholic beverage labeling, the Bureau of Alcohol, Tobacco, Firearms, and Explosives ("ATF") and the FDA agreed to split control.[183] The two agencies agreed that ATF would be responsible for promulgating labeling rules, but would agree to take action when the FDA found that substances contained in a product were dangerous or adverse to public health.[184] In return for giving up part of its authority, the FDA would retain the ability to independently recall tainted or dangerous alcoholic beverages.[185] In 2010, at the FDA's request, the Alcohol and Tobacco Tax and Trade Bureau ("TTB"), an arm of the ATF, issued a letter to four manufacturers of caffeinated alcoholic beverages, stating that the products were considered "adulterated" under the FDCA.[186] The TTB noted that it deferred to the FDA's determination as to whether the product was adulterated, and explained that any product considered adulterated under the FDCA would be considered "mislabeled under the [Federal Alcohol Administration Act.]"[187]

Likewise, the FDA has asserted authority over some of the USDA's meat and egg regulations.[188] Worried about food additives (an area regulated by the FDA) in egg and meat products (regulated by the USDA), the two agencies entered into an agreement to deal with the overlap.[189] Specifically, each agency regulates its own products, but subsequently submits the item to be regulated to the other agency for review.[190] The FDA's motivation for such an arrangement was to ensure that the ingredients added to meat and egg products were in line with the Agency's standards for all food additives, and could be categorized as "generally recognized as safe" ("GRAS"), the

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182 *See* U.S. DEP'T OF AGRIC., *supra* note 89.

183 *See* Elaine T. Byszewski, *What's in the Wine? A History of FDA's Role*, 57 FOOD & DRUG L.J. 545, 562 (2002).

184 Memorandum of Understanding Between the Food and Drug Administration and the Bureau of Alcohol, Tobacco and Firearms (Nov. 20, 1987), https://www.ttb.gov/main_pages/memo-understanding.shtml; *see also* Byszewski, *supra* note 183, at 562.

185 *See* Alcohol & Tobacco Tax & Trade Bureau, *supra* note 185; Industry Circular No. 2017-4, Voluntary Alcohol Beverage Recalls, ALCOHOL & TOBACCO TAX & TRADE BUREAU (Sept. 29, 2017), https://www.ttb.gov/industry_circulars/archives/17-4.shtml.

186 *Alcohol Beverages with Added Caffeine*, ALCOHOL & TOBACCO TAX & TRADE BUREAU, https://www.ttb.gov/main_pages/caffeine-added.shtml (last visited Dec. 1, 2017).

187 *Id.*

188 Memorandum of Understanding Between the Food Safety and Inspection Serv., U.S. Dep't of Agric. and the Food and Drug Admin., U.S. Dep't of Health & Human Services (Feb. 23, 1999), https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm117094.htm.

189 *Id.*

190 *See id.*

standard by which the FDA measures all food additives and ingredients.[191] Similarly, after years of conflict over the appropriate recommendation of fish consumption to combat mercury concerns,[192] the FDA and the EPA released a joint statement recommending that young children and women who were pregnant or breastfeeding refrain from, or severely limit, their consumption of fish.[193] Those recommendations have since been revised to reflect the FDA's stance that fish consumption imparts important health benefits, and that all Americans, including at-risk groups, should consume fish for its important health benefits, a stance previously renounced by the EPA.[194]

III. TO DECREASE CONSUMER CONFUSION, THE FDA SHOULD DEFINE "NATURAL" WITH THE GMO BILL IN MIND

Because the FDA is concerned with consumer confusion and has authority to regulate misleading labeling, it should require that "natural" cannot be used in conjunction with a QR code. As the above-described litigation demonstrates, consumers glancing at the front of a package label will likely assume that a "natural" representation precludes GMO ingredients. While a text or a symbol will disprove that assumption, the QR code will not. Because the QR code does not explain its purpose, a consumer seeking out a confirmation regarding the natural label as it pertains to GMOs will have no more information than if the QR code were absent. Furthermore, a reasonable consumer may presume that the product using the QR code does not contain GMOs if and when that consumer compares the product with the QR code to similar products using the text or symbol disclosure options.

Imagine the following scenario: a hypothetical consumer, like the one introduced at the beginning of this Article, grabs two bags of chips while grocery shopping. Both are labeled "All-Natural," or something substantially similar. When the consumer turns over the bags to compare ingredients, one

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191 *See id.*; Substances Generally Recognized as Safe, 81 Fed. Reg. 54,986, 55,029 (Aug. 17, 2016) (codified in scattered sections of 21 C.F.R.); *see also Generally Recognized as Safe (GRAS)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/ingredientspackaginglabeling/gras/ (last updated Sept. 26, 2018).

