2013

# Genetically Modified Food Fight: The FDA Should Step Up to the Regulatory Plate So States Do Not Cross the Constitutional Line

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

*Morgan Anderson Helme*∗

We know how many calories are in it. We know if it contains gluten, and its percentage of sodium out of an ideal daily diet.[1] Fat-free, sugar-free, may contain peanuts, all natural, and an excellent source of fiber—the label spells it all out for concerned consumers.[2] But despite this apparent glutton of information about the food we eat,[3] the use of genetically modified ingredients remains a guessing game in the grocery aisle.[4] Farms are rapidly expanding use of genetically engineered crops, which, in turn, increases their presence in food.[5] In 1997, 17% of U.S. soybean acreage was genetically modified.[6] Today,

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1. *See* Daniel A. Kracov & Joshua M. Glasser, *The Regulation of Foods and Food Additives*, *in* A PRACTICAL GUIDE TO FDA'S FOOD AND DRUG LAW REGULATION 257, 284 (Kenneth R. Piña & Wayne L. Pines eds., 4th ed. 2012).

2. *See id.* at 257, 282, 318.

3. *See id.* at 278.

4. *See* Kammi L. Rencher, *Food Choice and Fundamental Rights: A Piece of Cake or Pie in the Sky?*, 12 NEV. L.J. 418, 429 (2012).

5. *See* Sheldon Krimsky, *The Birth of Synthetic Biology and the Genetic Mode of Production*, *in* GENETICALLY ENGINEERED CROPS: INTERIM POLICIES, UNCERTAIN LEGISLATION 3, 10–11 (Iain E.P. Taylor ed., 2007) (describing the trajectory of plant modification from classical breeding to modern genetic engineering).

6. ECON. RESEARCH SERV., *Recent Trends in GE Adoption*, U.S. DEP'T OF AGRIC., http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx (last updated July 9, 2013).

that percentage has rocketed to 93%.[7] Other crops that are widely used in processed foods—from cooking oil to cornflakes—have followed similar trajectories.[8] The Grocery Manufacturers Association estimates between 75% and 80% of conventional processed foods contain genetically modified organisms (GMOs).[9]

As GMOs pervade the marketplace without long-term, unbiased research on their health impacts,[10] more consumers are demanding that they have a right to know if GMOs are present in their food.[11] Whole Foods recently announced it was responding to consumer demand by implementing mandatory labeling of genetically modified food, making it the first major retailer to require GMO labels.[12] Ben & Jerry's has announced that it will stop use of GMO ingredients in its ice cream by 2015,[13] and Chipotle has begun disclosing use of GMOs on its website in an effort to be transparent with consumers.[14] On a larger scale, at least sixty countries have implemented GMO labeling laws or

7. *Id*.

8. *See id*. (charting acreage of genetically engineered crops in the United States).

9. Press Release, Whole Foods Market, Studies Show GMOs in Majority of U.S. Processed Foods, 58 Percent of Americans Unaware of Issue (Oct. 7, 2012), *available at* http://www.prnewswire.com/news-releases/studies-show-gmos-in-majority-of-us-processed-foods-58-percent-of-americans-unaware-of-issue-104510549.html.

10. *Cf.* Chineme OK Anyadiegwu, *Health Risks of Genetically Modified Food: A Need for Unbiased Research into the Potential Health Risks of Genetically Engineered Crop Products*, 13 SAN JOAQUIN AGRIC. L. REV. 203, 210–12 (2003) (arguing that a lack of critical assessment fuels consumer concern).

11. *See* Memorandum from The Mellman Group, Inc. to Just Label It! (Mar. 22, 2012), *available at* http://justlabelit.org/wpcontent/uploads/2012/01/Mellman-Survey-Results.pdf (finding that 91% of Americans support mandatory labeling of GMOs).

12. Stephanie Strom, *Major Grocer to Label Foods with Gene-Modified Content*, N.Y. TIMES, Mar. 8, 2013, http://www.nytimes.com/2013/03/09/business/grocery-chain-to-require-labels-for-genetically-modified-food.html?pagewanted=all&r=0. The labels, which will be implemented by 2018, have not yet been created. *Id.*

13. Hunter Stewart, *Ben & Jerry's Will Stop Using Genetically-Modified Ingredients, Company Says*, HUFFINGTON POST (June 3, 2013), http://www.huffingtonpost.com/2013/06/02/ben-and-jerrys-gmos-genetically-modified_n_3372451.html?ncid=edlinkusaolp00000003.

14. Justin Bachman, *The Genetically Modified Burrito: Chipotle Tells All*, BLOOMBERG BUSINESSWEEK (June 18, 2013), http://www.businessweek.com/articles/2013-06-18/the-genetically-modified-burrito-chipotle-tells-all. Chipotle also intends to reduce use of GMOs, but does not believe it can completely eliminate them from its menus because of the nature of the U.S. food system. *Id.*

regulations.[15] The United States federal government[16] and twenty-five states[17] have also considered labeling requirements, but none has implemented GMO label mandates to date.[18]

California's November 2012 GMO labeling ballot measure[19] brought national attention to the debate, although it failed to pass by a narrow margin.[20] Despite this letdown at the polls, other states are continuing to pursue GMO labeling legislation.[21] While states may be eager to step in to protect consum-

15. Genetically Engineered Food Right-to-Know Act, S. 809, 113th Cong. § 2 (2013).

16. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992) [hereinafter *1992 Statement of Policy*] (refusing to mandate labeling). Rep. Dennis Kucinich proposed amendments to the Federal Food, Drug, and Cosmetic Act in seven consecutive House sessions to require food containing genetically engineered ingredients to be labeled accordingly, with no success. Genetically Engineered Food Right to Know Act, H.R. 3553, 112th Cong. (2011); Genetically Engineered Food Right to Know Act, H.R. 5577, 111th Cong. (2010); Genetically Engineered Food Right to Know Act, H.R. 6636, 110th Cong. (2008); Genetically Engineered Food Right to Know Act, H.R. 5269, 109th Cong. (2006); Genetically Engineered Food Right to Know Act, H.R. 2916, 108th Cong. (2003); Genetically Engineered Food Right to Know Act, H.R. 4814, 107th Cong. (2002); Genetically Engineered Food Right to Know Act, H.R. 3377, 106th Cong. (1999). Most recently, Sen. Barbara Boxer introduced the Genetically Engineered Food Right-to-Know Act in the Senate that would amend the Federal Food, Drug, and Cosmetic Act to require the FDA to promulgate mandatory labeling regulations for GMOs. S. 809, 113th Cong. (2013). A companion bill was introduced in the House by Rep. Peter DeFazio on the same day. Genetically Engineered Food Right-to-Know Act, H.R. 1699, 113th Cong. (2013). The bill was referred to committees in both the House and the Senate on April 24, 2013. Cong. Research Serv., *All Actions H.R.1699—113th Congress (2013–2014)*, CONGRESS.GOV, http://beta.congress.gov/bill/113thcongress/house-bill/1699/all-actions/ (last visited Oct. 16, 2013); Cong. Research Serv., *All Actions S.809—113th Congress (2013–2014)*, CONGRESS.GOV, http://beta.congress.gov/bill/113th-congress/senate-bill/809/all-actions/ (last visited Oct. 16, 2013).

17. *See Take Action in Your State*, RIGHT TO KNOW GMO, http://www.righttoknow-gmo.org/states (last visited Oct. 16, 2013) (showing states' GMO labeling efforts).

18. *Id.*

19. The California Right to Know Genetically Engineered Food Act, 2012 Cal. Legis. Serv. Proposition 37 (rejected by voters on Nov. 6, 2012), *available at* http://vig.cdn.sos.ca.gov/2012/general/pdf/text-proposed-laws.pdf [hereinafter Proposition 37].

20. DEBRA BOWEN, CAL. SEC'Y OF STATE, STATEMENT OF VOTE 13 (2013), *available at* http://www.sos.ca.gov/elections/sov/2012-general/sov-complete.pdf (reporting that 51.4% voted against labeling and 48.6% voted in favor).

21. *See Take Action in Your State*, *supra* note 17; *see also* Mike Hughlett, *Bills Would Require Labels on Genetically Engineered Food in Minnesota*, STAR TRIB., Feb. 28, 2013, http://www.startribune.com/business/194056041.html (describing genetically engineered labeling bills introduced in the Minnesota Legislature); Elaine Watson, *New Mexico GMO Labeling Bill Heads for*

ers, such regulations may not pass constitutional muster. New food labeling requirements could have considerable impact on interstate commerce, raising potential Commerce Clause objections.[22] Further, the Federal Food, Drug, and Cosmetic Act[23] already provides for extensive regulation of food labeling, perhaps implicating federal preemption.[24] If states take a stand on this issue, such regulations may not last for long.

