The Recent Enactment of National Mandatory GMO Labeling Law: Superior to a Voluntary Labeling Scheme But Unlikely to End the Labeling Controversy

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CONTENTS

INTRODUCTION

Labeling of foods that contain genetically modified (GM) ingredients has become the subject of extensive public debate throughout the nation.[1] Supporters of mandatory labeling sought to institute labeling requirements at the state level, and more than seventy bills have been introduced in more than thirty states to require labeling or prohibition of GM foods.[2] In 2013, the legislatures in Maine and Connecticut approved bills conditionally mandating GM labeling.[3] Maine's law will take effect when at least five

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1. Ross H. Pifer, *Mandatory Labeling Laws: What Do Recent State Enactments Portend for the Future of GMOs?*, 118 PENN. ST. L. REV. 789, 790 (2014).

2. *State Labeling Initiatives*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/state-labeling-initiatives [https://perma.cc/VFX9-GHMU].

3. Pifer, *supra* note 1, at 791.

contiguous states (including Maine) adopt similar legislation;[4] Connecticut's law will take effect once a combination of Northeastern states, with at least twenty million residents, endorses similar legislation.[5] These conditions are designed to protect these states from becoming the target in any lawsuit challenging the legislation.[6] In 2014, after these conditional laws were enacted, Vermont became the first state to initiate mandatory GM labeling with a so-called "no strings attached" law.[7] This requires that all food products that are "offered for sale in Vermont" and "entirely or partially produced with genetic engineering" must be identified with an appropriate label after July 1, 2016.[8]

After the passage of these state GMO labeling laws, the U.S. House of Representatives passed a bipartisan bill, the Safe and Accurate Food Labeling Act of 2015 (H.R. 1599),[9] amending Chapter IV of the Federal Food, Drug, and Cosmetic Act (FFDCA) and requiring the Food and Drug Administration (FDA) to continue to administer the voluntary consultation process for food products derived from GM plants.[10] If passed by the Senate and signed by the President, H.R. 1599 would have created a federal voluntary labeling standard and would have prevented states from enacting their own mandatory labeling laws.[11] However, H.R. 1599 was stalled in the Senate and was later replaced by a Senate bill, S. 764,[12] which stands in stark contrast to the approach advocated by the House.[13] On July 29, 2016, President Barack Obama signed S. 764 into law.[14] Unlike H.R. 1599, which would create a federal voluntary labeling scheme, S. 764 establishes mandatory national standards for labeling foods containing GM ingredients.[15] The statute also preempts all state level labeling laws,[16] including Vermont's, which went into effect after July 1, 2016.[17]

Part I of this Note provides background information about the major controversies related to GM foods, including the debate about whether

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4. *Id.* at 804.

5. *Id.*

6. Pamela Prah, *Many States Weigh GMO Labels*, PEW CHARITABLE TR. (Mar. 13, 2014), http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2014/03/13/many-states-weigh-gmo-labels [https://perma.cc/7JMC-6NQD].

7. Pifer, *supra* note 1, at 805.

8. *Id.*

9. *Final Vote Results for Roll Call 462*, HOUSE.GOV (July 23, 2015, 1:50 PM), http://clerk.house.gov/evs/2015/roll462.xml.

10. Safe and Accurate Food Labeling Act of 2015, H.R. 1599, 114th Cong. §101 (1st Sess. 2015).

11. *Id.* at § 203.

12. S. 764, 114th Cong. (2016) (enacted).

13. *See infra* Part II.

14. S. 764, 114th Cong. 130 Stat. 834, 834–38 (2016).

15. 7 U.S.C. § 1639b (2016).

16. *Id.* at § 1639i.

17. Pifer, *supra* note 1, at 805.

such foods should be labeled,[18] and the history of GMO labeling laws in the United States.[19] Part II compares S. 764 with H.R. 1599 and explains why a national mandatory labeling approach is superior to the voluntary labeling approach advocated by the House. Part III discusses the potential drawbacks and effect of S. 764 and finally concludes that the rulemaking process that will follow may create controversies and litigation.

I. BACKGROUND

A. What are GMOs and Who Benefits from Them?

The World Health Organization (WHO) defines genetically modified organisms (GMOs) as "organisms (i.e. plants, animals or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination."[20] In 1953, the discovery of the DNA double helix made it possible to alter the DNA structure; individual genes could then be removed, added, or inactivated.[21] In the early 1980s transgenic technology was developed, which was employed to isolate genes from one species and add them to another in order to express a desired trait.[22] Undesirable traits in traditional plant breeding methods could therefore be eliminated, and extra time involved in traditional methods could be saved.[23] This technology has also been used to remove a gene from animal DNA and insert it into plant DNA.[24] In 1982, Monsanto scientists were the first to genetically modify a plant cell,[25] and since the 1990s, adoption of GMOs by the United States and global producers has been unprecedentedly rapid.[26] In 2011, more than 395 million acres of GM crops were planted in the world by more than twenty-nine countries.[27] The United States leads the world in production of GM crops with 170 million acres.[28]

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18. *See infra* Part I.B.

19. *See infra* Part I.C.

20. *Frequently Asked Questions on Genetically Modified Foods*, WORLD HEALTH ORG., http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/ [https://perma.cc/C43R-6JBD].

21. Sally Noxon Vecchiarelli, Comment, *Mandatory Labeling of Genetically Engineered Food: Constitutionally, You Do Not Have a Right to Know*, 22 SAN JOAQUIN AGRIC. L. REV. 215, 218 (2012–2013).

22. *Id.*

23. *Id.*

24. *Id.*

25. *Id.*

26. Tara B. Ratanun, *Genetically Modified Organisms and Environmental Justice: Should Labeling be Mandatory on Products Containing Genetically Engineered Ingredients?*, 42 W. ST. L. REV. 111, 112 (2014).

