THE CONSTITUTIONALITY OF STATE-MANDATED LABELING FOR GENETICALLY ENGINEERED FOODS: A DEFINITIVE DEFENSE

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INTRODUCTION

As we write this, citizens in your state are working to secure the mandatory labeling of genetically engineered food. Genetically engineered (GE), or transgenic, foods—the products of agricultural biotechnology—have been contentious since companies introduced them for commercial use in America in 1996.¹ Nevertheless, unlike the governments of dozens of countries across the globe, the United States government does not require labeling for genetically engineered foods.² Consequently, Americans are left in the dark about whether the foods we buy are transgenic.

Into this breach, state labeling efforts have proliferated, in the venerable "states-as-laboratories" tradition of American federalism.³ Recent years have set new high watermarks in the rising tide of the labeling movement. In 2012, a California labeling ballot initiative was narrowly defeated—51.4% to 48.6%.⁴ In 2013, a Washington state initiative lost by only 38,000 votes—51% to 49%.⁵ Also in 2013, Connecticut and Maine

^{1.} Adoption of Genetically Engineered Crops in the U.S., USDA, http://www.ers.usda.gov/ data-products/adoption-of-genetically-engineered-crops-in-the-us/documentation.aspx (last updated July 14, 2014).

^{2.} *International Labeling Laws*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/ issues/976/ge-food-labeling/international-labeling-laws (last visited Dec. 6, 2014).

^{3.} See e.g., Oregon v. Ice, 555 U.S. 160, 170–71 (2009) ("We have long recognized the role of the States as laboratories for devising solutions to difficult legal problems."); United States v. Oakland Cannabis Buyers' Co-op., 532 U.S. 483, 502 (2001) (Stevens, J., concurring) (citation omitted).

^{4.} DEBRA BOWEN, CAL. SEC'Y OF STATE, STATEMENT OF VOTE: NOVEMBER 6, 2012, GENERAL ELECTION 13 (2012), *available at* http://www.sos.ca.gov/elections/sov/2012-general/sov-complete.pdf.

^{5.} Washington Mandatory Labeling of Genetically Engineered Food Measure, Initiative 522 (2013), BALLOTPEDIA, http://ballotpedia.org/Washington_Mandatory_Labeling_of_Genetically_ Engineered_Food_Measure,_Initiative_522_(2013) (last visited Dec. 6, 2014).

both passed labeling laws, albeit with clauses tying their effective dates to similar future state labeling laws.⁶ And in spring 2014, Vermont became the first state to pass a labeling law without strings, which is set to go into effect in 2016.⁷ In fall 2014, the labeling tide continued to rise, with both Oregon and Colorado voting on labeling ballot initiatives.⁸ Overall, in 2013–2014, more than thirty states introduced legislation on the labeling of genetically engineered foods, totaling over seventy separate bills.⁹ Americans are speaking loud and clear: polls regularly show that over 90% of Americans support the labeling of genetically engineered foods.¹⁰

What drives this nationwide public furor for labeling? In short, consumers are becoming more aware that while few whole foods are genetically engineered, a substantial majority of processed foods are now produced with genetic engineering. The public recognizes that having thousands of processed foods produced with genetic engineering, yet unlabeled, is deceptive, or at best confusing, to consumers.

Further, Americans are increasingly aware of the risks and negative impacts of genetically engineered crops, correctly seeing through several decades of myths that were carefully constructed by agrochemical companies to promote their genetically engineered crops. On the human health side, the public is realizing that the U.S. Food and Drug Administration (FDA) does not actually test the food safety of engineered foods; rather, it has confidential meetings with industry in which it merely reviews the industry's own testing—and even that is voluntary.¹¹ Americans are also realizing that no long-term or epidemiological studies in the United States have examined the safety of human consumption of genetically engineered foods, and that without labeling, there is no

^{6.} An Act To Protect Maine Food Consumers' Right To Know about Genetically Engineered Food and Seed Stock, 2014 Me. Laws 1; CONN. GEN. STAT. ANN. § 21a-92c (West 2013).

^{7.} Act 120: An Act Relating to the Labeling of Food Produced with Genetic Engineering, 2014 Vt. Acts & Resolves No. 120 [hereinafter Act 120], *available at* http://www.leg.state.vt.us/docs/2014/Bills/H-0112/ACT0120%20As%20Enacted.pdf.

^{8.} Ballot Measure Scorecard, 2014, BALLOTPEDIA, http://ballotpedia.org/Ballot_Measure_ Scorecard, 2014#November_4 (last visited Dec. 6, 2014); Niraj Chokshi, *GMO labeling measure makes Colorado's November Ballot*, WASH. POST (Aug. 20, 2014), http://www.washingtonpost.com/blogs/ govbeat/wp/2014/08/20/gmo-labeling-measure-makes-colorados-november-ballot/.

^{9.} CTR. FOR FOOD SAFETY, JUNE 2014 FACT SHEET: GE FOOD LABELING: STATES TAKE ACTION (2014), *available at* http://www.centerforfoodsafety.org/files/ge-state-labeling-fact-sheet-620141_28179.pdf.

^{10.} See, e.g., U.S. Polls on GE Food Labeling, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/us-polls-on-ge-food-labeling (last visited Dec. 6, 2014) (listing polls).

^{11.} For more on FDA regulation, see infra Part II.B.

accountability or traceability to link such foods to proliferating public health problems.¹²

On the environmental side, people are recognizing that genetically engineered crops are a key cog of inherently unsustainable industrial agriculture and cause significant adverse environmental impacts. Genetically engineered crops are essentially a pesticide-promoting technology: They are overwhelmingly engineered to be resistant to pesticides or produce pesticides, and consequently have dramatically increased overall pesticide output into our environment.¹³

On the agricultural side, transgenic contamination of conventional crops from engineered crops has caused U.S. farmers billions of dollars in market losses.¹⁴ And the widespread adoption of crops engineered for pesticide resistance has proliferated an epidemic of resistant "superweeds" now covering more than 60 million acres of U.S. farmland.¹⁵

Juxtaposed against these risks and impacts, the U.S. public is discovering that industry's hype is false. Namely, despite billions of dollars in research and nearly two decades of commercialization, there are no crops that are engineered to increase crop yields, reduce world hunger, or mitigate global warming; instead, the agrochemical companies that engineer crops have largely succeeded in making these crops resistant to their own products—pesticides.¹⁶

The bottom line is that, due to the risks and known adverse impacts of genetically engineered foods, Americans understandably think, at a minimum, that they deserve the right to choose whether to buy these foods. That is, American consumers believe they are entitled to the same right—the right to have labeling on genetically engineered foods—that Russian, Japanese, European, and Chinese consumers already enjoy.¹⁷

Notably, the movement to label genetically engineered foods is not an effort to stop the advance of science and technology; rather, this movement endeavors to offer the American public full disclosure, preserving the right of free choice and transparency in the marketplace and creating a healthier, more sustainable food industry. Requiring genetically engineered foods to be labeled will not adversely impact a company's ability to conduct new,

^{12.} See, e.g., Act 120 § 1(2).

^{13.} For information on genetic engineering and agricultural biotechnology, see infra Part I.

^{14.} Id.

^{15.} *Id*.

^{16.} *Id.*

^{17.} *International Labeling Laws*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/ issues/976/ge-food-labeling/international-labeling-laws (last visited Dec. 6, 2014).

forward-thinking research. In fact, if future genetically engineered products claim to benefit consumers, labeling provides companies with an opportunity to distinguish their purportedly beneficial products. However, virtually 100% of GE crops in the United States and the world (by acreage) are crops with pest management traits that provide no net benefits to consumers over traditional (non-GE) crops.¹⁸ Long-promised GE crops with alleged consumer benefits have failed to materialize, one of industry's main reasons for tooth-and-nail opposition to labeling.

Faced with this reality, the agrochemical industry has fought to stem the labeling tide at all costs, pouring unprecedented fortunes into lobbying against labeling. Lobbying disclosures show expenditures specifically for opposing GE food labeling (as opposed to more general, related topics) of over \$80 million between 2012 and the first quarter of 2014;¹⁹ opponents of mandatory labeling of genetically engineered food "spent more than \$27 million" in order to lobby against labeling laws in the first half of 2014 alone.²⁰ In order to narrowly defeat the California and Washington state ballot initiatives in 2012 and 2013, labeling opponents spent lavishly—over \$68 million total—smashing state initiative spending records.²¹ Leading up to the November 2014 election, industry again smashed state spending records, spending over \$20 million in Oregon, and an additional \$16 million in Colorado, bringing industry's state referendum total from 2012–

^{18.} See JORGE FERNANDEZ-CORNEJO & WILLIAM D. MCBRIDE, USDA, GENETICALLY ENGINEERED CROPS FOR PEST MANAGEMENT IN U.S. AGRICULTURE: FARM-LEVEL EFFECTS 1 (2000), available at http://www.ers.usda.gov/media/323484/aer786_1_.pdf; see also CLIVE JAMES, ISAAA, BRIEF 46: GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2013, at 7 (2013), available at http://www.isaaa.org/resources/publications/biotech_traits_annual_updates/download/Biotech%20Traits %20Annual%20Updates.pdf.

^{19.} Carey Gillam, U.S. GMO Crop Companies Double Down on Anti-Labeling Efforts, REUTERS (July 29, 2014) [hereinafter Gillam, Crop Companies], http://www.reuters.com/article/2014/ 07/29/usa-gmo-labeling-idUSL2N0Q30Y520140729?feedType=RSS&feedName=everything& virtualBrandChannel=11563; see also Carey Gillam, U.S. GMO Labeling Foes Triple Spending in First

Half of This Year Over 2013, REUTERS (Sept. 3, 2014, 3:44 PM) [hereinafter Gillam, *Foes Triple*], http://www.reuters.com/article/2014/09/03/us-usa-gmo-labeling-idUSKBN0GY09O20140903 (describing the lobbying expenditure increases after 2014, compared to previous contributions).

^{20.} Gillam, Foes Triple, supra note 19.

^{21.} Id.; see also Greg Giroux, Grocers' Group Spends Record Lobbying Amid Food-Labeling Fights, BLOOMBERG BUSINESSWEEK (Dec. 3, 2013), http://www.businessweek.com/news/2013-12-03/grocers-group-spends-record-lobbying-amid-food-labeling-fights (summarizing efforts to prevent states from passing GE labeling laws); Lewis Kamb, No on 522 Breaks Fundraising Record for Washington Initiative Campaigns, SEATTLE TIMES (Oct. 28, 2013), http://blogs.seattletimes.com/politicsnorthwest/2013/10/28/no-on-522-breaks-fundraising-record-for-washington-initiative-

campaigns/ (documenting the record-breaking fundraising campaign surrounding a GMO labeling initiative in Washington); *see also Action Alert: Bigger Battle, Bigger Boycott*, ORGANIC CONSUMERS ASSOCIATION, http://www.organicconsumers.org/bytes/ob425.html (last visited Dec. 6, 2014).

2014 to over \$100 million.²² According to Pamela Bailey, president of the Grocery Manufacturers' Association (GMA), defeating the California initiative was the food lobby's "single-highest priority" of 2012.²³

In addition to wielding money and, consequently, political influence, labeling opponents have created shiny new social media spin campaigns, complete with industry-friendly websites.²⁴ Moreover, industry has lobbied heavily for federal preemption legislation,²⁵ which would prohibit states from requiring labeling.²⁶ This latter goal was made public during a lawsuit against GMA for illegally concealing donors of an anti-labeling campaign, wherein the Washington State Attorney General's office obtained internal industry documents describing this endgame.

Finally, industry has resorted to threatening litigation in order to intimidate state legislatures and thereby prevent them from passing labeling legislation. Adding teeth to this threat, GMA and its allies sued Vermont in June 2014, arguing that courts should prohibit states from requiring labeling on genetically engineered foods,²⁷ despite the fact that these multinational corporations are already required to label genetically engineered foods in at

25. Rebekah Wilce, *Grocery Manufacturers Association Seeks to Pre-empt GMO Food Labeling*, PR WATCH (Mar. 6, 2014), http://www.prwatch.org/news/2014/03/12415/grocery-manufacturers-association-seeks-pre-empt-gmo-food-labeling.

^{22.} Dana Tims, New \$4.46 Million Donation to Anti-GMO-Labeling Campaign Breaks Oregon Record for Spending by One Side (Oct. 24, 2014, 10:20 AM), http://www.oregonlive.com/politics/ index.ssf/2014/10/new_446_million_donation_to_an.html; *Financial Summary*, COLO. ELECTIONS DIV., http://tracer.sos.colorado.gov/PublicSite/SearchPages/CommitteeDetail.aspx?OrgID=26735 (last visited Dec. 6, 2014); 68+20+16=104 in all four campaigns.

^{23.} Michele Simon, *Fighting GMO Labeling in California is Food Lobby's "Highest Priority"*, HUFFINGTON POST (July 30, 2013, 3:33 PM), http://www.huffingtonpost.com/michele-simon/fighting-gmo-labeling-in-_b_1719898.html.

^{24.} Gillam, Crop Companies, supra note 19.

^{26.} Stephanie Strom, *Food Companies Claim Victory Against Labeling Initiative in Washington State*, N.Y. TIMES (Nov. 6, 2013), http://www.nytimes.com/2013/11/07/us/politics/food-companies-claim-victory-against-labeling-initiative-in-washington-state.html?_r=2&; Michele Simon, *Industry's Secret Plan to Get the Feds to Kill GMO Labelling in Every State*, EAT DRINK POLITICS (Nov. 7, 2013), http://www.eatdrinkpolitics.com/2013/11/07/industrys-secret-plan-to-get-the-feds-to-kill-gmo-labeling-in-every-state/; Disclosure from Pamela G. Bailey, President and CEO, GMA Washington State, to Kurt Young, Compliance Officer, State of Washington Public Disclosure Committee (Oct. 9, 2013), *available at* http://www.eatdrinkpolitics.com/wp-content/uploads/GMA_Disclosure_WA_State.pdf.

^{27.} Neil Munshi & Aaron Stanley, *Food Industry Boosts Lobbying on Product Labeling*, FIN. TIMES (July 29, 2014), http://www.ft.com/cms/s/0/850c3b7e-173f-11e4-b0d7-00144feabdc0.html# ixzz39MulU0eA; *see* Lisa Baertlein, *U.S. Food Makers Sue to Stop Vermont's GMO Labeling Law*, REUTERS (June 12, 2014), http://www.reuters.com/article/2014/06/12/vermont-gmo-idUSL2N00T20620140612.

least sixty-four other countries.²⁸ However, the industry's arguments conflict with basic principles of federalism and constitutional law.

This Article addresses the constitutionality of state-mandated labeling for genetically engineered foods, explaining why courts should reject industry's legal challenges. Part I provides a brief background on agricultural biotechnology and genetic engineering, explaining agricultural biotechnology and separating industry's hype about genetically engineered crops from the reality. Part II demonstrates that labeling laws are consistent with the constitutional supremacy doctrine. Specifically, no federal statutes either expressly or impliedly preempt state laws requiring the labeling of genetically engineered foods, and federal oversight of genetically engineered foods is a mishmash of ineffective and voluntary policy documents-the antithesis of robust laws with authority to preempt. Part III explains that state labeling laws are consistent with the Constitution's Commerce Clause. That is, labeling laws do not contravene the "dormant" Commerce Clause because such laws do not discriminate and apply equally to in-state and out-of-state companies. Labeling laws also do not create any cognizable indirect burden on interstate commerce. And, even if they did, their benefits overwhelmingly outweigh any purported burdens. Part IV debunks industry's claims of an alleged First Amendment right to keep U.S. consumers in the dark about genetically engineered foods. State labeling laws simply require companies to disclose factual information about their products, and in so doing serve legitimate state interests in preventing consumer deception and confusion, as well as promoting, among other things, public health and environmental protection. Finally, Part V concludes that state laws mandating the labeling of genetically engineered foods benefit Americans and do not violate constitutional law

I. BACKGROUND ON AGRICULTURAL BIOTECHNOLOGY

Agricultural biotechnology is the use of recombinant DNA (rDNA) techniques and related tools to genetically engineer crops used for food, feed, and fiber.²⁹ The resulting products are known as "transgenic" or

^{28.} *International Labeling Laws*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/ issues/976/ge-food-labeling/international-labeling-laws (last visited Dec. 6, 2014).

^{29.} NAT'L CORN GROWERS ASS'N & U.S. GRAINS COUNCIL, AGRICULTURE BIOTECHNOLOGY REFERENCE GUIDE 37, 52, *available at* http://www.ncga.com/upload/files/documents/pdf/guide.pdf (last visited Dec. 6, 2014).

"genetically engineered."³⁰ Genetic engineering is not the same as traditional plant breeding, which involves identifying genetically similar plants with useful traits and crossing these plants to produce offspring with the desired characteristics. "[G]enetic engineering," in contrast, "is a powerful technology that allows scientists, for the first time ever, to combine genetic material from widely dissimilar and unrelated organisms—for example, bacterial genes with alfalfa genes or chicken genes with maize genes."³¹ In so doing, scientists produce combinations of genetic material that do not—and cannot—occur in nature.³²

A gene from one organism that scientists insert into a host organism of another species is called a "transgene," and organisms receiving the gene are "transgenic."³³ The transgenic construct consists of fragments of DNA assembled together in the laboratory. For example, for engineered "Roundup Ready" soybeans (the vast majority of current genetically engineered crop acreage is planted with Roundup Ready crops), the main part of the genetic construct—the coding region—is derived from a gene from the soil bacterium Agrobacterium (*Agrobacterium tumefaciens*) that allows plants to survive even when treated with the potent herbicide glyphosate.³⁴ This coding sequence was then fused to gene fragments from other species—cauliflower mosaic virus, petunia, and another strain of Agrobacterium—to control its expression in the host soybean plant.³⁵ Consider this explanation from *Scientific American* of how Roundup Ready crops were engineered by Monsanto:

^{30.} Ania Wiexzorek & Mark Wright, *History of Agricultural Biotechnology: How Crop Development has Evolved*, SCITABLE (2012), http://www.nature.com/scitable/knowledge/library/history-of-agricultural-biotechnology-how-crop-development-25885295.