This Note does not engage in the debate over the safety of GMOs. Rather, it contends that if consumers desire labeling mandates, such regulations must originate within the federal government. Part I provides an overview of mandatory GMO labeling, including proposed state regulations and the Food and Drug Administration's current stated position. Part II argues that states do not have constitutional authority to enact GMO labeling requirements. Finally, Part III addresses potential solutions and recommends voluntary labeling regulations with binding standards to the Food and Drug Administration (FDA). This Note concludes that state regulations requiring mandatory GMO labeling are unconstitutional, and urges the FDA to respond to the growing concern by enacting realistic, uniform regulations for labeling food produced from genetically engineered (GE) ingredients.

## I. GMO REGULATIONS AND THEIR CONSTITUTIONAL FRAMEWORK

This Part introduces current and proposed regulations of GMO labeling, and the constitutional framework for evaluating such regulations. Section A provides an overview of the FDA's current position on GMOs compared to the agency's historical role. Section B summarizes various state proposals for labeling genetically modified food. Finally, Section C introduces the con-

*State Legislature*, FOOD NAVIGATOR-USA.COM (Jan. 9, 2013), http://www.foodnavigator-usa.com/Regulation/New-Mexico-GMO-labeling-bill-heads-for-state-legislature (discussing mandatory labeling initiatives in New Mexico, Washington, Oregon, Florida, and Connecticut in 2013).

22. Steve Keane, *Can a Consumer's Right to Know Survive the WTO?: The Case of Food Labeling*, 16 TRANSNAT'L L. & CONTEMP. PROBS. 291, 312–14 (2006) ("State statutes that require labels on out-of-state products run the risk of burdening interstate commerce and creating a lack of political accountability.").

23. 21 U.S.C. §§ 341–343 (2006).

24. *See generally* Diane M. Allen, Annotation, *Federal Pre-Emption of State Food Labeling Legislation or Regulation*, 79 A.L.R. FED. 181 (1986) (discussing cases pertaining to federal law preempting food labeling laws).

stitutional considerations that state regulations will face if passed.

### A. FDA'S REGULATION OF GMOS (OR LACK THEREOF?)

The FDA is not a newcomer to the federal regulatory world, though its role has adapted over the years.[25] In its very early years, starting from its establishment in 1848, the agency (then the Agricultural Division of the Patent Office) served an advisory role to other federal agencies on scientific and technical matters.[26] The modern era of the FDA began in 1906 with the passage of the Pure Food and Drugs Act,[27] which provided the FDA with additional authority to enforce food and drug standards in interstate commerce.[28] The FDA at this time was only an enforcement agency, without authority to promulgate regulations or industry standards.[29]

Growing frustration with the 1906 Act's shortcomings[30] prompted Congress to pass the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).[31] The FDCA granted the FDA additional authority over medical devices and cosmetics,[32] and provided for pre-market approval of drugs.[33] Food regulations also expanded, with the FDA receiving authorization to establish enforceable standards for adulterated and misbranded food.[34] Section 341 grants authority to the FDA Secretary to promulgate and establish for most food "a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container."[35] Adulterated food is de-

25. Paul Hyman, *U.S. Food and Drug Law and FDA—A Historical Background*, *in* A PRACTICAL GUIDE TO FDA'S FOOD AND DRUG LAW AND REGULATION, *supra* note 1, at 21, 63.

26. *Id.*

27. *Id.* at 26.

28. *Id.*

29. *Id.*; *see also FDA History: 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) (describing the scope of the Pure Food and Drugs Act and the Bureau of Chemistry's role in enforcing it).

30. Hyman, *supra* note 25, at 30.

31. *See generally* 21 U.S.C. §§ 301–399 (2006).

32. Hyman, *supra* note 25, at 30, 35–36; *see also FDA History: The 1938 Food, Drug, and Cosmetic Act*, FDA, http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm (last updated Sept. 24, 2012).

33. Hyman, *supra* note 25, at 35; *FDA History: The 1938 Food, Drug, and Cosmetic Act*, *supra* note 32.

34. Hyman, *supra* note 25, at 34–35.

35. § 341. Exceptions to the FDA's authority to establish a definition,

fined in Section 342 as that containing "any poisonous or deleterious substance which may render it injurious to health,"[36] that which contains or may have been contaminated with "filth,"[37] or that which has been altered to increase its bulk or value.[38] Misbranded food is controlled under Section 343, which prohibits "false or misleading" labels,[39] requires imitation foods to be clearly labeled as such,[40] and mandates that foods subject to FDA standards of identity, quality, and container fill must conform to such standards.[41]

The regulatory scheme of the 1938 Act is still largely in place, though multiple amendments and acts have further expanded and defined FDA authority related to food regulations.[42] The Food Additives Amendment of 1958 gave the FDA power to require pre-approval of substances added to food.[43] A food additive is defined as that which may reasonably become a component of the food or affect the food's characteristics if it is "not generally recognized, among experts qualified by scientific training and experience to evaluate its safety . . . to be safe under the conditions of its intended use."[44] An exception to this definition is substances generally recognized as safe (GRAS).[45] The FDA grants GRAS status if it can be shown "not only that a substance is safe, but also that it is widely viewed as such by experts in the field."[46] The Nutrition Labeling and Education Act (NLEA) later overhauled food labeling requirements.[47] The NLEA provided for uniform, mandatory nutritional labeling controlled by the FDA, with express federal preemption over any non-identical state requirements.[48]

standard of identity, and standard of quality are butter and fresh or dried fruits and vegetables. *Id.*

36. § 342(a)(1).

37. § 342(a)(2).

38. § 342(b).

39. § 343(a).

40. § 343(c).

41. § 342(g)–(h).

42. Hyman, *supra* note 25, at 38.

43. § 348; Hyman, *supra* note 25, at 39.

44. § 321(s).

45. *See* 21 C.F.R. § 170.30(j) (2013).

46. Kracov & Glasser, *supra* note 1, at 272.

47. § 343-1; Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 6, 104 Stat. 2353, 2362–64 (1990), *available at* http://uscode.house.gov/statutes/1990/1990-101-0535.pdf.

48. § 343-1; Nutrition Labeling and Education Act § 6; Hyman, *supra* note 25, at 50.

It is within this regulatory framework that the FDA considers the use in food of new plant varieties developed through genetic modification.[49] The FDA considers GMOs to be GRAS,[50] so premarket review as food additives is not mandatory[51] unless there is a "safety question sufficient to call into question the presumed GRAS status."[52] However, voluntary premarket consultation is encouraged, under which the FDA primarily assesses:

> 1. Toxicants known to be characteristic of the host and donor species;
>
> 2. The potential that food allergens will be transferred from one food source to another;
>
> 3. The concentration and bioavailability of important nutrients for which a food crop is ordinarily consumed;
>
> 4. The safety and nutritional value of newly introduced proteins; and
>
> 5. The identity, composition and nutritional value of modified carbohydrates, or fats and oils.[53]

The process used to create the product is largely irrelevant to the FDA, as it operates under the assumption that the product itself is the key safety consideration.[54]

The FDA considers genetic modification to be a "continuum" of traditional breeding used for centuries to selectively encourage favorable traits in plants.[55] As such, the process of plant breeding used is irrelevant as long as the resulting products are "substantially equivalent."[56] Taking the position that

49. *See 1992 Statement of Policy*, *supra* note 16, at 22,988–89.

50. *Id.* at 22,990 ("With respect to transferred genetic material (nucleic acids), generally FDA does not anticipate that transferred genetic material would itself be subject to food additive regulation. Nucleic acids are present in the cells of every living organism, including every plant and animal used for food by humans or animals, and do not raise a safety concern as a component of food.").

51. Kathleen A. Merrigan, *Principles Driving U.S. Governance of Agbiotech*, *in* GENETICALLY ENGINEERED CROPS: INTERIM POLICIES, UNCERTAIN LEGISLATION, *supra* note 5, at 211.

52. *1992 Statement of Policy*, *supra* note 16, at 22,990.

53. *Id.* at 22,992.

54. Eva Merian Spahn, *Keep Away from Mouth: How the American System of Food Regulation Is Killing Us*, 65 U. MIAMI L. REV. 669, 694–95 (2011) (arguing for an overhaul of the U.S. food regulation scheme, including the adoption of a heightened duty of care for food producers).

55. *1992 Statement of Policy*, *supra* note 16, at 22,985–86 (explaining the FDA's interpretation of the FDCA relating to GMOs).