192 *See* Mark Holden, *FDA-EPA Public Health Guidance on Fish Consumption: A Case Study on Information Interagency Cooperation in "Shared Regulatory Space,"* 70 FOOD & DRUG L.J. 101, 125–32 (2015).

193 *Id.* at 128.

194 *FDA and EPA Issue Final Fish Consumption Advice*, U.S. FOOD & DRUG ADMIN. (Jan. 18, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm537362.htm; *see also* Holden, *supra* note 192, at 132. The examples given here are not exhaustive. Because the FDA's reach is so broad but often underutilized, the Agency has engaged in a number of agreements with other agencies. *See generally Domestic MOUs*, U.S. FOOD & DRUG ADMIN. (Oct. 6, 2016), http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/default.htm.

has a QR code on the back and the other contains a text or symbol disclosing the presence of GMO ingredients. The consumer is unfamiliar with the use of the QR code, which contains no language describing or qualifying the QR code's purpose, as required by the law.[195] However, based on experiences with other labeling regimes (e.g., organic, allergen information), the consumer assumes that if one product contains a disclosure of some sort, those products without that same disclosure must lack the disclosed ingredient or allergen in question. It is likely that this consumer, acting reasonably, will infer that the product labeled with a clear text or symbol is the product containing GMOs, and that the other is not. By relying on the information on the package, the consumer is misled into believing that the product with the QR code is free of GMOs.

Because so many consumers believe the word "natural" precludes the use of GMOs, the use of a QR code will prevent consumers from confirming—or disproving—that belief. Where a clear text or symbol will inform a consumer as to the accuracy of his or her belief about the presence of GMOs in a "natural" product, a QR code alone will provide no such confirmation. While the FDA has no authority over GMO labeling, it can promulgate rules about "natural" labeling, and has recently stated that it is considering changing its stance on "natural" labeling. In order to help consumers navigate the intersection between GMO and "natural" labels, the FDA should ban the use of "natural" when a manufacturer chooses the QR code as its disclosure method.

The FDA has its own reasons for supplementing the GMO bill, as it has already expressed concerns over the new law's QR code provision. In a letter to the Senate Agriculture Committee, the FDA wrote:

> We note that provisions to allow information regarding the [GMO] content of food to be presented only in an electronically accessible form and not on the package label would be in tension with FDA's statute and regulations, *which require disclosures on food labels.* For example, under FDA's provisions, information such as Nutrition Facts and the list of ingredients *must be displayed directly on the label.* To avoid potential conflicts, the drafters could make clear in this bill that it will not affect FDA's labeling requirements in the future.[196]

The FDA's observation that the QR code is in direct conflict with its own regulations and its need to notify Congress about such conflict indicate that it is predicting consumer confusion over the use of the QR code. As such, and in light of its renewed interest in natural labeling, a move to mitigate consumer confusion over the intersection of GMO and "natural" labeling by

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195 For legal requirements, see 7 U.S.C. § 1639b(d) (Supp. 2017).

196 *FDA/HHS Technical Assistance on Senate Agriculture Committee Draft Legislation to Establish a National Disclosure Standard for Bioengineered Foods*, U.S. FOOD & DRUG ADMIN., at 1 (June 27, 2016), http://www.centerforfoodsafety.org/files/fda-to-senate-ag-on-draft-legislation_29928.pdf (emphasis added). *See also* Letter from Roosevelt, *supra* note 169.

removing the use of "natural" in conjunction with a QR code would further the Agency's overall goal of preventing consumer confusion.

As stated earlier, the FDA has refused to define "natural" for a number of reasons, and it is not clear that those reasons have disappeared, or that defining the term will grant consumers the clarity they need.[197] Formally defining "natural" will be no easier or more difficult than it was before. For the same reasons that the FDA has resisted defining the term in the past, the Agency may find it difficult to formally define "natural" now and in the future. Limiting the word's use as it pertains to additional labeling schemes, such as this one, will help the FDA avoid overly defining the term or defining it incorrectly. Like the policy prohibiting the use of "natural" when a product contains added colors or synthetic ingredients, the FDA should prohibit its use when a manufacturer opts to use the QR code.

Furthermore, the new law does not touch upon "natural" labeling, and therefore allows the FDA to step into the "natural" realm.[198] There is nothing preventing the FDA from viewing its authority under the FDCA as a complement to the National Bioengineered Food Disclosure Standard, allowing the FDA to regulate the use of "natural" on the label to prevent "misleading" claims. A reading of the new law in conjunction with the FDCA supports the fact that the USDA has authority to promulgate rules about the requirements of whether a product needs to be labeled in accordance with the GMO law; the FDA retains its authority over packaging that may or may not be misleading, taken as a whole.[199] Once a manufacturer labels its product as containing a GMO, it leaves the USDA's jurisdiction and enters the FDA's. If the FDA believes the product's front label claim (i.e., "All-Natural," or something substantially similar) is misleading in conjunction with a QR code, it has the authority to ban such claims (even if it cannot regulate the use of the QR code).[200]

