LABELING GENETICALLY-ENGINEERED FOODS: AN UPDATE FROM ONE OF THE FRONT LINES OF FEDERALISM

BY

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Consumers in the United States have increasingly demanded that manufacturers of foods that are either directly genetically engineered or that contain genetically engineered ingredients ("GE foods") label their products as such. In general, federal law, in the form of the Food, Drug, and Cosmetic Act, lodges primary authority for approving and regulating the labeling of GE foods in the Food and Drug Administration (FDA), but the FDA has been reluctant to mandate labeling of GE foods. In light of this federal regulatory void, states have proposed their own GE food labeling requirements, generating protests from manufacturers and federalism challenges in the form of federal preemption claims.

In July 2016, Congress settled this federalism conflict, mandating that the Secretary of Agriculture promulgate federal regulations to govern GE food labeling and preempting state labeling requirements. This article explores the history of GE food labeling federalism in the United States, concluding that the 2016 statute leaves the relationship between state and federal authority fairly clear but creates new ambiguities regarding the relationship of the FDA and FDCA to the U.S. Department of Agriculture and the new law.

I. INTRODUCTION

Genetically-engineered (GE) plants and, recently, animals are increasingly common components of the human food supply in the United States,[1] resulting in what this article will refer to as "GE foods"—that is, human foods either that are directly genetically engineering

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[1] Dean D. Metcalfe, *et al.*, *Assessment of the allergenic potential of foods derived from genetically engineered crop plants*, 36 CRITICAL REVIEWS OF FOOD SCI. & NUTRITION 165, 165 (1996).

themselves or that contain genetically-engineered ingredients. As reported in 2016, "75 percent to 80 percent of foods [in the U.S.] contain genetically modified ingredients—most of those corn and soy-based. The Food and Drug Administration [FDA] says they are safe to eat."[2]

Despite this federal agency declaration of safety, and especially because genetic modification of foods is often effectively "hidden" in "popular processed food ingredients such as cornstarch, soybean oil or high-fructose corn syrup,"[3] consumers in the United States have increasingly demanded that GE food be labeled as such. Some people object to the whole idea of humans producing genetically modified organisms (GMOs) or worry about the potential environmental impacts of GE crops and other organisms.[4] Others just want to know what they are eating,[5] either to avoid potential allergens,[6] to avoid violating religious or medical food restrictions,[7] to adhere to dietary lifestyle choices such as veganism,[8] or, most generally, simply to leave food consumption choices to consumers, not to agribusiness and commercial food mega-

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[2] Associated Press, "Congress Passes GMO Food Labeling Bill," *NBC News*, http://www.nbcnews.com/health/health-news/congress-passes-gmo-food-labeling-bill-n609571 (July 14, 2016). "Only a handful of genetically engineered fruits and vegetables are available in the produce aisle, including Hawaiian papaya, some zucchini and squash and some sweet corn." *Id*.

[3] *Id*.

[4] "While some critics object to the use of this technology based on religious or philosophical bases, most critics object on the basis of environmental or health concerns. For instance, a 1999 publication showed *Bt* toxin had negative effects on butterfly populations in laboratory tests, leading to strong objections of *Bt* use, but follow-up studies in actual farming fields confirmed the safety of this technology." Gabriel Rangel, "From Corgis to Corn: A Brief Look at the Long History of GMO Technology," *Harvard University Science in the News*, http://sitn.hms.harvard.edu/flash/2015/from-corgis-to-corn-a-brief-look-at-the-long-history-of-gmo-technology/ (Aug. 9, 2015) (citations omitted).

[5] *E.g.*, LabelGMOs.org, *What Are We Eating?*, http://www.labelgmos.org/the_science_genetically_modified_foods_gmo (as viewed Jan. 13, 2017).

[6] *See generally* Metcalfe, *et al*., *supra* note 1, at 165-86 (assessing the allergenic potential of GE crops). The Union of Concerned Scientists acknowledges allergenic response as a real risk in GE foods, noting that "[t]his phenomenon was documented in 1996, as soybeans with a Brazil nut gene—added to improve their value as animal feed—produced an allergic response in test subjects with Brazil nut allergies." Union of Concerned Scientists, *Genetic Engineering Risks and Impacts*, http://www.ucsusa.org/food_and_agriculture/our-failing-food-system/genetic-engineering/risks-of-genetic-engineering.html#.WHkdgGPcyJU (as viewed Jan. 13, 2017).

[7] *E.g.*, CONRAD G. BRUNK & HAROLD COWARD, EDS., ACCEPTABLE GENES: RELIGIOUS TRADITIONS AND GENETICALLY MODIFIED FOODS (SUNY Press 2009).

[8] Claude Morton, "GMO Foods Are Not Vegan," *AND Magazine*, http://andmagazine.com/us/1366815775.html (as viewed Jan. 13, 2017).

industries.[9] In addition, because GE foods implicate food access and quality concerns as well as religious freedoms, the GE food labeling issue is relevant to human rights discussions, as well.[10]

From all of these overlapping camps, there has been in the United States an increasing consumer demand for food labeling to include information about GMO content. As Gabriel Rangel summarizes, since the 1990s,

> public awareness of the existence of GE foods increased, and calls for regulation of GE food grew louder, resulting in labeling requirements for GE food in many countries. Today, 64 countries have mandatory labeling laws for GE food. However, the United States still does not have a mandatory, nationwide labeling law, although many advocacy groups are lobbying to enact one. These groups argue that labeling GE food is important for consumer choice and for monitoring unforeseen problems associated with the technology. In contrast, groups opposing labels claim a law would unnecessarily eliminate consumer demand for current GE crops, causing steep increases in food price and resource utilization.[11]

Moreover, despite the United States' lack (until recently) of mandatory GE food labeling laws, the consumer demand for increased information about GE foods has had market effects. Thus, "[i]n 2013, Chipotle became the first restaurant chain to label menu items as 'GMO,' and in April of [2015], the company announced the elimination of all ingredients made with GMOs, citing their 'food with integrity journey'."[12]

However, a more basic legal question also arose in the GE food labeling debate: Who, exactly, should be in charge of GE food labeling? Traditionally, most food labeling requirements have come from the federal Food and Drug Administration (FDA) pursuant to the Food, Drug, and Cosmetic Act (FDCA),[13] as amended, and the FDA has taken the lead in approving GE foods for marketing.[14] However, the FDA has also eschewed mandatory labeling requirements

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[9] GMO Compass, *Labeling of GMO Products: Freedom of Choice for Consumers*, http://www.gmo-compass.org/eng/regulation/labelling/ (as viewed Jan. 13, 2017).

[10] Leslie Francis, Robin Kundis Craig, and Erika George, *Genetically Modified Foods: An Alternative Look at the Purpose for Product Labeling*. 71:1 FOOD & DRUG LAW JOURNAL 105, 129-33 (2016).

[11] Rangel, *supra* note 4 (citations omitted).

[12] *Id.*

[13] 21 U.S.C. §§ 321-399d (2012). The Act's food provisions are in Subchapter IV, 21 U.S.C. §§ 341-350l-1 (2012).

[14] *See infra* Part II.A.

for GE foods, concluding that their GE content is not a material enough fact to require labeling.[15] Nevertheless, in November 2015, it promulgated new guidelines for *voluntary* labeling of GE foods, including both the more common plant-based GE foods and the recently approved GE Atlantic salmon.[16]

In light of this rather light-handed federal approach to GE food labeling, some states—especially Vermont—began to enact their own GE food labeling requirements.[17] GE food producers protested in response that they faced the prospect of a 50-state patchwork of labeling requirements, a potentially costly food distribution nightmare.[18] They and various biotech companies spent about $100 million in 2015 alone to fight GE food labeling requirements.[19]

Thus, state GE food labeling laws presented a classic federalism conundrum: The federal government refused to act in ways that at least some citizens desired in a situation where national uniformity in the law, given the realities of pervasive interstate commerce in GE foods, is arguably most efficient for all concerned. Moreover, state intervention into the GE food labeling arena prompted classic federalism litigation in favor of federal supremacy—namely, claims of federal preemption.[20]

However, and particularly in response to Vermont's 2014 GE food labeling law, food companies also began to capitulate to individual states' laws. As *The New York Times* reported, "Campbell Soup was the first to break ranks, announcing in January [2016] that it would put G.M.O. labels on all its products nationally. General Mills, ConAgra and others quickly followed suit, and now many food packages contain tiny print affirming the presence of genetically engineered ingredients."[21]

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[15] *See infra* Part II.B and II.C.
[16] *See id.*
[17] *See infra* Part III.A.
[18] Stephanie Strom, "G.M.O. Labeling Bill Clears First Hurdle in Senate," *The New York Times*, https://www.nytimes.com/2016/07/07/business/gmo-labeling-bill-passes-first-hurdle-in-senate.html?_r=0 (July 6, 2016).
[19] *Id.*
[20] *See infra* Part III.B.
[21] Strom, *supra* note 18.

After federal preemption claims failed in the courts, Congress in late July 2016 expressly preempted state GE food labeling laws.[22] Congress also expressly ordered the *Secretary of Agriculture* to promulgate regulations to govern GE food labeling, leaving the FDA's residual authority regarding GE food labeling in some doubt.

This article explores the federalism battle over GE food labeling and Congress's resolution of it—although the exact contours of that resolution will depend on the regulations that the Secretary of Agriculture decides to issue by July 29, 2018. It begins in Part I with a brief history of the genetic modification of organisms and their current presence in human foods. Part II then surveys the FDA's authority over food labeling under the FDCA and its pre-2016 application of that authority to GE foods. Part III provides an overview of the multi-year drama among states, the courts, and Congress regarding the viability of state GE food labeling requirements, culminating in a comprehensive federal court decision upholding Vermont's GE food labeling law and Congress's July 2016 preemptive legislation. As noted, what Congress's preemption of state GE food labeling laws actually means will not be completely clear until the Secretary of Agriculture issues its new regulations. In the meantime, however, the new legislation has created other legal issues regarding the continued viability of state consumer protection laws when applied to GE foods and the FDA's continuing role in GE food regulation, which this article explores in Part IV. This article concludes that the FDA retains its role as the primary *regulator* of GE foods seeking entry into consumer markets. However, the exact contours of the FDA's and the states' continuing abilities to influence GE food labeling through, respectively, the FDCA's misbranding requirements and state consumer protection laws require further interpretation and development.

II. A BRIEF HISTORY OF GE FOODS

Humans have been genetically modifying their foods through plant and animal breeding for over 30,000 years.[23] Artificial selection in animal breeding occurred first in human history;

[22] *See infra* Part III.C.