56. ORG. FOR ECON. CO-OPERATION & DEV., SAFETY EVALUATION OF FOODS DERIVED BY MODERN BIOTECHNOLOGY 14 (1993), *available at* http://www.oecd.org/science/biosafety-biotrack/41036698.pdf ("The concept of substantial equivalence embodies the idea that existing organisms used as food, or as a source of food, can be used as the basis for comparison when assessing

GMOs do not "present any different or greater safety concern than foods developed by traditional plant breeding," the FDA does not require labeling to disclose genetic modification.[57] Such labeling would only be required if the new plant variety constituted misbranding by "differ[ing] from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted."[58] Those producers who wish to voluntarily label (whether indicating the use of bioengineering or lack thereof) may do so, and the FDA has released nonbinding guidance to help direct such labeling.[59] The FDA suggests that statements such as "GMO free" may be misleading without a uniform threshold level for GMOs above which the label cannot be used, which does not currently exist.[60] However, despite consumer support for GMO labeling, the FDA does not require it without a showing of adverse health effects.[61] In short, while the FDA has authority over food in interstate commerce and its labeling, it has yet to proceed beyond nonbinding recommendations when it comes to GMOs.

### B. STATES' STANCES ON GMO LABELS

State governments, on the other hand, have been eager to step in and take a stand on GMOs. In 2011 and 2012, nineteen states considered mandatory GMO labeling legislation.[62] Two

the safety of human consumption of a food or food component that has been modified or is new.").

57. *1992 Statement of Policy*, *supra* note 16, at 22,991 ( "[T]he agency does not believe that the method of development of a new plant variety . . . is normally material information within the meaning of 21 U.S.C. 321(n) and would not usually be required to be disclosed in labeling for the food.").

58. *Id.*

59. *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have not Been Developed Using Bioengineering; Draft Guidance*, FDA, *available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm (last updated Aug. 16, 2013) [hereinafter *Draft Guidance*].

60. *See id.*; *see also* DETECTING GENETICALLY MODIFIED ORGANISMS: CONFRONTING THE LIMITS OF TESTING TO RESOLVE A BIOTECH FOOD FIGHT, *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Summaries_-_reports_and_pubs/proceedings2.pdf ("[N]either protein testing nor DNA testing by themselves are sufficient to reach conclusions about the amount of GMOs present in shipment of grain or a truckload of tortillas.").

61. *1992 Statement of Policy*, *supra* note 16, at 22,991.

62. Ronnie Cummins, Letter to Organic Consumer, Posted in *Organic Bytes*, ORGANICCONSUMERS.ORG, http://organicconsumers.org/letter-9-18.htm (last visited Oct. 16, 2013).

states—California and Oregon—took the issue directly to the voters through ballot initiatives. California's Proposition 37, billed as the "Right to Know" Act,[63] received strong early backing,[64] but failed at the polls.[65] Supporters of the "Right to Know" Act attribute the loss to the last-minute injection of corporate funds from agro-chemical companies, such as Monsanto, to fight the initiative.[66] The "No on 37" campaign outspent the labeling supporters five-to-one.[67] Those against the ballot measure, however, declared it the result of logic and science winning out over fear.[68] In Oregon, voters struck down a similar ballot initiative in 2002.[69] Despite early polls showing 58% of voters supported the measure, 70.5% of voters rejected the bill.[70] In addition, New Mexico's legislature debated an amendment to the New Mexico Food Act requiring labeling for GMOs, but the measure died on the Senate floor on January 31, 2013.[71]

Despite these past defeats, states have continued to push for GMO labeling mandates. Vermont's House passed a bill to require GMO labels, which the Senate is not expected to consider until January 2014.[72] Connecticut and Maine both suc-

63. Proposition 37, *supra* note 19.

64. Cal. Bus. Roundtable & Pepperdine Univ., *Initiative Survey Series 2012*, CAL. BUS. ROUNDTABLE, http://www.cbrt.org/initiative-survey-series-2012/ (last visited Oct. 16, 2013) (showing that 69.4% of voters supported the initiative on Aug. 2, 2012).

65. Marc Lifsher, *California Voters Say No to Labeling Genetically Engineered Food*, L.A. TIMES, Nov. 7, 2012, http://articles.latimes.com/2012/nov/07/business/la-fi-mo-genetically-engineered-food-labeling-20121107.

66. Lynne Peeples, *Prop 37 GMO Labeling Law Defeated by Corporate Dollars and Deception, Proponents Say*, HUFFINGTON POST (Nov. 7, 2012), http://www.huffingtonpost.com/2012/11/07/proposition-37-gmo-labeling_n_2090112.html ("Prior to the opposition's $46 million push, proponents had held a consistent two-fold lead in the polls.").

67. *Id.*

68. *Id.* (quoting a statement from Dr. Henry I. Miller of the Hoover Institution, a think tank at Stanford University).

69. KERRY-ANN T. POWELL, VOTERS IN SEVEN CALIFORNIA COUNTIES CONSIDER BANNING GENETICALLY ENGINEERED AGRICULTURE 8 (2004*), available* at http://www.uspirg.org/sites/pirg/files/reports/California%20Counties_GE_Ag_USPIRG.pdf.

70. *Id.*

71. *See* Elaine Watson, *Lobbying by Agri-Business Killed New Mexico GMO Labeling Bill, Claim Supporters*, FOOD NAVIGATOR-USA.COM (Feb. 05, 2013), http://www.foodnavigator-usa.com/Regulation/Lobbying-by-agri-business-killed-New-Mexico-GMO-labeling-Bill-claim-supporters. *See generally* S.B. 18, 51st Leg., 1st Sess. (N.M. 2013).

72. Andrew Stein, *GMO Labeling Bill Positioned for Action Next Session*, VTDIGGER.ORG (May 7, 2013), http://vtdigger.org/2013/05/07/gmo-labeling-bill-positioned-for-action-next-session/.

ceeded in passing labeling bills in early 2013; however, the regulations will not go into effect unless other states, including a neighboring state, pass similar bills.[73] GMO labeling supporters in Washington submitted over 350,000 signatures—100,000 more than necessary to qualify an initiative to the Legislature—in support of genetically modified food labels.[74] The Legislature had an opportunity to pass the initiative as written, but took no action; the decision now turns to the voters on the November 2013 general election ballot.[75] Further, GMO label supporters are gaining ground in Oregon, Florida, and Minnesota to pursue legislation.[76] While no label mandates have taken effect yet,[77] wide voter support across party lines[78] suggests legislation will likely continue coming to the floor and cropping up in ballot initiatives.

The proposed state legislation has largely followed the same formula. First, the bills require genetically engineered food to be labeled as such. In Colorado, the mandatory language was either "genetically engineered" or "This product contains or was produced with a genetically engineered material."[79] Connecticut specified that raw agricultural commodities should be labeled "Genetically Engineered," while processed food should indicate "Partially Produced with Genetic Engineering" or "May be Partially Produced with Genetic Engineer-

73. Elaine Watson, *Maine House Backs GMO Labeling Bill*, FOOD NAVIGATOR-USA.COM (June 12, 2013), http://www.foodnavigator-usa.com/Regulation/Maine-House-backs-GMO-labeling-bill. Maine's bill requires five contiguous states to pass similar legislation in order to go into effect. *Id.* Connecticut would require four other states with an aggregate population of at least twenty million and at least one state must be neighboring. Jessica Corbett, *GMO Domino Effect*, IN THESE TIMES (Jul. 14, 2013), http://www.inthesetimes.com/article/15225/gmo_domino_effect/.

74. Jim Camden, *State May Vote on GMO Labeling*, THE SPOKESMAN-REV., Jan. 4, 2013, http://www.spokesman.com/stories/2013/jan/04/state-may-vote-on-gmo-labeling/.

75. Dan Flynn, *Campaign for GM Food Labeling Gets New State Battleground*, FOOD SAFETY NEWS (April 29, 2013), http://www.foodsafetynews.com/2013/04/olympias-inaction-sets-up-re-match-for-gm-food-labeling/.

76. *See supra* note 21 and accompanying text.

77. *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/#.UiuxMsbEPVk.

78. Memorandum from The Mellman Group, Inc., *supra* note 11, at 1 (finding in a survey of 1,000 2012 general election voters that 93% of Democrats, 89% of Republicans, and 90% of independents are in favor of labeling).