27. Vecchiarelli, *supra* note 21, at 219.

28. *Id.*

In order to understand who benefits from the development and marketing of GM crops, besides the biotechnology industry and seed companies, an understanding of the differences between first, second, and third generation GM crops is also needed. First generation products include Roundup Ready[29] and Bt,[30] which feature the enhanced input traits of herbicide tolerance and insect resistance, respectively.[31] Second generation products, such as golden rice, are engineered to possess enhanced output traits like better taste or vital nutrients to vulnerable populations.[32] Similar to second generation GM crops, third generation products also provide enhanced output traits; however, these output traits can provide benefits outside the traditional areas of food and fiber, such as a transgenic goat that produces milk containing human antithrombin.[33] In addition, crops can also be genetically engineered to produce pharmaceutical and industrial products, such as vaccines, antibodies, proteins, and biodegradable plastics.[34]

Different generation GM crops benefit different groups of people. The primary beneficiaries of the first generation crops are those who are involved with the production of these crops because the technology enables the products to be produced more efficiently by using fewer resources.[35] Because these beneficiaries are usually large-scale producers, this technology may undermine the livelihood of small-scale farmers.[36]

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29. "Roundup Ready crops are genetically engineered crops that have had their DNA altered to allow them to withstand the herbicide glyphosate (the active ingredient of Monsanto's herbicide Roundup)." *Roundup Ready Crops*, SOURCEWATCH, http://www.sourcewatch.org/index.php/Roundup_Ready_Crops [https://perma.cc/9S9Z-V6M6]. Roundup Ready crops in the U.S. include corn, soybeans, canola, cotton, sugarbeets, and alfalfa. *Id.* When planting these crops, a farmer can spray the entire crop with glyphosate, killing only the weeds and leaving the crop alive. *Id.* One concern with the heavy use of glyphosate on these crops is that it will lead to the development of glyphosate resistant weeds (i.e., "superweeds"). *Id.*; *see also* William Neuman & Andrew Pollack, *Farmers Cope with Roundup Resistant Weeds*, N.Y. TIMES (May 3, 2010), http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?_r=1 [https://perma.cc/5KZU-YEVL].

30. *Bacillus thuringiensis* (or Bt) is a soil-dwelling bacterium, commonly used as a biological pesticide. *Bacillus thuringiensis*, WIKIPEDIA, https://en.wikipedia.org/wiki/Bacillus_thuringiensis [https://perma.cc/XR7Q-WFCT]. "Since 1996 plants have been modified with short sequences of genes from *Bt* to express the crystal protein *Bt* makes. With this method, plants themselves can produce the proteins and protect themselves from insects without any external *Bt* and/or synthetic pesticide sprays." *Bacillus thuringiensis*, AROIAN LAB, http://www.bt.ucsd.edu/bt_crop.html [https://perma.cc/KK6S-D39X].

31. Pifer, *supra* note 1, at 798.

32. *Id.*

33. *Id.*

34. Idah Sithole-Niang, *Third Generation GM Crops: An Opportunity for Africa*, SCI DEV NET, http://www.scidev.net/global/biotechnology/opinion/third-generation-gm-crops-an-opportunity-for-afri.html [https://perma.cc/KDL9-2F4T].

35. Pifer, *supra* note 1, at 798.

36. Carmen G. Gonzalez, *Genetically Modified Organisms and Justice: The International Environmental Justice Implications of Biotechnology*, 19 GEO. INT'L ENVTL. L. REV. 583, 610 (2007).

The primary beneficiaries of the second and third generation products are consumers who desire products with enhanced output traits.[37]

B. GMO Controversies

It is not surprising that the rapid development of GM technology in such a short amount of time led to serious debates on various issues surrounding GM crops and foods. Some major controversies include their socioeconomic and environmental impacts, health effects, and labeling questions.[38] With respect to their socioeconomic and environmental impacts, proponents of biotechnology have argued that GM crops will alleviate hunger and protect the environment in the developing world by increasing agricultural productivity, enhancing nutritional quality, reducing the use of pesticides and herbicides, and producing crops that can withstand environmental stress.[39]

On the flip side, opponents of GM crops have raised many concerns. They have argued, contrary to the proponents' argument that GM crops have reduced the use of pesticides and herbicides, that recent empirical studies have confirmed that farmers growing GM crops in the United States have significantly increased their use of pesticides and herbicides; one of the reasons for this greater use was the evolution of herbicide resistance by weeds.[40] The introduction of these herbicide tolerant GM crops has increased both the quantity and the toxicity of the herbicides applied, which can lead to serious environmental and health concerns.[41] For instance, in 2015 the WHO declared that the world's most widely used herbicide, Monsanto's Roundup, also known as glyphosate, is a probable human carcinogen.[42] In addition to the increased use of herbicides and pesticides, the opponents have also argued that GM crops can diminish biodiversity, accelerate corporate takeover of the global food supply, and

37. Pifer, *supra* note 1, at 798.

38. *See generally* Sheldon Krimsky, *An Illusory Consensus Behind GMO Health Assessment*, 40 SCI., TECH., & HUM. VALUES 883 (2015); Gonzalez, supra note 36; Pifer, *supra* note 1; Vecchiarelli, *supra* note 21.

39. Gonzalez, *supra* note 36, at 586.

40. *Id.* at 608.