^{31.} Brief for Union of Concerned Scientists, Ctr. for Responsible Genetics, et al. as Amici Curiae Supporting Respondents at 9–10, Monsanto Co. v. Geerton Seed Farms, 561 U.S. 139 (2010) (No. 09-475).

^{32.} See, e.g., Stanley N. Cohen et al., Construction of Biologically Functional Bacterial Plasmids In Vitro, 70 PROC. OF THE NAT'L ACAD. OF SCI. 3240–44 (1973) ("We describe here the construction of new plasmid DNA species [A] new plasmid has been constructed from two DNA species of entirely different origin").

^{33.} *Transgenic Crops: An Introduction and Resource Guide*, DEP'T OF SOIL AND CROP SCIENCES COLO. UNIV. (last updated March 11, 2004), http://www.cls.casa.colostate.edu/TransgenicCrops/what.html.

^{34.} Janet Carpenter & Leonard Gianessi, *Herbicide Tolerant Soybeans: Why Growers Are Adopting Roundup Ready Varieties*, 2 AGBIOFORUM 65, 65 (1999), *available at* http://agbioforum.org/ v2n2/v2n2a02-carpenter.pdf; U.S. DEP'T OF AGRIC., DRAFT PLANT PEST RISK ASSESSMENT FOR DOUBLE HERBICIDE-TOLERANT SOYBEAN (GLYCINE MAX) EVENT FG72, PETITION 09-328-01p (Sept. 2011).

^{35.} Jerry Adler, The Growing Menace From Superweeds, SCI. AM., May 2011, at 78.

A seven-year search for the right gene ended in an outflow pipe from a Monsanto facility in Louisiana. There researchers looking for organisms that could survive amid the glyphosate runoff discovered a bacterium that had mutated to produce a slightly altered form of the EPSPS enzyme. The altered enzyme made the same three amino acids but was unaffected by glyphosate. Scientists isolated the gene that coded for it and, along with various housekeeping genes (for control and insertion of the gene for the enzyme) collected from three other organisms, implanted it in soybean cells with a gene gun.

This is a brute-force technology in which the selected DNA is wrapped around microscopic specks of gold that are blasted at soybean embryos, in hopes that at least a few will find their way to the right place on a chromosome. Tens of thousands of trials resulted in a handful of plants that could withstand glyphosate and pass the trait down to their descendants. Starting in 1996, Monsanto began selling these soybean seeds as Roundup Ready. Seeds for glyphosate-resistant cotton, canola and corn followed soon after.³⁶

Scientists cannot control where they insert a foreign gene in a target plant genome.³⁷ Rather, the genes can end up anywhere within native plant genes, thereby interrupting these genes or altering their function.³⁸ One way to envision the process of genetic engineering is to think of the genome as a book and of individual genes as the sentences that make up that book. Genetic engineering pastes new sentences into the book randomly, without any regard for the words already there. In fact, researchers rely on this process when they want to interrupt plant genes at random to study the effects of the resulting damage.³⁹ Moreover, the process whereby genetic engineering inserts genes into the host plant genome can be unpredictable. Genes may be inserted multiple times, in multiple locations, as intact genes or as gene fragments.⁴⁰

^{36.} Id.

^{37.} Martin Dagoberto, *Life, the Remix*, GENEWATCH, Jan.-March 2013, at 28, 29, *available at* http://www.councilforresponsiblegenetics.org/GeneWatch/GeneWatchPage.aspx?pageId=466.

^{38.} Id.

^{39.} Patrick J. Krysan et al., *T-DNA as an Insertional Mutagen in Arabidopsis*, 11 PLANT CELL 2283, 2283 (1999); Michael R. Sussman et al., *The Arabidopsis Knockout Facility at the University of Wisconsin-Madison*, 124 PLANT PHYSIOLOGY 1465, 1465 (2000); J. Alonso et al., *Genome-Wide Insertional Mutagenesis of Arabidopsis thaliana*, 301 SCIENCE 653 (2003).

^{40.} Sussman et al., *supra* note 39, at 1466; *Arabidopsis Sequence Indexed TDNA Insertion— Project FAQ*, SALK INST. GENOMIC ANALYSIS LAB., http://signal.salk.edu/tdna_FAQs.html (last visited Dec. 6, 2014) ("Approximately 50% of the lines contain a single insert [of foreign gene sequence], the

As this background illustrates, genetic engineering is an imprecise technology that causes random and, in some cases, large-scale mutations in crop genomes.⁴¹ It has a higher potential for generating unintended and potentially adverse human health effects than conventional breeding methods.⁴² In sum, genetic engineering is a novel technology with no demonstrated history of safe use.

Prefacing genetically engineered crops, the first patent on life was established in 1980 by the landmark case *Diamond v. Chakrabarty*, in which the U.S. Supreme Court ruled by a 5-4 margin that a living organism (in this instance, an engineered bacterium intended to clean up oil spills) could be patented.⁴³ According to the Court, because the patentee had introduced new genetic material within the bacterium cell, he had produced something that was not a product of nature and could thus be patentable subject matter.⁴⁴ *Chakrabarty* paved the way for the U.S. Patent and Trademark Office to decide in 1985 that sexually reproducing plants are patentable under the Patent Act, providing stronger protection and greater profit potential for seed companies.⁴⁵ Previously, such plants were only protected under the 1970 Plant Variety Protection Act, which created temporary exclusivity of use but exempted farmers, who could save and replant seed, and plant researchers, who could use protected varieties to breed improved plants.⁴⁶ In 2001, the 5-4 Supreme Court decision in *J.E.M.*

- 43. Diamond v. Chakrabarty, 447 U.S. 303, 304-05 (1980).
- 44. Id. at 307, 309–11.

other 50% of lines contain two or more inserts."). Both academic researchers studying weeds, *see id.*, and researchers at Monsanto's own facilities working with Roundup Ready transgenic crops have observed this phenomenon. Barry Palevitz, *DNA Surprise*, THE SCIENTIST (July 24, 2000), http://www.the-scientist.com/?articles.view/articleNo/12942/title/DNA-Surprise/.

^{41.} Allison K. Wilson, Jonathan R. Latham & Ricarda A. Steinbrecher, *Transformation-induced Mutations in Transgenic Plants: Analysis and Biosafety Implications*, 23 BIOTECHNOLOGY & GENETIC ENGINEERING REVS. 209, 222–23 (2006).

^{42.} COMM. ON IDENTIFYING AND ASSESSING UNINTENDED EFFECTS OF GENETICALLY ENGINEERED FOODS ON HUMAN HEALTH, INST. OF MED. & NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS 64, 65 fig. 3 (2004).

^{45.} Ex parte Hibberd, 227 U.S.P.Q. 443, 1985 WL 71986 at * 7 (B.P.A.I. Sept. 18, 1985).

^{46.} See 7 U.S.C. § 2543 (2012) (stating that the law does not interfere with the right "for a person to save seed produced by the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on the farm of the person"); J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Intern., Inc., 534 U.S. 124, 140 (2001) ("PVPA also contains exemptions for saving seed and for research. A farmer who legally purchases and plants a protected variety can save the seed from these plants for replanting on his own farm."). In addition, a protected variety for plant breeding or other bona fide research shall not

Ag Supply v. Pioneer Hi-Bred International upheld the granting of utility patents—which do not have similar exemptions—for plants.⁴⁷ These decisions opened the flood gates of expansive intellectual property rights in genetically engineered organisms and crops.

Consequently, firms raced to patent genetic resources and plant breeding technologies, and to purchase existing seed companies. The agricultural biotechnology industry emerged when chemical and pesticide companies such as Monsanto, DuPont, Syngenta, Bayer, and Dow rapidly acquired existing seed firms.⁴⁸ Dozens of mergers and acquisitions followed: At least 200 independent seed companies were bought and consolidated from 1996–2009.⁴⁹ Now, six dominant firms in the agricultural chemical market also account for 66% of the global commercial seed market.⁵⁰

As smaller and independent companies disappeared, farmers encountered fewer non-genetically engineered seed options, as well as higher prices.⁵¹ Based on seed patents, companies currently require farmers to sign contracts called "technology use agreements," which prohibit saving and replanting the seed in the age-old farming tradition and instead require farmers to repurchase seed annually; these companies vigorously prosecute farmers for suspected violations of contract terms.⁵²

constitute an infringement of the protection provided under this chapter."). The utility patent statute does not contain similar exemptions. 35 U.S.C. § 101 (2012).

^{47.} J.E.M. Ag Supply, Inc., 534 U.S. at 127, 129, 140, 145. In J.E.M. Ag Supply, Inc., the petitioner argued that utility patents could not be issued for plants because the Plant Variety Protection Act, 7 U.S.C. § 2321 (for sexually reproducing plants like corn and soybeans) and the Plant Patent Act, 35 U.S.C. §161 (for plants reproducing asexually, i.e., through grafting) were the exclusive federal statutory tools for acquiring patent-like protection for plants. The Supreme Court disagreed and held that utility patents could be issued for plants. J.E.M. Ag Supply, 534 U.S. at 145.

^{48.} Philip H. Howard, Visualizing Consolidation in the Global Seed Industry: 1996-2008, 1 SUSTAINABILITY 1266, 1272–74 (2009).

^{49.} KRISTINA HUBBARD, FARMER TO FARM CAMPAIGN ON GENETIC ENGINEERING, OUT OF HAND: FARMERS FACE THE CONSEQUENCES OF A CONSOLIDATED SEED INDUSTRY 4 (Dec. 2009), *available at* http://farmertofarmercampaign.com/Out%20of%20Hand.FullReport.pdf.

^{50.} ETC GROUP, WHO WILL CONTROL THE GREEN ECONOMY 22, 25 (Nov. 2011), *available at* http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/pdf_file/ETC_wwctge_4web_Dec2011.pdf.

^{51.} HUBBARD, *supra* note 49, at 25–38.

^{52.} *Id.* at 46; Monsanto Co. v. Parr, 545 F. Supp. 2d 836, 838 (N.D. Ind. 2008); Monsanto Co. v. Scruggs, 459 F.3d 1328, 1333 (Fed. Cir. 2006); Monsanto Co. v. McFarling, 363 F.3d 1336 (Fed. Cir. 2004); Monsanto Co. v. Trantham, 156 F. Supp. 2d 855 (W.D. Tenn. 2001); *see generally* CTR. FOR FOOD SAFETY, REPORT, MONSANTO V. U.S. FARMERS 13, 23–48, app. A (2005), *available at* http://www.centerforfoodsafety.org/files/cfsmonsantovsfarmerreport11305.pdf (discussing the lawsuits brought against farmers for violating technology use agreements).

U.S. adoption of transgenic crops has been rapid but primarily limited to the major commodity crops, in which genetically engineered varieties now make up the vast majority: soybean (94% transgenic in 2014), cotton (96% in 2014), corn (93% in 2014), and canola (95% in 2008).⁵³ So far, genetically engineered food has been an American-dominated experiment: In 2009 in the United States, total acreage was 158 million acres, dwarfing that of the next closest countries, which are Brazil (52 million), Argentina (52 million), Canada (20 million), India (20 million), and China (9 million).⁵⁴ These six countries make up 95% of the world's transgenic cultivation.⁵⁵ In stark contrast, the total global acreage of transgenic crops is under 3% of all agricultural land, with 97% remaining non-transgenic.⁵⁶

Crucially, despite a quarter century of promises and fifteen years of commercialization, "agricultural biotechnology has failed to make any progress towards reducing world hunger, ameliorating global malnutrition, combating global warming, or creating miracle drugs through GE plant and animal 'biofactories.'"⁵⁷ Instead, biotechnology firms have delivered a handful of genetically engineered commodity crops that produce pesticides and/or withstand direct application of herbicides.⁵⁸ Herbicide resistance lends crops the ability to survive direct application of a broad-spectrum herbicide that kills nearby weeds.⁵⁹ Over five of every six acres of transgenic crops worldwide (85%) are engineered for herbicide resistance.⁶⁰

^{53.} For soybean, cotton and corn, *see Adoption of Genetically Engineered Crops in the U.S.*, U.S. DEP'T AGRIC., http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-cropsin-the-us.aspx#.U_4nt0uwyao (last updated Aug. 26, 2014) (follow "Genetically engineered varieties of corn, upland cotton, and soybeans, by State and for the United States, 2000-14" link to Excel spreadsheet). For canola in North Dakota, where most U.S. canola is grown, *see* RICH ZOLLINGER ET AL., N.D. STATE UNIV. EXTENSION SERV., PESTICIDE USE AND PEST MANAGEMENT PRACTICES IN NORTH DAKOTA 2008 at 23 tbl.21 (2009), *available at* http://library.ndsu.edu/tools/dspace/load/?file=/ repository/bitstream/handle/10365/16357/w1446final20100616.pdf?sequence=1.

^{54.} See, e.g., A Recession Ends, the Fall Campaign Revs Up, WALL ST. J. (Sept. 25, 2010, 12:01 AM), http://online.wsj.com/article/SB10001424052748703384204575510561292390660.html? KEYWORDS=high-tech+harvest (select "High Tech Harvest: Genetically Modified Crops are Growing Up" infographic).

^{55.} FRIENDS OF THE EARTH INT'L, WHO BENEFITS FROM GE CROPS? 7 (Feb. 2011), available at http://www.foei.org/wp-content/uploads/2014/04/18-foei-who-benefits-report-mr.pdf

^{56.} Id. at 7.

^{57.} George Kimbrell & Paige Tomaselli, A "Fisheye" Lens on the Technological Dilemma: The Specter of Genetically Engineered Animals, 18 ANIMAL L. 75, 90 (2011).

^{58.} DIANA DONLON, FOOD AND CLIMATE: CONNECTING THE DOTS, CHOOSING A WAY FORWARD 21 (Cameron Harsh et al. eds., Mar. 2014), *available at* http://www.centerforfoodsafety.org/files/foodclimate_51242.pdf.

^{59.} Id. at 21.

^{60.} Ctr. For Food Safety, *Genetically Modified (GM) Crops and Pesticide Use* 1 (Feb. 2009), http://www.co.lake.ca.us/Assets/BOS/GE+Crops+Committee/6.+GM+Crops+and+Pesticide+Use.pdf.

And although the industry claims that these herbicide-resistant crops increase yields, the only independent study of their results (by the Union of Concerned Scientists) concluded that they *do not*, but noted that traditional breeding successes *do* increase yields.⁶¹

Monsanto, which is now the world's largest seed company,⁶² has used genetic engineering primarily to create patented "Roundup Ready" crops for use with its Roundup herbicide. In the United States, the vast majority (more than 95%) of herbicide-resistant soybean crops are glyphosate-resistant, with glyphosate being the active ingredient in Monsanto's Roundup.⁶³ American soybeans, corn, cotton, canola, and sugar beets are now primarily Roundup Ready.⁶⁴ This has made glyphosate the most heavily used chemical pesticide in history, with approximately 250 million pounds applied in U.S. agriculture in 2011 alone.⁶⁵ In the sixteen years from

[T]he first report to closely evaluate the overall effect genetic engineering has had on crop yields in relation to other agricultural technologies. It reviewed two dozen academic studies of corn and soybeans, the two primary genetically engineered food and feed crops grown in the United States. Based on those studies, the UCS report concluded that genetically engineering herbicide-tolerant soybeans and herbicide-tolerant corn has not increased yields. Insect-resistant corn, meanwhile, has improved yields only marginally. The increase in yields for both crops over the last 13 years, the report found, was largely due to traditional breeding or improvements in agricultural practices.

Failure to Yield: Evaluating the Performance of Genetically Engineered Crops (2009), UNION OF CONCERNED SCIENTISTS (Apr. 2009), http://www.ucsusa.org/food_and_agriculture/our-failing-food-system/genetic-engineering/failure-to-yield.html.

62. Chittur Subramanian Srinivasan, *Concentration in Ownership of Plant Variety Rights:* Some Implications for Developing Countries, 28 FOOD POL'Y 519, 525 tbl. 1 (2003).

63. MADELINE FISHER, MANY LITTLE HAMMERS: FIGHTING WEED RESISTANCE WITH DIVERSIFIED MANAGEMENT 5 (Sept. 2012), *available at* https://www.agronomy.org/files/publications/ csa-news/many-little-hammers.pdf.

64. USDA figures show that 94% of all soybeans, 91% of all cotton, and 89% of all corn grown in the United States in 2014 were genetically engineered, herbicide-resistant varieties—nearly all Roundup Ready. *Adoption of Genetically Engineered Crops in the United States: 1996–2014*, U.S. DEP'T OF AGRIC., http://www.ers.usda.gov/media/185551/biotechcrops_d.html (last visited Dec. 6, 2014) (showing entries for HT [herbicide-tolerant] soybeans, cotton and corn). Nearly all genetically engineered, herbicide-resistant crops are Roundup Ready. *See* William Neuman & Andrew Pollack, *Farmers Cope with Roundup-Resistant Weeds*, N.Y. TIMES (May 3, 2010), http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?_r=1&pagewanted=all ("Today, Roundup Ready crops account for about 90 percent of the soybeans and 70 percent of the corn and cotton grown in the United States.").

65. Pesticide National Synthesis Project, *Pesticide Use Maps—Glyphosate*, U.S. GEOLOGICAL SURVEY (2011), http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2011& map=GLYPHOSATE&hilo=L&disp=Glyphosate.