79. S. 01-146, 63d Gen. Assemb., 1st Reg. Sess. § 25-5-411 (Colo. 2001).

ing."[80] Hawaii's legislature has heard at least seven labeling bills,[81] which would have required labels to state "THIS PRODUCT CONTAINS A GENETICALLY ENGINEERED MATERIAL, OR WAS PRODUCED WITH A GENETICALLY ENGINEERED MATERIAL."[82] In addition to specific language, the bills specify the size and appearance of the disclaimer. Washington's legislation detailed that the label "must appear either: (a) On the front package or label of any such commodity; or (b) In the case of such a commodity that is not separately packaged or labeled, on a label appearing on the retail store shelf or bin."[83] Some states stipulate specific font sizes,[84] while others, such as Vermont, simply require the statement to be "prominently placed thereon with such conspicuousness . . . as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[85]

The state legislation also defines what is to be considered genetically modified food. Colorado's proposed bill provides for the definition to shift with advances of science:

> "Genetically engineered food" means the following: (a) All foods derived in whole or in part from a genetically engineered virus, microorganism, plant, livestock, or other organism if such genetically engineered material can be detected at a level at least twice the limits of detection of the most sensitive method commercially available for detection of that particular type of genetically engineered material.[86]

New Mexico would require labeling for any food where "genetically engineered material accounts for more than one-tenth percent of the weight of any portion of that food."[87] Others simply state that food is genetically modified if any ingredient

80. H.R. 5117, 2012 Leg., Feb. Sess. § 2(a) (Conn. 2012).

81. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, LEGISLATION TRACKER 2006 (2007), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/PIFB_Legislative_Tracker.pdf.

82. *See, e.g.*, H.R. 2034, 26th Leg., Reg. Sess. § 328(a) (Haw. 2012).

83. S. 6298, 62d Leg., 2012 Reg. Sess. § 3(1) (Wash. 2012).

84. *See, e.g.*, H.R. 2808, 2012 Leg., 87th Sess. § 2 Subd.1. (Minn. 2012) (requiring the GE label to be "in boldface print of not less than ten-point type").

85. H.R. 722, 2012 Gen. Assemb., Reg. Sess. § 4060(a)(6) (Vt. 2012).

86. S. 01-146, 63d Gen. Assemb., 1st Reg. Sess. § 25-5-402(12.3) (Colo. 2001).

87. S. 906, 47th Leg., 1st Sess. § 4(A) (N.M. 2005); *cf.* Proposition 37, *supra* note 19 (providing an exception for processed food where no GMOs "account[] for more than one-half of one percent of the total weight" and there are no more than ten genetically engineered ingredients).

is produced with genetic engineering.[88] States differ on whether to consider animals fed with genetically modified materials as genetically modified food themselves.[89] Finally, the proposed bills provide that violations of the labeling mandate will be a misdemeanor.[90]

States thus have very similar ideas about what GMO labeling should look like. Despite this apparent meeting of the minds, however, states may not have the authority to regulate in this arena.

### C. CONSTITUTIONAL HURDLES FOR STATE REGULATIONS

Even if a state capitalizes on the public demand for GMO labels and passes a bill mandating disclosure, the legislation may not withstand constitutional challenges. While the federal government largely works alongside state governments to regulate food,[91] state regulations must still comply with the limits of the Commerce Clause and federal preemption or risk invalidation.[92]

#### 1. Commerce Clause

The Commerce Clause gives Congress the power "[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."[93] The Supreme Court's judicial oversight has delineated over the years the extent to which Congress's power may restrict state regulation.[94] The Commerce Clause itself is a grant of power—not a prohibition on state regulation unless Congress elects to regulate the area.[95] The modern view of the Commerce Clause allows Congress

88. H.R. 5117, 2012 Leg., Feb. Sess. § 1(3) (Conn. 2012).

89. *Compare* H.R. 4025, 2001 Leg., Reg. Sess. § 1105(a)(xvi) (Mich. 2001) (stipulating that food derived from an animal fed with or treated with GMOs is itself genetically modified), *with* H.R. 5117, 2012 Leg., Feb. Sess. § 2(c)(1) (Conn. 2012) (creating an exception for animals "fed or injected with any genetically-engineered food").

90. *See, e.g.*, H.R. 2808, 2012 Leg., 87th Sess. § 2 Subd. 5 (Minn. 2012).

91. Fred H. Degnan, *The Food and Drug Administration—How It Is Organized and Works*, *in* A PRACTICAL GUIDE TO FDA'S FOOD AND DRUG LAW AND REGULATION, *supra* note 1, at 118.

92. *See* Edward P. Richards, III, *Overview of the U.S. Legal System*, *in* A PRACTICAL GUIDE TO FDA'S FOOD AND DRUG LAW AND REGULATION, *supra* note 1, at 2–3 (explaining federal commerce powers).

93. U.S. CONST. art. I, § 8, cl. 3.

94. Richards, *supra* note 92, at 2.

95. James L. Buchwalter, Annotation, *Construction and Application of Dormant Commerce Clause, U.S. Const. Art. I, § 8, cl. 3—Supreme Court Cas-*

to "(1) Regulate the channels of interstate commerce; (2) protect the 'instrumentalities,' persons, and things involved with interstate commerce from any threat; and, (3) regulate those activities having a 'substantial relation to interstate commerce.'"[96]

The Court has also held that state regulations may be further restrained—even if Congress has not acted—under the concept of the "Dormant" Commerce Clause.[97] A court's inquiry under a Dormant Commerce Clause challenge has two considerations.[98] The first consideration is if the regulation is discriminatory[99] between in-state and out-of-state economic interests.[100] If it is discriminatory, it is virtually per se unconstitutional.[101] If it is facially neutral, the court proceeds to the second consideration, applying a balancing standard to determine whether the "local benefits outweigh the incidental burdens to interstate commerce."[102] The court should particularly consider a regulation's effects on interstate commerce if multiple states were to regulate in the same area,[103] and if a less burdensome regulation could achieve the same benefit.[104]

2. Federal Preemption

The Dormant Commerce Clause can be considered a form of implied preemption.[105] However, preemption extends beyond

*es*, 41 A.L.R. FED. 2d 1 (2009).

96. Jason C. Glahn, *I Teach You the Superman: Why Congress Cannot Constitutionally Prohibit Genetic Modification*, 25 WHITTIER L. REV. 409, 418 (2003) (quoting U.S. v. Lopez, 514 U.S. 549, 558–59 (1995)).

97. *E.g.*, Okla. Tax Comm'n v. Jefferson Lines, Inc., 514 U.S. 175, 179–80 (1995).

98. Catherine Gage O'Grady, *Targeting State Protectionism Instead of Interstate Discrimination Under the Dormant Commerce Clause*, 34 SAN DIEGO L. REV. 571, 573–74 (1997).

99. *Id.*

100. Or. Waste Sys., Inc. v. Dep't of Envtl. Quality, 511 U.S. 93, 99 (1994).

101. O'Grady, *supra* note 98, at 574.

102. Emily Robertson, Note, *Finding a Compromise in the Debate over Genetically Modified Food: An Introduction to a Model State Consumer Right-to-Know Act*, 9 B.U. J. SCI. & TECH. L. 156, 181–82 (2003).

103. *Cf.* Bibb v. Navajo Freight Lines, 359 U.S. 520, 526–30 (1959) (stating that the existence of conflicting regulations in neighboring states must be considered when assessing a regulation's potential burden on interstate commerce).

104. Dean Milk Co. v. City of Madison, 340 U.S. 349, 354 (1951) (examining the constitutional conflicts of state regulations for hormone-produced milk); *see also* Dan L. Burk, *The Milk Free Zone: Federal and Local Interests in Regulating Recombinant bST*, 22 COLUM. J. ENVTL. L. 227, 294 (1997).