41. *Id.*

42. INT'L AGENCY FOR RES. ON CANCER, WORLD HEALTH ORG., IARC MONOGRAPHS VOLUME 112: EVALUATION OF FIVE ORGANOPHOSPHATE INSECTICIDES AND HERBICIDES (Mar. 20, 2015), https://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf [https://perma.cc/7XG3-4E2H]; *see also* Doug Gurian-Sherman, *The Battle Over the Most Used Herbicide Heats Up As Nearly 100 Scientists Weigh In*, CIVIL EATS (Mar. 10, 2016), http://civileats.com/2016/03/10/the-battle-over-the-glyphosate-herbicide-heats-up-as-nearly-100-scientists-weigh-in/ [https://perma.cc/38VW-W9B5].

increase hunger and poverty by benefiting commercial agribusiness at the expense of small farmers.[43]

With respect to the debate about the potential health effects of consuming GM foods, many sources have claimed that there is nothing inherently unsafe about GM foods.[44] The FDA has also taken the position that GM foods do not differ in any significant way from traditional foods.[45] However, a closer investigation into the existing scientific literature has revealed that the so-called scientific consensus on the issue of GMO safety is illusory and the outcome of studies on the health effects of GM crops lacks consistency.[46] Professor Sheldon Krimsky has summarized three categories of researchers who have conducted research on potential health effects of consuming GM foods.[47] One category of researchers state that there is no need to test GM products as long as we know the proteins coded by the transferred genes and the host organisms.[48] According to this group of researchers, transgenic products are considered as safe as or safer than traditional hybrid crops or other nontransgenic methods.[49] The second category of researchers contend that each GM product must be tested for a variety of possible effects.[50] They argue that science cannot claim that a product of genetic modification is safe without undertaking a testing program that includes multiyear and multigenerational tests in animals fed on GM crops.[51] The third group of researchers assert that GM crops, when fed to animals, have exhibited harmful effects compared to non-GMO controls and that these results should draw attention to human health concerns.[52]

In addition to the issue of health effects, labeling of GM foods has also become the subject of extensive public debate throughout the nation.[53] Proponents of mandatory labeling, including organic food companies and food activists, argue that people have a right to know what is in their food.[54] Moreover, they argue that labeling laws can force transparency on an industry that tends to be dominated by only a few large corporations

43. Gonzalez, *supra* note 36, at 603.

44. *See, e.g.*, AM. ASS'N FOR THE ADVANCEMENT OF SCI., STATEMENT BY THE AAAS BOARD OF DIRECTORS ON LABELING OF GENETICALLY MODIFIED FOODS (Oct. 20, 2012), https://www.aaas.org/sites/default/files/AAAS_GM_statement.pdf [https://perma.cc/C8S9-9LF2].

45. *See* Vecchiarelli, *supra* note 21, at 216.

46. *See* Krimsky, *supra* note 38, at 884.

47. *Id.*

48. *Id.*

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.*

53. *See* Pifer, *supra* note 1, at 790.

54. *See, e.g.*, JUST LABEL IT!, http://www.justlabelit.org/right-to-know-center/ [https://perma.cc/KXZ5-3HS9].

like Monsanto and Dupont.[55] Those who oppose labeling laws, such as seed and biotechnology companies, as well as some scientists, have argued that labeling laws could lead to higher food prices and abusive private litigation against food companies, could demonize GM foods in a way that is disproportionate to the risks involved, and could create a stigma effect that would hinder future research into using GM foods to improve nutrition or to help ameliorate the effects of climate change.[56] This Note will focus on the labeling issue and discuss why the federal government should not preempt states from enacting their own mandatory labeling laws.

C. History of GMO Labeling Laws in the United States

For decades, the United States did not have a uniform federal law that required mandatory labeling for GM foods. On July 29, 2016, after years of debate and legislative stalemate, President Barack Obama signed Senate Bill 764 (S. 764) into law, which created a federal labeling standard for foods containing GM ingredients.[57] Before the passage of S. 764, supporters of mandatory labeling had sought to institute labeling requirements at the state level, and more than seventy bills had been introduced in more than thirty states to require labeling or prohibition of GM foods.[58] For example, in 2012 the California Right to Know Genetically Engineered Food Act (Proposition 37) brought a national focus upon the issue of mandatory labeling.[59] Under this proposition, all GM food products would require labeling unless one of nine specifically delineated exemptions applied.[60] Groups with national interests on this issue were intensely involved in attempts to influence voters and raised more than $55 million for advocacy efforts, including $9.2 million spent by proponents and $46 million spent by opponents.[61] In 2012, California voters rejected Proposition 37 by a narrow margin of 51.41% to 48.59%.[62]

One year after the defeat of Proposition 37, Washington State voters considered Initiative 522, which would have required labeling of most GM foods.[63] The spending on Initiative 522 mirrored that on California's Proposition 37, with $20.1 million spent in opposition to the initiative and

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55. *See* Colin O'Neil, *Fact-checking the GMO Labeling Debate*, HILL (Mar. 23, 2015), http://thehill.com/blogs/congress-blog/healthcare/236636-fact-checking-the-gmo-labeling-debate [https://perma.cc/38ZH-ZURA].

56. *Id.*

57. *See* 7 U.S.C. § 1639b (2016).

58. *State Labeling Initiatives*, *supra* note 2.

59. *See* Pifer, *supra* note 1, at 799.

60. *Id.* at 800.

61. *Id.* at 801.

62. *Id.*

63. *Id.* at 802.

$7 million spent in favor of it.[64] Similar to what happened in California, 48.91% of Washingtonians voted in favor of Initiative 522 while 51.09% voted against.[65]

In other parts of the country advocates for mandatory labeling laws had more success using the more traditional legislative process.[66] In 2013, legislatures in Maine and Connecticut approved bills conditionally mandating GM labeling.[67] For example, the Maine law will become effective when at least five contiguous states (including Maine) adopt similar legislation;[68] in Connecticut, the law will take effect once a combination of Northeastern states with at least twenty million residents endorses similar legislation.[69] The conditions are designed to protect these states from becoming the target of a lawsuit challenging the legislation.[70]