^{61.} DOUG GURIAN-SHERMAN, UNION OF CONCERNED SCIENTISTS, FAILURE TO YIELD: EVALUATING THE PERFORMANCE OF GENETICALLY ENGINEERED CROPS 1–5 (Apr. 2009), available at http://www.ucsusa.org/sites/default/files/legacy/assets/documents/food_and_agriculture/failure-to-yield.pdf. *Failure to Yield* was:

1996 to 2011, U.S. agriculture sprayed an extra 527 million pounds of herbicides because of genetically engineered crops.⁶⁶

The extraordinary use of pesticides associated with genetically engineered crops has had profound environmental consequences. For example, over the past two decades, the massive use of glyphosate with Roundup Ready crops has contributed to an alarming decline in the monarch butterfly population east of the Rocky Mountains.⁶⁷ Monarch caterpillars feed only on milkweed plants,⁶⁸ which were once common in corn and soybeans fields. However, glyphosate has nearly eradicated common milkweed from cropland in the Midwest, the monarchs' major breeding range, thus depriving monarch caterpillars of their chief food source.⁶⁹ Glyphosate is also a leading culprit in herbicidal drift injury to sensitive crops.⁷⁰ Thus, it may also injure wild plants that pollinators and many other organisms depend upon for food (i.e., as a source of nectar), as well as habitat in agriculture-dominated landscapes like the Midwest.⁷¹ Glyphosate is so heavily used that it is frequently detected in the air, rain, and water bodies of the Midwest and South.⁷² Glyphosate-containing Roundup formulations are extremely toxic to tadpoles and frogs and likely have contributed to the worldwide decline in frog populations.⁷³

The dramatic surge in glyphosate use with Roundup Ready crops is also responsible for an epidemic of "superweeds" that have evolved a resistance to the herbicide on over 60 million acres in the United States

^{66.} Charles M. Benbrook, *Impacts of genetically engineered crops on pesticide use in the* U.S.—the first sixteen years, 24 ENVTL. SCI. EUR. 1, 3 (2012) available at http://www.enveurope.com/ content/pdf/2190-4715-24-24.pdf.

^{67.} After 90 Percent Decline, Federal Protection Sought for Monarch Butterfly, CTR. FOR FOOD SAFETY (Aug. 26, 2014), http://www.centerforfoodsafety.org/press-releases/3418/after-90-percent-decline-federal-protection-sought-for-monarch-butterfly.

^{68.} *Id*.

^{69.} Id. 70. Assoc. of Am. Pesticide Control

^{70.} Assoc. of Am. Pesticide Control Officials, 2005 Pesticide Drift Enforcement Survey Report, http://www.aapco.org/documents/surveys/DriftEnforce05Rpt.html (last visited Dec. 6, 2014).

^{71.} After 90 Percent Decline, Federal Protection Sought for Monarch Butterfly, supra note 67.

^{72.} Feng-Chih Chang, Matt F. Simcik & Paul D. Capelz, Occurrence and Fate of the Herbicide Glyphosate and its Degradate Aminomethylphosphonic Acid in the Atmosphere, 30 ENVTL. TOXICOLOGY AND CHEMISTRY 548, 548–50 (2011); Richard H. Coupe et. al., Fate and Transport of Glyphosate and Aminomethylphosphonic Acid in Surface Waters of Agricultural Basins, 68 PEST MGMT. Sci. 16, 16–17 (2012).

^{73.} See Rick A. Relyea, *The Lethal Impact of Roundup on Aquatic and Terrestrial Amphibians*, 15 ECOLOGICAL ADAPTATIONS 1118, 1120–23 (2005) (concluding that exposure to Roundup causes high mortality rates in tadpoles and terrestrial amphibians, but that it is unclear whether the increase was due to the surfactant or the active ingredient glyphosate).

alone⁷⁴—an area the size of Wyoming. In response, pesticide firms are poised to introduce a host of "next-generation" genetically engineered crops resistant to multiple toxic herbicides, such as Agent Orange component 2,4-D and the closely related dicamba.⁷⁵ Far from providing a solution to glyphosate-resistant weeds, these new genetically engineered crops will lead to vastly increased herbicide use, such as a three- to seven-fold rise in agricultural use of 2,4-D, and increasingly intractable weeds resistant to multiple herbicides.⁷⁶ The chemical 2,4-D is linked to higher risk of cancer,⁷⁷ Parkinson's disease,⁷⁸ and developmental disorders,⁷⁹ and is also an environmental toxin.⁸⁰ Increased spraying of 2,4-D-resistant crops will exacerbate these impacts. Genetically engineered crops resistant to multiple herbicides are agricultural biotechnology's major research and development focus.⁸¹ If approved by the U.S. government and widely planted, crops engineered for resistance to multiple herbicides will cause incalculable

80. Freese, Comments to USDA, supra note 76.

81. See Petitions for Determinations of Nonregulated Status, U.S. DEP'T OF AGRIC., http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml (last visited Dec. 6, 2014) (showing GE crops resistant and tolerant to multiple herbicides represent a major part of research and developmental focus in agricultural biotechnology).

^{74.} Benbrook, *supra* note 66, at 1–2, 4; Kent Fraser, *Glyphosate Resistant Weeds*— *Intensifying, Stratus Research*, STRATUS AGRIC. RESEARCH (Jan. 25, 2013), http://www.stratusresearch.com/blog/glyphosate-resistant-weeds-intensifying; *see generally* CHARLES BENBROOK, IMPACTS OF GENETICALLY ENGINEERED CROPS ON PESTICIDE USE IN THE UNITED STATES: THE FIRST THIRTEEN YEARS 3, 23, 31, 36 (2009) (outlining the problem of herbicide resistance due to Roundup Ready crops), *available at* http://www.organic-center.org/reportfiles/GE13YearsReport.pdf.

^{75.} See Bill Freese, Going Backwards: Dow's 2, 4-D-Resistant Crops and More Toxic Future, FOOD SAFETY REV. (Ctr. for Food Safety, Wash., D.C.), Winter 2012, at 3, available at http://www.centerforfoodsafety.org/files/fsr_24-d.pdf (detailing the newest plans to engineer crops to be resistant to more pesticides).

^{76.} Bill Freese, Comments to USDA APHIS on Dow AgroSciences LLC; Draft Environmental Impact Statement for Determination of Nonregulation Status of Herbicide Resistant Corn and Soybeans at 9 (Mar. 11, 2014), *available at* http://www.centerforfoodsafety.org/files/cfs-enlist-draft-eis-science-comments-i_77655.pdf; Bill Freese & Martha L. Crouch, Comments to EPA on Notice of Receipt of Application to Register New Use of Dicamba on Monsanto's Dicamba-Resistant MON 87708 Soybean at 2 (Sept. 21, 2012), *available at* http://www.centerforfoodsafety.org/files/cfs-science-comments-on-dicamba-use-registration-for-dicamba-resistant-soybeans.pdf.

^{77.} See, e.g., Leah Schinasi & Maria E. Leon, Non-Hodgkin Lymphoma and Occupational Exposure to Agricultural Pesticide Chemical Groups and Active Ingredients: A Systematic Review and Meta-Analysis, 11 INT'L J. ENVTL. RES. & PUB. HEALTH 4449, 4520 (2014) (finding that 2, 4-D may be a carcinogen to humans).

^{78.} Caroline M. Tanner et al., *Occupation and Risk of Parkinsonism*, 66 ARCHIVES OF NEUROLOGY 1106, 1112 (2009).

^{79.} Vincent F. Garry et. al, *Pesticide Appliers, Biocides, and Birth Defects in Rural Minnesota*, 104 ENVTL. HEALTH PERSP. 394, 394 (1996), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1469337/pdf/envhper00335-0054.pdf (noting that pesticide exposure is linked to increased birth defects).

harm to human health and the environment through vastly increased use of toxic weed-killers.

Finally, another major impact of genetically engineered crops is genetic, or transgenic, contamination—the unintended, undesired presence of transgenic material in organic or conventional (non-genetically engineered) crops, as well as wild plants. Transgenic contamination happens through, among other means, wind or insect pollen drift, seed mixing, faulty or negligent containment, and weather events.⁸²

Harm from transgenic contamination manifests in several ways. As the U.S. Supreme Court has explained, this "injury has an environmental as well as an economic component."⁸³ The agronomic injury can cause significant and widespread economic damage: Past transgenic contamination episodes have cost U.S. farmers billions of dollars.⁸⁴ In addition, the harm is irreparable because once contamination occurs, it becomes difficult, if not impossible, to contain, resulting in a fundamental loss of choice for farmers and consumers.⁸⁵ Unlike standard chemical

^{82.} See Geertson Seed Farms v. Johanns, No. C 06-01075 CRB, 2007 WL 518624, at *4 (N.D. Cal. Feb. 13, 2007) ("Biological contamination can occur through pollination of non-genetically engineered plants or by the mixing of genetically engineered seed with natural, or non-genetically engineered seed."); Michelle Marvier & Rene C. Van Acker, *Can Crop Transgenes Be Kept on a Leash*?, 3 FRONTIERS ECOLOGY & ENV'T 99, 100–01 (2005) ("The movement of transgenes follows many different routes. The most obvious one is via pollen, which can be carried long distances by either wind or pollinators.").

^{83.} Monsanto Co. v. Geertson Seed Farms, 561 U.S. 139, 155 (2010).

^{84.} See Carey Gillam, U.S. Organic Food Industry Fears GMO Contamination, REUTERS (Mar. 12, 2008), http://in.reuters.com/article/2008/03/12/biotech-crops-contaminationidINN1216250820080312 (describing the struggle for farmers and natural food retailers in light of the threat to the purity of organic crops); Andrew Harris & David Beasley, *Bayer Agrees to Pay \$750 Million to End Lawsuits Over Gene-Modified Rice*, BLOOMBERG (July 2, 2011), http://www.bloomberg.com/news/2011-07-01/bayer-to-pay-750-million-to-end-lawsuits-over-

genetically-modified-rice.html (reporting \$750 million dollar settlement from genetically engineered rice contamination class action litigation); K.L. Hewlett & G.S.E. Azeez, *The Economic Impacts of GM Contamination Incidents on the Organic Sector* (2008), *available at* http://orgprints.org/12027/1/The_Economic_Impacts_of_GM_Contamination_Incidents_on_the_Organic_Sector.pdf (examining the global economic impact of GM crops); Stuart Smyth et al., *Liabilities and Economics of Transgenic Crops*, 20 NATURE BIOTECH. 537, 538–39 (2002) (discussing the large economic burden of rectifying past contaminations).

^{85.} See, e.g., Geertson Seed Farms, 2007 WL 518624, at *9 ("For those farmers who choose to grow non-genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop."); *see also*, Ctr. for Food Safety v. Vilsack, No. C 08–00484 JSW, 2009 WL 3047227, at *8 (N.D. Cal. Sept. 21, 2009) (affirming that "[a] federal action that eliminates a farmer's choice to grow non-genetically engineered crops, or a consumer's choice to eat non-genetically engineered food, is an undesirable consequence") (internal quotation marks omitted) (quoting *Geertson Seed Farms*, 2007 WL 518624, at *8 (N.D. Cal. Feb. 13, 2007)).

pollution, transgenic contamination is a living pollution that can propagate itself over space and time via gene flow.⁸⁶ In fact, the risk of contamination itself creates costly burdens for organic and conventional farmers and businesses, such as the need for contamination testing or buffer zones.⁸⁷

In addition to economic harms, the escape of transgenes into wild or feral plant populations is, in most cases, irreparable.⁸⁸ Oregon, for example, continues the Sisyphean task of trying to find and destroy feral populations of Monsanto's "Roundup Ready" genetically engineered bentgrass that escaped field trials in that state over a decade ago.⁸⁹ Such transgenic contamination is widespread and has been documented around the world,⁹⁰

87. Geertson Seed Farms, 561 U.S. at 154.

88. See, e.g., DOUG GURIAN-SHERMAN, CONTAMINATING THE WILD? GENE FLOW FROM EXPERIMENTAL FIELD TRIALS OF GENETICALLY ENGINEERED CROPS TO RELATED WILD PLANTS 1, 6 (2006), available at http://www.centerforfoodsafety.org/files/contaminating_the_wild_report_41399.pdf (presenting evidence that genetically engineered crops pose a risk to wild populations if genetically modified genes are allowed to merge with feral plants).

89. Mitch Lies, *Feds Mum on GMO Spread*, CAPITAL PRESS (Nov. 18, 2010, 3:01 AM), http://www.capitalpress.com/content/ml-bentgrass-111910#.U9IGp_ldVZo; *see* Int'l Ctr. Tech. Assessment v. Johanns, 473 F. Supp. 2d 9, 13, 29 (D.D.C. 2007) (citing Ctr. for Food Safety v. Johanns, 451 F. Supp. 2d 1165, 1183–86 (D. Haw. 2006)) (holding that agency's oversight of field trials, which resulted in the contamination of a National Grassland, violated the National Environmental Policy Act); *see also* Lies, *Bentgrass, supra* note 86 (discussing the escape of genetically modified bentgrass in Oregon).

90. Transgenes Escape into the Wild, supra note 86, at 7; Rex Dalton, Modified Genes Spread to Local Maize, 456 NATURE 149, 149 (2008); Maria Isabel Manzur, Chile Enters the List of Countries Contaminated With GMOs, NW RESISTANCE AGAINST GENETIC ENG'G, http://www.nwrage.org/ content/chile-enters-list-countries-contaminated-gmos (last visited Dec. 6, 2014) ("During 2007, 216 cases of transgenic contamination were registered in 57 countries, which means that contamination is widespread in the world."); Graeme Smith, Illegal GM Crops are Found In Scotland, HERALD SCOTLAND (Sept. 13, 2008), http://www.heraldscotland.com/illegal-gm-crops-are-found-in-scotland-1.889451; Elizabeth Rosenthal, Questions on Biotech Crops with No Clear Answers, N.Y. TIMES (June 6, 2006), http://www.nytimes.com/2006/06/06/business/worldbusiness/06geneside.html; Gene Flow Underscores Growing Concern over Biotech Crops, ASSOCIATED PRESS (Sept. 22, 2004), http://www.lobbywatch.org/archive2.asp?arcid=4384; Andrew Pollack, Can Biotech Crops Be Good Neighbors?, N.Y. TIMES (Sept. 26, 2004), http://www.nytimes.com/2004/09/26/weekinreview/26poll.html; Lyle F. Friesen et al., Evidence of Contamination of Pedigreed Canola (Brassica napus) Seedlots in Western Canada with Genetically Engineered Herbicide Resistance Traits, 95 AGRONOMY J. 1342, 1342–43 (2003); Simon Jeffery, Rogue Genes: An Unauthorised Strain of GM Crops Has Been

^{86.} Rachel Bernstein, *Study Details Wild Crop of Genetically Modified Canola*, PITTSBURGH POST-GAZETTE (Aug. 14, 2010, 12:00 AM), http://www.post-gazette.com/news/science/2010/08/14/ Study-details-wild-crop-of-genetically-modified-canola/stories/201008140136; *see Transgenes Escape into the Wild*, NEW SCIENTIST, Feb. 21, 2009, at 7 (describing a new study on transgenic contamination in Mexico); *Geertson Seed Farms*, 2007 WL 518624, at *5 ("Once the gene transmission occurs and a farmer's seed crop is contaminated with the Roundup Ready gene, there is no way for the farmer to remove the gene from the crop or control its further spread."); *see also* Mitch Lies, *Bentgrass Eradication Plan Unveiled*, CAPITAL PRESS (June 16, 2011) [hereinafter Lies, *Bentgrass*], http://www.capitalpress.com/content/ml-scotts-061711 (noting an example of transgenic seeds propagating several miles from the source site and their persistence over time).

with a report from an environmental organization documenting thirty-nine cases in 2007 and more than 200 in the last decade.⁹¹ Contamination incidents have not been limited to a single crop or region; rather, corn, rice, canola, alfalfa, and other crops have all been contaminated by transgenes. A 2008 U.S. Government Accountability Office (GAO) study analyzed several major transgenic contamination incidences from the past decade and stated that they may have caused over a billion dollars in damages.⁹² The GAO concluded, "the ease with which genetic material from crops can be spread makes future releases likely."⁹³

II. STATE LABELING IS FULLY CONSISTENT WITH FEDERAL PREEMPTION DOCTRINE

Preemption is the basic principle that, under the Supremacy Clause of the U.S. Constitution, state laws that conflict with federal law are "without effect" and preempted.⁹⁴ Federal law can preempt state law through express preemption, field preemption, or implied conflict preemption.⁹⁵ As the Supreme Court has explained:

Congress' intent may be explicitly stated in the statute's language or implicitly contained in its structure and purpose. In the

Found Across England and Scotland, GUARDIAN (Aug. 16, 2002), http://www.theguardian.com/science/2002/aug/16/gm.food/print; Alex Roslin, *Modified Pollen Hits Organic Farms: Genetically Altered Strains Spread by Wind*, TORONTO STAR (Sept. 30, 2002), http://pqasb.pqarchiver.com/thestar/doc/438493453.html; Fred Pearce, *The Great Mexican Maize Scandal*, NEW SCIENTIST, June 15, 2002, at 14.

^{91.} GREENPEACE INT'L, GM CONTAMINATION REGISTER REPORT 2007 at 5 (2008), *available at* http://www.greenpeace.org/international/press/reports/gm-contamination-register-2007; Gillam, *supra* note 84.