[23] Rangel, *supra* note 4 (citation omitted).

scientists and historians believe that the dog was the first animal that humans manipulated genetically through artificial selection, starting about 32,000 years ago.[24] Controlled plant breeding, in turn, emerged around 7800 BCE.[25] These "basic" techniques wrought significant changes in the species to which humans devoted their attention, from dogs to wheat and corn to bananas; indeed, few consumers today would even recognize the wild analogs of contemporary foods for what they are.[26]

However, traditional plant and animal breeding has generally been limited by the gene variations naturally occurring in the species being bred.[27] Genetic engineering, in contrast, allows scientists both to amplify existing gene expression in particular species (for example, speeding growth or making strawberries more sweet) and to import genes from completely foreign species.[28]

Genetic engineering most commonly relies on recombinant DNA technology, in which researchers use enzymes and other mechanisms to cut a gene out of the DNA of one organism and splice it into the DNA of another organism.[29] Working with bacteria, Stanley Cohen and Herbert Boyer first successfully used this technique in 1973 to transfer antibiotic resistance from one strain of bacteria to another.[30] "One year later, Rudolf Jaenisch and Beatrice Mintz utilized a similar procedure in animals, introducing foreign DNA into mouse embryos."[31]

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[24] *Id*. (citation omitted).

[25] *Id*. (citation omitted).

[26] *Id*. (citation omitted).

[27] While this statement is generally true, gene mix-ups in plant foods can occur naturally as a result of bacterial transfers and as a result of radiation-induced mutagenesis as well as genetic engineering. Thus, the line between traditional plant breeding and genetic engineering can be rather thin. Genetic Literacy Project, *GMO FAQ: How does genetic engineering differ from conventional plant breeding*, http://gmo.geneticliteracyproject.org/FAQ/how-does-genetic-engineering-differ-from-conventional-breeding/ (as viewed Jan. 13, 2017).

[28] *See generally* Matthew Niederhuber, "Insecticidal Plants: The Tech and Safety of GM Bt Crops," *Harvard University Science in the News*, http://sitn.hms.harvard.edu/flash/2015/insecticidal-plants/ (Aug. 10, 2015) (describing the use of *Bacillus thuringiensis* (*Bt*) genes in corn and other crops).

[29] Anthony J.F. Griffiths, "Recombinant DNA Technology," *Encyclopaedia Britannica*, https://www.britannica.com/science/recombinant-DNA-technology (as updated Aug. 28, 2009).

[30] Rangel, *supra* note 4 (citation omitted).

[31] *Id*. (citation omitted).

Since then, genetic engineering "has been applied to microorganisms, plants, and animals."[32] In 1980, the U.S. Supreme Court in *Diamond v. Chakrabarty* allowed researchers to patent their living GE products[33]—in that case, a bacterium genetically engineered to consume petroleum after an oil spill.[34] Patented products of genetic engineering are also important in the pharmaceutical industry, and in 1982, the FDA approved Humulin, the first pharmaceutical manufactured using genetic engineering.[35] Humulin is human insulin produced in genetically-engineered bacteria.[36] In 2009, the FDA approved Atryn, the first time that it had approved a drug produced in a genetically-engineered animal.[37] Atryn treats a rare blood-clotting disorder.[38]

With respect to foods, food *plants* have been an early and repeated focus of genetic engineering. In the United States, the U.S. Department of Agriculture (USDA), through its Animal and Plant Health Inspection Service (APHIS), approves most GE crops for growing in fields[39] pursuant to the Plant Protection Act,[40] although the FDA approves these crops' use as human food.[41] Field trials of GE crops began in 1987 under the USDA's supervision.[42] However,

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[32] U.S. Food & Drug Administration, *Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs* 3, http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm113903.pdf (as updated June 2010) [hereinafter 2010 FDA ANIMAL GUIDANCE].

[33] 447 U.S. 303, 309-10 (1980).

[34] *Id*. at 305.

[35] Rangel, *supra* note 4 (citation omitted).

[36] *Id*. (citation omitted).

[37] *Id*. (citation omitted).

[38] *Id*. (citation omitted).

[39] Animal & Plant Health Inspection Service, U.S. Department of Agriculture, *How the Federal Government Regulates Biotech Plants*, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_regulations/ct_agency_framework_roles (as updated Feb. 1, 2016). APHIS has also compiled a more comprehensive list of the federal statutes and regulations governing GE plants at https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_regulations/ct_biotech_laws_and_regs_framework (as updated Jan. 26, 2016).

[40] 7 U.S.C. §§ 7701-7786.

[41] Animal & Plant Health Inspection Service, U.S. Department of Agriculture, *How the Federal Government Regulates Biotech Plants*, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_regulations/ct_agency_framework_roles (as updated Feb. 1, 2016). *See also* discussion *infra* Part II.B. and sources cited therein.

[42] Rangel, *supra* note 4 (citation omitted). For a complete history of the USDA's approvals of GE crops, see the studies available through Economic Research Service, U.S. Department of Agriculture, *Adoption of Genetically*

the exact focus of these engineering efforts varies, a fact that is relevant to the labeling debate because the resulting changes in food plants vary considerably. In broad strokes, there are three general categories of GE food plants: crops genetically engineered to improve the qualities of the food itself, in terms of taste, nutritional value, or marketability; crops genetically engineered to produce their own pesticides; and crops genetically engineered to withstand herbicide application.

Food improvements constitute some of the first efforts in GE plant food production. For example, the U.S. Department of Agriculture (USDA) approved the first genetically-engineered crop, Calgene's FLAVR SAVR™ tomato, in 1992.[43] "These tomatoes were modified to include a DNA sequence that inhibited production of a natural tomato protein, increasing the firmness and extending the shelf life of the Flavr Savr variety."[44] However, while consumers in the United States were willing to pay two to five times the normal price for these (unlabeled) GE tomatoes, their United Kingdom counterparts began objecting two years later when (labeled) GE tomato paste was sold there.[45] Genetic engineering to improve food quality arguably culminated in 2000 with the development of "golden rice," which was genetically engineered to address Vitamin A deficiencies in many developing nations—deficiencies that can kill up to 500,000 people per year.[46]

Most efforts to genetically engineer crops to produce their own pesticides involve transplanting genes from a common bacterium, *Bacillus thuringiensis* (*Bt*).[47] *Bt* naturally produces a fairly effective toxin that has been used for crop protection since 1928, even without genetic engineering; genetic engineering allows the crops themselves to manufacture the toxic *Bt*

Engineered Crops in the U.S., https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/ (as updated Oct. 19, 2016).

[43] Rangel, *supra* note 4 (citation omitted).

[44] *Id*. (citation omitted).

[45] Ian Murnaghan, "Development and History of GM Foods," *Genetically Modified Foods*, http://www.geneticallymodifiedfoods.co.uk/development-history-gm-foods.html (updated Aug. 17, 2016).

[46] Rangel, *supra* note 4 (citation omitted).

[47] Niederhuber, *supra* note 28 (citation omitted).

crystalline proteins.[48] As a result, "[s]o called Bt crops are highly effective at combating pests such as European corn borer, rootworm, corn earworm, tobacco budworm, and bollworm."[49] The U.S. Environmental Protection Agency (EPA) approved the first insecticide-producing plant crop in 1995[50] pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the federal statute that governs licensing of pesticides.[51] The EPA approved *Bt* corn in 1996, and now the majority of corn grown in the United States has been genetically engineered to include the *Bt* toxin-producing gene.[52] Most studies indicate that use of these *Bt* GE crops reduces pesticide use,[53] but long-term safety for humans has not been evaluated.[54]

Herbicide-resistant crops began appearing in 1996,[55] and the most famous set of these crops are Monsanto's RoundUp Ready™ varieties, which are genetically engineered to be resistant to the herbicide glyphosate, the main ingredient in Monsanto's RoundUp™.[56] Monsanto introduced Roundup Ready™ soybeans in 1996, and this technology has now been applied to many other crops, including corn, maize, canola, and sugar beets.[57] Proper use of Roundup

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[48] *Id*.

[49] *Id*. (citations omitted).

[50] Rangel, *supra* note 4 (citation omitted).

[51] 7 U.S.C. §§ 136-136y.

[52] Rangel, *supra* note 4 (citation omitted). Specifically, "[p]lantings of *Bt* corn grew from about 8 percent of U.S. corn acreage in 1997 to 19 percent in 2000 and 2001, before climbing to 29 percent in 2003 and 79 percent in 2016. The increases in acreage share in recent years may be largely due to the commercial introduction of new *Bt* corn varieties resistant to the corn rootworm and the corn earworm, in addition to the European corn borer, which was previously the only pest targeted by *Bt* corn." Economic Research Service, U.S. Department of Agriculture, *Recent Trends in GE Adoption*, https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption/ (as updated Nov. 3, 2016).

[53] Niederhuber, *supra* note 28 (citations omitted).

[54] Union of Concerned Scientists, *supra* note 6.

[55] Rangel, *supra* note 4 (citation omitted).

[56] *Id*. (citation omitted). "Glyphosate works by preventing plants from being able to make the proteins they need to survive. Since virtually all plants make these essential proteins the same way, glyphosate affects nearly all plants." Jordan Wilkerson, "Why Roundup Ready Crops Have Lost Their Allure," *Harvard University Science in the News*, http://sitn.hms.harvard.edu/flash/2015/roundup-ready-crops/ (Aug. 10, 2015) (citation omitted).

[57] Rangel, *supra* note 4 (citation omitted). According to the USDA, "Based on USDA survey data, HT soybeans went from 17 percent of U.S. soybean acreage in 1997 to 68 percent in 2001 and 94 percent in 2014, 2015, and 2016. Plantings of HT cotton expanded from about 10 percent of U.S. acreage in 1997 to 56 percent in 2001, 91 percent in 2014, but declined to 89 percent in 2015 and 2016. The adoption of HT corn, which had been slower in previous years, has accelerated, reaching 89 percent of U.S. corn acreage in 2014, 2015, and 2016." Economic Research Service, U.S. Department of Agriculture, *Recent Trends in GE Adoption*, https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption/ (as updated Nov. 3, 2016).