In 2014, after these conditional laws were enacted, Vermont became the first state to initiate mandatory GM labeling with a so-called "no strings attached" law.[71] Pursuant to this statute, "all food products that are 'offered for retail sale in Vermont' and that contain genetically modified ingredients must be identified with an appropriate label" beginning July 1, 2016.[72] Depending on the product, "the label must indicate that the food or food product was 'produced with genetic engineering,' 'partially produced with genetic engineering,' or that it 'may be produced with genetic engineering.'"[73] Vermont's Attorney General is charged with enforcement of this law and has been granted authority to engage in rulemaking for its implementation.[74]

On the federal level, the FDA regulates food labeling pursuant to its authority under the Federal Food, Drug, and Cosmetic Act.[75] "The overarching requirements of the FFDCA as to what must be revealed in a food label are broad and general."[76] "The FFDCA also requires that all [food] labeling . . . 'reveal all facts that are material in light of representations made or suggested by labeling or with respect to consequences which may result from use' of the product."[77]

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64. *Id.*
65. *See* Pifer, *supra* note 1, at 799.
66. *Id.* at 803.
67. *Id.* at 791.
68. *Id.* at 804.
69. *Id.*
70. *See* Prah, *supra* note 6.
71. *See* Pifer, *supra* note 1, at 805.
72. *Id.* at 790.
73. *Id.*
74. *Id.* at 805.
75. *See* Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT'L ENVTL. L. REV. 717, 723 (2000).
76. *Id.*
77. *Id.* at 724.

Although the revelation requirements of the FFDCA are broad and general, the FDA has claimed that there is "neither a scientific nor a legal basis to require such [mandatory] labeling" for GM foods.[78] The FFDCA only requires food producers to disclose information about the composition of the food product itself, not the method or conditions of its production, unless the method or conditions result in significant differences in the composition of the food.[79] Because the FDA takes the position that GM foods do not differ in any significant way from traditional foods,[80] it is not surprising that under the FFDCA genetic modification, in the absence of material food composition change, does not require labeling.[81] Additionally, the FDA does not ordinarily require testing or other premarket review of GM foods but has instead created a system of voluntary consultation to assist GM food manufacturers in determining whether labeling or other actions are needed.[82]

On July 23, 2015, the U.S. House of Representatives overwhelmingly passed the Safe and Accurate Food Labeling Act of 2015 (H.R. 1599),[83] which aimed to provide "clarity and uniformity for the labeling of food products containing genetically engineered plants or ingredients, seeking to eliminate confusion among consumers."[84] H.R. 1599 amends Chapter IV of the FFDCA[85] and requires the FDA to continue to administer the "consultation process" established under the FDA's *Statement of Policy: Food Derived from New Plant Varieties*, which was published in the Federal Register on May 29, 1992 (57 Fed. Reg. 22,984).[86] In its policy statement, the FDA stated that it is a prudent practice for manufacturers of food derived from new plant varieties, including genetically engineered plants, to consult with the agency on safety and regulatory questions.[87] To respond to the food industry's

78. Robert E. Brackett, *Bioengineered Foods*, U.S. FOOD & DRUG ADMIN. (June 14, 2005), http://www.fda.gov/NewsEvents/Testimony/ucm112927.htm [https://perma.cc/7GZ8-P4RC].

79. *See* Goldman, *supra* note 755, at 724–25.

80. *Id.* at 726.

81. *Id.* at 727.

82. *Id.* at 726.

83. *See H.R. 1599: Safe and Accurate Food Labeling Act of 2015*, GOVTRACK, https://www.govtrack.us/congress/votes/114-2015/h462 [https://perma.cc/7CYX-3KCF].

84. *H.R. 1599: The Safe and Accurate Food Labeling Act*, ENERGY & COM. COMMITTEE: FACT SHEET (July 17, 2015), https://energycommerce.house.gov/fact-sheet/hr-1599-safe-and-accurate-food-labeling-act [https://perma.cc/7SDT-W8BP].

85. The Safe and Accurate Food Labeling Act of 2015, H.R. 1599, 114th Cong. § 101 (1st Sess. 2015).

86. *Id.* (proposing to amend 21 U.S.C. 3501 § 424(a)).

87. *See Consultation Procedures under FDA's 1992 Statement of Policy: Foods Derived from New Plant Varieities*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096126.htm [https://perma.cc/JG8U-8NJ6].

inquiries about the appropriate consultation procedures, the FDA developed guidance in 1996 that describes a process through which developers can consult with the agency.[88]

In the guidance, the FDA explained that the agency will not conduct a comprehensive scientific review of data generated by the food manufacturers during the consultation process.[89] Instead, based on agency scientists' evaluations of the available information voluntarily provided by developers, it will consider "whether any unresolved issues exist regarding the food derived from the new plant variety that would necessitate legal action by the agency if the product were introduced into commerce."[90] To further explain what constitutes "unresolved issues," the guidance listed several examples, including "significantly increased levels of plant toxicants or anti-nutrients, reduction of important nutrients, new allergens, or the presence in the food of an unapproved food additive."[91] When all safety and regulatory issues are resolved, the FDA will consider the consultation process to be completed.[92]

In addition to reaffirming that the FDA should continue to administer this voluntary consultation process, H.R. 1599 also provides that "the use of genetic engineering does not, by itself, constitute information that is material for purposes of determining whether there is a difference between a food produced from, containing, or consisting of a genetically engineered plant and a comparable food."[93] With respect to a labeling requirement, H.R. 1599 gives the FDA the authority to require labeling only if it determines that:

> (A) there is a material difference in the functional, nutritional, or compositional characteristics, allergenicity, or other attributes between the [GM] food . . . and its comparable [non-GM] food; and
>
> (B) the disclosure of such material difference is necessary to protect public health and safety or to prevent the label or labeling of the [GM] food so produced from being false or misleading in any particular.[94]

If passed by the Senate and signed by the President, H.R. 1599 would create a uniform federal voluntary labeling standard and would preempt states from enacting their own mandatory GMO labeling laws.[95]

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88. *See id.*
89. *See id.*
90. *Id.*
91. *Id.*
92. *Id.*
93. The Safe and Accurate Food Labeling Act of 2015 § 101 (proposing to amend 21 U.S.C. 3501 § 424(b)(1)).
94. *Id.* (proposing to amend 21 U.S.C. 3501 § 424(b)(2)).
95. *Id.* at § 203.