105. *See* Degnan, *supra* note 91, at 118.

the Commerce Clause. Preemption occurs in areas of shared regulatory power where state and federal laws conflict.[106] When this occurs, federal law takes priority, and inconsistent state regulations are null and void.[107] Preemption takes on four forms: implied, express, field, and conflict.[108] Implied preemption exists where the federal government has authority over the area pursuant to the Supremacy Clause and the Commerce Clause.[109] Express preemption occurs where a federal law explicitly bars states from regulating in that area.[110] For instance, the NLEA provides that "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce" certain requirements for food or labeling covered under the Act.[111] The court will then consider whether the state regulation is within the scope of the federal regulation and thus invalid.[112]

Conflict preemption occurs where there is no express statement in the law, but the state and federal regulations cannot both be followed.[113] Conflict preemption does not mean that a state cannot regulate in the area, just that competing purposes prevent the state's particular regulation.[114] Field preemption is "a species of conflict pre-emption."[115] In these cases, there is not a direct conflict, but Congress has "so completely occupied the field"[116] that there is "no room" for state regulation.[117] If Congress has occupied the field, it completely bars states from regulating in the area as deference to Congress's determination that state exclusion is necessary and proper.[118]

State regulations thus face significant constitutional hurdles when regulating areas Congress has acted in or that may

106. *See* Richards, *supra* note 92, at 4.
107. *See id.*; *see also* Degnan, *supra* note 91, at 118.
108. Kinley Corp. v. Iowa Utils. Bd., 999 F.2d 354, 358 n.3 (8th Cir. 1993).
109. *See* Degnan, *supra* note 91, at 118.
110. *See* Richards, *supra* note 92, at 4.
111. 21 U.S.C. § 343-1 (2006).
112. *See* Robertson, *supra* note 102, at 166.
113. Burk, *supra* note 104, at 250.
114. *Id.* at 250–51.
115. English v. Gen. Elec. Co., 496 U.S. 72, 79 n.5 (1990).
116. Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 256 (1984).
117. *See* Paul Wolfson, *Preemption and Federalism: The Missing Link*, 16 HASTINGS CONST. L.Q. 69, 72 (1988) (citing Pacific Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 203–04 (1983); Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).
118. *Id.* at 72–73.

be considered Congress's sole territory. As Part II will show, this likely poses a significant barrier to states' attempts to impose mandatory GMO labeling.

## II. STATE GMO LAWS CANNOT WITHSTAND CONSTITUTIONAL CHALLENGES

This Part considers whether constitutional concerns invalidate state GMO regulations. First, Section A analyzes state labeling laws' impact on interstate commerce under a Dormant Commerce Clause balancing test. Section B then addresses whether federal labeling regulations preempt state regulations. This Part concludes that state regulations are likely barred both under a Dormant Commerce Clause evaluation and under federal preemption considerations.

### A. MANDATORY LABELS IMPROPERLY TIP THE BALANCE OF LOCAL INTERESTS AND NATIONAL IMPACTS

When courts evaluate claims that a state regulation violates the Dormant Commerce Clause, the first inquiry is if the regulation is facially discriminatory.[119] For example, a Massachusetts law that imposed a tax on milk but provided a subsidy to in-state producers was considered discriminatory because the tax was "effectively imposed only on out-of-state products."[120] In the case of state GMO label requirements, manufacturers both in and out of the state equally bear the cost and duty of labeling food products, and thus they are unlikely to be overruled as discriminatory.[121] To the extent that the regulations favor manufacturers and growers who do not use genetically engineered crops, such as the organic food industry, the impact is not limited to in-state producers.[122]

However, such regulations must still be considered under the *Pike* balancing test.[123] The balancing test considers whether a state's interest is sufficient to allow the incidental burden on

119. *See* Or. Waste Sys. v. Dep't of Envtl. Quality, 511 U.S. 93, 99 (1994).

120. W. Lynn Creamery, Inc. v. Healy, 512 U.S. 186, 194 (1994).

121. *See* Keane, *supra* note 22, at 313.

122. *See* Grocery Mfrs. of Am. v. Gerace, 755 F.2d 993, 1003 (2d Cir. 1985); *see also* Robertson, *supra* note 102, at 183.

123. *See* United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 346 (2007) (stating that the *Pike* balancing test applies where there are legitimate state concerns with incidental effects on interstate commerce).

interstate commerce to continue.[124] If there is a legitimate local interest, then courts look to the extent of the burden and if alternate actions could promote the same interest with a lesser impact.[125]

1. Local Interests

The purpose and design of state GMO regulations, supporters argue, is to allow consumers to make informed choices about what they eat and protect consumers since GMOs have not been affirmatively proven safe.[126] Courts have previously found that consumer education and protection is a legitimate state interest.[127] This interest lies within the states' police power to protect its citizens' health and welfare.[128] However, it is unclear whether GMOs pose any threat to health and welfare.[129] If GMOs pose no greater risk than traditional food, it casts doubt on states' ability to regulate them separately under the guise of consumer protection.[130] Without health and safety concerns, the state's interest relies on protecting consumers' right to know what is in their food. Courts have held that this alone is insufficient to support labeling mandates.[131] The FDA

124. *See* Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

125. *Id.*

126. *Facts—Yes on Prop 37*, CAL. RIGHT TO KNOW, http://www.carighttoknow.org/facts (last visited Oct. 16, 2013).

127. *See, e.g.*, *Grocery Mfrs. of Am.*, 755 F.2d at 1003–04 (holding that distinguishing between real cheese and alternative cheese is a legitimate state concern).

128. Michele M. Bradley, *The States' Role in Regulating Food Labeling and Advertising: The Effect of the Nutrition Labeling and Education Act of 1990*, 49 FOOD & DRUG L.J. 649, 652 (1994).

129. *Compare* Chelsea Snell et al., *Assessment of the Health Impact of GM Plant Diets in Long-Term and Multigenerational Animal Feeding Trials: A Literature Review*, 50 FOOD & CHEMICAL TOXICOLOGY 1134, 1143 (2012) ("[T]he available long-term studies do not yield new safety concerns [compared to 90-day studies] and confirm that the studied GM varieties (most of them are major commercial products) are nutritionally equivalent to their non-GM conventional counterparts."), *with* Anyadiegwu, *supra* note 10, at 210 ("Some effects of new technology are visible and dramatic, but many are delayed and uncertain. Therefore, an assessment of such risk and the design of strategies to reduce them require the use of scientific and technical information." (footnotes omitted) (internal quotation marks omitted)).

130. *But see* Robertson, *supra* note 102, at 182 (arguing that Right to Know acts are constitutional and within the scope of states' police power).

131. *See, e.g.*, Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 74 (2d Cir. 1996) ("Were consumer interest alone sufficient, there is no end to the information that states could require manufacturers to disclose about their production methods.").

maintains that genetically engineered foods do not present any "different or greater safety concerns" than conventionally bred foods.[132] Courts give significant deference to the FDA's scientific judgment,[133] and therefore would be unlikely to find substantial state interest unless presented with scientific evidence of safety risks.[134]

2. National Burdens

Assuming in the alternative that states have a local interest in GMO regulations—albeit one weakened by a lack of definitive safety risks—the courts will then determine if the burdens on interstate commerce exceed the intrastate benefits.[135] The burden of such labeling mandates stands to be significant. If California, for instance, was to pass GMO laws, it would affect 12% of the nation's food market.[136] Food producers would have to evaluate the cost of changing their labels for one state compared to the cost of simply avoiding California.[137] In the past, California regulations have not remained isolated in California.[138] There are several possible explanations for this California effect: "[E]ither because its regulations or bans encourage other states or the federal government to adopt them, or because they force producers to change their offerings nationwide, or because they force the regulated industry to seek preemptive nationwide regulation."[139] Whatever the reason may be, California's GMO regulations will likely reverberate nationwide.[140]

132. Letter from Lester M. Crawford, Deputy Comm'r, FDA, to John A. Kitzhaber, Governor, Or. (Oct. 4, 2002), *available at* http://www.bio.org/sites/default/files/Kitzhaber.pdf.

133. *See, e.g.*, Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 179 (D.D.C. 2000).

134. *Cf. id.* (suggesting that if the FDA's position was shown to be irrational, e.g., by the production of contrary scientific evidence, it would not be entitled to deference).

135. *See* O'Grady, *supra* note 98, at 574.

136. Baylen J. Linnekin, *The "California Effect" & the Future of American Food: How California's Growing Crackdown on Food & Agriculture Harms the State & the Nation*, 13 CHAP. L. REV. 357, 357–58 (2010).

137. *Cf. id.* at 358 ("Companies that can no longer market a food in California may be forced to decide whether that product—robbed of twelve percent of its potential market—is still viable.").

138. *Id.* at 384–85. For example, when California banned trans fats, many state and local governments subsequently introduced similar measures. *Id.* at 378.

139. *Id.* at 384–85.

140. *See id.* at 389 ("California's mushrooming food and agricultural regu-

This effect has been observed in other states as well. Until 2011, a Pennsylvania regulation required bread producers to print a mark evidencing registration with the state on all bread packaging.[141] Producers with multi-state operations found it cheaper and simpler to include this marking on all packaging.[142] However, the inconspicuous language "Reg. Penna. Dept. Agr."[143] likely had a more neutral impact on consumers than a label such as Connecticut's proposed "Partially Produced with Genetic Engineering" label.[144] If consumers see GMOs as a decision factor in their purchases, such labeling operates as a warning as it "clearly suggests one choice over another."[145] Labeling mandates can thus influence consumer purchases nationwide even if only passed in one state. The impact may be magnified if multiple states pass different labeling requirements, which could require packaging to contain several variously worded GMO warnings in order to comply with all regulations.[146]

GMO label supporters argue that labeling changes occur frequently and the changes required by the mandate would entail no cost to the producers.[147] But the cost of a new label is not the only cost involved—producers must know whether their products contain GMOs in order to comply with labeling requirements.[148] This entails segregation of GE and non-GE crops all the way from farmer to producer, which would mean infrastructure modifications, including separating crops (potentially requiring buffer land to avoid cross-pollination), establishing

lations and bans—the result of the state's propensity toward hyper-regulation and the resultant California effect—are spreading across America.").