Ready™ crops can reduce the use of more toxic pesticides, soil loss from tilling, and the environmental toxicity of agricultural runoff.[58] However, extensive commercial use of Roundup Ready™ crops, and hence the Roundup™ herbicide, has led to evolution of so-called "superweeds" that are resistant to glyphosate. "Twenty-four cases of glyphosate-resistant weeds have been reported around the world, 14 of which are in the United States."[59] As a result, the USDA now estimates that Roundup Ready™ crops may actually be increasing herbicide use in the United States,[60] and the Union of Concerned Scientists notes that:

> the most damaging impact of GE in agriculture so far is the phenomenon of pesticide resistance. Millions of acres of U.S. farmland are now infested by weeds that have become resistant to the herbicide glyphosate. Overuse of Monsanto's "Roundup Ready" trait, which is engineered to tolerate the herbicide, has promoted the accelerated development of resistance in several weed species.[61]

Animal-based GE *foods* are, so far, a much more limited category of GE foods. Researchers have been successfully engineering animals since the 1980s, beginning with mice, rabbits, and pigs,[62] and patented transgenic animals (i.e., animals that contain the genes of two or more species) now include chickens, cows, dogs, monkeys, and sheep, as well.[63] For the most part, however, animals have not been genetically engineered for *food*. Instead, like the famous "Harvard mouse"—genetically engineered to acquire cancer—most of these genetically engineered animals have been developed for medical research purposes[64] or, as noted, to produce

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[58] Wilkerson, *supra* note 56 (citations omitted).
[59] *Id*. (citation omitted).
[60] *Id*. (citation omitted).
[61] Union of Concerned Scientists, *supra* note 6.
[62] 2010 FDA ANIMAL GUIDANCE, *supra* note 32, at 3.
[63] Douglas Robinson & Nina Medlock, Diamond v. Chakrabarty*: A Retrospective on 25 Years of Biotech Patents*, 17 INTELLECTUAL PROP. & TECH. L.J. 12, 13 (Oct. 2005), *available at* https://bannerwitcoff.com/media/_docs/library/articles/Chakrabarty.pdf.
[64] *Id*.

pharmaceuticals. A particularly intriguing subset of research animals have been genetically modified to glow in the dark.[65]

The absence of animal-based GE food changed in late 2015, when AquaBounty Technologies, Inc., completed the FDA approval process for its AquAdvantage™ salmon.[66] AquaBounty genetically engineered Atlantic salmon to grow faster:

> GE salmon were developed by injecting rDNA composed of a promoter from another fish, an ocean pout, and a growth hormone gene from a Pacific Chinook salmon into fertilized eggs of Atlantic salmon. Subsequent selection and breeding led to the development of the AquAdvantage Salmon line, which produces growth hormone throughout the year. The year-round production of growth hormone allows for continuous feeding and growth of AquAdvantage Salmon. Growth hormone production of non-GE Atlantic salmon decreases during the winter months, and Atlantic salmon stop feeding and growing during this period.[67]

As is discussed more fully in Part II, the FDA approved this food for marketing in the United States in November 2015. In an interesting move, however, Congress used the budget process in January 2016 to block importation and sale of this GE fish until the FDA came up with labeling guidelines for it.[68]

As the salmon controversy suggests, the FDA's role in GE food approvals is an important component of the federalism debate over GE food labeling. This article therefore turns to the FDA's authorities and its past pronouncements regarding GE food labeling.

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[65] Lauren Hansen, "7 genetically modified animals that glow in the dark," *The Week*, http://theweek.com/articles/464980/7-genetically-modified-animals-that-glow-dark (April 30, 2013).

[66] Harold F. Upton & Tadlock Cowan, Congressional Research Service, *Genetically Engineered Salmon* 10-11 (Dec. 8, 2015), *available at* http://nationalaglawcenter.org/wp-content/uploads/assets/crs/R43518.pdf.

[67] *Id*. at 11.

[68] Brady Dennis, "FDA bans imports of genetically engineered salmon—for now," *The Washington Post*, https://www.washingtonpost.com/news/to-your-health/wp/2016/01/29/fda-bans-imports-of-genetically-engineered-salmon-for-now/?utm_term=.b9c2901f2262 (Jan. 29, 2016).

III. THE FDA'S AUTHORITY OVER GE FOODS

A variety of federal statutes govern the labeling of human foods, generally splitting federal food labeling authority between the USDA and the FDA.[69] These two agencies have generally shared this authority amicably and with relatively little conflict. Indeed, in 2007, the USDA described its primary food labeling responsibilities as applying to meat, poultry, and eggs, while in general the FDA had labeling authority for all other foods[70]—including GE foods.

The FDA's food labeling authority derives from the FDCA. While the agency and the FDCA are probably best known for their regulation of medicinal drugs, the FDCA, as its title suggests, covers a wide variety of subjects—human drugs, medical devices, animal drugs, cosmetics, food additives, supplements and vitamins, and, of course, food. This Part provides an overview of the FDA's authorities regarding food approval and labeling, including how the FDA has exercised those authorities with respect to GE food.

A. The Basics of Food Regulation under the FDCA

With respect to foods, the FDCA gives the FDA responsibility to "protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled."[71] The FDA has broad authority under this Act to impose any labeling requirements that the agency deems necessary "to promote honesty and fair dealing in the interest of consumers . . . ."[72]

The FDCA defines "food" to be "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[73] As is

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[69] Besides the FDCA and its amendments (FDA), these statutes include, *inter alia*: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y (EPA); the Federal Meat Inspection Act (FMIA), 21 U.S.C. §§ 601-683 (USDA); the Poultry Products Inspection Act (PPIA), 21 U.S.C. §§ 451-472 (USDA); and the Organic Foods Production Act, 7 U.S.C. §§ 6501-6524 (USDA).

[70] FOOD SAFETY & INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS 8-9 (Aug. 2007), *available at* https://www.fsis.usda.gov/shared/PDF/Labeling_Requirements_Guide.pdf.

[71] 21 U.S.C. § 393(b)(2).

[72] *Id.* § 341.

[73] *Id.* § 321(f). A "label," in turn, is:

> a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word,

typical under the FDCA,[74] the Act's food provisions focus on preventing foods from being adulterated[75] or misbranded.[76] A food is adulterated if it contains poisonous or unsanitary ingredients or if valuable constituents have been removed or substituted,[77] and the FDA may recall any food item if there is a "reasonable probability" that it is adulterated.[78]

More relevant to this article, foods are "misbranded" if labels either contain affirmatively misleading representations or fail to reveal "material" information.[79] Thus, while the prohibitions on food adulteration protect the basic safety of human foods, the misbranding prohibitions focus on the accuracy of and consumer necessity for food labeling.

A key question of statutory interpretation with respect to GE food labeling under the FDCA is whether genetic engineering is a "material" fact for purposes of misbranding liability.[80] The Act does not define "material," but the FDA has identified a number of situations in which food alteration may be "material" for purposes of triggering labeling requirements:

> Historically, the agency has interpreted the term ["material"], within the context of food, to mean information about the attributes of the food itself. For example, FDA has required special labeling in cases where the absence of such "material" information may: (1) pose special health risks . . .; (2) mislead the consumer in light of other statements made on the labeling . . .; or (3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic (e.g., taste, smell, or texture), or functional characteristics of the food it resembles when in fact it does not . . . . Further, section 403(i) of the FD&C Act and FDA regulations require that each food bear a common or

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> statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

Id. § 321(k).

[74] *See id.* § 331(a)-(c) (establishing adulteration and misbranding as generally prohibited acts).

[75] *Id.* § 342.

[76] *Id.* § 343.

[77] *Id.* § 342(a)-(i).

[78] *Id.* § 350l(a).

[79] *Id.* § 321(n).

[80] For a more detailed discussion of the FDA's food labeling authority under the FDCA and its potential applicability to GMO foods, see generally Francis, Craig, & George, *supra* note 10, at 105-134.

> usual name or, in the absence of such a name, an appropriately descriptive term . . . .[81]

Nevertheless, the FDA has so far resolved this "materiality" question in the negative for both plant- and animal-based GE foods, as is discussed in more detail below.

B. The FDA's Treatment of Plant-Based GE Foods

The FDA has always regulated plant-based GE foods pursuant to the FDCA's food provisions. Because genetic engineering generally adds traits or properties to plant foods, the perhaps most logical subgroup of these food provisions for the FDA to use would have been the food additive requirements.[82]

According to the 1958 Food Additive Amendments[83] to the FDCA, a food additive is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food . . . ."[84] The FDCA as amended requires the FDA to determine that additives are safe before they can be marketed.[85] Potential marketers may petition the FDA for pre-market approval of new additives, and they must present all relevant safety data regarding the additive's intended use to the FDA.[86] An interdisciplinary team with in the FDA reviews this information, and if it determines that the

[81] U.S. Food & Drug Administration, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm (Nov. 2015).

[82] For a more complete description of the food additive approval process and GRAS evaluations, see Francis, Craig, & George, *supra* note 10, at 108-17.

[83] PUB. L. NO. 85-929, 72 Stat. 1784 (1958).

[84] 21 U.S.C. § 321(2)(s).

[85] *Id*. § 348.

[86] 21 C.F.R. § 171.1 (2016).

product is safe based on a "fair evaluation" of the data, it will grant marketing approval,[87] subject to public scrutiny through a notice-and-comment rulemaking process.[88]

Of course, many food additives, like salt, have been used for millennia. In the Food Additives Amendments, Congress allowed a food additive to be marketed without the extensive approval process if the additive was already in common use or if experts generally recognize the additive to be safe—the GRAS exception.[89] Additives can qualify as GRAS if their safety is generally recognized in the expert community or if they were in common use before 1958.[90]

After Congress enacted the Nutrition Labeling and Education Act (NLEA) in 1990,[91] people began asking the FDA how it would address GE foods. This would have been the opportune moment for the FDA to invoke the food additive approval and GRAS processes for GE foods. In addition, treating GE foods as food additives would have settled the labeling question, because Congress requires food additives to be labeled.[92]

Instead, however, in 1992 the FDA published its "Statement of Policy: Foods Derived from New Plant Varieties,"[93] focusing its attention on the "materiality" of genetic engineering for purposes of the FDCA's food labeling and misbranding requirements. In this policy, the FDA concluded that it "is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way" and that it does not consider GE foods to pose any greater risks to consumers than foods derived from traditional breeding methods.[94] As a result, the FDA determined that the fact that a plant-based food contains GMOs is not "material information within the meaning of 21 U.S.C. 321(n) and would not usually be

[87] 21 U.S.C. § 348(c)(3).
[88] For a complete description of the process, see Thomas G. Neltner et al., *Navigating the U.S. Food Additive Regulatory Program*, 10:6 COMPREHENSIVE REVIEWS IN FOOD SCIENCE AND FOOD SAFETY 342-368 (October 25, 2011), http://onlinelibrary.wiley.com/doi/10.1111/j.1541-4337.2011.00166.x/pdf.
[89] 21 C.F.R. § 170.3. (2016).
[90] *Id*.
[91] PUB. L. NO. 101-535, 104 Stat. 2353 (1990).
[92] 21 U.S.C. § 343(k).
[93] U.S. Food & Drug Administration, Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992).
[94] *Id*. at 22,991.

required to be disclosed in labeling for the food."[95] The FDA thus presumes that plant-based GE foods do not need to be labeled as such, and the U.S. District Court for the District of Columbia upheld this determination in 2000.[96]

Nevertheless, in its 1992 policy statement, the FDA did not determine, precisely, that GE foods are GRAS. Instead, in 1996, it introduced a new voluntary consultation process for GE foods that parallels the GRAS determination process.[97] Under this process, the FDA has completed more than 150 consultations regarding plant-based GE foods,[98] including pineapples, potatoes, corn, soybeans, apples, canola, plums, papaya, sugar beets, rice, cantaloupe, tomatoes, radicchio, and squash, which collectively have been genetically engineered for pest resistance, virus resistance, herbicide tolerance, increased fertility, altered ripening, altered color, increased protein content, or decreased polyunsaturated fat, among other things.[99]

In November 2015, the FDA took a more nuanced approach to plant-based GE food labeling, issuing new guidance to manufacturers regarding voluntary labeling of plant-based GE foods.[100] Notably, while the FDA continued to maintain that the mere fact of genetic engineering was not enough to require food labeling, it did acknowledge that particular genetic engineering projects may in fact create food properties that are sufficiently novel or different from consumer expectations as to constitute "material" information that must be included in a food label. As the FDA explained:

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[95] *Id*.