Food and biotechnology companies that oppose mandatory labeling of GM foods have spent tremendous resources to lobby for this kind of anti-labeling bill. According to a report by the Environmental Working Group, food and biotechnology companies spent $63.6 million in 2014 to lobby for legislation that made reference to GMO labeling—almost three times what they spent in 2013.[96] These expenditures dwarfed those spent by GMO labeling advocates, who only spent $1.6 million in 2013 and $2.6 million in 2014.[97] In 2015, lobby expenditures by food and biotechnology companies increased again; they have reported expenditures of $51.6 million in just the first two quarters of the year.[98]

Subsequently, H.R. 1599 was stalled in the Senate and later replaced by S. 764, which stands in stark contrast to the approach advocated by the House. The House of Representatives approved S. 764, and President Obama signed it into law on July 29, 2016.[99] Unlike H.R. 1599, which would create a federal voluntary labeling standard for GM foods,[100] S. 764 establishes mandatory national standards for labeling foods containing GM ingredients.[101] It also gives the U.S. Department of Agriculture (USDA) the authority to define which ingredients count as GM ingredients for the purposes of the law[102] and directs the USDA to begin the process of deciding exactly what food manufacturers will be required to label.[103] The agency is supposed to complete this process within two years.[104] S. 764 also preempts all state level labeling laws,[105] including Vermont's, which went into effect on July 1, 2016. It will also preempt the bills passed in Connecticut and Maine that required contiguous states to pass similar bills.

II. A COMPARISON BETWEEN H.R. 1599 AND S. 764

Compared with the voluntary labeling approach advocated by the House in H.R. 1599, the enactment of S. 764 is a better solution. First, mandatory labeling is superior because the FDA's position that there is no

96. Libby Foley, *Corporate Spending to Fight GMO Labeling Skyrockets*, EWG (Apr. 23, 2015), http://www.ewg.org/research/anti-label-lobby [https://perma.cc/58XU-AHST].

97. *Id.*

98. Shannon Van Hoesen, *Big Food Companies Spend Millions to Defeat GMO Labeling*, EWG (Aug. 4, 2015), http://www.ewg.org/release/big-food-companies-spend-millions-defeat-gmo-labeling [https://perma.cc/8L52-4QDU].

99. S. 764, 114th Cong. 130 Stat. 834, 834–38 (2016).

100. The Safe and Accurate Food Labeling Act of 2015, H.R. 1599, 114th Cong. § 101 (1st Sess. 2015).

101. 7 U.S.C. § 1639(b) (2016).

102. *Id.* at § 1639.

103. *Id.* at § 1639(b).

104. *Id.*

105. *Id.* at § 1639(i).

scientific basis to require labeling of GM foods is unjustified. Although the biotechnology industry and some prominent scientists have cited studies to support the safety of GM foods, experts like Sheldon Krimsky have pointed out that there is only an "illusory" scientific consensus behind GMO health assessment.[106] In his recent article, Professor Krimsky has identified twenty-six individual studies that have reported adverse effects or uncertainties after feeding GM crops to animals.[107] He also performed a search in *PubMed* and *Web of Science* and found eight systematic reviews examining animal feeding studies of GMO health effects from 2008 to 2014.[108] These systematic reviews present mixed results. Some reviews found identifiable adverse effects on animals fed on GM crops.[109] Other reviews suggest that although it appears there are no adverse effects of GM crops on many species of animals in acute and short-term feeding studies, serious debate exists about the effects of long-term and multigenerational feeding studies, and the scarcity of the scientific evidence published to date prevents conclusive claims of safety, or lack of safety, of GM food products.[110]

In addition to the lack of long-term and multigenerational feeding studies on animals, there are no epidemiological studies available that investigate the potential effects of consuming GM foods on human

106. *See generally* Krimsky, *supra* note 38.

107. *Id.* at 12.

108. *Id.* at 3.

109. For example, in 2011 a review conducted by Maghari and Ardekani noted that many scientific data indicate that animals fed on GM crops have been harmed or even died. Krimsky, *supra* note 38, at 3–4. "Rats exposed to transgenic potatoes or soya had abnormal young sperm; cows, goats, buffalo, pigs and other livestock grazing on Bt-maize, GM cottonseed and certain biotech corn showed complications including early deliveries, abortions, infertility and also many died." *Id.* at 4. In 2008, another review conducted by Magana-Gomez and Calderon de la Barca reported that "[t]he most common result [of animal feeding experiments] has been that there were no effects at the macroscopic level; however, organelles and other subcellular structures are clearly affected, as shown at ultramicroscopic levels." *Id.* at 5. In a third review conducted by Snell et al. in 2012, after acknowledging the small number of available studies, the authors reported that "[t]he results of most of the rather few studies conducted with GM foods indicate that they may cause hepatic, pancreatic, renal, and reproductive effects and may alter hematological, biochemical, and immunologic parameters the significance of which remains unknown. . . . [These] results indicate that many GM foods have some common toxic effects." *Id.* at 4.