Many who argue against GMO labeling point out that there is no evidence that GMO consumption causes physical harm.[201] That argument could be extended to the FDA entering into this realm: unlike other areas, where a misleading label could cause consumer harm (allergies, gluten insensitivities, kosher, etc.), the lack of harm here precludes FDA authority, and

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197 *See generally* Anahad O'Connor, *Is Your Food 'Natural'? F.D.A. to Weigh In*, N.Y. TIMES: WELL (May 17, 2016, 5:31 AM), http://well.blogs.nytimes.com/2016/05/17/is-your-food-natural-f-d-a-to-weigh-in/?_r=0; Margot Pollans, *The Labeling Shortcut*, SLATE (May 5, 2016, 9:00AM), http://www.slate.com/articles/health_and_science/science/2016/05/the_fda_s_quest_to_define_natural_won_t_give_us_better_food.html.

198 *See generally* 7 U.S.C. § 1639 (Supp. 2017); Glenn S. Kerner, *Food for Thought: The Federal GMO Labeling Law*, FOOD SAFETY MAG. (Feb./Mar. 2017), https://www.foodsafetymagazine.com/magazine-archive1/februarymarch-2017/food-for-thought-the-federal-gmo-labeling-law/.

199 7 U.S.C. § 1639 (not changing the FDA's authority over packaging accuracy); 21 U.S.C. § 343 (2012) (FDA's authority); Kerner, *supra* note 199.

200 *See* Kerner, *supra* note 199.

201 *See, e.g.*, The Editors, *supra* note 30.

promulgating any rule in that realm would be an overextension of its authority. However, that consumers do not suffer any physical harm after consuming GMOs is irrelevant. Individuals all have their own reasons for avoiding GMOs, and by passing this law, Congress created an interest in consumer knowledge about the presence of GMOs. Because the law makes accessing this information more difficult, and perhaps impossible for some, those who are unable to benefit from the law are in fact harmed. And because that harm comes from misleading statements, the FDA holds authority.

In *American Meat Institute v. U.S. Department of Agriculture*,[202] the D.C. Circuit dealt with such an issue.[203] In 2002, Congress passed a law requiring country-of-origin labeling,[204] with enforcement and rules to be determined by the USDA.[205] The court dealt with the question of the disclosure's constitutionality under the First Amendment.[206] When evaluating First Amendment questions under a required disclosure scheme, courts will uphold a requirement that is "reasonably related to the State's interest in preventing deception of consumers."[207] If a requirement is reasonably related, it usually presents no First Amendment concerns.[208] As such, the court needed to decide if a country-of-origin requirement was a strong enough government interest to control the manufacturer's speech.[209] In examining the government's interest in such a requirement, the court discussed, among other things, consumers' interest in knowing where their food originated (e.g., the purpose of a country-of-origin label).[210] More importantly, the court noted that "the 'precise interests' served by the 2013 rule *are simply those advanced by Congress in adopting the statute*."[211] Instead of banning country-of-origin disclosures, Congress decided that consumer knowledge about where one's meat originated was worth a required disclosure.[212] The court

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202 760 F.3d 18 (D.C. Cir. 2014) (en banc).

203 *Id.* at 20.

204 As described in Section II.A.1, COOL labeling was partially repealed in 2015. *See* AGRIC. MKTG. SERV., U.S. DEP'T OF AGRIC., *supra* note 80; *see also* Nancy Fink Huehnergarth, *Quashing Consumers' Right-to-Know, Congress Repeals Country-of-Origin-Labeling for Beef and Pork*, FORBES (Dec. 21, 2015, 4:56 PM), http://www.forbes.com/sites/nancyhuehnergarth/2015/12/21/quashing-consumers-right-to-know-congress-repeals-country-of-origin-labeling-for-beef-and-pork/#7b6c84a33fb3.

205 *Am. Meat Inst.*, 760 F.3d at 20 (explaining that the Secretary of Agriculture was tasked with implementing COOL labels).

206 *Id.* The court relied on *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985) in its discussion, which is the dispositive First Amendment case addressing required disclosures. The First Amendment issues raised in disclosure statements are beyond the scope of this comment.

207 *See Zauderer*, 471 U.S. at 651, 651–52 n.14.

208 *See id.*

209 *See, e.g.*, *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 21 (D.C. Cir. 2014) (en banc).

210 *See id.* at 23–24.

211 *Id.* at 25 (emphasis added).

212 *See id.* at 23.

saw a valid interest in this congressionally created knowledge,[213] and therefore, the law presented no First Amendment concerns.[214]

The same analysis could be extended to the current GMO disclosure standard. By passing this law, Congress decided that GMO information is something that consumers deserve to know. Despite Vermont's law serving as motivation,[215] Congress was not obligated to pass a law requiring disclosure. It elected to require disclosure, instead of banning it, which was certainly its prerogative. As such, a standard that may confuse consumers and deprive them of the information Congress deemed important does in fact create harm.