[96] Alliance for BioIntegrity v. Shalala, 116 F. Supp. 2d 166, 178-79 (D.D.C. 2000).

[97] FDA Office of Premarket Approval, *Guidance on Consultation Procedures Foods Derived from New Plant Varieties*, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096126.htm (as revised Oct. 1997) (last visited Jan. 15, 2017).

[98] U.S. Food & Drug Administration, *How FDA Regulates Foods from Genetically Engineered Plants*, http://www.fda.gov/Food/IngredientsPackagingLabeling/GEPlants/ucm461831.htm (as updated Sept. 16, 2016).

[99] U.S. Food & Drug Administration, *Biotechnology Consultations on Food from GE Plant Varieties*, http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=Biocon&sort=FDA_Letter_Dt&order=DESC&startrow=1&type=basic&search= (as updated Dec. 14, 2016, and viewed Jan. 15, 2017).

[100] U.S. Food & Drug Administration, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm (Nov. 2015).

> For example, if oil from a genetically engineered canola plant has a significantly different amount of lauric acid such that the fatty acid composition of the oil is significantly changed compared to traditional canola oil, the term 'canola oil' no longer adequately identifies or describes the nature of the oil or its characterizing properties, particularly since oils are distinguished by their fatty acid profiles.[101]

Thus, the FDA set the stage for food-by-food assessments of GE foods' FDCA materiality and, potentially, tailored GE food labeling requirements to avoid misbranding liability.

Moreover, the FDA also used this guidance to make clear that voluntary GE food labeling "is acceptable to FDA, provided that such labeling is truthful and not misleading. Some consumers are interested in the information provided in such labeling."[102] As a result, under this new guidance:

> Food manufacturers may voluntarily label their foods with information about whether the foods were not produced using bioengineering, as long as such information is truthful and not misleading. In general, an accurate statement about whether a food was not produced using bioengineering is one that provides information in a context that clearly refers to bioengineering technology. Examples of such statements include:
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> - "Not bioengineered."
> - "Not genetically engineered."
> - "Not genetically modified through the use of modern biotechnology."
> - "We do not use ingredients that were produced using modern biotechnology."
> - "This oil is made from soybeans that were not genetically engineered."
> - "Our corn growers do not plant bioengineered seeds."[103]

While the FDA generally counseled against using the term "GMO," it also assured manufacturers that it would not take enforcement actions based on the use of that term, so "long as the food is, in fact, not derived from a genetically engineered plant and the food's labeling is not otherwise false or misleading, as further discussed in this guidance."[104] Finally, before manufacturers voluntarily labeled their foods as bioengineered or not bioengineered, the FDA

[101] *Id.* Part II.
[102] *Id.*
[103] *Id.* Part III.B.
[104] *Id.*

recommended that they substantiate those claims through documentation (say, regarding the use of organic foods) and testing.[105]

D. The New GE Food in the Market: Animal-Based GE Food

Until late November 2015, the FDA's interest in GE foods concentrated almost entirely on plants. However, in that month, it approved the first animal-based GE food, AquaBounty's genetically-modified Atlantic salmon, for human consumption.[106]

In contrast to plant-based GE foods, which the FDA regulates through the FDCA's food provisions, in 2009 the FDA determined that it would regulate food from GE animals through the FDCA's animal drug provisions, requiring a New Animal Drug Application and approval before those foods could be marketed.[107]

Under the FDCA, drugs for humans and animals are defined together and include:

> (A) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease *in man or other animals*; and (C) articles (other than food) intended to affect the structure or any function of the body of *man or other animals*; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).[108]

In general, moreover, animal drugs must meet the same safety and efficacy requirements as human drugs,[109] imposing a relatively high burden of proof on manufacturers before they can be marketed.

The FDA determined that GE animals meet the FDCA's definition of "animal drug." Specifically,

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[105] *Id.* Part III.D.

[106] Andrew Pollack, "Genetically Engineered Salmon Approved for Human Consumption," *The New York Times*, Nov. 19, 2015, http://www.nytimes.com/2015/11/20/business/genetically-engineered-salmon-approved-for-consumption.html?_r=0.

[107] 2010 FDA ANIMAL GUIDANCE, *supra* note 32, at 4-7.

[108] 21 U.S.C. § 321(1)(g)(1) (emphasis added).

[109] *Id.* § 360b.

> The rDNA construct in a GE animal that is intended to affect the structure or function of the body of the GE animal, regardless of the intended use of products that may be produced by the GE animal, meets the FFDCA drug definition. A non-heritable rDNA construct that is intended to affect the structure or function of a GE animal or to cure, mitigate, or treat a disease in the animal also meets the drug definition.[110]

For example, the approved genetically-engineered AquAdvantage Atlantic salmon reach market size faster than conventional salmon[111] and hence the genetic engineering affects the normal functioning of these fish. As a result, food from GE animals is subject to a much more stringent approval process than food from GE plants. For example, AquaBounty filed a New Animal Drug Application with the FDA in 2009, which is what the FDA formally approved in November 2015[112]—a six-year regulatory investment to bring this food to market in addition to the time AquaBounty spent engineering the fish in the first place.

With respect to *labeling* of the new GE salmon, however, the FDA concluded, as was true for genetically-modified plants, that:

> the composition, nutritional profile, and safety of food from AquAdvantage Salmon do not differ from food from non-GE, farm-raised Atlantic salmon in any material way, and thus it is as safe and nutritious as food from non-GE, farm-raised Atlantic salmon. For these reasons, we concluded that there is no basis to require additional labeling of food derived from AquAdvantage Salmon.[113]

Nevertheless, immediately after issuing its approval and its conclusion that genetically-engineered salmon sold as food do not have to be labeled as such, the FDA issued new draft guidance for voluntary labeling of salmon.[114] This draft guidance closely parallels that for

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[110] 2010 FDA ANIMAL GUIDANCE, *supra* note 32, at 6.

[111] *Id*. ("Significantly more of these Atlantic salmon grow to at least 100 grams within 2,700 Celsius degree-days than their comparators.").

[112] U.S. Food & Drug Administration, New Animal Drugs in Genetically Engineered Animals; opAFP-GHc2 Recombinant Deoxyribonucleic Acid Construct, 80 Fed. Reg. 73,104, 73,104 (Nov. 24, 2015).

[113] *Id*. at 73,194.

[114] U.S. Food & Drug Administration, Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon; Draft Guidance for Industry; Availability, 80 Fed. Reg. 73,193 (Nov. 24, 2015).

voluntary labeling of plant-based GE foods.[115] But for Congress's intervention in January 2016, therefore, consumers could have been buying AquAdvantage Salmon without knowing it.

Thus, by the end of 2015 the FDA had embraced voluntary food labeling with respect to the use (or not) of genetic engineering in a particular food's production. Moreover, it acknowledged that some genetic engineering of foods may produce "material" changes in food content that would require labeling under the FDCA. Nevertheless, the FDA had never mandated comprehensive labeling of GE foods. Given this lack of federal regulation, states began to impose their own food labeling requirements, generating an eventual congressional reaction, to which this article now turns.

IV. STATE ATTEMPTS TO REQUIRE GE FOOD LABELING, FEDERAL PREEMPTION BATTLES IN COURT, AND CONGRESS'S JULY 2016 RESPONSE

A. State Statutes Affecting GE Food Labeling

By early 2016, California, Connecticut, Florida, Maine, and Vermont had enacted statutes potentially relevant to the labeling of GE foods. California's Business and Professions Code[116] and Florida's Deceptive and Unfair Trade Practices Act[117] are the most oblique of these state-law requirements, but in 2014 the U.S. District Court for the Southern District of Florida concluded that both statutes supported claims against cereal and snack food manufacturers who labeled their products as "all-natural" despite actual or probable GMO content.[118]

A number of states have considered GE food labeling laws,[119] but only a handful have actually enacted them. Maine, like the FDA, embraced voluntary food labeling, and "[b]eginning

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[115] *See generally* U.S. Food & Drug Administration, *Draft Guidance for Industry: Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon*, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm469802.htm (Nov. 2015) (providing guidelines for labeling of both non-genetically-engineered and genetically-engineered Atlantic salmon).

[116] CAL. CODE CIVIL DIV. D. §§ 1750-1785.

[117] FLA. STAT. ANN. §§ 501.201-501.23.

[118] Garcia v. Kashi Co., 43 F. Supp. 3d 1359, 1383-87 (S.D. Fla. 2014).

[119] Such states include, for example: Colorado, *see generally* In re Title, Ballot Title and Submission Clause, and Summary for 1999-2000 No. 265, 3 P.3d 1210 (Colo. 2000) (*en banc*); Missouri, *see generally* State ex rel. Gateway Green Alliance v. Welch, 23 S.W.3d 861 (Mo. Ct. App. 2000); and Oregon, *see generally* Bates v. Rosenblum, 325 P.3d 725 (Or. 2014).

January 1, 2002, a label may be placed on any food, food product or food ingredient offered for sale in the State designating that food, food product or food ingredient as free of or made without recombinant deoxyribonucleic acid technology, genetic engineering or bioengineering."[120] However, the regulations implementing this program "must allow any food 1% or less of which consists of genetically engineered ingredients to be labeled as free of genetically engineered ingredients."[121] Maine further provided for verification of these labeling claims, and labeling claims that turned out to be false would subject the manufacturer to liability for misbranding.[122]

Connecticut enacted actual GE food labeling requirements, but those requirements would enter into force only if two pre-conditions were met:

> (1) Four states, not including this state, enact a mandatory labeling law for genetically-engineered foods that is consistent with the provisions of this subsection, provided one such state borders Connecticut; and (2) the aggregate population of such states located in the northeast region of the United States that have enacted a mandatory labeling law for genetically-engineered foods that is consistent with this subsection exceed twenty million based on 2010 census figures . . . .[123]

However, if the law ever entered into effect, both "(A) food intended for human consumption, and (B) seed or seed stock that is intended to produce food for human consumption, that is entirely or partially genetically-engineered," would have had to be labeled as being genetically engineered,[124] subject to some exceptions.[125]

The most comprehensive of the state GE food labeling laws was Vermont's.[126] Vermont cited four purposes for its labeling statute, emphasizing that its legislation was intended to:

> (1) Public health and food safety. Establish a system by which persons may make informed decisions regarding the potential health effects of the food they purchase and consume and by

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[120] 7 ME. REV. STAT. ANN. § 530-A(1).
[121] *Id.*
[122] *Id.* §§ 530-A(2), (3).
[123] CONN. GEN. STAT. ANN. § 21a-92c(a).
[124] *Id.*
[125] *Id.* § 21a-92c(b).
[126] VT. STAT. ANN. §§ 3041-3048.