^{92.} See U.S. GOV'T ACCOUNTABILITY OFFICE, GENETICALLY ENGINEERED CROPS: AGENCIES ARE PROPOSING CHANGES TO IMPROVE OVERSIGHT, BUT COULD TAKE ADDITIONAL STEPS TO ENHANCE COORDINATION AND MONITORING 1, 14–16, 44 (Nov. 2008) [hereinafter *GAO Report*], available at http://www.gao.gov/new.items/d0960.pdf ("After two decades of experience with field trials, it is widely acknowledged that unauthorized releases of regulated material from field trial sites are likely to occur in the future").

^{93.} Id. at 3.

^{94.} Maryland v. Louisiana, 451 U.S. 725, 746 (1981); *see*, *e.g.*, M'Culloch v. Maryland, 17 U.S. (4 Wheat.) 316, 427 (1819) ("It is of the very essence of supremacy to remove all obstacles to [a supreme government's] action within its own sphere").

^{95.} Holk v. Snapple Beverage Corp., 575 F.3d 329, 334 (3d Cir. 2009) (citing Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985)); *Hillsborough Cnty., Fla.*, 471 U.S. at 713 (citing Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977), Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)); *see id.* (reviewing the forms of preemption which arise under the Supremacy Clause).

absence of an express congressional command, state law is preempted if that law actually conflicts with federal law, or if federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it.⁹⁶

Notably, preemption analysis is not undertaken on a clean slate; rather, it is guided by two fundamental principles. "First, 'the purpose of Congress is the ultimate touchstone in every preemption case.""⁹⁷ Second, courts begin with the "assumptions that the historic police powers of the States" are not to be preempted by a federal statute "unless that was the clear and manifest purpose of Congress."⁹⁸ This "presumption against preemption" applies in the context of state-mandated labeling of genetically engineered foods because such labeling concerns health and safety,⁹⁹ as well as food and beverage labeling and branding, which are areas traditionally "within the province of state regulation."¹⁰⁰ This presumption applies to both express and implied preemption, regardless of whether there is federal regulation in the area.¹⁰¹ Finally, even assuming that this presumption is overcome, if a preemption clause is susceptible to multiple interpretations, a court "ha[s] a duty to accept the reading that disfavors preemption."¹⁰²

^{96.} Cipollone v. Liggett Grp., 505 U.S. 504, 516 (1992) (internal citations and quotation marks omitted).

^{97.} Wyeth v. Levine, 555 U.S. 555, 565 (2009) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (quoting Retail Clerks v. Schermerhorn, 375 U.S. 96, 103 (1963))).

^{98.} *Medtronic, Inc.*, 518 U.S. at 485 (1996) (internal quotation marks omitted) (quoting *Rice*, 331 U.S. at 230).

^{99.} See, e.g., Hillsborough Cnty., Fla., 471 U.S. at 716 (1985) (noting "the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation.").

^{100.} *Holk*, 575 F.3d at 334 (citing Plumley v. Massachusetts, 155 U.S. 461, 472 (1894)) ("Health and safety issues have traditionally fallen within the province of state regulation. This is true of the regulation of food and beverage labeling and branding."); *see Plumley*, 155 U.S. at 472 ("[I]f there be any subject over which it would seem the states ought to have plenary control . . . it is the protection of the people against fraud and deception in the sale of food products.").

^{101.} See Wyeth, 555 U.S. at 565–66 n.3 (2009) ("The presumption thus accounts for the historic presence of state law but does not rely on the absence of federal regulation.").

^{102.} Bates v. Dow Agrosciences, 544 U.S. 431, 449 (2005); *see also* Riegel v. Medtronic, Inc., 552 U.S. 312, 335 (2008) (quoting *Bates*, 544 U.S. at 432) (holding that the courts ordinarily disfavor preemption)).

A. Federal Oversight of Genetically Engineered Foods Does Not Preempt States

The overarching problem labeling opponents face is that their wishedfor federal preemption cannot emanate from a void; and that is basically the case with respect to U.S. laws regulating genetically engineered organisms. The United States has no single overarching law or federal agency that oversees the products of biotechnology. There are no laws that were drafted and passed with the intent to regulate genetically engineered organisms. Instead, the U.S. government oversees genetically engineered products using a mosaic of laws that predate the advent of biotechnology, implemented by several agencies. It is tough to see where the required "clear and manifest" congressional intent to preempt could stem from,¹⁰³ when Congress has never addressed genetically engineered organisms nor enacted any law intended to regulate them.

Instead, to oversee genetically engineered organisms, federal agencies apply their pre-existing legislative authorities, which were never intended for that purpose. This 1986 policy is known as the Coordinated Framework for the Regulation of Biotechnology (the Framework),¹⁰⁴ developed by a task force of the White House Office of Science and Technology Policy.¹⁰⁵ While revolutionary change in patent law was making genetic engineering profitable, public interest organizations began raising significant concerns about health and environmental safety. In fact, it was at this time that the first approval of experimental field testing (of a genetically engineered bacterium) was successfully challenged in court after the approving agency failed to analyze the potentially significant environmental impacts.¹⁰⁶ Demands by the growing biotechnology industry, which sought assurance of future commercialization and market stability, coupled with the growing uproar over its potential risks, culminated in the development of the Framework.¹⁰⁷ In setting this policy, the Reagan administration sought to both assure consumers that emerging, novel products had undergone government review and approval, and simultaneously protect U.S. technological advancements from international competition and

^{103.} Medtronic, Inc., 518 U.S. at 484 (citing Rice, 331 U.S. at 230).

^{104.} Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302 (June 26, 1986).

^{105.} Id. at 23,302-23,303.

^{106.} Found. on Econ. Trends v. Heckler, 756 F.2d 143, 145, 160 (D.C. Cir. 1985).

^{107.} See Environmental Implications of Genetic Engineering: Hearing Before the Subcomm. on Science, Research and Tech., Comm. on Sci. & Tech., 98th Cong. (1983) (discussing the development of genetic engineering, the purported benefits and concerns it presents, and efforts to resolve the concerns).

commercialization.¹⁰⁸ Notably, the biotech industry's influence and interests weighed heavily in the formulation of the policy.¹⁰⁹

Since that time, the FDA, the U.S. Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA) have shared responsibility for regulating products of biotechnology in the United States.¹¹⁰ The FDA oversees food safety issues and genetically engineered animals;¹¹¹ the EPA oversees the impacts of crops engineered with pesticidal substances, as well as transgenic microbes;¹¹² and the USDA regulates all other transgenic plants, overseeing their field trials and commercialization.¹¹³

A significant body of academic literature analyzes the Framework,¹¹⁴ which is beyond the scope of this Article. In summary, numerous scholars

^{108.} See, e.g., Kurt Eichenwald et al., Biotechnology Food: From the Lab to a Debacle, N.Y. TIMES (Jan. 25, 2001), http://www.nytimes.com/2001/01/25/business/25FOOD.html. According to Henry Miller, who oversaw biotech policy at FDA from 1979–1994: "In this area, the U.S. government agencies have done exactly what big agribusiness has asked them to do and told them to do." *Id.* Moreover, "[e]ven longtime Washington hands said that the control this nascent industry exerted over its own regulatory destiny—through the Environmental Protection Agency, the Agriculture Department and ultimately the Food and Drug Administration—was astonishing." *Id.*

^{109.} See *id.* (quoting a senior research fellow responsible for biotechnology issues at the FDA, who stated, "In this area, the U.S. government agencies have done exactly what big agribusiness has asked them to do and told them to do").

^{110.} Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,303–04 (June 26, 1986).

^{111. 21} U.S.C. § 341–42 (1938) (providing FDA regulation of adulterated foods); Press Release, U.S. Food & Drug Admin., FDA Issues Final Guidance on Regulating Genetically Engineered Animals (Jan. 15, 2009), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ ucm109066.htm (describing FDA regulation of genetically engineered animals).

^{112.} See 7 U.S.C. § 136 (2006) (giving the EPA authority to regulate pesticides); see also EPA's Regulation of Biotechnology for Use in Pest Management, U.S. ENVTL. PROTECTION AGENCY (May 2014), http://www.epa.gov/oppbpd1/biopesticides/reg_of_biotech/eparegofbiotech.htm (outlining EPA's regulation of biotechnology).

^{113.} See Plant Protection Act, 7 U.S.C. §§ 7702(16), 7754 (2012) (granting the secretary of agriculture the authority to regulate genetically engineered plants); *How the Federal Government Regulates Biotech Plants*, U.S. DEP'T AGRIC., http://www.usda.gov/wps/portal/uusd/usdahome? contentidonly=true&contentid=biotech-plants.xml (last visited Dec. 6, 2014) (outlining federal regulation of genetically engineered plants).

^{114.} See, e.g., Rebecca Bratspies, Is Anyone Regulating? The Curious State of GMO Governance in the United States, 37 VT. L. REV. 923, 928–31 (2013) (examining the framework's history, purpose, and consequences); Gregory N. Mandel, Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals, 45 WM. & MARY L. REV. 2167, 2230–37 (2004) (exploring the framework's regulatory gaps, inconsistencies and overlap between the various agencies and their regulation of genetically engineered organisms); Keith Aoki, Food Forethought: Intergenerational Equity and Global Food Supply—Past, Present, and Future, 2011 WIS. L. REV. 399, 463–64 (2011) (concluding that inter-agency cooperation sounds good in theory, but the result has been ineffective regulation); Margaret R. Grossman, Biotechnology, Property Rights and the Environment, 50 AM. J. COMP. L. 215, 223–26 (2002) ("Congress has not enacted regulatory

have pointed out that the Framework's patchwork of shared responsibility leaves many holes in the oversight of genetically engineered organisms, resulting in "piecemeal and all together ineffective regulation,"¹¹⁵ and "sizable gaps in coverage, with the concomitant risk of significant harms slipping through the cracks and into the environment."¹¹⁶ Scholars have further noted that, under the Framework, "environmental risks posed by genetically engineered organisms are not addressed in a coherent manner," in part because there is no single law that governs the products of genetic engineering.¹¹⁷ In lieu of new legislation, the laws agencies use were

measures specifically designed to address the risks and concerns connected with biotechnology"); Rebecca Bratspies, Some Thoughts on the American Approach to Regulating Genetically Modified Organisms, 16 KAN. J.L. & PUB. POL'Y 393, 406-07 (2007) (criticizing the "substantial equivalence," doctrine for permitting agencies to act simultaneously as regulators and promoters for GE technology); John Charles Kunich, Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering, 74 S. CAL. L. REV. 807, 823-24 (2001) (criticizing the framework's conclusion that techniques of genetic engineering are not inherently risky and that genetic engineering is not regulated as a process, but rather that the products are regulated in the same way as products of any other technology); Douglas A. Kysar, Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice, 118 HARV. L. REV. 525, 558-59 (2004) (concluding that the framework embraced the "substantial equivalence" doctrine resulting in policymakers determining that no new laws were required to regulate GE organisms, and exploring criticisms that responsible agencies have diluted their powers in regulating GE crop varieties); Mary Jane Angelo, Regulating Evolution for Sale: An Evolutionary Biology Model for Regulating the Unnatural Selection of Genetically Modified Organisms, 42 WAKE FOREST L. REV. 93, 112-41 (2007) (providing a detailed history of the framework and the specific regulatory powers each agency has to regulate biotechnology); D. L. Uchtmann, Starlink—A Case Study of Agricultural Biotechnology Regulation, 7 DRAKE J. AGRIC. L. 159, 169–70 (2002) (exploring the framework and noting the fact that there was no alternative, all-encompassing biotechnology statute when the framework was developed); Doug Farquhar & Liz Meyer, State Authority to Regulate Biotechnology Under the Federal Coordinated Framework, 12 DRAKE J. AGRIC. L. 439, 457 (2007) ("Congress wrote many of the laws used to govern biotechnology before scientists even knew that rDNA modifications were possible, and the laws are not keeping pace with new technological developments."); Gregory N. Mandel, Toward Rational Regulation of Genetically Modified Food, 4 SANTA CLARA J. INT'L L. 21, 22, 38-39, 59 (2006) (exposing inefficiencies and overlap problems of regulatory power between the three agencies, and encouraging more communication between agencies).

115. Aoki, *supra* note 114, at 464; *see also* Angelo, *supra* note 114, at 142 (noting that the "agencies regulate in a piecemeal fashion with no clear standards to guide their decisions on whether a GMO should be permitted to be released into the environment"); Kunich, *supra* note 114, at 823 ("[M]ultiple agencies are charged with monitoring disparate portions of [GE regulations] with no effective means for ensuring comprehensive and consistent coverage."); Cinnamon Carlarne, *From the USA with Love: Sharing Home-Grown Hormones, GMOs, and Clones with A Reluctant Europe,* 37 ENVTL. L. 301, 318 (2007) ("[W]hile these three agencies participate in regulating GM products, regulatory authority is fragmented and no single agency has clear or decisive control. Due to its complexity, the U.S. regulatory regime lacks the type of clarity and coordination necessary to effectively handle such a weighty issue.").

116. Grossman, supra note 114, at 226.

117. See e.g., Kunich, supra note 114, at 823 (outlining the current state of the law regarding the regulation of GE plants).

written "before scientists even knew that rDNA modifications were possible" and, as a consequence, agencies have difficulty "keeping pace with new technological developments."¹¹⁸ In applying existing authorities under the Framework, scholars charge that U.S. agencies have made a mere "pastiche" of the laws and, as a result, "diluted these statutory powers" as applied to genetically engineered crops.¹¹⁹ These failings are due in part to the Framework's focus on the "products" rather than the "process" of genetic engineering.¹²⁰

As a result of the Framework's flawed paradigm, there have been "multiple failures on the part of regulatory agencies to recognize that genetically modified products sometimes do create new and different issues than those raised by the conventional products they routinely regulate."¹²¹ And federal agencies have not "adequately address[ed] the unique degree of exposure potential and the unique evolutionary impacts GMOs may have."¹²² Instead, the "limited nature of regulatory review" fails to result in

A major problem with "substantial equivalence" is that it permits agencies to act

simultaneously as regulators and promoters for this new technology

The Coordinated Framework assumes that 'by the time a genetically engineered product is ready for commercialization, it will have undergone substantial review and testing during the research phase, and thus, information regarding its safety should be available.' However, the limited nature of regulatory review shapes the development of safety information in a fashion that does not promote a full consideration of all risks associated with these novel organisms. Because of the assumption of substantial equivalence, the onus and burden of proof is on the authorities to prove that a GMO is unsafe before they may impose use restrictions. This is directly contrary to the European approach and has led to jockeying in the international trade context.

^{118.} Farquhar & Meyer, supra note 114, at 457.

^{119.} Kysar, supra note 114, at 559.

^{120.} See Uchtmann, supra note 114, at 208 ("On its surface, the regulatory system focuses on the 'products' of biotechnology, not the process. Nevertheless, the 'process' of biotechnology is often important as the trigger for special regulatory oversight."); Kysar, supra note 114, at 641 (arguing that the process/product distinction is responsible for many of the problems in regulating GE products); Mandel, Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals, supra note 114, at 2242 ("The cause of many of the deficiencies [of the framework]... can be traced to two problematic presumptions that formed the Coordinated Framework's foundation: (1) that the techniques of biotechnology are not inherently risky, and (2) that biotechnology should not be regulated as a process—that is, the products of biotechnology should be regulated in the same manner as conventionally created products."). Rebecca Bratspies has added that:

Bratspies, Some Thoughts on the American Approach to Regulating Genetically Modified Organisms, supra note 114, at 406–07 (quoting Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,304 (June 26, 1986)).

^{121.} Mandel, Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals, supra note 114, at 2243.

^{122.} Angelo, supra note 114, at 142.

a fulsome analysis of the risks of genetically engineered organisms.¹²³ In those ways, the U.S. system stands in stark contrast to the more precautionary approach the majority of the rest of the world takes.¹²⁴

In the legal preemption context, any reliance on the Framework is wholly misplaced, as the gaps and holes in the piecemeal and uncoordinated Framework demonstrate that the federal government has not "occupied" this field. But reliance on the Framework is not misplaced just because the Framework is the antithesis of coordinated or comprehensive.

More fundamentally, the Framework is *not a law*. It is neither a statute nor a regulation; instead, the Framework is merely a thirty-year-old *policy document*.¹²⁵ As a policy document, it neither carries the force of law nor purports to set statutory or regulatory standards.¹²⁶ Consequently, the Framework cannot be a source of preemption.¹²⁷

Further, for purposes of implied conflict or obstacle preemption, governmental policies are only relevant indicators of preemptive intent to the extent they are the result of *Congress's* "purposes and objectives."¹²⁸ In contrast, the Framework is an executive branch document; it was not established by, nor does it represent, any congressional purpose or directive. No statute's language or legislative history even mentions the Framework. In fact, because the Framework was not issued pursuant to any congressional delegation of authority, it is ineligible for any deference at

125. Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. at 23,302 ("Announcement of policy").

126. See, e.g., Found. on Econ. Trends v. Johnson, 661 F. Supp. 107, 109 (D.D.C. 1986) ("The Framework and definitions contained therein are set forth to guide policymaking, not to regulate.").

127. *See* Fellner v. Tri-Union Seafoods, 539 F.3d 237, 243 (3d Cir. 2008) ("[W]e must reiterate, lest the analysis become unmoored, that it is federal *law* which preempts contrary state law; nothing short of federal law can have that effect.") (emphasis in original).

^{123.} Bratspies, Some Thoughts on the American Approach to Regulating Genetically Modified Organisms, supra note 114, at 406–07.

^{124.} Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 186 (2006) ("[T]he U.S. approach differs greatly from the international approach embodied by the Codex principles and Cartagena Protocol, most significantly by not adopting the precautionary principle that would require premarket approval conditioned upon a case-by-case risk assessment to consider the intended and unintended effects of the GM product *before* its release. In promulgating its regulatory scheme, FDA appears to have given little weight to the scientific uncertainty and risks recognized by its EU counterparts as inherent in GMOs.").