Alternatively, it is possible that the "harm" caused by this law is more than a lack of information. In declaring Vermont's GMO labeling law constitutional, the U.S. District Court for the District of Vermont based its decision on the *potential* for GMOs to cause harm.[216] In passing the law, Vermont's General Assembly declared a number of findings that dealt with GMOs' potential to cause harm.[217] The relevant findings stated:

> (D) There is a lack of consensus regarding the validity of the research and science surrounding the safety of genetically engineered foods, as indicated by the fact that there are peer-reviewed studies published in international scientific literature showing negative, neutral, and positive health results.
>
> (E) There have been no long-term or epidemiologic studies in the United States that examine the safety of human consumption of genetically engineered foods.[218]

The findings further stated:

> (A) There are conflicting studies assessing the health consequences of food produced from genetic engineering.
>
> (B) The genetic engineering of plants and animals may cause unintended consequences.
>
> (C) The use of genetically engineered crops is increasing in commodity agricultural production practices, which contribute to genetic homogeneity, loss of biodiversity, and increased vulnerability of crops to pests, diseases, and variable climate conditions.
>
> (D) Cross-pollination of or cross-contamination by genetically engineered crops may contaminate organic crops and, consequently, affect marketability of those crops.
>
> (E) Cross-pollination from genetically engineered crops may have an adverse effect on native flora and fauna. The transfer of unnatural deoxyribonucleic acid to wild relatives can lead to

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213 *See id.* at 25.

214 *Id.* at 27.

215 *See* Daley, *supra* note 97.

216 *See* Grocery Mfrs. Ass'n v. Sorrell, 102 F. Supp. 3d 583, 634 (D. Vt. 2015).

217 *See id.* at 597–98.

218 Act of May 8, 2014, No. 120, § 1(4)(A)-(E), VT. STAT. ANN. tit. 9, §§ 3041–3048 (West 2018); *see also Grocery Mfrs. Ass'n*, 102 F. Supp. 3d at 597.

> displacement of those native plants, and in turn, displacement of the native fauna dependent on those wild varieties.[219]

In evaluating the required GMO disclosure, the court noted that any disclosure requirement must be "reasonably related" to a government interest, or that the disclosure must "promote informed consumer decision-making."[220] The government interest could not be solely "consumer curiosity."[221] However, the court noted that the Assembly's emphasis on inconclusive scientific studies indicated that the law was based on more than consumer curiosity.[222] Preventing potential negative environmental impacts and taking an affirmative stance against potential health issues were deemed sufficient concerns to warrant the labeling law.[223]

As explained above, there is no clear evidence that GMOs cause harm. However, in the eyes of many policymakers and some courts, the inconclusiveness of studies on GMOs and the potential for harm are enough to warrant a clear disclosure.[224] This potential for harm, paired with a consumer's disadvantage in seeking out GMO information, provides a firm basis for the FDA's authority.

CONCLUSION

The solution proposed here will not solve all consumer confusion over the "natural" or GMO debate. There will still exist some situations in which consumers may be confused over "natural" claims, GMO labeling, or a combination of the two. However, this Article has proposed and defended a way in which the FDA can mitigate the failures of this new law, placing a small, yet substantial dent in the litigation arising over this issue and helping consumers make more informed decisions about GMO foods. Further, this solution defends an agency's broad reading of its authority in situations in which a law fails certain groups, as exemplified by the National Bioengineered Food Disclosure Standard. When these situations arise, agencies should not be afraid to assert their own authority if and when they see failure in later statutes. While agencies should be careful not to overstep their authority, they should not be afraid to use that authority to supplement laws that fail in certain ways.

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219 Act of May 8, 2014, No. 120, § 1(4)(A)-(E), VT. STAT. ANN. tit. 9, §§ 3041–3048 (West 2018); *see also Grocery Mfrs. Ass'n*, 102 F. Supp. 3d at 597.

220 *Grocery Mfrs. Ass'n*, 102 F. Supp. 3d at 627, 634 (first quoting Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985); then quoting *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 556 F.3d 114, 134 (2d Cir. 2009)).

221 *Id.* at 630.

222 *Id.* at 631.

223 *Id.*

224 *See id.*

As smartphone use and internet access become more prevalent and more accessible, the benefits of using technology to better inform consumers and the public at large may soon outweigh the drawbacks. However, until that point is reached, consumers are at a disadvantage when they must take additional and sometimes unnecessary steps to access that information. If and when agencies see consumers at such a disadvantage, they should use their authority as broadly as their enabling statutes allow in order to give American citizens the optimal benefit of laws passed under these schemes.