141. *See* Pennsylvania Food Act, 31 PA. STAT. §§ 20.1–20.18 (1994), *repealed by* Act 106 of 2010, P.L. 1039, No. 106 § 8 (2010). Pennsylvania law now states, "The secretary *may* promulgate regulations *allowing* food establishments to label their food products as having been registered by the department." 3 PA. CONS. STAT. § 5735 (2010) (emphasis added).

142. Linnekin, *supra* note 136, at 377.

143. *See generally* 7 PA. CODE § 46.3 (2004).

144. H.R. 5117, 2012 Leg., Feb. Sess. § 2(a) (Conn. 2012).

145. Donna M. Byrne, *Cloned Meat, Voluntary Food Labeling, and Organic Oreos*, 8 PIERCE L. REV. 31, 36, 77–78 (2009) ("When presented with information on a label, assuming they notice it, and they do not always notice it, the unknowing consumers tend to perceive the label information as a *warning*. The label does two things—it tells them there is an issue of concern, serving an educational function, and it *warns* them about this product." (footnote omitted)).

146. *See* Bradley, *supra* note 128, at 653.

147. *Facts—Yes on Prop 37*, *supra* note 126.

148. *See* Byrne, *supra* note 145, at 69.

distinct storage and processing facilities, and transporting GE and non-GE crops separately.[149] Opponents of California's now-rejected labeling initiative estimate that if non-GE ingredients replace GE ingredients, the cost to consumers would be a mid-point of at least $348 per California household.[150]

Evaluating the impact in other countries that have imposed GMO labeling mandates can further illuminate potential burdens on interstate commerce. A study of the impact of voluntary versus mandatory labeling found that "[M]andatory labelling in the European Union (EU) has resulted in the virtual disappearance of any GM-labelled product, so in practice EU consumers do not have a choice when they go shopping."[151] Mandatory labeling in Japan similarly resulted in an effective elimination of GM products.[152] History thus indicates that mandatory labeling could destroy a segment of the food market.[153] This potential lack of choice, combined with the price increases forced on all consumers, poses a significant burden on interstate commerce that outweighs the state benefit of informed shoppers.[154]

As such, since mandatory state GMO labels would encumber purchases and food supplies nationwide, as well as increasing costs from farmers all the way up to consumers, the regulations would likely fail a Dormant Commerce Clause balancing test. These burdens on interstate commerce exceed any possible

149. *See* NORTHBRIDGE ENVTL. MGMT. CONSULTANTS, THE GENETICALLY ENGINEERED FOODS MANDATORY LABELING INITIATIVE 20–22 (Jul. 25, 2012), *available at* http://www.noprop37.com/files/Prop.-37-Will-Raise-Grocery-Bills-400-Annually.pdf.

150. *See id.* at 7, 34 (stating that two possible compliance scenarios result in costs of $401 and $348 per household, respectively). *But cf.* Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 192 (2006) ("The estimated costs for the more extensive GM labeling options under consideration in the United Kingdom, New Zealand, and Australia were calculated as $3 to $10 a year per person.").

151. Guillaume P. Gruère et al., *What Labelling Policy for Consumer Choice? The Case of Genetically Modified Food in Canada and Europe*, 41 CANADIAN J. ECON. 1472, 1474 (2008).

152. Guillaume P. Gruère & S.R. Rao, *A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule*, 10 AGBIOFORUM 51, 54 (2007).

153. *See id.* Gruère and Rao observe that China appears to be the only country with mandatory labeling where GM products are still readily available. *Id.* at 54 n.2.

154. *Cf. supra* note 131 and accompanying text (noting the weakness of a consumer curiosity interest).

local interest of informing consumers.

### B. FDA LABEL REGULATIONS LEAVE LITTLE ROOM FOR STATE MANDATES

If courts do not invalidate state labeling mandates under the implied preemption of the Dormant Commerce Clause, the regulations would likely still be unconstitutional through express or field preemption.

Express preemption seems like a simple case—either the federal law precludes state interference with explicit language or it does not. An actual express preemption consideration, however, is not so simple, as courts must scrutinize the explicit language to determine the boundaries of the preemptive scope.[155] Courts have not yet considered whether the express preemption of the NLEA would extend to state GMO labels,[156] but such an interpretation is unlikely.[157] To determine the scope of preemption, courts will look to congressional intent.[158]

When passing the NLEA, Congress specifically limited the scope to nutritional labeling because extending the scope to warning labels posed a danger to the Act's passage.[159] As Senator Orrin Hatch explained, "[T]he compromise makes clear that the national uniformity in food labeling that is set forth in the legislation has absolutely no effect on preemption of State or local requirements that relate to such things as warnings about foods or components of food."[160] Further, Congress was explicit within the Act that its preemption was limited to the scope defined therein, leaving little wiggle room.[161] Congress did not want to ban states entirely from food labeling,[162] especially considering its reliance on states to help enforce FDA regulations.[163] Even if the Act omitted this preemption limitation, the mere existence of any express preemption statement precludes implied preemption to expand the scope further.[164]

155. *See* Burk, *supra* note 104, at 249–50.

156. Robertson, *supra* note 102, at 165.

157. *Cf.* Burk, *supra* note 104, at 249 ("[I]n each instance the two interests will be balanced, accommodating local regulation wherever possible.").

158. *Id.* at 166.

159. *See* Bradley, *supra* note 128, at 659–60.

160. 136 CONG. REC. 33,429 (1990) (statement of Sen. Orrin Hatch).

161. *See* 21 U.S.C. § 343-1 (2006) (explicitly listing what state and local governments may not do under the Act); *see also* Burk, *supra* note 104, at 258.

162. *See* Burk, *supra* note 104, at 259.

163. *See* Degnan, *supra* note 91, at 118–19.

164. *Cf.* Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 517 (1992). *But see*

However, even if the NLEA does not preempt state GMO labels, preemption may still be found in other federal regulations.[165] The entire scope of food regulations—expanding beyond the NLEA—could implicate field preemption, in that Congress has so occupied the field as to exclude states from regulating.[166] Neither the motive behind the state regulation nor its result is relevant; field preemption prevents any state regulations in that field, even if the regulations "appear to support or further the purpose of the federal statutes."[167] As with express preemption, courts typically look to congressional intent to determine if field preemption is applicable.[168] As the congressional record, discussed earlier,[169] demonstrates, excluding states from the realm of labeling was not Congress's intent.[170] This stated intent may be enough to overcome field preemption arguments, as there is a "strong presumption against preemption."[171]

However, the Court recently has deviated from this traditional preemption analysis in some cases.[172] In *AT&T Mobility v. Concepcion*, for example, the Court found that one of the Agency's objectives was to "protect corporations from hostile courts and interfering tort actions."[173] The Court held that a clause reserving state regulations could not uphold regulations that stood as an obstacle to that objective.[174] Courts could simi-

Freightliner Corp. v. Myrick, 514 U.S. 280, 287–89 (1995) (arguing that express preemption suggests that Congress did not intend to preempt other matters, but does not foreclose all possibility of implied preemption).

165. *See* Bradley, *supra* note 128, at 660.

166. *See* Burk, *supra* note 104, at 251 (citing Wolfson, *supra* note 117, at 77–78) (discussing a "delicate balance" theory, according to which some courts will reject state or local legislation in an otherwise open area to avoid disrupting the delicate balance of an apparently precise legislative scheme).

167. *See id.* at 250.

168. *See, e.g.*, Hines v. Davidowitz, 312 U.S. 52, 67 (1941) (considering whether a state law was "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress").

169. *See supra* text accompanying notes 160–63.

170. *See, e.g.*, 136 CONG. REC. 33,428–29 (1990) (statement of Sen. Orrin Hatch).

171. Bradley, *supra* note 128, at 658.

172. Pamela A. Vesilind, *Emerging Constitutional Threats to Food Labeling Reform*, 17 NEXUS: CHAP. J.L. & POL'Y 59, 68 (2012) ("[T]he analyses bypassed any substantive discussion or application of the traditional presumption that state police powers are preserved absent clear congressional intent to the contrary.").