> which, if they choose, persons may avoid potential health risks of food produced from genetic engineering.
>
> (2) Environmental impacts. Inform the purchasing decisions of consumers who are concerned about the potential environmental effects of the production of food from genetic engineering.
>
> (3) Consumer confusion and deception. Reduce and prevent consumer confusion and deception by prohibiting the labeling of products produced from genetic engineering as "natural" and by promoting the disclosure of factual information on food labels to allow consumers to make informed decisions.
>
> (4) Protecting religious practices. Provide consumers with data from which they may make informed decisions for religious reasons.[127]

The statute imposed labeling requirements any food offered for retail sale in Vermont that is "entirely or partially produced with genetic engineering."[128] Such foods had to be positively labeled to indicate their genetic engineering status,[129] but manufacturers also "shall not label the product on the package, in signage, or in advertising as 'natural,' 'naturally made,' 'naturally grown,' 'all natural,' or any words of similar import that would have a tendency to mislead a consumer."[130] However, the statute also created eight exemptions, including animal foods where the animal itself has not been genetically engineered (even though it may have been fed genetically-engineered plants) and "[a] raw agricultural commodity or processed food derived from it that has been grown, raised, or produced without the knowing or intentional use of food or seed produced with genetic engineering."[131] Finally, Vermont's statute also spelled out a series of sanctions and penalties for non-compliance.[132]

B. Federal Preemption Litigation Before 2016

[127] *Id.* § 3041.
[128] *Id.* § 3043(a)(2).
[129] *Id.* § 3043(b).
[130] *Id.* § 3043(c).
[131] *Id.* § 3044.
[132] *Id.* §§ 3048.

Under the basic federalism balance of the U.S. Constitution, states retain all authority not expressly assigned to the federal government.[133] Moreover, even in arenas where the federal government is empowered to act, such as interstate commerce,[134] the U.S. Supreme Court maintains a presumption that states and the federal government can regulate concurrently—that is, that the federal government's regulatory actions generally do not displace state regulation on the same subject.[135]

Nevertheless, under the U.S. Constitution's Supremacy Clause,[136] Congress can preempt state law if it so chooses. The U.S. Supreme Court recognizes three general types of federal preemption: express preemption, where Congress explicitly negates the ability of states to regulate in a certain area or with regard to certain subjects; implied preemption (or "field preemption"), where Congress's action in a particular area of law or on a particular subject implicitly displaces state authority to act in the same area; and conflict preemption, where a state law actually conflicts with the specific requirements of federal law.[137]

By definition, therefore, claims of federal preemption are assertions of the superiority of the federal government to dictate the contours and requirements of certain areas of law. Successful federal preemption claims tip the federalism balancing of regulatory authority decisively in favor of the federal government and eliminate the states' abilities to participate in certain areas of law.

Given the number of federal laws relevant to food and GE crop labeling in existence even before 2016,[138] federal preemption claims posed a serious legal threat to state GE food labeling laws like Vermont's. However, federal preemption claims in the context of state-law

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[133] U.S. CONST., amend. X.

[134] U.S. CONST., art. 1, § 8, cl. 3.

[135] Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005).

[136] U.S. CONST., art. VI, cl. 2.

[137] Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985).

[138] Besides the FDCA and its amendments, these statutes include, *inter alia*: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y; the Federal Meat Inspection Act (FMIA), 21 U.S.C. §§ 601-683; the Poultry Products Inspection Act (PPIA), 21 U.S.C. §§ 451-472; and the Organic Foods Production Act, 7 U.S.C. §§ 6501-6524.

requirements for GE food labeling almost universally failed, culminating in the decision of the U.S. District Court for the District of Vermont to uphold Vermont's labeling law against a variety of federal preemption (and other) challenges.

This section examines the major threads of GE food labeling preemption litigation that courts have decided, ending with the challenges to Vermont's GE food labeling statute and the Vermont District Court's decision to dismiss most challenges to that state law.

1. State-Law Liability for Bt Corn Co-Mingling and Preemption Claims under FIFRA

Some of the initial challenges to GE crops were state-law claims against pesticide producing *Bt* corn, which the EPA had approved pursuant to FIFRA,[139] the federal licensing statute that governs pesticides. When the EPA registers a pesticide for use under FIFRA, it also imposes labeling requirements, and FIFRA creates its own misbranding liability.[140] In addition, FIFRA expressly provides that states "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different those required under" FIFRA.[141] As a result, FIFRA preempts state laws, including tort claims, that could affect federally-mandated pesticide labeling requirements, especially state-law claims based on a failure to warn.[142]

The EPA's initial FIFRA registration for StarLink GE corn prohibited use of the corn for direct human consumption.[143] In 2002, the U.S. District Court for the Northern District of Illinois decided *In re StarLink Corn Products Liability Litigation*,[144] in which numerous plaintiffs "allege[d] that defendants Aventis CropScience USA Holdings, Inc. (Aventis) and Garst Seed Company (Garst) disseminated a product that contaminated the entire United States' corn supply,"[145] co-mingling StarLink GE corn with corn intended for human consumption. The

[139] 7 U.S.C. §§ 136-136y.
[140] *Id.* §§ 136(p), (q), 136a(c)(9), 136j(a)(2).
[141] *Id.* § 136v(b).
[142] In re StarLink Corn Products Liability Litigation, 212 F. Supp. 2d 828, 836 (N.D. Ill. 2002) (citations omitted).
[143] U.S. Environmental Protection Agency, *EPA's Regulation of* Bacillus thuringiensis *(*Bt*) Crops*, https://archive.epa.gov/pesticides/biopesticides/web/html/regofbtcrops.html (May 2002).
[144] 212 F. Supp. 2d 828 (N.D. Ill. 2002).
[145] *Id.* at 833.

plaintiffs asserted state common-law claims based on "negligence, strict liability, private nuisance, public nuisance and conversion,"[146] claims under the Tennessee Consumer Protection Act of 1997,[147] and claims under the North Carolina Unfair Trade Practices Act.[148] The issue was whether FIFRA's labeling requirements preempted any or all of these claims.

Under a close examination of what FIFRA does and does not preempt, the Northern District of Illinois concluded that the plaintiffs could maintain their claims based on allegations "that Aventis instructed seed representatives to tell farmers that StarLink was safe for human consumption and that the EPA was going to issue a tolerance for Cry9C in food products," because "[s]uch statements directly contradict the approved label" and hence were not preempted.[149] FIFRA also did not preempt the plaintiffs' claims that the defendant failed to warn downstream third parties that the GE corn was unfit for human consumption or that the defendants violated duties that the EPA had imposed in its limited pesticide registration.[150] However, FIFRA *did* preempt the plaintiffs' product defect claims, because these claims were really based on the defendants' failure to warn against co-mingling of the GE corn with normal corn.[151]

2. State-Law Liability for Labeling GE Foods "Organic" and Preemption Claims under the Federal Organic Foods Production Act

GE food labeling preemption claims have also consistently failed under the federal Organic Foods Production Act (OFPA).[152] This statute instructed the Secretary of Agriculture to create a federal certification program for organic foods.[153] The statute itself provides that:

> To be sold or labeled as an organically produced agricultural product under this chapter, an agricultural product shall—

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[146] *Id.*
[147] TENN. CODE ANN. §§ 47-18-101 to 47-18-131.
[148] N.C. GEN. STAT. § 75–1.1 (1999).
[149] *In re StarLink Corn*, 212 F. Supp. 2d. at 837.
[150] *Id.* at 837-38.
[151] *Id.* at 837-38.
[152] 7 U.S.C. §§ 6501-6524.
[153] 7 U.S.C. § 6503.

> (1) have been produced and handled without the use of synthetic chemicals, except as otherwise provided in this chapter;
>
> (2) except as otherwise provided in this chapter and excluding livestock, not be produced on land to which any prohibited substances, including synthetic chemicals, have been applied during the 3 years immediately preceding the harvest of the agricultural products; and
>
> (3) be produced and handled in compliance with an organic plan agreed to by the producer and handler of such product and the certifying agent.[154]

In addition, under the Act's enforcement provisions, "[a]ny person who knowingly sells or labels a product as organic, except in accordance with this chapter, shall be subject to a civil penalty of not more than $10,000."[155]

In the GE food preemption cases involving the OFPA, plaintiffs allege state-law claims (generally based on California's consumer protection laws) that would impose liability on GE food producers who label their products as "organic." When the food producers asserted federal preemption by the OFPA, however, they universally failed.

The U.S. District Court for the Northern District of California decided the first of these cases, *Jones v. ConAgra Foods, Inc.*,[156] in 2012, concluding that the OFPA did not expressly preempt the California law-based claims, nor did California consumer protection laws conflict with the Act.[157] In 2014, the U.S. District Court for the Southern District of Texas explicitly followed the *ConAgra* decision in a class action lawsuit against Whole Foods, based on California consumer protection laws, on behalf of all consumers who "have purchased Whole Foods's private-label 365 Organic and 365 Everyday Value (collectively "365 Brands") products that are allegedly falsely labelled as being organic, natural, and/or GMO-free."[158] The court concluded that the OFPA "does not indicate a clear and manifest purpose to occupy the field, nor

[154] *Id.* § 6504.
[155] *Id.* § 6519(c)(1).
[156] 912 F. Supp. 2d 889 (N.D. Cal. 2012).
[157] *Id.* at 894-96.
[158] Gedalia v. Whole Foods Market Services, Inc., 53 F. Supp. 3d 943, 946 (S.D. Tex. 2014).

does it conflict with relevant California law."[159] In 2015, the California Supreme Court also agreed that the OFPA does not preempt state-law liability for the labeling of GE foods as "organic."[160]

3. State-Law Liability for Labeling GE Foods as "Natural" and Preemption Claims Under the FDCA

State-law challenges to food labels proclaiming that GE foods are "natural" generally confront the FDA's labeling authority under the NLEA amendments to the FDCA.[161] This FDA's labeling authority actually creates two types of preemption arguments in these cases: first, that the FDA's authority to regulate the use of "natural" in food labels preempts state law that would impose liability for GE foods so labeled; and second, that courts should defer to the FDA's primary jurisdiction to decide the proper use of the word "natural" on food labels.[162] Courts, however, have overwhelmingly allowed state-law claims to proceed against GE foods labeled to be "natural" despite both of these federal supremacy arguments.[163]

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[159] *Id*. at 949 (citing Jones v. ConAgra Foods Inc., 912 F.Supp.2d 889, 893 (N.D. Cal. 2012)).

[160] Quesada v. Herb Time Farms, Inc., 361 P.3d 868, 874-85 (Cal. 2015).

[161] PUB. L. NO. 101–535, 104 Stat 2353 (1990).

[162] *E.g.*, Gedalia, 53 F. Supp. 3d at 949-50.

[163] Regarding preemption, *see id*. at 949 (holding that the FDCA does not implicitly preempt a California law-based claim against GE foods labeled as "natural"). *See also generally* In re ConAgra Foods, Inc., 90 F. Supp. 3d 919 (C.D. Cal. 2015) (certifying a state-law-based class action lawsuit against a cooking oil manufacturer based on its use of "natural" in labels for cooking oils derived from GE crops).