110. For instance, in 2013 a review conducted by Bawa and Anilakumar found that "not much is known about . . . [GMOs] long-term effects on human beings." Krimsky, *supra* note 38, at 5. The authors concluded that "[o]ne has to agree that there are many opinions about scarce data on the potential health risks of GM food crops, even though these should have been tested for and eliminated before their introduction." *Id.* In 2011, another review conducted by Domingo and Bordonaba noted that "the number of studies specifically focused on safety assessment of GM plants is still limited[,]" and "most of the studies demonstrating that GM foods are as nutritional and safe as those obtained by conventional breeding, have been performed by biotechnology companies or associates, which are also responsible of [sic] commercializing these GM plants." *Id.* at 4.

health.[111] Although it is often claimed that "'trillions of GM meals' have been eaten in the U.S. with no ill effects," no epidemiological studies in a human population have been carried out because GM foods are not monitored or labeled after their release or sale, and it is scientifically impossible to trace patterns of consumption and their associated impacts.[112] Thus, claims that GM foods are safe for human health based on the experience of North American populations have no scientific basis.[113] Furthermore, other obstacles, such as the lack of funding independent of proprietary interests and the manufacturers' denial of access to research materials, have also hampered rigorous assessment of GMO safety.[114] Thus, it is scientifically unjustifiable for the FDA to conclude that GM crops are as safe as conventional non-GM crops.

Contrary to the FDA's ignorance of the potential risks imposed by the consumption of GM foods, policy makers in other countries have recognized the risks and employed measures to address such risks. For instance, the 2003 Cartagena Protocol on Biosafety is an international agreement ratified by 166 governments worldwide that seeks to protect biological diversity from the risks posed by GM technology and allows signatory states to take measures to protect themselves against threats of danger from GM crops and foods, even in the case of lack of scientific certainty.[115]

The approach taken in Europe for GM crops and foods—both at the national level and in the European Union (EU)—also stands in great contrast to the voluntary labeling approach proposed by the House.[116] In 1996, when the U.S. exported its first crop of GM soybeans and corn to the EU, the arrival of these foods attracted considerable media attention and significantly increased public awareness and concern throughout Europe.[117] In 2000, in response to public protests and the increased demand for the labeling of GM foods, the EU issued a relatively strict standard, requiring the labeling of food if at least 1% of which was genetically modified.[118]

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111. Angelika Hilbeck et al., *No Scientific Consensus on GMO Safety*, 27 ENVTL. SCI. EUR. 4, 2 (2015).

112. *Id.*

113. *Id.* at 2.

114. *Id.* at 1.

115. *Id.* at 4.

116. Diahanna Lynch & David Vogel, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*, COUNCIL ON FOREIGN REL. (Apr. 5, 2001), http://www.cfr.org/agricultural-policy/regulation-gmos-europe-united-states-case-study-contemporary-european-regulatory-politics/p8688 [https://perma.cc/8LYW-8RJK].

117. *Id.*

118. *Id.*

Second, due to the lack of scientific consensus on the issue of GMO safety, Congress should adopt the "precautionary principle" and enact a law that would grant the public the right to know and the power to avoid potential risks associated with long-term consumption of GM foods. The mandatory labeling law, S. 764, which requires disclosure of GM ingredients, resonates better with the precautionary principle.

The precautionary principle has its roots in German environmental policy and has served as a central element in various international environmental treaties, such as the Cartagena Protocol on Biosafety[119] discussed in Part III. One of the earliest and substantial formulations of the precautionary principle was adopted in the 1992 Rio Declaration, which provides that "[i]n order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[120]

A more comprehensive definition of the precautionary principle "was spelled out in a January 1998 meeting of scientists, lawyers, policy makers, and environmentalists at Wingspread, headquarters of the Johnson Foundation in Racine, Wisconsin."[121] The Wingspread Statement on the Precautionary Principle states that "[w]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[122] Key components of the 1998 Statement include (1) taking preventative action in the face of uncertainty, (2) shifting the burden of proof to the proponents of an activity, (3) exploring a wide range of alternatives to possibly harmful actions, and (4) increasing public participation in decision making.[123] The core of the precautionary principle is the simple idea that "decision makers should act in advance of scientific certainty to protect the environment (and with it, the well-being of future generations) from incurring harm."[124] In other words, "in order to avoid or minimize risks whose consequences are uncertain but

119. David Kriebel et al., *The Precautionary Principle in Environmental Science*, 109 ENVTL. HEALTH PERSP., No. 9, 871 (2001).

120. *Rio Declaration on Environment and Development*, UNITED NATIONS ENV'T PROGRAMME, http://www.unep.org/Documents.Multilingual/Default.asp?documentid=78&articleid=1163 [https://perma.cc/QPX5-S7H3].

121. Carolyn Raffensperger, *The Precautionary Principle: A Fact Sheet*, SCI. & ENV'L HEALTH NETWORK, http://www.sehn.org/Volume_3-1.html#a1 [https://perma.cc/ABM5-USJN].

122. Jeanne Marie Zokovitch Paben, *Green Power & Environmental Justice-Does Green Discriminate?*, 46 TEX. TECH L. REV. 1067, 1106–07 (2014).

123. Kriebel et al., *supra* note 1199, at 871.

124. CAROLYN RAFFENSPERGER ET AL., PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE 23 (1999).

potentially serious, there must be proactive action."[125] Therefore, this principle has been referred to as the "[b]etter safe than sorry" principle.[126]

Although the U.S. government claims that "it does not adhere to or admit to any deference to the precautionary principle in domestic or international law and it resists international agreements that espouse the precautionary principle,"[127] it has also passed certain domestic environmental statutes, such as the Clean Air Act (CAA), that espouse this principle in one form or another.[128] For instance, a certain provision of the CAA has been read to implicitly invoke the precautionary principle. In *Ethyl Corp. v. Environmental Protection Agency*, the D.C. Circuit held that the language of Section 211 in the CAA makes it a precautionary statute.[129] The court stated that "[r]egulatory action may be taken before the threatened harm occurs; indeed, the very existence of such precautionary legislation would seem to demand that regulatory action precede, and optimally, prevent, the perceived threat."[130]