^{128.} See Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372–73 (2000) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)) (stating that Federal law can impliedly preempt state law when it "conflicts," which means it is "impossible for a private party to comply with both," or when state law "stands as an *obstacle* to the accomplishment and execution of the *full purposes and objectives of Congress.*") (emphases added) (internal quotation marks omitted).

all.¹²⁹ The Framework is simply irrelevant for purposes of preemption analysis.

B. FDA's Genetically Engineered Foods Policy

The FDA applies its pre-existing authority to genetically engineered foods pursuant to the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA).¹³⁰ The FFDCA grants FDA the authority and imposes a statutory duty to regulate, among other things, food additives and adulterated foods; the act also prohibits the misbranding of food.¹³¹ The FFDCA does not address genetically engineered foods or labeling, and the FDA does not have specific regulations applying the FFDCA to genetically engineered foods.

Instead, as with the Framework, the FDA decided to interpret its statutory authority regarding genetically engineered foods in a "statement of policy" issued in 1992.¹³² In this guidance document, the FDA determined that genetically engineered substances added to food would be presumed by the agency to be "generally recognized as safe" (GRAS) and thus exempt from the food additive requirement.¹³³ Absent this policy pronouncement, genetically engineered substances would have been defined and classified as food additives (i.e., substances used in food or components of food or that might affect the characteristics of food) and thus would have required premarket safety testing, approval, and labeling.¹³⁴

^{129.} United States v. Mead, 533 U.S. 218, 226–27 (2001) (citing Chevron U.S.A. v. Natural Res. Def. Council, 467 U.S. 837, 842–43 (1984)) (holding that agency decisions that are not made pursuant to legislative directives are not entitled to deference under *Chevron*, but may be entitled to some deference if the agency's decision is based on a permissible construction of the statute).

^{130.} Genetically Engineered Foods: Hearing Before the S. Comm. on Basic Research, 106th Cong. (2009) (statement of James H. Maryanski, Biotechnology Coordinator, Food and Drug Admin.), available at http://www.fda.gov/newsevents/testimony/ucm115032.htm.

^{131. 21} U.S.C. §§ 331, 334, 341, 346 (2012); Holk v. Snapple Beverage Corp., 575 F.3d 329, 331 (3d Cir. 2009) (citing *Fellner*, 539 F.3d at 251).

^{132.} Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,985 (May 29, 1992); Consultation Procedures under FDA's 1992 Statement of Policy—Foods Derived from New Plant Varieties: Guidance on Consultation Procedures, U.S. FOOD & DRUG ADMIN. (Revised Oct. 1997), http://www.fda.gov/food/guidanceregulation/ucm096126.htm.

^{133.} Paulette Gaynor, *How U.S. FDA's GRAS Notification Program Works*, FOOD SAFETY MAG. Dec. 2005/Jan. 2006, *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/ucm083022.htm.

^{134. 21} U.S.C. § 348(b) (2012); see also Consultation Procedures under FDA's 1992 Statement of Policy, supra note 132 (detailing the process through which a firm may obtain FDA approval in regard to safety and labeling concerns).

Pursuant to the FDA's guidance, the manufacturer, not the FDA, determines whether a genetically engineered substance is GRAS, and any consultation with FDA on that decision is strictly voluntary.¹³⁵ Hence, it would be misleading to say that the FDA "approves" genetically engineered foods. The FDA neither makes an approval "finding" for genetically engineered foods nor undertakes any independent analysis of their health impacts or safety.¹³⁶ Rather, the FDA engages in a voluntary consultation with industry in which it reviews summaries of data industry chooses to present, and this process culminates in the agency sending a "no questions" letter conveying the developer's (not FDA's) assurances.¹³⁷

In *Alliance for Bio-Integrity v. Shalala*, the FDA's 1992 policy was challenged but upheld.¹³⁸ Internal FDA documents produced in the litigation showed that numerous FDA scientists raised objections to the policy and argued that potential unintended effects of the transformation

^{135.} See 21 U.S.C. § 348(b) (outlining the process by which unsafe food additives are deemed to be an exception and explaining the situations in which these additives may safely be used); Warren Ausubel, *Federal Regulation of Genetically Engineered Food Additives and Pesticides*, 4 HIGH TECH. L. J. 115, 131 (1989) (noting that a company may use a substance that is generally recognized as safe without providing notice to the FDA).

^{136.} See William Freese & David Schubert, Safety Testing and Regulation of Genetically Engineered Foods, 21 BIOTECH. & GENETIC ENG'G REVS. 299, 303–04 (2004) ("The review process... makes it clear that, contrary to popular belief, the FDA has not formally approved a single GE crop as safe for human consumption. Instead, at the end of the consultation, the FDA merely issues a short note summarizing the review process and a letter that conveys the crop developer's assurances that the GE crop is substantially equivalent to its conventional counterpart.").

^{137.} See Biotechnology Consultations on Food from GE Plant Varieties, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing (last visited Dec. 6, 2014) (listing industry consultations with the FDA and providing links to FDA memos and letters); *see also* Freese & Schubert, *supra* note 136, at 304–05 (describing the highly deferential review process the FDA engages in when analyzing a genetically engineered substance). An example of the language of a typical FDA response, from an April 13, 2011 letter to Dow on a corn engineered to be resistant to the pesticide 2,4-D:

Based on the safety and nutritional assessment Dow has conducted, it is our understanding that Dow has concluded that DAS-40278-9 corn is not materially different in any respect relevant to food or feed safety from corn varieties currently on the market and that the genetically engineered corn does not raise issues that would require premarket review or approval by FDA....

Based on the information Dow has provided to FDA, we have no further questions concerning the new corn variety, DAS-40278-9 corn, at this time. However, as you are aware, it is Dow's continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Letter from Mitchell A. Cheeseman, Acting Director, Office of Food Additive Safety, to Craig Blewett, Regulatory Leader, Dow AgroSciences LLC (Apr. 13, 2011), *available at* http://www.fda.gov/food/foodscienceresearch/biotechnology/submissions/ucm254643.htm.

^{138.} Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 170, 181 (D.D.C. 2000).

process involved in genetic engineering necessitated mandatory review before commercialization; they were overruled.¹³⁹

As that case established, the FDA's 1992 statement of policy regarding genetically engineered foods—like the Framework—does not have the force of law. In fact, the court in *Alliance for Bio-Integrity* specifically ruled against the idea that the FDA's 1992 guidance has the force of law by rejecting the plaintiffs' arguments that this statement of policy was subject to the Administrative Procedure Act's (APA) notice-and-comment procedures and the National Environmental Policy Act's (NEPA) analysis requirements because the statement was a guidance document, not a rule-making that had the force of law.¹⁴⁰

The plaintiffs in *Alliance* also challenged the FDA's decision not to require labeling, but the court upheld the agency's position that it lacked the authority to require labeling because it had concluded that the change (genetic engineering) did not meet its self-created definition of "materiality."¹⁴¹ The correctness of that decision aside,¹⁴² labeling opponents are hard pressed to find federal preemption from a source that has itself disclaimed any authority over the subject matter. As the U.S. Supreme Court has explained, "There is no federal pre-emption *in vacuo*, without a constitutional text or a federal statute to assert it."¹⁴³ In any event,

Regularity of procedure—whether it be the rulemaking and adjudicatory procedures of the APA or others which Congress may provide for a particular purpose—not only ensures that state law will be preempted only by federal "law," as the Supremacy Clause provides, but also imposes a degree of accountability on decisions which will have the profound effect of displacing state laws, and affords some protection to the states that will have their laws displaced and to citizens who may hold rights or expectations under those laws.

Fellner v. Tri-Union Seafoods, 539 F.3d 237, 245 (3d Cir. 2008).

^{139.} Freese & Schubert, *supra* note 136, at 307 ("[T]hese issues were recognized by FDA scientists in the early 1990's, but their recommendations to require testing for unintended effects were overruled."); *see Key FDA Documents Revealing Hazards of Genetically Engineered Foods—And Flaws with How the Agency Made Its Policy*, ALLIANCE FOR BIO-INTEGRITY, http://3dd.816.myftpupload.com/24-fda-documents (last visited Dec. 3, 2014) (hosting the FDA documents).

^{140.} *See Shalala*, 116 F. Supp. 2d at 173, 175 (concluding that the FDA did not violate the APA or NEPA); Similarly the Third Circuit has noted that:

^{141.} See Shalala, 116 F. Supp. 2d at 178–79 (discussing the need for the FDA to establish "materiality" before it can require labeling).

^{142.} Center for Food Safety, Petition Seeking Mandatory Labeling for Genetically Engineered Foods, available at http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/the-cfs-legal-petition-to-label-genetically-engineered-foods (providing FDA with a legal blueprint and impetus for requiring nationwide labeling of genetically engineered foods).

^{143.} P.R. Dep't of Consumer Affairs v. Isla Petroleum Corp., 485 U.S. 495, 501, 503 (1988).

the FDA has never indicated a position that states cannot require labeling, in the 1992 policy or elsewhere.¹⁴⁴

Finally, the FDA's 1992 policy on genetically engineered foods could not have preemptive effect because it is merely a statement of policy.¹⁴⁵ The most similar analog is the "natural" foods context. In *Holk v. Snapple*, the Third Circuit ruled that a similar longstanding FDA policy on use of the term "natural" did not impliedly preempt state-law claims based on that term, explaining that "it is federal *law* which preempts contrary state law; nothing short of federal law can have that effect."¹⁴⁶ As in *Holk*, the FDA's adoption of the 1992 policy was unilateral, lacking the "fairness and deliberation that should underlie a pronouncement of [legal] force."¹⁴⁷

There simply is no federal "law" regarding labeling of genetically engineered foods that potentially preempts state law, let alone federal law expressing the "clear and manifest" congressional intent that is required in order to overcome the Supreme Court's presumption against preemption.

C. Existing Federal Food Labeling Laws Do Not Preempt State Labeling of Genetically Engineered Foods

Labeling opponents also raise the Nutritional Labeling Education Act (NLEA), which amended the FFDCA in 1990, in preemption arguments.

^{144.} *Cf.* Baltimore & Ohio R. R. Co. v. Oberly, 837 F.2d 108, 115 (3d Cir. 1988) ("[W]e believe that it is essential that an agency declare, at a high level of specificity, its intention that its *in* action preempt state law before we may assume such a desire and give it legal effect.") (emphasis in original).

^{145.} See, e.g., United States v. Mitchell, 39 F.3d 465, 470 (4th Cir. 1994) ("For regulations to have the force and effect of law they must first be 'substantive' or 'legislative-type' rules, as opposed to 'interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice."") (quoting Chrysler Corp. v. Brown, 441 U.S. 281, 301–02 (1979)). In 2001, FDA issued a draft guidance on the voluntary labeling of food produced through genetic engineering. See Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance, U.S. FOOD & DRUG ADMIN. (Jan. 2001), http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/

labelingnutrition/ucm059098.htm ("This draft guidance represents FDA's current thinking on voluntary labeling of foods indicating whether foods have or have not been developed using bioengineering."). As with the 1992 policy, the draft guidance does not have the force of law and thus cannot serve as a basis of implied preemption. *See id.* ("This draft guidance . . . does not create or confer any rights for or on any person and does not operate to bind FDA or the public.").

^{146.} Holk v. Snapple Beverage Corp., 575 F.3d 329, 340 (3d Cir. 2009) (emphasis in original) (quoting Fellner v. Tri-Union Seafoods, 539 F.3d 237, 243 (3d Cir. 2008)); *see* Mwantembe v. TD Bank, 669 F. Supp. 2d 545, 553 (E.D. Pa. 2009) (citing *Holk*, 575 F.3d at 339–40) ("Agency action that lacks the fairness of the 'formal, deliberative process' inherent in notice and comment rulemaking and agency adjudication, such as issuance of a policy statement, guidance or letter, does not have the force of law to preempt a state law.").

^{147.} Holk, 575 F.3d at 340 (quoting United States v. Mead, 533 U.S. 218, 230 (2001)).

However, as with FDA's 1992 policy, industry's reliance on the NLEA is wholly misplaced because the NLEA does not preempt state-mandated labeling of genetically engineered foods.

Congress enacted the NLEA "to clarify and to strengthen [the FDA's] legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods."¹⁴⁸ The Act contains an express preemption provision prohibiting states from enacting laws or regulations that are "not identical" to the NLEA's nutrition labeling requirements.¹⁴⁹ The express preemption provision lists the specific categories it covers.¹⁵⁰ In particular, the NLEA increased and standardized nutrition content definitions and labeling requirements, imposed limitations on health claims, changed the form of ingredient labeling and standards of identity, and required more uniform serving sizes.¹⁵¹ Unsurprisingly, given the NLEA's primary focus on nutritional information, the statute does not address genetic engineering. As a result, the NLEA does not preempt state labeling for foods produced through genetic engineering: Such labels do not constitute nutritional information, and they do not impinge on any other area covered by the NLEA.

Crucially, Congress made plain that there can be no implied preemption from the NLEA by declaring that the statute "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted."¹⁵² In other words, NLEA preemption is either express or non-existent. To constitute express preemption, state-mandated labeling of genetically engineered foods would need to impose labeling requirements that are different from those required by the NLEA—but state labels do not do this. Indeed, the NLEA *cannot* expressly preempt state

^{148.} H.R. REP. NO. 101-538, at 7 (1990).

^{149. 21} U.S.C. § 343-1(a) (2012).

^{150.} *Id.* § 343-1(a); *see generally id.* § 343 (outlining the labeling requirements for various food types).

^{151.} The Impact of the Nutritional Labeling and Education Act of 1990 on the Food Industry, 47 ADMIN. L. REV. 605, 606 (1995) (and citations therein).

^{152. 21} U.S.C. § 343-1 (construction of Pub. L. No. 101-535, (1)); *Holk*, 575 F.3d at 336 (quoting 21 U.S.C. § 343-1 (construction of Pub. L. No. 101-535, (1)); *but see* 21 U.S.C. § 343-1 (construction of Pub. L. No. 101-535, (3)) (including savings clause that explains that the NLEA's preemption provision shall not be construed to affect possible implied preemption from other federal sources).

labeling since this law and its implementing regulations neither cover nor even reference the labeling of food produced by genetic engineering.¹⁵³

Courts interpret the NLEA to preempt any additional or different requirements placed on the manufacturer by a state regarding nutrient contents—such as requirements to label trans-fats.¹⁵⁴ In fact, "[t]he only State requirements that are subject to preemption are those that are affirmatively different from the Federal requirements."¹⁵⁵ Notably, labeling foods produced through genetic engineering is not "nutrition[al] information" as defined by the NLEA and FDA regulations.¹⁵⁶ Under the NLEA, labeling foods produced through genetic engineering is not a nutrition-level or health-benefit claim,¹⁵⁷ and such labeling is wholly distinct from labeling the nutrient content of foods. Similarly, the NLEA defines health claims as those that link specific nutrient information to alleged disease reduction (e.g., "may reduce the risk of heart disease").¹⁵⁸ A label on genetically engineered food is not a health claim, as defined by the NLEA, because it does not link specific nutrients to a health benefit or to disease reduction.

In sum, "the purpose of the NLEA... is not to preclude all state regulation of nutritional labeling, but to 'prevent State and local governments from adopting inconsistent requirements with respect to the labeling of nutrients."¹⁵⁹ Because the NLEA does not address labeling for

157. 21 C.F.R. §§ 101.13(b), 101.14(a); *see* 21 U.S.C. § 343-1(a)(5) (preempting states from establishing requirements for the claims described by the statute); *cf. id.* § 343(r)(1) (listing the health-related issues which may be included in labeling statements, not including GE food concerns).

158. 21 C.F.R. § 101.14(a).

159. Astiana v. Ben & Jerry's Homemade, Inc., C 10-4387 PJH, 2011 WL 2111796, at *8 (N.D. Cal. May 26, 2011) (quoting H. REP. NO. 101-538, 1990 WL 259223, at *3337 (1990)).

^{153.} *Cf.* Guerrero v. Target Corp., 889 F. Supp. 2d 1348, 1360–61 (S.D. Fla. 2012) (holding that Florida's honey standard was not preempted by the NLEA because there is no federal standard of identity for honey).

^{154.} Chacanaca v. Quaker Oats Co., 752 F. Supp. 2d 1111, 1118-19 (N.D. Cal. 2010).

^{155.} Beverages: Bottled Water, 60 Fed. Reg. 57,076, 57,120 (Nov. 13, 1995) (Final Rule) ("Section 403A(a)(1) of the act only effects preemption with respect to matters on which a Federal requirement exists Therefore, the only State requirements that are subject to preemption are those that are affirmatively different from the Federal requirements on matters that are covered by section 403A(a)."); *Chacanaca*, 752 F. Supp. at 1118 (quoting Chavez v. Blue Sky Natural Beverage Co., 268 F.R.D. 365, 372 (N.D. Cal. 2010) (quoting *In re* Pepsico, Inc., 588 F. Supp. 2d 527, 532 (S.D.N.Y. 2008) (quoting Beverages: Bottled Water, 60 Fed.Reg. 57,076, 57,120 (Nov. 13, 1995) (to be codified at 21 C.F.R. pt. 129))).

^{156. 21} U.S.C. § 343-1(a)(4); *see id.* (preempting states from establishing nutrition labeling requirements); 21 C.F.R. § 101.9(c) (2013) (failing to include information about whether a product is genetically engineered within the definition of nutrition information); *cf.* 21 U.S.C. § 343(q)(1) (listing the situations in which a food would need to be labeled for nutritional purposes, and notably, based on the language, present GE is not nutritional information in the statute).

genetically engineered foods, and because such labeling does not cover any categories also covered by the NLEA, this statute does not preempt a state law requiring the labeling of genetically engineered foods.