Regarding the primary jurisdiction issue, the Southern District of Texas neatly summarized the case law as follows:

> Whole Foods cites to *Cox v. Gruma Corp*., 12–CV–6502 YGR, 2013 WL 3828800, at *2 (N.D. Cal. July 11, 2013), as an instance where primary jurisdiction was successfully invoked to defer to the FDA the question of whether the existence of GMO ingredients was allowed under a product labelled "natural." However, in response to the Cox court's request for agency guidance, the FDA informed the court in a letter that it would refrain from defining the term "natural" due to limited resources and the agency's need to address other matters. FDA Letter at 2–3, *Cox v. Gruma Corp*., No. 12–CV–6502 YGR, 2013 WL 3828800 (N.D. Cal. July 11, 2013). "[M]ost other federal courts that have addressed whether GMOs are 'natural' have declined to stay or dismiss the case based on the primary jurisdiction doctrine." *Rojas v. Gen. Mills, Inc*., 12–CV–05099–WHO, 2013 WL 5568389, at *6 n. 4 (N.D. Cal. Oct. 9, 2013) (citing *In re Frito–Lay*, 2013 WL 4647512, at *6–7; *In re ConAgra Foods, Inc*., No. 11–05379–MMM, 2013 WL 4259467, at *4–5 (C.D. Cal. Aug. 12, 2013); *Krzykwa v. Campbell Soup Co*., 946 F. Supp. 2d 1370 (S.D. Fla. 2013)). Here, deference to the FDA would likely be unfruitful due to the agency's long-standing reluctance to officially define the term "natural."

Gedalia, 53 F. Supp. 3d at 949-50. *But see* In re Kind LLC "Healthy and All Natural Litigation," --- F. Supp. 3d ---, 2016 WL 4991471, at *6 (S.D.N.Y. Sept. 15, 2016) (concluding that "the Second Circuit's primary jurisdiction test

4. Comprehensive Preemption Challenges to Vermont's 2014 GE Food Labeling Law

The cases discussed above demonstrate that litigants have been using a variety of state laws for over a decade to successfully challenge manufacturers' handling and labeling of GE foods. However, the laws involved in these cases did not establish a mandatory state-law-based GE food labeling regime, per se. Instead, the *Bt* corn litigation for the most part reinforced FIFRA's labeling and registration requirements, while the "organic" and "natural" litigation worked primarily to prohibit labeling claims for GE foods that were at least plausibly misleading to ordinary consumers, in the absence of concrete federal law on these topics. As a result, these cases are best viewed as rather limited state incursions into federal food labeling authority. Specifically, these cases showcased particular state-law applications of shared state and federal policies to control pesticide use and to avoid consumer deception in food labeling.

In contrast, Vermont's comprehensive GE food labeling law *did* create a mandatory state-law GE food labeling regime that in many ways supplanted, rather than reinforced, the FDA's determination that genetic engineering was ordinarily non-material information for purposes of food labeling and its voluntary labeling policies. In *Grocery Manufacturers Association v. Sorrell*,[164] the U.S. District Court for the District of Vermont had to decide, in the context of the State of Vermont's motion to dismiss, whether the plaintiffs stated claims in the form of several constitutional challenges to the Vermont statute,[165] including express and conflict preemption claims based on the FDCA, the Federal Meat Inspection Act (FMIA),[166] and the Poultry Products Inspection Act (PPIA).[167]

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weighs in favor of staying the action. Accordingly, Plaintiffs' 'all natural' claims are stayed pending the FDA's rulemaking process.").

[164] 102 F. Supp. 3d 583 (D. Vt. 2015).

[165] Besides the federal preemption claims, the plaintiffs asserted constitutional challenges under the dormant Commerce Clause, *id*. at 604-10; First Amendment, *id*. at 621-42; and Due Process Clause. *Id*. at 642-45. The Vermont District Court dismissed the dormant Commerce Clause challenges, *id*. at 610, and found the Vermont statute constitutional with respect to most of the First Amendment claims. *Id*. at 636. However, it deemed the plaintiffs likely to succeed on their First Amendment challenge to Vermont's regulation of the word "natural," *id*. at 641-42, and one of the "void for vagueness" Due Process challenges. *Id*. at 645. The defendant State of Vermont, in turn, argued that the plaintiffs lacked constitutional standing to bring some of their preemption claims, but it lost under the generous standards of a motion to dismiss. *Id*. at 618-19.

[166] 21 U.S.C. §§ 601-695.

[167] 21 U.S.C. §§ 451-472.

With regard to the FDCA and its NLEA amendments, the Vermont District Court first noted that the FDCA itself "does not contain any express preemption language, [and hence] it does not, itself, provide a basis for Plaintiffs' express preemption claims."[168] In contrast, "[t]he NLEA contains five express preemption clauses that prohibit states from enacting food labeling requirements that are 'not identical' to certain mandatory food labeling requirements set forth in the FDCA."[169] Nevertheless, given the lack of FDA action on GE food labeling, the court concluded that "in order for preemption to apply, the FDCA must require the labeling information at issue; the NLEA must indicate that the mandatory federal labeling requirement is entitled to preemptive effect; and [the Vermont statute's] GE disclosure requirement must govern this same information."[170] The FDA's lack of action foreclosed all express preemption claims,[171] while the Vermont statute did not opine on the safety of GE ingredients or GE foods and hence did not conflict with the FDA's pronouncements on these subjects.[172]

Plaintiffs were more successful with their non-FDCA preemption claims. However, given the Vermont statute's exemption of most meats, it was unlikely that both it and the FMIA or PPIA would apply to the same GE food products, lessening the practical import of these preemption decisions—a fact that the Vermont District Court recognized.

The court summarized the preemptive effect of the FMIA and the PPIA as follows:

> "The labeling of meat and poultry products shipped in interstate commerce is specifically controlled by the [FMIA] and the [PPIA] and their respective regulations." Both acts are administered by the USDA, and both acts "contain substantially identical preemption language which permits some concurrent state enforcement but prohibits state '[m]arking, labeling, packaging, or ingredient

[168] *Grocery Manufacturers*, 102 F. Supp. 3d at 611 (citing Grocery Mfrs. of Am., Inc. v. Gerace, 755 F.2d 993, 997 (2d Cir.), *aff'd*, 474 U.S. 801 (1985)).
[169] *Id.* at 611-12 (citing 21 U.S.C. § 343–1(a)(1)–(5)).
[170] *Id.* at 613-14.
[171] *Id.* at 615.
[172] *Id.* at 615-17.

requirements in addition to, or different than, those' mandated by federal law."[173]

Because the Vermont GE food labeling statute "mandates a GE disclosure that is clearly in addition to and different than the marking, labeling, and packaging requirements imposed under the FMIA and PPIA," that statute's "GE disclosure requirement is therefore expressly preempted for products subject to those federal laws"[174]—*i.e.*, with respect to GE meat and poultry products. Moreover, according to the court, the Vermont statute's restrictions on the use of "natural" in connection with GE foods "is also in addition to and different than the labeling requirements of the FMIA and the PPIA, which do not prohibit or regulate 'natural' terminology."[175] As a result, these provisions were also preempted.[176]

Nevertheless, the Vermont District Court also held that these preemption successes could not support a preliminary injunction, in large part because, given its exemption of meat, the Vermont GE food labeling statute was unlikely to apply to the food products that the FMIA and PPIA actually govern. Specifically, the court concluded, "in the absence of more concrete evidence that Plaintiffs' members actually manufacture GE food products that are non-exempt under [the Vermont statute] and subject to the FMIA or PPIA, the court cannot find a likelihood that Plaintiffs will succeed on the merits of their FMIA and PPIA preemption claims at trial."[177] As a result, the court dismissed all of the plaintiffs' federal preemption claims.[178]

C. Congress's 2016 Preemption of State Laws

Exactly four weeks after Vermont's GE food labeling law went into effect on July 1, 2016,[179] Congress and President Obama settled the GE food labeling federalism question,

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[173] *Id*. at 619 (quoting and citing Grocery Manufacturers of America, Inc. v. Gerace, 755 F.2d 993, 997 (2d Cir. 1985) (citing 21 U.S.C. § 678 (FMIA); 21 U.S.C. § 467e (PPIA))).
[174] *Id*. at 620.
[175] *Id*.
[176] *Id*.
[177] *Id*.
[178] *Id*. at 621.
[179] Phil Lempert, "Sorry Food Industry, The Historic GMO Food Labeling Bill is Anything But," *Forbes.com Food & Agriculture*, http://www.forbes.com/sites/phillempert/2016/08/01/sorry-food-industry-the-historic-gmo-food-labeling-bill-is-anything-but/#25a7f0c55e39 (Aug. 1, 2016).

amending the Agricultural Marketing Act of 1946 (AMA)[180] with the Safe and Accurate Food Labeling Act of 2015 (SAFLA)[181] to preempt state labeling requirements and to require a national bioengineered food disclosure standard. The amendments also shift responsibility for GE food labeling from the FDA to the Secretary of Agriculture.[182] In its 2016 annual report, the House Committee on Agriculture described the purpose of the 2016 amendments expressly in federalism terms—specifically, the need for national uniformity in GE food labeling. It stated:

> The Safe and Accurate Food Labeling Act of 2015 would ensure *national uniformity* regarding labeling of foods derived from genetically engineered plants *by preventing a patchwork of conflicting state or local labeling laws which inherently interfere with interstate and foreign commerce*. This legislation will create a consumer-friendly, science-based, uniform food labeling framework for products produced using genetically engineered ingredients. *By ensuring that food labeling is the sole purview of the Federal Government, the bill guarantees that state labeling mandates do not mislead and misinform consumers*. Additionally, the bill will prevent the costly price hikes associated with a patchwork of state labeling laws. By creating a national non-GE certification program that is overseen by the U.S. Department of Agriculture (USDA), this bill brings transparency and consistency to an area of food labeling where it is urgently needed. This program mimics the widely popular National Organic Program and will provide those who prefer to buy non-GE foods a reliable means of doing so. Similar to organics, non-GE foods also are a small percentage of the U.S. food market. The USDA Certified Organic program is a successful precedent for labeling the exception rather than the rule.[183]

In the AMA more generally, Congress "declare[d] that a sound, efficient, and privately operated system for distributing and marketing agricultural products is essential to a prosperous agriculture and is indispensable to the maintenance of full employment and to the welfare, prosperity, and health of the Nation."[184] The Act vests a number of authorities in the Secretary of

[180] 7 U.S.C. § 1621-1639j.
[181] PUB. L. NO. 114-216, § 1, 130 Stat. 838 (July 29, 2016) (adding 21 U.S.C. § 1639i).
[182] 7 U.S.C. §§ 1638-1638d.
[183] H.R. REP. NO. 114-896, 114th Cong., 2d Sess. 2016, 2016 WL 7471589 (Dec. 27, 2016) (emphasis added).
[184] 7 U.S.C. § 1621.