The precautionary principle addresses the problem of scientific uncertainty by shifting the burden of proof. Under most environmental statutes that do not espouse the precautionary principle, the government bears the burden to show that an activity or product poses a risk and, therefore, environmental measures are warranted.[131] In contrast, under precautionary statutes, the burden shifts to the party who plans on introducing a product to prove that the product is safe.[132] The Federal Insecticide, Fungicide, and Rodenticide Act is an example of a statute that shifts the burden to pesticide manufacturers to show that "their product will not have 'unreasonable adverse effects on the environment.'"[133]

Further, state governments have also engaged in regulations that use the precautionary principle approach. A state level example is California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65),[134] which includes a discharge prohibition and a warning obligation provision. The discharge prohibition provision prohibits a person, "in the course of doing business," from "knowingly discharg[ing] or releas[ing] a

125. Paben, *supra* note 1222, at 1107.

126. *Id.*

127. Mystery Bridgers, *Genetically Modified Organisms and the Precautionary Principle: How the GMO Dispute Before the World Trade Organization Could Decide the Fate of International GMO Regulation*, 22 TEMP. ENVTL. L. & TECH. J. 171, 186 (2004).

128. Lynch & Vogel, *supra* note 1166.

129. Ethyl Corp. v. Env't Prot. Agency, 541 F.2d 1, 13 (D.C. Cir. 1976).

130. *Id.*

131. Nathaniel Garrett, *"Life is the Risk We Cannot Refuse:" A Precautionary Approach to the Toxic Risks We Can*, 17 GEO. INT'L ENVTL. L. REV. 517, 544 (2005).

132. *Id.*

133. *Id.*

134. CAL. HEALTH & SAFETY CODE §§ 25249.5–25249.13 (West 1992).

chemical known to the state to cause cancer or reproductive toxicity into water or into land where such chemical passes or probably will pass into any source of drinking water."[135] The warning obligation requires any person "in the course of doing business" to give a clear and reasonable warning to the public if she knowingly and intentionally exposes any individual to a chemical known to the state to cause cancer or reproductive toxicity.[136] Therefore, this statute shifts the burden of demonstrating the safety of exposures to products manufacturers, and by shifting the burden, the statute reversed the normal incentive for the industry to seek delay in the regulatory process, and encouraged it to reformulate its products and make them safer.[137]

Although Proposition 65 created considerable controversies at its initial stage, it soon had a rapid and successful implementation.[138] Its reliance on information disclosure is more effective than the federal government's direct regulatory approach by setting standards, especially in the consumer marketplace, because consumers can be extremely sensitive to the disclosure of adverse health and safety information; therefore, instead of providing warnings and risking significant sales losses, many businesses chose to reformulate their products.[139] Proposition 65 did not cause a significant detrimental effect on the agricultural and manufacturing businesses as the industries had speculated before the enactment of this law,[140] and most companies have reformulated their products nationwide, giving the Proposition a national effect, the so-called "California effect."[141]

With respect to the issue of GMO labeling, Congress should adopt an approach similar to Proposition 65 based on the precautionary principle. Although Proposition 65 was enacted to protect the public from the exposure of carcinogens and reproductive toxins,[142] there are some general similarities between Proposition 65 and mandatory GMO labeling laws. For example, Proposition 65 and mandatory GMO labeling laws are both consumer disclosure acts. Just like the product manufacturers who had opposed the enactment of Proposition 65, biotechnology industry and food manufacturers also oppose the enactment of mandatory labeling laws, and they share similar concerns, such as increased manufacturing costs and

135. *Id.* § 25249.5.

136. *Id.* § 25249.6.

137. PERCIVIL ET AL., ENVIRONMENTAL REGULATION LAW, SCIENCE, AND POLICY 330–38 (7th ed. 2013).

138. *Id.* at 332.

139. *Id.* at 338.

140. *Id.* at 333–34.

141. *Id.* at 336.

142. *Id.* at 330–34.

frivolous lawsuits. However, the overall success of California's Proposition 65 should at least give policy makers some confidence that the speculated drawbacks of this type of consumer disclosure act may not be as detrimental as the manufacturers have argued, and the benefits of disclosure could eventually outweigh its potential drawbacks.

Similar to the positive effect of Proposition 65 due to its burden shifting to the manufactures, after Congress adopts the precautionary principle for GMO labeling it also could reverse the normal incentive of biotechnology and food companies to delay comprehensive testing of GMO food products associated with the voluntary labeling system. Moreover, with a carefully crafted legislation, a mandatory GMO labeling law could avoid those concerns shared by all consumer disclosure acts. Take California's Proposition 37 ("Label GMO") and the concern of abusive private litigation for example: although California's Proposition 37 has been rejected by voters, a study has compared Label GMO with Proposition 65 and concludes that although the adoption of Label GMO would likely result in private lawsuits to enforce its provisions, important differences between Label GMO and Proposition 65 will substantially reduce the potential that Label GMO will result in abusive private litigations associated with Proposition 65.[143] The differences include the following: (1) Label GMO would apply to a much narrower economic sector than Proposition 65, (2) Label GMO would provide businesses with greater legal certainty than Proposition 65, and (3) Label GMO would allow businesses more exceptions from its provisions than Proposition 65.[144]

Third, H.R. 1599's national voluntary labeling approach would deprive the states that have already passed mandatory labeling laws of the opportunity to "test out" their choice, which may provide valuable information for future legislation, either on the state or federal level. For example, these mandatory labeling laws may help shed light on some important issues of the ongoing debates, such as the impact of GMO labeling on food prices. The biotechnology industry argues that mandatory GMO labeling requirements will drive up food prices for consumers; however, proponents of GMO labeling laws argue that there is no evidence showing that requiring food manufacturers to label products that contain GMO ingredients will increase food prices.[145] An independent study

143. James C. Cooper, Proposition 65 and the Proposed California Right to Know Genetically Engineered Foods Act: A Comparison of Litigation Incentives, (unpublished manuscript), http://www.anh-usa.org/wp-content/uploads/2012/07/Prop65-and-GMO-Label-Initiative.pdf.