The U.S. Supreme Court recently reiterated the intended narrowness of the NLEA's preemption provision in POM Wonderful LLC v. Coca-Cola *Co.* The Court held that the FFDCA did not preclude a private party from bringing a Lanham Act claim challenging food labeling as misleading.¹⁶⁰ The case dealt with two federal statutes and was thus a preclusion case, not a preemption case. Yet preemption principles were still "instructive insofar as they are designed to assess the interaction of laws that bear on the same subject."¹⁶¹ In so analyzing, the Court discussed the narrowness of the NLEA's preemption provision as evincing congressional intent that the FFDCA not preclude Lanham Act suits, emphasizing that it is significant "that the complex preemption provision distinguishes among different FDCA requirements" and "forbids state-law requirements that are of the type but not identical to only certain FDCA provisions with respect to food and beverage labeling."¹⁶² While couched in the context of a competing federal statute, the Court nonetheless highlighted that "[by] taking care to mandate express preemption of some state laws, Congress if anything indicated it did not intend the FDCA to preclude requirements arising from other sources."¹⁶³

Even ignoring, *arguendo*, the NLEA's express prohibition on implied preemption, there still is no implied conflict, obstacle, or field preemption from the NLEA, the FFDCA, or any other source of federal labeling requirements.¹⁶⁴ Implied conflict preemption occurs only when it is

^{160.} Pom Wonderful LLC v. Coca-Cola Co., No. 12-761, slip op. at 1–3, 17 (U.S. June 12, 2014).

^{161.} Id. at 8.

^{162.} *Id.* at 10 (emphasis added); *see also id.* (noting that the preemption provision, § 343-1(a) covers "some but not all" of the subsection of § 343).

^{163.} Pom Wonderful, slip op. at 11 (emphases added).

^{164.} Any preemption allegations based on meat and poultry laws, the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA), are irrelevant, because state labeling laws exempt meat from any animals fed genetically engineered grains. *E.g.*, Act 120, *supra* note 7. Steaks from cows fed genetically engineered corn, or eggs from chickens fed the same, are not within the scope of state labeling laws. *Id.* This scope is logical, because such labeling might otherwise confuse consumers into thinking the animal *itself* was genetically engineered. It is also in accord with international labeling standards. For example, in the European Union, "products obtained from animals fed with genetically modified feed" do not need labels. Council Regulation 1829/2003, 2003 O.J. (L 268) 2, 3 (EU). Further, there are no current nor known future genetically engineered "meat" or "poultry" animals for food, such as genetically engineered beef, chicken, or pork, to which state laws might apply, although the Food and Drug Administration is considering approving a genetically engineered salmon, which would be the first GE animal for food. Tara MacIssac, *Superfish: FDA*

"physically impossib[le]" for manufacturers to comply with both federal and state requirements.¹⁶⁵ It is simply not physically impossible for manufacturers to comply with both state labeling of genetically engineered foods and the NLEA because there is no conflicting NLEA (or other federal) labeling requirement. And while conflict preemption can also arise where a state law acts "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,"¹⁶⁶ Congress has not expressed a purpose contrary to the labeling of genetically engineered food in the NLEA or in any other act. Thus, a state law requiring the labeling of genetically engineered foods cannot be an obstacle to the purposes of Congress and is therefore not subject to conflict preemption. Indeed, the FFDCA's general "overriding purpose [is] to protect the public health."¹⁶⁷ The NLEA is concerned with "meeting consumer food information needs."¹⁶⁸ Hence, informing consumers by labeling genetically engineered foods would plainly further—not interfere—with Congress's purposes.

Finally, state-mandated labels on genetically engineered foods are not subject to field preemption because federal law does not "occupy the field" of food labeling. Prior to the NLEA, the FFDCA did not have an express preemption provision.¹⁶⁹ Even in enacting the NLEA, Congress included limitations and exceptions to the express provision indicating that it was aware of state laws operating in the area of food labeling.¹⁷⁰ Preemption arguments are "particularly weak [when] Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts."¹⁷¹

In sum, labeling opponents do not have a preemption case because federal law does not preempt state labeling of genetically engineered foods

166. Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

167. United States v. Bacto-Unidisk, 394 U.S. 784, 798 (1969).

168. 136 Cong. Rec. 20,423 (1990) (Rep. Emerson).

169. Holk v. Snapple Beverage Corp., 575 F.3d 329, 338 (3d Cir. 2009) (citing Wyeth v. Levine, 555 U.S. 555, 577 (2009)).

170. Id. at 338.

Reviews First GE Animal for Human Consumption, EPOCH TIMES (Apr. 20, 2013, 4:24 AM), http://www.theepochtimes.com/n3/15166-superfish-fda-reviews-first-ge-animal-for-human-

consumption. For more on genetically engineered animals, see generally Kimbrell & Tomaselli, supra note 57.

^{165.} *See, e.g.*, Fla. Lime & Avocado Growers v. Paul, 373 U.S. 132, 142–43 (1963) (discussing preemption arising from incompatible state and federal laws); English v. Gen. Elect. Co., 496 U.S. 72, 79 (1990) (stating that implied conflict preemption occurs when it is "impossible for a private party to comply with both state and federal requirements").

^{171.} Wyeth, 555 U.S. at 575 (quoting Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 166–67 (1989)).

either expressly or impliedly, or through conflict, obstacle or field preemption.¹⁷² Any industry preemption challenge to state-mandated labeling of genetically engineered foods therefore cannot stand.

III. STATE-REQUIRED LABELING DOES NOT VIOLATE THE DORMANT COMMERCE CLAUSE

While the Constitution's Commerce Clause only expressly serves as a grant of power to Congress to regulate interstate commerce, the U.S. Supreme Court also interprets the clause as an implicit restriction on certain state regulations of interstate commerce.¹⁷³ This implicit restraint is known as the negative or "dormant" Commerce Clause.¹⁷⁴ Its purpose is to prevent "economic Balkanization"—i.e., the concern that an individual state might jeopardize the nation's economy if it burdens "the flow of commerce across its borders" in a way "that commerce wholly within those borders would not bear."¹⁷⁵ The Clause's restrictions are not absolute; rather, they are limited by federalism's favoring of state and local autonomy.¹⁷⁶ States can regulate local matters even if interstate commerce may be affected.¹⁷⁷ Consequently, "[a]s long as a state does not needlessly obstruct interstate trade or attempt to 'place itself in a position of economic isolation,' it

^{172.} And that is precisely why industry is presently lobbying so hard for Congress to pass the "Deny Americans the Right to Know" or "DARK" Act, the goal of which is to expressly preempt state labeling laws. Press Release, Ctr. for Food Safety, Big Food's "DARK Act" Introduced in Congress (Apr. 9, 2014), *available at* http://www.centerforfoodsafety.org/press-releases/3053/big-foods-dark-act-introduced-in-congress; *see also* Wilce, *supra* note 25. The introduction of the DARK Act also evinces congressional intent that members of Congress do not think that existing federal statutes preempt states from requiring labeling.

^{173.} U.S. CONST. art. I, § 8, cl. 3 ("Congress shall have Power . . . to regulate Commerce with foreign Nations, and among the several States, and with the Indian tribes."); Okla. Tax Comm'n v. Jefferson Lines, Inc., 514 U.S. 175, 179–80 (1995) (citing Quill Corp. v. North Dakota, 504 U.S. 298, 309 (1992)).

^{174.} For cases analyzing whether a state action violates the Commerce Clause, *see Okla. Tax Comm'n*, 514 U.S. at 179 (citing *Quill Corp.*, 504 U.S. at 309) ("[W]e have consistently held [the Commerce Clause's] language to contain a further, negative command, known as the dormant Commerce Clause . . . "); Nw. States Portland Cement Co. v. Minnesota, 358 U.S. 450, 458 (1959). *See also* Hughes v. Oklahoma, 441 U.S. 322, 326 (1979) ("The Commerce Clause has accordingly been interpreted by this Court not only as an authorization for congressional action, but also, even in the absence of a conflicting federal statute, as a restriction on permissible state regulation."); Lewis v. BT Investment Managers, Inc., 447 U.S. 27, 35 (1980) ("Although the Clause thus speaks in terms of powers bestowed upon Congress, the Court has recognized that it limits the power of the States to erect barriers against interstate trade.").

^{175.} Okla. Tax Comm'n, 514 U.S. at 179-80.

^{176.} Dep't of Revenue of Ky. v. Davis, 553 U.S. 328, 338 (2008).

^{177.} Lewis, 447 U.S. at 36 (internal quotes omitted) (quoting Raymond Motor Transp., Inc. v. Rice, 434 U.S. 429, 440 (1978)).

retains broad regulatory authority to protect the health and safety of its citizens and the integrity of its natural resources."¹⁷⁸

A sacrosanct principle of American federalism is that a "courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."¹⁷⁹ Hence, "[i]f successful, those experiments may often be adopted by other states without Balkanizing the national market or by the federal government without infringing on state power."¹⁸⁰ To that end, the dormant Commerce Clause prohibits only "economic protectionism" by individual states acting in their own interest—that is, "regulatory measures designed to benefit instate economic interests by burdening out-of-state competitors."¹⁸¹

In analyzing whether a given state law complies with the dormant Commerce Clause, courts generally apply a two-step approach.¹⁸² First, a state law is subject to strict scrutiny if it clearly discriminates against interstate commerce¹⁸³ in one of three ways: (1) by discriminating against interstate commerce on its face; (2) by harboring a discriminatory purpose; or (3) by discriminating in its effect.¹⁸⁴ Such discrimination means that a law creates "differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter."¹⁸⁵ A clearly discriminatory law passes constitutional muster only if it "promotes a legitimate state interest that cannot be achieved through any reasonable nondiscriminatory alternative."¹⁸⁶ A plaintiff bears the burden of

182. Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 578-79 (1986).

183. Hughes v. Oklahoma, 441 U.S. 322, 336–37 (1979); *see also Brown-Forman*, 533 U.S. at 579 ("When a state statute directly . . . discriminates against interstate commerce . . . we have generally struck down the statute without further inquiry.").

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

186. Cherry Hill Vineyard v. Baldacci, 505 F.3d 28, 33 (1st Cir. 2007); *see* Maine v. Taylor, 477 U.S. 131, 138 (1986) (holding that if "a state law is shown to discriminate against interstate commerce 'either on its face or in practical effect,' the burden falls on the State to demonstrate both that the statute 'serves a legitimate local purpose,' and that this purpose could not be served as well by available nondiscriminatory means." (quoting *Hughes*, 441 U.S. at 336)).

^{178.} Maine v. Taylor, 477 U.S. 131, 151 (1986) (citations omitted) (quoting Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 527 (1935)).

^{179.} New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

^{180.} Rocky Mountain Farmers' Union v. Corey, 730 F.3d 1070, 1087 (9th Cir. 2013), cert. denied 134 S.Ct. 2884 (2014).

^{181.} New Energy Co. of Ind. v. Limbach, 486 U.S. 269, 273–74 (1988); see also Davis, 553 U.S. at 337–38 (upholding a Kentucky law that provided preferential tax breaks to in-state residents who invested in bonds issued by the state and its municipalities); Wyoming v. Oklahoma, 502 U.S. 437, 454 (1992) (invalidating a law requiring coal-fired electric utilities to burn a mixture containing at least 10% Oklahoma-mined coal because the law excluded coal mined from other states based solely on its origin and, thus, discriminated both on its face and in practical effect).

^{184.} Southold v. E. Hampton, 477 F.3d 38, 48 (2d Cir. 2007).

establishing that a state law has the discriminatory purpose or effect he or she alleges.¹⁸⁷ The same standard applies to a state law with "extraterritorial effect," meaning that it has the practical effect of controlling commerce occurring wholly outside the state.¹⁸⁸

Second, when a law is not discriminatory on its face but has an indirect effect on interstate commerce, courts apply the balancing test established in *Pike v. Bruce Church, Inc.* In *Pike*, the Court held that "[w]here the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits."¹⁸⁹

State laws requiring labeling for genetically engineered foods do not clearly discriminate against interstate commerce. Consequently, they are subject to the *Pike* test. Under the *Pike* analysis, these laws are constitutional because they regulate even-handedly, promote the public interest, and have only incidental effects on interstate commerce that are far exceeded by the benefits they provide.

A. State Laws Requiring the Labeling of Genetically Engineered Foods Are Not Clearly Discriminatory

A state law requiring the labeling of genetically engineered food is not clearly discriminatory facially, purposefully, or in effect. First, such laws are not facially discriminatory because they do not discriminate between instate and out-of-state interests in order to favor the former over the latter. Rather, genetically engineered food labeling laws require all manufacturers to label their foods, regardless of whether the manufacturer is based or located in or out of a given state. In other words, state labeling applies to all food offered for retail sale irrespective of where it was produced and with no exception for locally produced food,¹⁹⁰ as demonstrated by the labeling

^{187.} *Hughes*, 441 U.S. at 336; Black Star Farms v. Oliver, 600 F.3d 1225, 1230 (9th Cir. 2010) (citing *Hughes*, 441 U.S. at 336).

^{188.} *See, e.g.*, Healy v. Beer Institute, Inc., 491 U.S. 324, 337–39, 343 (1989) (holding that Connecticut's beer-pricing-affirmation-statute impermissibly controlled commercial activity wholly outside state lines and was therefore unconstitutional); Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 645 (6th Cir. 2010) (discussing the per se invalidity of an extraterritorial regulation under the Dormant Commerce Clause).

^{189.} Pike v. Bruce Church, 397 U.S. 137, 142 (1970) (citing Huron Cement Co. v. Detroit, 362 U.S. 440, 443 (1960)).

^{190.} Of course, state labeling laws do have limitations on their scope. Animal feed consisting of genetically engineered grains is not required to be labeled. Similarly, foods that are contaminated by transgenic content as opposed to intentionally engineered, are not required to be labeled. Act 120

requirements of the laws passed in Vermont, Connecticut, and Maine, as well as the proposed requirements of the ballot initiatives in California, Washington, and Oregon.¹⁹¹ The U.S. Supreme Court has repeatedly instructed that state laws that "do[] not affect simple protectionism, but regulate[] evenhandedly ... without regard to whether [businesses] are from outside the State" are plainly constitutional.¹⁹²

Second, state genetically engineered food labeling laws do not clearly discriminate in purpose because they do not promote in-state economic protectionism. Instead, state labeling laws are intended to enable consumers to make informed decisions about the potential health, environmental, and religious consequences of the foods they purchase. These laws inform consumers, reduce consumer confusion and deception, and allow consumers to make purchasing decisions in light of the public health concerns and unknowns regarding engineered foods and the adverse environmental impacts caused by their production.

In fact, rather than serving in-state protectionism, state genetically engineered food labeling laws plainly spell out their legitimate, nonprotectionist purposes in express legislative findings. For example, Vermont's Act 120 states its purposes as:

^{§ 3044(2),} or foods with de minimis amounts of genetically engineered content—less than 0.9 percent of the total weight of the processed food—are exempt from labeling, Act 120 § 3044(5); *see* Grocery Mfrs. of Am. v. Gerace, 755 F.2d 993, 1003 (2d Cir. 1985) ("[T]o the extent that [the statute] indirectly advantage[s] the dairy industry, that effect is not necessarily limited to in-state dairy producers.").

^{191.} An Act To Protect Maine Food Consumers' Right To Know About Genetically Engineered Food, 2014 Me. Laws 1, 2; CONN. GEN. STAT. § 21a-92c (2013); Letter from Kate Brown, Secretary of State, to All Interested Parties (Jan. 6, 2014), *available at* http://oregonvotes.org/irr/2014/044text.pdf; Act 120, *supra* note 7, § 3043(a); *Washington Initiative* 522 (2013), BALLOTPEDIA, http://ballotpedia.org/Washington_Initiative_522_(2013), Full_Text_of_Initiative (last visited Dec. 9, 2014); *Text_of_California Proposition_37_Washington_2012/29* (last visited Dec. 9, 2014).

^{192.} Minnesota v. Clover Leaf Creamery, 449 U.S. 456, 471 (1981) (internal quotation marks omitted); *see also* United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 345 (2007) (upholding a flow control ordinance which treated "in-state private business interests exactly the same as out-of-state ones, [and therefore did] not discriminate against interstate commerce for purposes of the dormant Commerce Clause"); *Boggs*, 622 F.3d at 648–49 (rejecting arguments that an Ohio regulation requiring a factual disclosure accompanying labeling of dairy products from cows not treated with a drug was discriminatory in effect because the regulation either benefited or burdened instate and out-of-state farmers the same way); *Gerace*, 755 F.2d at 1003 (holding that a New York law requiring the labeling of products resembling traditional cheeses did not violate the dormant Commerce Clause because it evenhandedly applied to products originating in- or out-of-state); Brown & Williamson Tobacco Corp. v. Pataki, 320 F.3d 200, 216 (2d Cir. 2003) ("[I]n order to show a discriminatory effect on interstate commerce, the Plaintiffs must demonstrate that the Statute confers on their in-state counterparts a competitive advantage.").

Establish[ing] a system by which persons may make informed decisions regarding the potential health effects of the food they purchase and consume and by which, if they choose, persons may avoid potential health risks of food produced from genetic engineering....

Inform[ing] the purchasing decisions of consumers who are concerned about the potential environmental effects of the production of food from genetic engineering....

Reduc[ing] and prevent[ing] 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....