Agriculture.[185] Notably, even prior to the 2016 amendments, the AMA rubbed up against the food provisions of the FDCA; for example, the Secretary has explicit authority to set standards of quality for ice cream,[186] over the labeling requirements for honey,[187] and over "country of origin" labeling on agricultural products.[188] However, litigation battles pitting the AMA's requirements against the FDCA's appear to be non-existent, underscoring that the two federal agencies have long shared food labeling jurisdiction with little apparent conflict.

Against this background, therefore, the first critical component of the 2016 amendments is that they shift primary authority over GE food labeling from the FDA to the USDA.[189] Second, and more importantly, the amendments establish the federal government as the primary and exclusive authority over GE food labeling. Specifically, under the new provisions, by July 2018 the Secretary of Agriculture must "establish a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered . . . ."[190] The amendments define "food" by cross-reference to the FDCA,[191] while:

> The term "bioengineering", and any similar term, as determined by the Secretary, with respect to a food, refers to a food—
>
> (A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and
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> (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.[192]

The new federal GE food labeling provisions will require some interpretation regarding the exact foods to which they apply. The amendments state both that they "shall apply to any

[185] *Id.* § 1622.
[186] *Id.* § 1622(c).
[187] *Id.* § 1622(h)(6).
[188] *Id.* §§ 1638-1638d.
[189] "Secretary" is explicitly defined in the new provisions to be the Secretary of Agriculture. *Id.* § 1639(3).
[190] *Id.* § 1639b(a)(1).
[191] *Id.* § 1639(2).
[192] *Id.* § 1639(1).

claim in a disclosure that a food bears that indicates that the food is a bioengineered food,"[193] but also that they

> shall apply only to a food subject to—
>
> (1) the labeling requirements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or
>
> (2) the labeling requirements under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.) only if—
>
> (A) the most predominant ingredient of the food would independently be subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or
>
> (B) (i) the most predominant ingredient of the food is broth, stock, water, or a similar solution; and
>
> (ii) the second-most predominant ingredient of the food would independently be subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).[194]

Moreover, "[t]he definition of the term 'bioengineering' under section 1639 of this title shall not affect any other definition, program, rule, or regulation of the Federal Government."[195] Thus, the applicability of the USDA's new GE food labeling regulations under SAFLA could be subject to the FDA's actions regarding GE foods under the FDCA.

Moreover, Congress also mandated some exemptions from the new labeling requirements. Among other things, the Secretary's regulations must "prohibit a food derived from an animal to be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance" and must "determine the amounts of a bioengineered substance that may be present in food, as appropriate, in order for the food to be a bioengineered food . . . ."[196] Moreover, if a food is certified as "organic" under the Organic Foods Production Act of 1990,[197] "the certification shall be considered sufficient to

[193] *Id.* § 1639a(a).
[194] *Id.* § 1639a(c).
[195] *Id.* § 1639a(b).
[196] *Id.* § 1639b(b)(2).
[197] 7 U.S.C. §§ 6501-6522.

make a claim regarding the absence of bioengineering in the food, such as 'not bioengineered', 'non-GMO', or another similar claim."[198]

Contrary to popular reporting, the 2016 amendments do not precisely require the USDA to actually mandate GE food labeling. Instead, by July 29, 2018, the USDA shall "establish a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered," and "[a] food may bear a disclosure that the food is bioengineered only in accordance with regulations promulgated by the Secretary in accordance with this subchapter."[199] Given the lack of further guidance and definition in the amendments, the "disclosure standard" conceivably could be a requirement of no disclosure.

Nevertheless, Congress does appear to have intended that the USDA indeed require some disclosure of GE food status: The amendments mandate that the USDA's regulations "require that the form of a food disclosure under this section be a text, symbol, or electronic or digital link, but excluding Internet website Uniform Resource Locators not embedded in the link, with the disclosure option to be selected by the food manufacturer,"[200] and "[i]t shall be a prohibited act for a person to knowingly fail to make a disclosure as required under this section."[201] Even so, the amendments' enforcement provisions are fairly weak. There is no penalty specified, for example, for violating the disclosure standard,[202] and although the Secretary of Agriculture has authority to audit food manufacturers' compliance,[203] "[t]he Secretary shall have no authority to recall any food subject to this subchapter on the basis of whether the food bears a disclosure that the food is bioengineered."[204]

What the 2016 amendments *clearly* do, however, is restrict state regulation of GE food labeling. Thus,

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[198] PUB. L. NO. 114-216, § 2, 130 Stat. 838 (July 29, 2016) (amending 7 U.S.C. § 6524).
[199] 7 U.S.C. § 1639b(a)(1), (b)(1).
[200] *Id.* § 1639b(b)(2)(D).
[201] *Id.* § 1639b(g)(1).
[202] *See id.* § 1639b(g)(1) (specifying no penalty).
[203] *Id.* § 1639b(g)(3).
[204] *Id.* § 1639b(g)(4).

> no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce any requirement relating to the labeling or disclosure of whether a food is bioengineered or was developed or produced using bioengineering for a food that is the subject of the national bioengineered food disclosure standard . . . that is not identical to the mandatory disclosure requirement under that standard.[205]

In addition, the Act expressly preempts any state laws about both GE food labeling and genetically-engineered seeds:

> No State or a political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food or seed in interstate commerce any requirement relating to the labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered (which shall include such other similar terms as determined by the Secretary of Agriculture) or was developed or produced using genetic engineering, including any requirement for claims that a food or seed is or contains an ingredient that was developed or produced using genetic engineering.[206]

This preemption provision also cross-references the FDCA's definition of "food."[207]

Nevertheless, under the amendment's savings provision, nothing in the new provisions, "or any regulation, rule, or requirement promulgated in accordance with [them] shall be construed to preempt any remedy created by a State or Federal statutory or common law right."[208] Thus, at least on its face, SAFLA preserves state-law *remedies* for improperly labeled GE foods based on non-labeling-related statutes, including state consumer protection laws, and it preserves all FDCA liability for misbranded foods. The next Part will examine some of these remaining issues in more detail.

V. WE'RE NOT DONE YET: LEGAL ISSUES REMAINING UNDER THE SAFE AND ACCURATE FOOD LABELING ACT

A. The Division of Authority over GE Foods between the Secretary of Agriculture and the FDA

[205] 7 U.S.C. § 1639b(e).
[206] *Id.* § 1639i(b).
[207] *Id.* § 1639i(a).
[208] *Id.* § 1639j.

Congress's 2016 enactment of SAFLA clearly did not alter the FDA's authority to regulate the *marketing* of GE foods under the FDCA. Thus, the FDA's consultation procedures for plant-based GE foods and its New Animal Drug Application requirements for GE animals marketed as food remain in place, subject only to the FDA's own refinements.

A bit less clear is the exact interaction between the FDCA's misbranding and labeling requirements and SAFLA's national disclosure standard. For example, in Section 1639a(c) of the new amendments, Congress stated that the USDA's new standard applies "only to a food subject to . . . the labeling requirements under the Federal Food, Drug, and Cosmetic Act . . . ."[209] As Part II discussed in detail, the FDA has determined that, in general, GE foods are *not* subject to the FDCA's labeling requirements. Read literally, therefore, Section 1639a(c) means that the USDA's new disclosure standard applies only to GE foods in which the genetic engineering produces a new or altered food characteristic that the FDA considers "material" for purposes of the FDCA's labeling and misbranding requirements—i.e., that the FDA, not the USDA, actually controls the applicability of the new requirements.

Assuming that Congress intended the 2016 amendments to ensure that GE food labeling would actually occur, however, this interpretation of Section 1639a(c) substantially vitiates, if not outright contradicts, congressional intent. Moreover, it goes against the grain of SAFLA as a whole. Given the 2016 amendments' repeated cross-reference to the FDCA's definition of "food,"[210] a better interpretation of Section 1639a(c) is that the USDA's new disclosure standard will apply to all FDCA "foods," because all such "foods" are subject to the FDCA's misbranding provisions and hence potentially to FDCA labeling requirements.

SAFLA also creates an issue regarding the relation between the USDA's GE food disclosure standard and misbranding liability under the FDCA. Given SAFLA's cross-referencing of the FDCA's definition of "food,"[211] its lack of a specified penalty for violating the

[209] *Id.* § 1639a(c).
[210] *Id.* §§ 1639(2), 1639i(a).
[211] *Id.*

USDA's disclosure regulations,[212] and its explicit preservation of other federal remedies,[213] it seems a rather straightforward interpretation that violation of the USDA's GE food disclosure standard could, and should, constitute misbranding under the FDCA. To give fair warning to GE food manufacturers and for legal clarity, however, the FDA would be well advised to formally adopt this interpretation into its FDCA food regulations, especially because Congress in SAFLA did not explicitly tie the USDA's new disclosure standard to FDCA misbranding liability, nor did it give either the USDA or the FDA direct authority to use the FDCA to enforce the new USDA regulations.

A closer question might arise if the FDA decides to require more specific disclosures for specific GE foods of "material" information under the FDCA than the USDA would require under SAFLA. For example, the USDA's disclosure standard could easily focus on the *fact* of genetic engineering but not require disclosure of the exact food alterations that result from that engineering. The FDA, in contrast, might consider the actual alteration made to be the material point for purposes labeling under the FDCA. Suppose a food producer want to offer to consumers a non-peanut plant food genetically engineered to produce peanut proteins, which can in turn produce an allergic response in peanut-sensitive consumers. The USDA regulations might consider the manufacturer to be in compliance with the national disclosure standard if the food's label states that the food is genetically engineered, but the FDA might require a far more specific warning about the peanut allergens.

Again, SAFLA appears to preserve the FDA's GE food labeling authority under these circumstances. First, "[t]he definition of the term 'bioengineering' under section 1639 of this title shall not affect any other definition, program, rule, or regulation of the Federal Government."[214] Second, nothing in the new provisions, "or any regulation, rule, or requirement promulgated in accordance with [them] shall be construed to preempt any remedy created by a . . . Federal

[212] *See id*. § 1639b(g) (specifying no penalties and explicitly prohibiting the Secretary of Agriculture from recalling non-complying foods).
[213] *Id*. § 1639j.
[214] *Id*. § 1639a(b).

statutory or common law right."[215] Thus, if the USDA's disclosure regulations do not adequately address the requirements necessary to avoid misbranding liability under the FDCA for particular GE foods, the FDA should retain authority to supplement GE food labeling requirements, especially with respect to health and safety issues.

B. The Future Role of State Laws in GE Food Labeling

Like many federal statutes that address food labeling, SAFLA creates a statutory gauntlet for courts to navigate regarding what state laws, precisely, the Act preempts and what state laws it preserves. These preemption issues will, of course, partially turn on the exact contents of the USDA's new regulations. As of mid-January 2017, the USDA has not proposed any regulatory content.[216] Nevertheless, on August 1, 2016, the USDA sent letters to all 50 states, notifying them of the new Act and its potential preemption effect and advising the states to "fully review the scope and effect of this new Federal law in advance of taking any action or considering any new state initiatives related to the regulation of labels for foods that are genetically engineered or that contain genetically engineered ingredients."[217] Thus, the USDA is, in effect, already asserting fairly comprehensive federal preemption of state laws affecting GE food labeling.