173. *Id.* at 70.

174. AT&T Mobility LLC v. Concepcion, 131 S. Ct. 1740, 1748 (2011) (holding that the Federal Arbitration Act preempts California's judicial rule declaring class arbitration waivers unconscionable).

larly find an objective in federal food regulation laws to protect producers from having to comply with and defend against regulations varying from state to state. Senator Hatch argued as much when introducing the NLEA on the Senate floor:

> [I]t is wrong to permit each of the 50 States to require manufacturers of 20,000 packaged food items to display different health and diet information on identical products sold throughout this country. And, it is wrong to burden the manufacturer with the fear of potentially 50 different lawsuits from 50 different State attorneys general, even if similar cases have been dismissed or settled.[175]

If courts read such an objective into the NLEA, then state GMO laws may be considered an extension of this concern. Thus, states could be preempted as an obstacle to Congress's intent despite the reservation of states' power to create and enforce additional labeling requirements.

In addition to congressional intent, courts reviewing state GMO laws will likely consider the position of the FDA, which the Court has found to be "dispositive" regarding preemption.[176] The Court held in *Medtronic v. Lohr* that the FDA is "uniquely qualified" to make this determination as "the federal agency to which Congress has delegated its authority to implement the provisions of the Act."[177] The FDA maintains that labeling GMOs is unnecessary and potentially misleading in the absence of scientific evidence of safety risks.[178] This position has been set forth in guidance documents that, though not binding, are still entitled to deference by the courts.[179] The FDA's position is that the presence of genetically modified ingredients is not material and thus does not require special labeling,[180] a decision informed by the Agency's expertise in food regulations. This determination should not be limited to federal regulations, but should extend to bar state regulations, and should play a significant role in courts' determination of field preemption.

If looking solely to congressional intent, the argument for express or field preemption is weak. However, when the expert

175. 136 CONG. REC. 33,428 (1990) (statement of Sen. Orrin Hatch).

176. Eric G. Lasker, *FDA Position on Federal Preemption Consistent with Law and Public Health*, LEGAL BACKGROUNDER, Feb. 25, 2005, at 1, 3 (quoting Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 714 (1985)).

177. Medtronic, Inc. v. Lohr, 518 U.S. 470, 496 (1996).

178. *Draft Guidance*, *supra* note 59.

179. *See, e.g.*, Grocery Mfrs. of Am. v. Gerace, 755 F.2d 993, 1002 (2d Cir. 1985) ("The distinctions between formal rules and interpretive rules or general statements of policy are often vague.").

180. *Draft Guidance*, *supra* note 59.

opinion of the FDA—granted its authority by Congress—is justifiably taken into consideration, it is likely that courts will find states have been preempted from the field of mandatory GMO labels. Coupled with state labeling regulations' impact on interstate commerce, a Dormant Commerce Clause analysis would likely also block state GMO regulations. These two significant constitutional concerns stand as a substantial barrier to mandatory GMO labeling originating in state governments.

## III. CONSTITUTIONAL CONCERNS SHOULD SPUR THE FDA TO STEP UP AND STEP IN

This Part argues that FDA implementation of GMO labeling is preferable to state regulations. Section A argues that consumer demand is an important factor that the FDA can and should consider as an impetus for labeling. Section B suggests a reasonable labeling scheme should be voluntary and should measure GMO presence in finished products. Such a program balances consumer concern with manufacturing burdens.

### A. THE FDA SHOULD REMOVE STATES' TEMPTATION TO REGULATE AND ADDRESS CONSUMER DEMAND

Regardless of the constitutional consequences of state regulations, federal regulation is the preferable method to answer consumer concern regarding GMOs. In response to Oregon's GMO labeling initiative in 2002, the FDA itself argued that such state GMO label mandates are improper because they would "require different labels for different states impeding the free flow of commerce between the states."[181] FDA regulation of GMOs, conversely, would create uniformity in labeling and relieve producers of the burden of a muddled system of state regulations.[182] The FDA has asserted its authority over monitoring the safety of the nation's food supply.[183] However, because it views GMOs as essentially the same as their conventional counterparts, the FDA does not believe they fall under this safety umbrella.[184]

If the FDA cannot regulate GMOs under safety concerns,

181. Crawford, *supra* note 132, at 1.

182. See Erik Benny, *"Natural" Modifications: The FDA's Need to Promulgate an Official Definition of "Natural" that Includes Genetically Modified Organisms*, 80 GEO. WASH. L. REV. 1504, 1516–17 (2012) (arguing for similar FDA regulation of the use of "natural" on food labels).

183. Crawford, *supra* note 132, at 1.

184. *Id.*

then can the FDA regulate because of consumer demand? It thinks not. Its current position is that federal regulations cannot be upheld simply on consumer demand unless a material difference first sparks that demand.[185] This has not always been the FDA's position, however. The FDA requires labeling of food treated with irradiation even though it has determined that "there is no concern about the safety of such treatment."[186] This label mandate is thus based not on safety, but on consumer concern. The Agency explicitly credited consumer concern as the motive behind this regulation. "[T]he large number of consumer comments requesting retail labeling attest to the significance placed on such information by consumers. . . . Because of these comments, FDA had decided to require that the label and labeling of food products bear the appropriate statements to inform consumers that the food has been irradiated."[187]

The FDA also found such labeling valuable because consumers cannot observe irradiation without labeling.[188] The same argument can be made for GMOs. The FDA received 1.1 million signatures related to Just Label It's petition for GMO labeling.[189] Despite the large number of consumer comments—more than any previous petition filed with the FDA[190]—the FDA's response was simply that it needs more time to make a decision.[191] The FDCA has not changed since the decision to label irradiated foods in 1986, so the motivation behind the FDA's dismissal of consumer concern in the case of GMOs is unclear.[192] Since the FDA has previously regulated based on consumer concern,[193] and a large segment of the population is

185. *See* Burk, *supra* note 104, at 271.

186. Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376, 13,388 (Apr. 18, 1986).

187. *Id.*

188. Strauss, *supra* note 150, at 184.

189. *FDA Responds to 1.1 Million*, JUST LABEL IT (Apr. 5, 2012), http://justlabelit.org/fda-responds-to-1-1-million/. *See generally* Docket No. FDA-2011-P-0723-0001/CP.

190. Monica Eng, *FDA Finally Responds to GMO-Labeling Campaign but Differs on Numbers of Supporters*, CHI. TRIB., Mar. 28, 2012, http://www.chicagotribune.com/features/food/stew/chi-gmolabeling-campaign-claims-a-million-supporters-but-fda-doesnt-agree-20120328,0,1662591.story. While over one million people submitted comments, those submitted via the petition were officially counted as one comment since these names were signed to identical form letters. *Id.* As such, the FDA contends it received only 394 comments. *Id.*

191. *Id.*

192. *Cf.* David Alan Nauheim, *Food Labeling and the Consumer's Right to Know: Give the People What They Want*, 4 LIBERTY U. L. REV. 97, 125 (2009).

193. *See, e.g.*, 21 C.F.R. pt. 179 (2013); *supra* notes 186–87 and accompany-

concerned about GMOs,[194] the FDA should reverse course and establish labeling regulations despite a lack of known safety risk.

### B. A FEDERAL GMO LABELING REGULATION SHOULD BALANCE CONSUMER INTERESTS AND SCIENTIFIC EVIDENCE

A regulation fueled by curiosity rather than necessity should be moderate in scope. This consideration should influence the FDA's implementation of GMO regulations. The two biggest decisions in designing a labeling law are (1) whether it should be mandatory or voluntary and (2) when to measure GMO presence. This Section argues for voluntary labeling with GMO presence tested on the finished product as a solution that balances consumer concern and production burdens.

#### 1. Mandatory Versus Voluntary

Current international labeling regimes can be a helpful starting point for developing a labeling program for the United States. There is not an early leader in popularity between mandatory versus voluntary systems.[195] Jurisdictions such as Canada, Hong Kong, and South Africa have adopted voluntary plans, while mandatory requirements are in place in Australia, Japan, Brazil, and China.[196] The EU, operating under a view that GMOs are not safe until proven so, has a mandatory regime requiring labels on food produced with GMOs.[197] When coupled with a negative perception of GMOs, however, mandatory labeling can push genetically modified (GM) food out of the market.[198] Mandatory labeling of GMOs also has the effect of raising prices, as practices of the entire market must change to accommodate the new requirements.[199]

Voluntary labeling indicating an absence of GMOs, on the other hand, passes the costs on to those parties who spurred

ing text.