Provid[ing] consumers with data from which they may make informed decisions for religious reasons.¹⁹³

Other state labeling laws have similar findings of purpose.¹⁹⁴ Such express findings and purpose statements belie any claims that labeling laws intend to discriminate against out-of-state interests because courts "assume that the objectives articulated by the legislature are actual purposes of the statute."¹⁹⁵ And unintentional, coincidental market impacts that happen to fall differentially on in- and out-of-state producers pass muster under this standard: While a state law may impact some large out-of-state corporations more than a given in-state business,¹⁹⁶ the dormant Commerce Clause "protects the interstate market, not particular interstate firms."¹⁹⁷

^{193.} Act 120, *supra* note 7, § 3041; *see also* Letter from Kate Brown, *supra* note 191 (containing Section 2 of the attached initiative which describes the purposes of the Act as promoting public health, protecting consumers, and giving consideration to the environment, economic development, and religious practices).

^{194.} Letter from Kate Brown, supra note 191 (containing Section 5 of the attached initiative).

^{195.} *Clover Leaf Creamery*, 449 U.S. at 463 n.7 (1981); *accord* Am. Beverage Ass'n v. Snyder, 735 F.3d 362, 372 (6th Cir. 2013) ("Absent concrete evidence *from the statutory language* that the unique-mark requirement is purposefully discriminatory, Plaintiff cannot prevail on this claim." (emphasis added)).

^{196.} Although, arguably the opposite would be true, because multinational corporations already label genetically engineered food in many markets overseas. *See supra* note 17 and accompanying text.

^{197.} Exxon Corp. v. Governor of Maryland, 437 U.S. 117, 127 (1978); *see also* Nat'l Ass'n of Optometrists & Opticians v. Harris, 682 F.3d 1144, 1148 (9th Cir. 2012) ("[T]here is not a significant burden on interstate commerce merely because a non-discriminatory regulation precludes a preferred, more profitable method of operating a retail market."); Energy & Env't Legal Inst. v. Epel, No. 11-CV-00859-WJM-BNB, 2014 WL 1874977, at *6 (D. Colo. May 9, 2014) ("The dormant Commerce Clause neither protects the profits of any particular business, nor the right to do business in any particular manner.").

Third, state labeling laws are not discriminatory in effect. The courts have explained that "[w]here neither facial discrimination nor an improper purpose has been shown, the evidentiary burden to show a discriminatory effect is particularly high."¹⁹⁸ Labeling opponents could not meet this "particularly high" burden because there is no evidence that state mandated labeling discriminates against out-of-state interests in effect.

In fact, if anything, the opposite is true: State labeling laws have an *increased and singular burden on in-state retailers*, not out-of-state companies. Namely, state laws requiring the labeling of genetically engineered foods assign responsibility for labeling genetically engineered raw whole foods (as opposed to processed, packaged foods) to retailers. For example, Vermont's Act 120 requires that, "in the case of any raw agricultural commodity that is not separately packaged, the retailer shall post a label appearing on the retail store shelf or bin in which the commodity is displayed for sale with the clear and conspicuous words 'produced with genetic engineering."¹⁹⁹ Other state laws and bills have similar mandates for retailers.²⁰⁰ Manufacturers, on the other hand, whether in or out of state, are responsible for labeling packaged raw commodities and processed foods that are genetically engineered.²⁰¹ While manufacturers could be anywhere, on-site food retailers will necessarily be in-state; thus, labeling requires an additional burden on in-state food businesses.

Finally, even if a state law did facially, purposefully, or effectively distinguish between out-of-state and in-state manufacturers, and somehow unevenly burden the latter, the law would still be constitutional as long as its rationale was substantive (i.e., more processed foods are produced outside of the state) and not tantamount to economic protectionism. Here, the Ninth Circuit's recent opinion in *Rocky Mountain Farmers' Union* is instructive.

In that case, the American Fuels & Petrochemical Manufacturers Association and other industry groups asserted that the Low Carbon Fuel Standard established by the California Air Resources Board (CARB) violated the dormant Commerce Clause.²⁰² The fuel standard, which served

^{198.} Rocky Mountain Farmers' Union v. Corey, 730 F.3d 1070, 1100 (9th Cir. 2013), cert. denied, 134 S. Ct. 2884 (2014).

^{199.} Act 120, supra note 7, § 3043(b)(2).

^{200.} An Act To Protect Maine Food Consumers' Right To Know About Genetically Engineered Food, 2014 Me. Laws 1, 2; CONN. GEN. STAT. § 21a-92c (2013); Act 120, *supra* note 7, § 3043(b)(2); Letter from Kate Brown, *supra* note 191 (containing Section 5); *Washington Initiative 522 (2013), supra* note 191; *Text of California Proposition 37 (November 2012), supra* note 191.

^{201.} Act 120 § 3043(b)(1), (3).

^{202.} Rocky Mountain Farmers' Union, 730 F.3d at 1107.

to reduce greenhouse gas (GHG) emissions by spurring the development and production of low-carbon fuels,²⁰³ included ethanol provisions requiring fuel blenders that supply California to keep the average carbon intensity of their fuel below a declining annual limit.²⁰⁴ In addition, recognizing crude oil's increasingly severe climate impacts, CARB's fuel standard included crude oil provisions that promoted the development of alternative fuels.²⁰⁵

The *Rocky Mountain* plaintiffs asserted that the fuel standard discriminated against out-of-state commerce, and that the standard impermissibly regulated extraterritorial ethanol production.²⁰⁶ The district court agreed, holding that the fuel standard (1) facially discriminated against out-of-state ethanol; (2) discriminated against out-of-state crude oil in purpose and effect; and (3) impermissibly engaged in extraterritorial regulation of ethanol.²⁰⁷

The Ninth Circuit, however, reversed,²⁰⁸ holding that the fuel standard was not facially discriminatory. The court reasoned that although the standard expressly assigned different carbon intensity ratings to ethanol that happened to coincide with out-of-state locations, those differences were due to the actual carbon intensity of the fuel (i.e., some out-of-state locations produced ethanol with higher carbon intensity than some in-state locations), and not due to some facially discriminatory reason.²⁰⁹ As the Ninth Circuit explained, the dormant Commerce Clause is not a "blindfold" and "does not invalidate by strict scrutiny state laws or regulations that incorporate state boundaries for good and non-discriminatory reason[s]. It does not require that reality be ignored in lawmaking."²¹⁰

209. *Id.* at 1089–90 ("[T]he Fuel Standard considers location, but only to the extent that location affects the actual GHG emissions attributable to a default pathway. Under dormant Commerce Clause precedent, if an out-of-state ethanol pathway does impose higher costs on California by virtue of its greater GHG emissions, there is a nondiscriminatory reason for its higher carbon intensity value. Stated another way, if producers of out-of-state ethanol actually cause more GHG emissions for each unit produced, because they use dirtier electricity or less efficient plants, CARB can base its regulatory treatment on these emissions. If California is to successfully promote low carbon-intensity fuels, countering a trend towards increased GHG output and rising world temperatures, it cannot ignore the real factors behind GHG emissions.")

210. Id. at 1107.

^{203.} Id. at 1079, 1106.

^{204.} Id. at 1079-80.

^{205.} Id. at 1084-85.

^{206.} Id. at 1087.

^{207.} Id. at 1077-78, 1086.

^{208.} Id. at 1107.

Further, the Ninth Circuit reversed the district court's holding that the crude oil provisions were discriminatory in purpose and effect, and remanded for the lower court to apply the *Pike* balancing standard to those provisions.²¹¹ According to the Ninth Circuit, the crude oil provisions "burdened and benefitted in-state industries at the state level," indicating a lack of discriminatory purpose.²¹² Furthermore, the requisite "substantial evidence" of an actual—rather than hypothetical—discriminatory effect was wholly lacking.²¹³

As in *Rocky Mountain*, state laws requiring the labeling of genetically engineered foods do not discriminate against out-of-state entities facially, in purpose, or in effect.

B. State Labeling Laws Do Not Impermissibly Regulate Extraterritorially

State labeling laws also do not violate the dormant Commerce Clause by impermissibly regulating "commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State."²¹⁴ Here, the "critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundary of the state."²¹⁵ In modern times, cases finding extraterritorial regulation are exceedingly rare.²¹⁶

State-mandated genetically engineered food labeling laws do not violate the extraterritoriality doctrine. Such laws do not speak to whether genetically engineered foods need to be labeled outside the state. In fact, the state labeling laws do not purport to regulate or control genetically engineered foods at all. The laws also do not require other jurisdictions to adopt reciprocal standards before their food can be sold in the given state. And the laws do not force "an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another."²¹⁷

216. *E.g., Rocky Mountain Farmer's Union*, 730 F.3d at 1101 ("In the modern era, the Supreme Court has rarely held that statutes violate the extraterritoriality doctrine.").

217. Healy, 491 U.S. at 337 (citing Brown-Forman Distillers, 476 U.S. at 579); see Nat'l Elec. Mfrs. Ass'n. v. Sorrell, 272 F.3d 104, 107, 110 (2d Cir. 2001) (holding that a Vermont statute that

^{211.} Id.

^{212.} Id. at 1100.

^{213.} Id.

^{214.} Healy v. Beer Inst., Inc., 491 U.S. 324, 336, 339 (1989) (citing Edgar v. MITE Corp., 457 U.S. 624, 642–43 (1982) (plurality opinion)). The *Healy* court determined that a law that required liquor sold in Connecticut to be sold at a price "no higher than the lowest price at which the same product can be sold in any other State" constituted an extraterritorial regulation. *Id.* at 332.

^{215.} *Id.* at 336 (citing Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 579 (1986)).

Moreover, it is irrelevant for dormant Commerce Clause purposes that genetically engineered food laws in some states might indirectly compel multinational corporations to label the same foods in other states. After all, although "[s]tates may not mandate compliance with their preferred policies in wholly out-of-state transactions, . . . they are free to regulate commerce and contracts within their boundaries with the goal of influencing the out-of-state choices of market participants."²¹⁸

In any event, as a factual matter, dozens of states have introduced state labeling legislation in the past two years,²¹⁹ and others are currently considering passing such laws via ballot initiatives in November 2014.²²⁰ This legislation shows consistency and uniformity.²²¹ Among other things, the laws (1) require that the same labeling language be placed on the same processed and raw food products; (2) include the same definitions of key terms; and (3) contain the same or similar statements of purpose and findings.²²² The laws are consistent with international labeling standards as well.²²³ There simply is no "evidence that conflicting, legitimate legislation

218. Rocky Mountain Farmers' Union, 730 F.3d at 1103 (citing Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 679 (2003)).

219. See supra note 200 and accompanying text.

220. *GE Food Labeling: States Take Action*, CTR. FOR FOOD SAFETY (June 10, 2014), http://www.centerforfoodsafety.org/fact-sheets/3067/ge-food-labeling-states-take-action.

221. Compare Act 120, supra note 7, § 3043(a) (requiring genetically engineered foods be labeled based upon the given regulations, with some minor exceptions) with CONN. GEN. STAT. § 1a-92c (2013) (regulating GE products in a similar manner to Vermont) and An Act To Protect Maine Food Consumers' Right To Know About Genetically Engineered Food, 2014 Me. Laws 1, 2 (regulating GE products in a similar manner to Vermont), and Colorado Mandatory Labeling of GMOs Initiative, Proposition 105 (2014), BALLOTPEDIA, http://ballotpedia.org/Colorado_Mandatory_Labeling_of_GMOs_Initiative, Proposition_105_(2014),_Full_text_of_initiative (last visited Dec. 9, 2014) (proposing to regulate GE products in a similar manner to Vermont) and Letter from Kate Brown, supra note 191 (containing Section 2 of the attached initiative which mandates a labeling framework that accounts for public health, the environment, consumer protection, economic development, and religious and cultural interests); see also State Labeling Initiatives, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/state-labeling-initiatives (last visited Dec. 9, 2014) (compiling information on state initiatives to label genetically engineered food).

222. Compare Act 120, Sec. 1(5)(A) ("Public opinion polls . . . indicate that a large majority of Vermonters want foods produced with genetic engineering to be labeled as such.") with Letter from Kate Brown, *supra* note 191, (containing Section 1 of the attached initiative which states "Oregon consumers have the right to know whether the foods they purchase were produced with genetic engineering so they can make informed purchasing decisions.")

223. See International Labeling Laws, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/international-labeling-laws (last visited Dec. 9, 2014) (providing an overview of international labeling laws).

required labeling of mercury containing lamps did not practically control out-of-state commerce because it did not "inescapably require manufacturers to label all lamps wherever distributed," and "manufacturers could arrange for their production and distribution processes to produce lamps labeled solely for the Vermont market").

is already in place or that the threat of such legislation is both actual and imminent."²²⁴

Regardless, even conflicting state labeling laws do not raise the specter of extraterritoriality, so long as each state regulates only the food labeling in its own jurisdiction. *Rocky Mountain Farmers' Union* is again instructive. In that case, the Ninth Circuit looked to the historical example of organic food labeling (which is the evolutionary antecedent of genetically engineered food labeling) as the basis for rejecting the district court's conclusion that the fuel standard at issue produced extraterritorial regulation by interfering with the uniformity of interstate commerce.²²⁵ The court explained the natural role of states in paving the way for national standards when the issue is uniformity, observing that objections to the speed of that progression are properly addressed to Congress, not the courts:

So long as California regulates *only fuel consumed in California*, the Fuel Standard does not present the risk of conflict with similar statutes.

If we were to invalidate regulation every time another state considered a complementary statute, we would destroy the states' ability to experiment with regulation. Successful experiments inspire imitation both vertically, as when the federal government followed California's lead on air pollution, and horizontally, as shown by the federal Organic Foods Production Act of 1990, 7 U.S.C. §§ 6501-23, adopted after twenty-two states, starting with Oregon, enacted organic food labeling standards. After nearly half of the states acted, Congress provided a uniform standard. As it did there, Congress may decide that uniformity is warranted and set a national fuel standard. If it does so after several states have acted, it will have the benefit of their experiments. But when or if such uniformity is desirable is not a question for courts. The proliferation of organic labeling standards did not threaten our economic union, and the possibility that many states might perform lifecycle analysis on fuel sold within their borders does not risk the

^{224.} S.D. Myers v. City of San Francisco, 253 F.3d 461, 469–70 (9th Cir. 2001) ("However, upon close examination of Supreme Court precedent it is apparent that the Court has never invalidated a state or local law under the dormant Commerce Clause based upon mere speculation about the possibility of conflicting legislation.").

^{225.} Rocky Mountain Farmers' Union v. Corey, 730 F.3d 1070, 1101 (9th Cir. 2013), cert. denied, 134 S. Ct. 2884 (2014).

"competing and interlocking local economic regulation that the Commerce Clause was meant to preclude."²²⁶

The Sixth Circuit's decision in *International Dairy Foods v. Boggs* also illuminates this issue. In *Boggs*, dairy producers challenged an Ohio regulation that prohibited the labeling of some dairy products as being free of a genetically engineered hormone called recombinant bovine growth hormone (rBGH), a drug sometimes given to cows to increase their milk production.²²⁷ As public knowledge of the drug's use grew,²²⁸ consumer demand for rBGH-free dairy products increased.²²⁹ The plaintiffs' members thus entered into contracts with their farmer suppliers to ensure their milk was from cows not treated with rBGH, and they labeled their products to reflect this fact.²³⁰ As more of the dairy market became "rBGH-free," Monsanto, the then-owner of the genetically engineered drug rBGH, began a state and federal campaign to prohibit the labeling practice.²³¹ They succeeded in part in Ohio, prompting the *Boggs* lawsuit.

The Sixth Circuit rejected the producers' dormant Commerce Clause challenge. As relevant here, the plaintiffs argued that the rule impermissibly governed extraterritorially because their "complex national distribution channels" would "force them to create a nationwide label" consistent "with Ohio's requirements."²³² The court disagreed because the rule's requirements

have no direct effect on the Processors' out-of-state labeling conduct. That is to say, how the Processors label their products in Ohio has no bearing on how they are required to label their products in other states (or vice versa). Nor does compliance with

^{226.} *Id.* at 1105 (emphases added) (internal citations omitted) (quoting Healy v. Beer Inst., Inc., 491 U.S. 324, 337 (1989)).

^{227.} Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 632 (6th Cir. 2010).

^{228.} *About rbGH*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/1044/ rbgh/about-rbgh (last visited Dec. 9, 2014).

^{229.} Boggs, 622 F.3d at 633.

^{230.} Id.

^{231.} Battle over rBGH-free Labeling Continues in U.S. States, THE ORGANIC & NON GMO REP. (March 2008), http://www.non-gmoreport.com/articles/mar08/rBGH-free_labeling_U.S.php; see, e.g., Donald L. Barlett & James B. Steele, Monsanto's Harvest of Fear, VANITY FAIR (May 2008), http://www.vanityfair.com/politics/features/2008/05/monsanto200805 (noting, among other things, Monsanto's efforts to move into milk production with intentions to increase the use of growth hormones in cattle).

^{232.} Boggs, 622 F.3d at 647.

the Ohio Rule raise the possibility that the Processors would be in violation of the regulations of another state. \dots^{233}

In sum, state labeling laws do not impermissibly regulate extraterritorially because they do not purport to regulate any aspect of food production or labeling beyond their own state lines.

C. The Benefits of State Labeling of Genetically Engineered Foods Far Exceed Any Speculative Burdens on Interstate Commerce

Labeling opponents' arguments against state labeling laws fare no better under the second dormant Commerce Clause standard—*Pike* balancing. As noted, under *Pike*, where a law "regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is *clearly excessive* in relation to the putative local benefits."²³⁴ Any incidental impacts on interstate commerce from state labeling of genetically engineered foods do not outweigh, and certainly are not "clearly excessive," compared to the substantial benefits to public welfare.

As an initial matter, plaintiffs have the burden to overcome a state's presumptively constitutional labeling law. That is, under the *Pike* balancing test, "a plaintiff must first show that the statute imposes a substantial burden before the court will 'determine whether the benefits of the challenged laws are illusory."²³⁵ Thus, with state labeling of genetically engineered foods, the analysis likely ends at square one, because any claims of a "substantial burden" for *Pike* purposes are legally inadequate, if not outright inaccurate.