144. *Id.*

145. *GMO Labeling and Food Prices*, JUST LABEL IT, http://www.justlabelit.org/about-ge-foods-center/ge-labeling-and-food-prices/ [https://perma.cc/4RFA-NZRD].

conducted to determine whether there is a connection between changes to product labels and prices set by U.S. supermarket operators found that "label changes are a minor element in the complex and fluid mix of pricing considerations that drive the price of an individual product."[146] The study also noted that, at the corporate level, pricing decisions are established by supermarket operators based on their desired brand image, branding goals, and overall positioning in the local market.[147] Although production costs are certainly taken into account in pricing decisions, marketing and economic researchers have agreed that it is demand-oriented factors, such as consumer demographics, rival pricing, market, chain, and store characteristics, which have a far greater impact on product prices.[148] Food manufacturers' overall production costs are also affected by a wide range of factors, including costs of ingredients, energy, manufacturing, packaging, and marketing expenses.[149] The cost associated with label changes is just one of these factors.[150] Moreover, voluntary label changes are regularly made by food manufacturers.[151] For instance, as part of the manufacturers' innovation cycle, food companies often redesign packaging and labels.[152] Economists have noted that most changes made to labels are known in advance by food manufacturers, and costs associated with label changes can be incorporated into the manufacturing cycle.[153]

III. AN ASSESSMENT OF THE EFFECT OF S. 764

Although S. 764's mandatory labeling approach is a better solution than H.R. 1599, it has several potential drawbacks. First, the law allows manufacturers to choose what type of label they use: it can be a simple text label on the package, a symbol, a 1–800 number, or a QR code that can be scanned with a smartphone.[154] The fact that the law does not require a simple disclosure on the package can be inconvenient for consumers, may discourage the public from exercising their right to know, and

146. Kai Robertson, *Independent Study: Why Label Changes Don't Affect Food Prices*, JUST LABEL IT (Sept. 11, 2013), http://www.justlabelit.org/wp-content/uploads/2013/09/Kai-Roberston-Food-Labeling-Study-2013.pdf [https://perma.cc/BD2S-LS46].

147. *Id.* at 2.

148. *Id.* at 1.

149. *Id.* at 6.

150. *Id.*

151. *Id.* at 5.

152. *Id.*

153. *Id.* at 6.

154. *See* 7 U.S.C. §§ 1639b(b)(2)(D), (F) (2016); *see also* Andrew Amelinckx, *What You Need to Know About the New GMO Labeling Law*, MOD. FARMER (Aug. 8, 2016), http://modernfarmer.com/2016/08/gmo-labeling-law/ [https://perma.cc/M4TJ-LD5T].

discriminates against many consumers who cannot afford or do not own smartphones.[155]

Second, the law gives the USDA broad authority to define which ingredients count as GM ingredients and allows the agency to determine how much of a bioengineered substance must be present to require a GM label.[156] If the agency sets a high threshold, many GM ingredients could be exempted from the mandatory labeling requirement.[157] The law also gives the agency the authority to ultimately decide what exactly will and will not be required to be labeled; as a result, many common refined products like oil made from soy or canola may not be required to be labeled because although they are made from GM crops, the final products "don't fit the law's definition of 'bioengineering' and don't necessarily contain genetic material."[158]

CONCLUSION

S. 764's mandatory labeling scheme is superior to the voluntary labeling approach proposed by H.R. 1599. The FDA's position that there is no scientific basis for requiring labeling of GM foods is unjustified.[159] Although the biotechnology industry and some scientists have cited studies to support the safety of GM foods, a closer review of available scientific research on GMO safety has revealed that published research results are contradictory, little has been done on long-term and multigenerational animal feeding studies, and no epidemiological studies are available on the effect of GM foods on humans.[160] Other obstacles, such as the lack of funding independent of proprietary interests and manufacturers' denial of access to research materials have also hampered rigorous assessment of GMO safety.[161] Therefore, due to the lack of scientific consensus on the issue of GMO safety, Congress should adopt the precautionary principle and enact a law that would grant the public the right to know and the power to avoid potential risks associated with long-term consumption of GM foods. S. 764, which requires mandatory disclosure of GM ingredients, resonates better with the precautionary principle.

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155. *See* Amelinckx, *supra* note 1544.

156. 7 U.S.C. §§ 1639(1), 1639b(b)(2)(B).

157. Mary Clare Jalonick, *Critics Say Federal Bill to Require GMO Labels on Food Falls Short*, PORTLAND PRESS HERALD (July 14, 2016), http://www.pressherald.com/2016/07/14/congress-approves-bill-requiring-gmo-labels-on-food/ [https://perma.cc/93C4-8TXU].

158. *See* Amelinckx, *supra* note 1544.

159. *See supra* Part II.

160. *See supra* Part II. *See generally* Krimsky, *supra* note 38; Hilbeck et al., *supra* note 111, at 2.

161. Hilbeck et al., *supra* note 111, at 1.

Although the mandatory approach adopted by S. 764 is superior, S. 764 has its own drawbacks. Because S. 764 allows manufacturers to use a 1-800 number or a QR code instead of a simple text disclosure on the package, the public may be discouraged from exercising their right to know and the consumers who cannot afford or do not own smartphones cannot access such information.[162]

Moreover, because S. 764 gives the USDA very broad authority, many GM ingredients could be exempted from the mandatory labeling requirement,[163] and many common refined products like oil made from soy or canola may not be required to be labeled.[164] Because S. 764 leaves many details to be worked out by the agency, controversies and battles during the rulemaking process are likely to continue.

162. *See supra* Part III; Amelinckx, *supra* note 1544.
163. *See supra* Part III*;* Jalonick, *supra* note 157.
164. *See supra* Part III; Amelinckx, *supra* note 1544.