194. THOMSON REUTERS, NATIONAL SURVEY OF HEALTHCARE CONSUMERS: GENETICALLY ENGINEERED FOOD (Oct. 2010), *available at* http://www.justlabelit.org/wp-content/uploads/2011/09/NPR_report_GeneticEngineeredFood-1.pdf. The survey of more than 100,000 U.S. households found that 14.6% view genetically engineered foods as not safe and 64.1% are unsure of their safety, with 93.1% supporting labeling of such foods. *Id.*

195. *See* Gruère & Rao, *supra* note 152, at 52–53.

196. *Id.* at 52.

197. Spahn, *supra* note 54, at 695–96.

198. *See* Gruère et al., *supra* note 151, at 1492–94.

199. *See* Strauss, *supra* note 150, at 192.

the change and value the information—consumers who want non-GM foods and producers who want to woo them.[200] The FDA should take this approach since there is little scientific evidence of a pressing concern that would necessitate GMO labeling with the exception of consumer desire.[201] Some argue that this cost should be borne by those who benefit from GM technology and consequently advocate for labels indicating the presence of GMOs.[202] However, this ignores that it is not farmers and producers alone who bear the costs of GMO labeling, but also consumers.

Voluntary labeling will also allow the market to respond to changing consumer demand.[203] If consumers respond positively to the voluntary labeling, more producers can change methods in order to meet that demand,[204] utilizing it as a "positive marketing tool to consumers."[205] Conversely, mandatory labeling in Europe has had the opposite effect, in that it has virtually shut GM food out of the market.[206] A voluntary labeling program thus allows the market to change in accordance with consumer values, rather than imposing anti-GMO values on all consumers by making GMO food prohibitively expensive to produce.[207] Additionally, unlike the FDA's current non-binding guidelines,[208] a voluntary program could set out compulsory standards for those who choose to label to ensure transparency in the meaning of a non-GMO label.

The FDA has previously rejected voluntary labeling with the language "GMO free" because it considers the term misleading, as most consumers equate "free" with "zero."[209] However, other countries with established GMO labeling have delineated a threshold level by which a certain percentage of GMOs can be present in food and still be considered GMO free.[210] The-

200. *Cf.* Byrne, *supra* note 145, at 69–70 (arguing that mandatory labeling results in indifferent consumers paying more for no added benefit).

201. *See, e.g.*, Crawford, *supra* note 132, at 1.

202. *See* Strauss, *supra* note 150, at 193.

203. *See* Gruère et al., *supra* note 151, at 1493.

204. *See id.* at 1493–94.

205. Strauss, *supra* note 150, at 193.

206. Gruère et al., *supra* note 151, at 1474.

207. *See id.* at 1486–92 (contending that a mandatory labeling program will tend to increase production costs such that sellers may be practically forced to switch to non-GM products).

208. *See Draft Guidance*, *supra* note 59.

209. *See id.*

210. *See* Colin A. Carter et al., *California's Proposition 37: Effects of Mandatory Labeling of GM Food*, AGRIC. & RESOURCE ECON. UPDATE, July/Aug.

se threshold levels range from 0.9% in the EU to 5% in Japan and Canada.[211] Establishing too strict of a threshold could be dangerous to suppliers, as producers could reject more crops because of GMO contamination.[212] The FDA believes that methods of detection at low percentage levels are currently inaccurate.[213] However, some grain producers have supported Europe's 0.9% standard as reasonable and attainable in the United States.[214] Using this standard has the added benefit of allowing producers to meet GMO thresholds in foreign markets as well.[215]

2. Production Process Versus Finished Product Measurement

Whether a food exceeds the threshold level further depends upon if regulations target GMOs in the finished product or in the production process.[216] The process-based definition considers genetically modified to mean any food made with GM ingredients, even if no trace remains detectable in the finished product.[217] Labeling regulations based on this definition thus must monitor producers and rely more heavily on self-reporting of compliance.[218] Where the finished product is the concern, however, tests can confirm the presence of GMOs.[219] As Guillaume P. Gruère and S.R. Rao explain, "This difference is crucial for enforcement: a product-based system can be enforced with testing equipment and can filter a cheater, whereas a process-based system requires viable and trustable documentation

2012, at 3, 6, *available at* http://giannini.ucop.edu/media/are-update/files/articles/V15N6_2.pdf.

211. *Id.*

212. *See, e.g.*, *Grain Suppliers Express Concerns About the Non-GMO Project*, THE ORGANIC & NON-GMO REPORT (Sept. 2007), http://www.non-gmoreport.com/articles/sept07/the_non-GMO_project.php (stating that grain suppliers contend a very low threshold would be practically unworkable due to contamination concerns).

213. *Draft Guidance*, *supra* note 59 ("[A] threshold would require methods to test for a wide range of genetic changes at very low levels in a wide variety of foods. Such test methods are not available at this time.").

214. *Grain Suppliers Express Concerns About the Non-GMO Project*, *supra* note 212.

215. *See id.*

216. *See* Gruère & Rao, *supra* note 152, at 52.

217. GUILLAUME P. GRUÈRE, LABELING POLICIES OF GENETICALLY MODIFIED FOOD: LESSONS FROM AN INTERNATIONAL REVIEW OF EXISTING APPROACHES, INT'L FOOD POL'Y RESEARCH INST. (2007), *available at* http://www.cbd.int/doc/external/mop-04/ifpri-pbs-policy-07-en.pdf.

218. *See id.*

219. *See id.*

systems."[220] The product-based system not only provides a quantifiable answer of GMO percentages in foods, but it does so with little additional burden to the producer (unlike the extensive record-keeping and reporting obligations the process-based system would compel).[221] Therefore, a voluntary labeling requirement should apply to finished products as it is verifiable and provides the assurance consumers desire.

3. Consumer Confusion

One final hurdle for a labeling program is the concern that it will cause consumer confusion. Voluntary labeling can create the impression in consumers that if "GMO free" is worthy of a place on the label, then those products without the language must somehow be inferior.[222] In response to similar concerns over irradiation labeling, the FDA stated, "[A]ny confusion created by the presence of a retail label requirement can be corrected by proper consumer education programs, and the presence of a retail label statement should not deter the development of this technology."[223] Requiring an additional statement on packaging that "The United States Food and Drug Administration has determined that there is no significant difference between food produced from genetically modified and conventional crops" could further address this concern.[224] The FDA could reevaluate this requirement and eventually remove it, pending consumer education programs and a review of their effectiveness in modifying consumer knowledge of GMO safety.

The voluntary labeling of food as "GMO free" would allow producers and consumers who value non-GM food to market and buy products based on this interest without saddling the rest of the market with the cost and burden. This labeling system would work hand in hand with market initiatives such as

220. Gruère & Rao, *supra* note 152, at 52.

221. *See, e.g.*, ALAN MCHUGHEN, LABELING GENETICALLY MODIFIED (GM) FOODS 2 (June 22, 2008), *available at* http://www.agribiotech.info/details/McHugen-Labeling%20sent%20to%20web%2002.pdf (arguing that a process-based labeling scheme would create immense practical difficulties in terms of implementation).

222. *See* Byrne, *supra* note 145, at 49.

223. Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376, 13,389 (Apr. 18, 1986).

224. *Cf.* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 79 (2d Cir. 1996) (Leval, J., dissenting) (indicating support for a Vermont law requiring a similarly worded label on dairy products from cows treated with growth hormones).

those from Whole Foods[225] or Ben & Jerry's,[226] but provide consumers with further assurance that a non-GMO label means the same from brand to brand. Voluntary labels with enforceable standards thus prevent consumer deception while allowing the market to dictate the value of GMO free food.

## CONCLUSION

While the FDA has thus far refused to address GMO labeling, the Agency is the proper choice to enact regulations. Its hesitance to do so is not based on an inability to regulate in this arena. If it continues to waver, states may capitalize on consumer demand and fill the void, even though such regulations likely violate the Dormant Commerce Clause and would be preempted by any subsequent federal regulation on the matter.

The FDA should create GMO regulations that balance consumer interests with the dearth of unbiased scientific evidence of negative health effects.[227] Voluntary labeling—pursuant to clear, reasonable, and enforceable definitions of what products contain GMOs—allows manufacturers who wish to capitalize on concerned consumers to do so without burdening other manufacturers or impacting national food supplies. This approach addresses the somewhat unknown nature of GMOs while precluding states from fear mongering and creating consumer confusion with regulations of their own. Although this solution does not provide consumers with the full breadth of information they may desire, it allows consumer choice while respecting developing scientific understanding and constitutional boundaries.

225. Strom, *supra* note 12.
226. Stewart, *supra* note 13.
227. *See, e.g.*, Anyadiegwu, *supra* note 10, at 213–17.