Nevertheless, existing jurisprudence regarding labeling law preemption provides good initial guidance for navigating SAFLA's new provisions. The Act clearly and expressly preempts state and local government laws that "directly or indirectly" impose "any requirement relating to the labeling or disclosure of whether a food is bioengineered or was developed or produced using bioengineering for a food that is the subject of the national bioengineered food disclosure standard . . . that is not identical to the mandatory disclosure requirement under that standard."[218] Moreover, the U.S. Supreme Court has made it clear that state "requirements" subject to such preemption provisions include both positive enactments like statutes and regulations and

[215] *Id.* § 1639j.

[216] *See* U.S. Department of Agriculture, *GMO Disclosure & Labeling*, https://www.ams.usda.gov/rules-regulations/gmo (as viewed Jan. 14, 2017) (the USDA's web-based clearinghouse for information on the new law).

[217] U.S. Department of Agriculture, *State Preemption Letters*, https://www.ams.usda.gov/sites/default/files/media/GMOExemptionLettersto50Governors.pdf (Aug. 1, 2016).

[218] 7 U.S.C. § 1639b(e).

common-law duties and judge-made rules, such as through tort liability.[219] However, because federal express preemption provisions are read narrowly and in favor of state regulation,[220] this provision of SAFLA preempts only those state and local laws and requirements that: (1) apply to foods subject to the federal disclosure requirements (and only to the extent that they so apply); (2) address whether a food is bioengineered or produced through bioengineering under the federal definition; and (3) are not identical to the federal disclosure requirements.[221]

Again, SAFLA's more general preemption provision states that:

> No State or a political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food or seed in interstate commerce any requirement relating to the labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered (which shall include such other similar terms as determined by the Secretary of Agriculture) or was developed or produced using genetic engineering, including any requirement for claims that a food or seed is or contains an ingredient that was developed or produced using genetic engineering.[222]

Strictly construed in accordance with the same case law, this provision preempts only: (1) labeling requirements; (2) that apply to foods and seeds in interstate commerce; and (3) that relate to whether a food or seed is genetically engineered, was developed or produced through genetic engineering, or contains an ingredient that was developed or produced through genetic engineering.

In contrast, nothing in SAFLA "or any regulation, rule, or requirement promulgated in accordance with [them] shall be construed to preempt any remedy created by a State . . . statutory or common law right."[223] Faced with similar statutory language, courts hold that state law can provide additional *remedies* for federal law violations even when the relevant federal statute

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[219] Bates v. Dow Agrosciences, LLC, 544 U.S. 431, 443 (2005).
[220] Cipollone v. Liggett Group, Inc., 505 U.S. 504, 518 (1992).
[221] *See, e.g.*, Chacanaca v. Quaker Oats Co., 752 F. Supp. 2d 1111, 1118-19 (N.D. Cal. 2010) (breaking down the exact requirements for preemption under the NLEA in a similar way).
[222] 7 U.S.C. § 1639i(b).
[223] *Id.* § 1639j.

preempts independent state *requirements* on the same legal subject.[224] Thus, at the very least, states remain free to impose state-law remedies for violations of the Act and the USDA's bioengineered foods disclosure standard, especially given the absence of federal penalties for such violations.

The Act and the USDA also preserve existing case law regarding the non-preemption of state-law claims against manufacturers who label GMO foods as "organic." The Act explicitly establishes that certification under the federal OFPA is sufficient for manufacturers to label those foods as "GMO free" or with similar language.[225] Moreover, the Act requires the USDA to consider the importance of consistency between the national bioengineered food disclosure standard and "organic" certification under the OFPA,[226] and on September 19, 2016, the USDA issued a guidance memorandum regarding this consistency that stressed that certified organic foods cannot contain GE components or ingredients and that certified organic foods would not be subject to disclosure requirements under SAFLA.[227] Therefore, in conjunction with SAFLA's preservation of state-law remedies and the OFPA's non-preemption of state consumer protection laws,[228] the Act almost certainly preserves the authority of states to prohibit food manufacturers from labeling GE foods as "organic" and to provide consumer remedies against those manufacturers who do.

In contrast, the fate of state laws and requirements that affect whether GE foods can be labeled as "natural" is very much up in the air. Even before Congress enacted SAFLA, the FDA, in response to citizen petitions, initiated the first steps of a rulemaking regarding use of the term

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[224] *See*, *e.g.*, Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (concluding that the Medical Device Amendments to the FDCA preempt state-law requirements for medical devices but allow a state-law damages remedy for violations of federal requirements); Symens v. SmithKline Beecham Corp., 152 F.3d 1050, 1054-55 (8th Cir. 1998) (concluding that the Virus-Serum-Toxin Act preempts state-law requirements but not state-law remedies).

[225] PUB. L. NO. 114-216, § 2, 130 Stat. 838 (July 29, 2016) (amending 7 U.S.C. § 6524).

[226] 7 U.S.C. § 1639b(f).

[227] Memorandum from Elanor Starmer, Administrator, Agricultural Marketing Service, U.S. Department of Agriculture, to AMS Deputy Administrators, dated Sept. 19, 2016, at 3, 4, *available at* https://www.ams.usda.gov/sites/default/files/media/PolicyMemoGMODisclosureNOPConsistency.pdf.

[228] *See* discussion *supra* Part III.B.2 and cases cited therein.

"natural" in food labeling.[229] Its initial "request for comments" period closed on May 10, 2016.[230] Even this tentative initiation of a rulemaking process led the U.S. District Court for the Southern District of New York in September 2016 to stay state-law litigation based on "all natural" labeling of GE foods in deference to the FDA's primary jurisdiction.[231] Now, under the new Act, the USDA may also take up the issue of whether bioengineered foods can be labeled "natural" under the national disclosure standard.

If the FDA and/or the USDA concludes that GE foods cannot be labeled as "natural," the existing case law allowing state-law remedies when manufacturers so label their GE foods should stand: The FDCA will still fail to preempt these claims,[232] and SAFLA preserves state-law remedies for a label term that violates the USDA's disclosure standard.[233] In contrast, if the FDA and/or the USDA concludes that GE foods *can* be labeled as "natural," then their allowance of such labeling will preempt state-law prohibitions against such labeling under basic federal conflict preemption principles.[234]

If both agencies remain silent on the issue, however, a split of preemption analysis will arise. If the FDA eventually refuses to regulate the use of "natural" under the FDCA, the case law concluding that state laws prohibiting its use on GE food labels are *not* preempted should remain in force:[235] The FDCA will not preempt state prohibitions on labeling GE foods as

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[229] U.S. Food & Drug Administration, *"Natural" on Food Labeling*, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm (last updated Sept. 14, 2016, and as viewed on Jan. 14, 2017).

[230] *Id*. Comments submitted to the FDA may be viewed at https://www.regulations.gov/docket?D=FDA-2014-N-1207.

[231] In re Kind LLC "Healthy and All Natural Litigation," --- F. Supp. 3d ---, 2016 WL 4991471, at *6 (S.D.N.Y. Sept. 15, 2016) (concluding that "the Second Circuit's primary jurisdiction test weighs in favor of staying the action. Accordingly, Plaintiffs' 'all natural' claims are stayed pending the FDA's rulemaking process.").

[232] *See* discussion *supra* Part III.B.3 and cases cited therein.

[233] 7 U.S.C. § 1639j.

[234] Conflict preemption occurs when "compliance with both federal and state regulations is a physical impossibility," Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963), or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hines v. Davidowitz, 312 U.S. 52, 67 (1941). State laws that prohibit GE foods from being labeled as "natural" when federal law allows such labeling would stand as an obstacle to the implementation of federal labeling laws, and hence the state laws would be conflict preempted.

[235] *See* discussion *supra* Part III.B.3 and cases cited therein.

"natural." In contrast, if the USDA remains silent regarding the use of "natural," state laws that effectively prohibit manufacturers from labeling GE foods as "natural" would be labeling requirements that relate to whether a food is bioengineered (as opposed to simply supplying a remedy for violations of *the USDA's* requirements) and hence would be preempted.[236]

VI. CONCLUSION

Congress has now declared that GE food labeling is the province of the federal government, a decision that makes federalism and economic sense given the national commerce in foods, especially processed foods. A main focus of Congress's 2016 amendments was to preempt state GE food labeling laws, and Congress has done so relatively clearly in light of existing case law, despite the fact that some details will have to wait for the USDA's new regulations. Specifically, Congress has effectively preempted the states from imposing different labeling requirements for GE foods than what the USDA eventually requires, but it has left the states wide discretion to impose additional state remedies for violations of these new federal labeling requirements. Thus, there remains a distinct possibility that non-conforming GE food manufacturers will face different levels and kinds of liability across the 50 states if they fail to properly label their GE foods, even though those labeling requirements will be nationally uniform.

In addition, states retain considerable latitude regarding whether and how stringently they wish to police GE food manufacturers who choose label their products "organic." However, what will happen with "natural" labeling is unclear as this article goes to press, including the basic issue of whether states will have any role whatsoever in policing the use of "natural" in connection with GE foods.

Given this relative clarity regarding state preemption, it is somewhat ironic that Congress simultaneously created several *federal* regulatory ambiguities regarding how the USDA's new GE food labeling authority will dovetail with the FDA's unchanged authority over foods and

[236] 7 U.S.C. § 1639i(b).

food labeling under the FDCA. One reading of the Act, for example, effectively gives the FDA the authority to decide *which* GE foods are subject to the USDA's new disclosure standard. Even rejecting that reading, however, serious questions remain regarding the exact relationship between SAFLA's national bioengineered food disclosure standard and the FDCA's misbranding provisions for foods, especially if the FDA determines that additional labeling requirements are necessary for particular GE foods beyond USDA's national disclosure standard.

Given the long history of relative legal peace between the FDA's and USDA's food labeling authorities and GE product authorities, however, the two agencies optimally should work out an agreement *before* the USDA's new regulations go into effect regarding how they will blend their labeling authorities regarding GE foods. Such coordination has a longstanding precedent with respect to GE crops: In 1986, the EPA, FDA, and USDA agreed on a formal coordination policy for federal regulation of biotech plants.[237] In the context of GE food labeling, similarly clear coordination will almost certainly require the FDA to promulgate new regulations of its own, particularly with respect to whether violations of the USDA's disclosure standard and requirements constitute "misbranding" under the FDCA. Conversely, the USDA in its regulations may want to explicitly cross-reference any future FDA "materiality" requirements for particular GE foods, making those labeling requirements part of the required disclosures under SAFLA. By working together immediately, the USDA and FDA can foreclose much of the confusion and controversy that might otherwise arise under the new Act, perhaps finally bringing the GE food labeling controversy in the United States to a legal conclusion.

[237] Animal & Plant Health Inspection Service, U.S. Department of Agriculture, *Coordinated Framework: How the Federal Government Regulates Biotech Plants*, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_regulations/ct_agency_framework_roles (as updated Feb. 1, 2016).