Although state labeling laws might impose incidental burdens in the form of increased business costs, lost profits, or the withdrawal of sales from a state market, those types of alleged burdens are not legally cognizable for dormant Commerce Clause purposes because they do not "impair the free flow of materials and products across state borders."²³⁶

^{233.} *Id.* Nor did the rule have a significant effect on an area where national uniformity was indispensable, such as the regulation of railcars. *Id.* (citing Southern Pacific Co. v. Arizona, 325 U.S. 761 (1945)).

^{234.} Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970) (emphasis added).

^{235.} Ass'n des Eleveurs de Canards et D'Oies v. Harris, 729 F.3d 937, 951–52 (9th Cir. 2013) (quoting Nat'l Ass'n of Optometrists & Opticians v. Harris, 682 F.3d 1144, 1155 (9th Cir. 2012)).

^{236.} Yakima Valley Mem'l. Hosp. v. Wash. State Dep't. of Health, 731 F.3d 843, 847 (9th Cir. 2013) (quoting *Nat'l Ass'n of Optometrists & Opticians*, 682 F.3d at 1155).

"The decision of whether a nondiscriminatory regulation nevertheless significantly burdens interstate commerce depends 'on the interstate *flow of goods*....' [A] significant burden on interstate commerce does not exist simply because the nondiscriminatory ... regulations affect the structure of the market."²³⁷ In other words, "there is not a significant burden on interstate commerce merely because a non-discriminatory regulation precludes a preferred, more profitable method of operating a retail market."²³⁸ Courts have repeatedly held that the fact that manufacturers "may be financially burdened does not demonstrate that there is a burden on interstate commerce."²³⁹

Further, even assuming there is a burden on the flow of interstate commerce, the second prong of the *Pike* test focuses on the benefits of the challenged law, an inquiry to which the nature of the state's interests involved is critical.²⁴⁰ As an initial matter, the general subject of food labeling is one traditionally occupied by states.²⁴¹ The U.S. Supreme Court has emphasized that "a State's power to regulate commerce is never greater than in matters traditionally of local concern," and that "regulations that touch upon safety... are those that 'the Court has been most reluctant to invalidate."²⁴²

Beyond that, a state's interests are best established by each law's express purposes.²⁴³ These purposes include informing consumers, reducing

^{237.} Id. (emphasis in original) (quoting Nat'l Ass'n of Optometrists & Opticians, 682 F.3d at 1153); see Exxon Corp. v. Governor of Maryland, 437 U.S. 117, 127 (1978) (explaining that a Maryland law prohibiting oil refinery owners from also operating gas stations would cause some refiners to withdraw, but "interstate commerce is not subjected to an impermissible burden simply because an otherwise valid regulation causes some business to shift from one interstate supplier to another"); Minnesota v. Clover Leaf Creamery, 449 U.S. 456, 472 (1981) ("[T]he inconvenience of having to conform to different packaging requirements in Minnesota and the surrounding States should be slight.").

^{238.} *Nat'l Ass'n of Optometrists & Opticians*, 682 F.3d at 1148; *see also* Energy & Env't Legal Inst. v. Epel, No. 11-CV-00859-WJM-BNB, 2014 WL 1874977, at *6 (D. Colo. May 9, 2014) ("The dormant Commerce Clause neither protects the profits of any particular business, nor the right to do business in any particular manner.").

^{239.} Dex Media W., Inc. v. Seattle, 793 F. Supp. 2d 1213, 1237 (W.D. Wash. 2011); *Exxon Corp.*, 437 U.S. at 126–27; Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 110–11 (2d Cir. 2001).

^{240.} Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

^{241.} *See, e.g.*, Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977) (reviewing the notion that food labeling is traditionally state mediated); *see also* Florida Lime & Avocado Growers v. Paul, 373 U.S. 132, 144 (1963) (stating that the preparation of foods is within a state's authority to regulate).

^{242.} Kassel v. Consol. Freightways Corp., 450 U.S. 662, 679 (1981) (citation omitted) (quoting Raymond Motor Transp., Inc. v. Rice, 434 U.S. 429, 443 (1978)).

^{243.} Pac. Nw. Venison Producers v. Smitch, 20 F.3d 1008, 1012, 1017 (9th Cir. 1994); see id. ("Even in the context of dormant commerce clause analysis, the Supreme Court has frequently

consumer confusion and deception, and allowing consumers to make purchasing decisions in light of the public health concerns and unknowns regarding engineered foods and the adverse environmental impacts caused by their production.

Courts have long held such state interests in, *inter alia*, public health and environmental protection to be legitimate and substantial, outweighing any incidental burdens on interstate commerce. For over a century, the Supreme Court has emphasized the importance of allowing states to protect their citizens from fraud and deception, particularly in the area of food products:

> If there be any subject over which it would seem the States ought to have plenary control, and the power to legislate in respect to which it ought not to be supposed was intended to be surrendered to the general government, it is the protection of the people against fraud and deception in the sale of food products.²⁴⁴

Furthering public health and safety are also venerable state interests,²⁴⁵ as are conservation and environmental protection.²⁴⁶ Similarly, protecting local agricultural interests is a recognized legitimate interest.²⁴⁷ That the nature and extent of the potential health and environmental impacts of genetically engineered crops have not yet been conclusively established does not matter. In *Maine v. Taylor*, the U.S. Supreme Court reviewed a Maine statute that prohibited the import of live baitfish in order to protect native species from the

admonished that courts should not second-guess the empirical judgments of lawmakers concerning the utility of legislation." (internal quotation marks omitted)).

^{244.} Plumley v. Massachusetts, 155 U.S. 461, 472 (1894).

^{245.} Hughes v. Oklahoma, 441 U.S. 332, 337 (1979) (citing Locomotive Fireman v. Chicago, Rock Island & Pac. Ry. Co., 393 U.S. 129, 143–44 (1968)); Parker v. Brown, 317 U.S. 341, 362 (1943); United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 346–47 (2007) (finding that recycling incentives and enforcement conferred significant health and environmental benefits).

^{246.} *Hughes*, 441 U.S. at 337; *see* Minnesota v. Clover Leaf Creamery Co., 449 U.S. 456, 458, 461–62, 470–72 (1981) (upholding a Minnesota law banning the retail sale of milk in plastic, nonreturnable, non-refillable containers because the state's interests in promoting conservation of energy and other natural resources and easing solid waste disposal problems were a legitimate state concern that outweighed any incidental burden on interstate commerce).

^{247.} *Parker*, 317 U.S. at 367–68; *see also* Hampton Feedlot v. Nixon, 249 F.3d 814, 817, 820– 21 (8th Cir. 2001) (upholding a Missouri law addressing price discrimination in livestock sales even though it would burden interstate commerce because the state government had legitimate interests including preservation of the family farm and the state's rural economy).

potential risks from parasites carried in baitfish. ²⁴⁸ The Court explained:

"[T]he constitutional principles underlying the commerce clause cannot be read as requiring the State of Maine to sit idly by and wait until potentially irreversible environmental damage has occurred or until the scientific community agrees on what disease organisms are or are not dangerous before it acts to avoid such consequences."²⁴⁹

Rather, states have "a legitimate interest in guarding against imperfectly understood environmental risks, despite the possibility that they may ultimately prove to be negligible."²⁵⁰

Finally, the context of the inquiry is also important: Challengers may disagree with a state's interests or findings regarding the risks of genetically engineered foods, or the purposes of labeling, but disagreement is not enough to invalidate a law. Rather, when states enact statutes that affect interstate commerce, they "are not required to convince the courts of the correctness of their legislative judgments."²⁵¹ Here, state legislatures are determining that laws mandating labeling on genetically engineered foods will enable consumers to make informed health and safety decisions. The dormant Commerce Clause is not an opportunity to "second-guess the empirical judgments of lawmakers."²⁵² Rather, challengers have to "convince the court that the legislative facts on which the classification is apparently based could not reasonably be conceived to be true by the governmental decisionmaker."²⁵³ State legislatures can, and do, reasonably believe that genetically engineered food labeling laws would further legitimate public interests.

In sum, state labeling is constitutional because such laws regulate evenhandedly to effectuate legitimate public interests: the substantial and well-established interests in preventing consumer confusion and deception, and providing consumers with information related to potential health and environmental impacts. Such labeling laws have little to no cognizable

^{248.} Maine v. Taylor, 477 U.S. 131, 133 (1986).

^{249.} Id. at 148 (quoting United States v. Taylor, 585 F. Supp. 393, 397 (D. Me. 1984)).

^{250.} Id.

^{251.} Clover Leaf Creamery, 449 U.S. at 464.

^{252.} CTS Corp. v. Dynamics Corp. of Am., 481 U.S. 69, 92 (1978) (quoting Kassel v. Consol. Freightways Corp., 450 U.S. 662, 679 (1981) (Brennan, J., concurring)).

^{253.} *Clover Leaf Creamery*, 449 U.S. at 464 (internal citations and quotation marks omitted) (quoting Vance v. Bradley, 440 U.S. 93, 111 (1979)).

impact on the flow of interstate commerce because they do not stand as a market barrier. To the extent that these labeling laws burden interstate commerce, such a burden plainly would not outweigh the myriad benefits of labeling, let alone be "clearly excessive." Accordingly, state-mandated labeling of genetically engineered foods complies with the dormant Commerce Clause.

IV. LABELING GENETICALLY ENGINEERED FOODS IS CONSISTENT WITH THE FIRST AMENDMENT AND FURTHERS ITS PURPOSES

Labeling opponents argue that they have a First Amendment right to keep consumers in the dark about whether their foods are genetically engineered. However, the fundamental purpose of the First Amendment is to protect *individual* speech on "public issues" and "governmental affairs," not *commercial* speech.²⁵⁴

The U.S. Supreme Court has defined commercial speech as "expression related solely to the economic interests of the speaker and its audience."²⁵⁵ In fact, the Court only extended constitutional protection to commercial speech in 1976.²⁵⁶ Prior to that time, commercial speech was expressly outside the First Amendment's umbrella.²⁵⁷ Even now, its protection is more limited: Commercial speech occupies a "subordinate position in the scale of First Amendment values."²⁵⁸

Language on products differs from other messaging in part because government authority over commercial transactions "justifies its concomitant power to regulate commercial speech that is linked inextricably to those transactions."²⁵⁹ Unlike personal or political expression, which the First Amendment protects as valuable to both

258. Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 456 (1978).

259. 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 499 (1996) (internal quotation marks omitted) (quoting Friedman v. Rogers, 440 U.S. 1, 10 n.9 (1979)).

^{254.} Buckley v. Valeo, 424 U.S. 1, 14 (1976) (quoting Mills v. Alabama, 384 U.S. 214, 218 (1966)).

^{255.} Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 561 (1980) (citing Va. State Bd. Pharm. v. Citizens Consumer Council, 425 U.S. 748, 762 (1976)).

^{256.} *Va. State Bd. of Pharm.*, 425 U.S. at 762 (establishing certain limited free speech protections for commercial speakers); *see* Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 629 (1985) (observing that *Virginia State Board of Pharm.* "held for the first time that the First Amendment precludes certain forms of regulation of purely commercial speech").

^{257.} Valentine v. Chrestensen, 316 U.S. 52, 54 (1942), *overruled by*, *Va. State Bd. of Pharm.*, 425 U.S. 748, 758–61, 770 (following the progression of First Amendment jurisprudence to eventually provide explicit protections for commercial speech).

speakers and listeners,²⁶⁰ the extension of limited protection to commercial speech "is justified principally by the value to consumers of the information such speech provides."²⁶¹ Accordingly, a company's "constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal,"²⁶² and commercial disclosure requirements, as opposed to commercial speech bans, are preferred.²⁶³ In the words of the Second Circuit:

Commercial disclosure requirements are treated differently from restrictions on commercial speech because mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests. Such disclosure furthers, rather than hinders, the First Amendment goal of discovery of truth and contributes to the efficiency of the marketplace of ideas.²⁶⁴

Thus within commercial speech there are "material differences between disclosure requirements and outright prohibitions."²⁶⁵ Whereas prohibitions on commercial speech prevent a corporation from "conveying information to the public," commercial disclosures merely "provide somewhat more information than [the company] might otherwise be

^{260.} Kleindienst v. Mandel, 408 U.S. 753, 775 (1972) (Marshall, J., dissenting) ("[T]he First Amendment protects... the freedom to hear as well as the freedom to speak.... The activity of speakers becoming listeners and listeners becoming speakers in the vital interchange of thought is the means indispensable to the discovery and spread of political truth." (internal quotation marks omitted) (quoting Whitney v. California, 274 U.S. 357, 375 (1927))).

^{261.} Zauderer, 471 U.S. at 651 (citing Va. State Bd. Pharm., 425 U.S. at 762).

^{262.} *Id.* (emphasis in original); *see id.* at 652 n.14 (holding that the "right of a commercial speaker not to divulge accurate information" is not "fundamental").

^{263.} *Id.* at 652 n.14 ("[A]ll our discussions of restraints on commercial speech have recommended disclosure requirements as one of the acceptable less restrictive alternatives to actual suppression of speech." (citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 565 (1976))).

^{264.} Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 113–14 (2d Cir. 2001) (internal citations and quotation marks omitted); *see id.* ("[T]he individual liberty interests guarded by the First Amendment, which may be impaired when personal or political speech is mandated by the state, are not ordinarily implicated by compelled commercial disclosure." (internal citations omitted)); *see Va. State Bd. of Pharm.*, 425 U.S. at 771–72 ("The First Amendment . . . does not prohibit the State from insuring that the stream of commercial information flow cleanly as well as freely.").

^{265.} Zauderer, 471 U.S. at 650.

inclined to present."²⁶⁶ Consequently, the First Amendment interests effected by a disclosure requirement are "substantially weaker than those at stake when speech is actually suppressed,"²⁶⁷ and commercial disclosure requirements (e.g., product labeling) merit a different level of constitutional scrutiny than commercial speech bans—namely, rational-basis review and intermediate scrutiny, respectively.²⁶⁸

A. Background on Commercial Speech and the First Amendment

Over recent decades, several U.S. Supreme Court cases have shaped First Amendment jurisprudence on commercial speech. In Central Hudson Gas & Electric Corporation v. Public Service Commission of New York, the Court considered a prohibition on commercial speech.²⁶⁹ New York's Public Service Commission had banned promotional advertising by electrical utilities, declaring that such advertising contravened a national policy of conserving energy.²⁷⁰ The utilities challenged that restriction as contrary to the First Amendment.²⁷¹ Balancing free speech concerns regarding speech prohibitions against the lowered protection that commercial speech receives, the Court settled on intermediate scrutiny.²⁷² Initially, Central Hudson held that to receive any First Amendment protection, commercial speech "must concern lawful activity and not be misleading."273 Then, for a ban on that non-misleading speech to be constitutional, it must (1) further a "substantial" governmental interest, (2) directly advance that interest, and (3) be no more extensive than necessary to serve that interest.²⁷⁴

^{266.} *Id.* at 650. The Court explained that "in virtually all our commercial speech decisions to date, we have emphasized that... disclosure requirements trench much more narrowly on an advertiser's interests than do flat prohibitions on speech." *Id.* at 651.

^{267.} Id. at 652.

^{268.} See, e.g., Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 556 (6th Cir. 2011) (asserting that "[l]aws that restrict speech are fundamentally different than laws that require disclosures, and so are the legal standards governing each type of law," and explaining that *Central Hudson* "set[s] forth the standard for restricting commercial speech," while *Zauderer* "set[s] forth the standard for requiring commercial-speech disclosures"); *accord* United States v. Marzzarella, 614 F.3d 85, 96 (3d Cir. 2010); *Sorrell*, 272 F.3d 104 at 115; *see also* Spirit Airlines v. U.S. Dep't of Transp., 687 F.3d 403, 413 (D.C. Cir. 2012) (recognizing that disclosure requirements "are not the kind of limitations that the Court refers to when invoking the *Central Hudson* standard of review").

^{269.} Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 567-68 (1980).

^{270.} Id. at 559.

^{271.} Id. at 560.

^{272.} Id. at 573 (Blackmun, J., concurring).

^{273.} Id. at 566.

^{274.} Id.

Five years later, in *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, the Court considered both a ban on commercial speech and a compelled commercial disclosure requirement.²⁷⁵ The petitioner contested Ohio Disciplinary Rules that prohibited certain kinds of attorney advertising and required a disclosure for others.²⁷⁶ The Court applied *Central Hudson*'s intermediate scrutiny test to the ban,²⁷⁷ and the petitioner contended that *Central Hudson* also applied to Ohio's disclosure requirement.²⁷⁸ However, recognizing that disclosure requirements do not implicate First Amendment concerns over speech bans,²⁷⁹ as well as the limited nature of the protection extended to commercial speech,²⁸⁰ the Court instead applied a rational-basis test to the disclosure requirement.²⁸¹

The Court explained that the petitioner "overlook[ed] material differences between disclosure requirements and outright prohibitions on speech."²⁸² In particular, "Ohio ha[d] not attempted to prevent attorneys from conveying information to the public; it ha[d] only required them to provide somewhat more information than they might otherwise be inclined to present."²⁸³ The Court ultimately upheld the disclosure requirement because Ohio's required disclosure mandated inclusion only of "purely factual and uncontroversial information"²⁸⁴ and was reasonably related to the state's interest.²⁸⁵

In 2010, the Court reaffirmed *Zauderer*, again applying rational-basis review to a compelled commercial disclosure.²⁸⁶ Under *Zauderer*'s rational-basis standard,²⁸⁷ the Court has explained, "legislation is presumed to be

^{275.} Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985).

^{276.} *Id.* at 638–39.

^{277.} *Id.* at 642–44.

^{278.} Id. at 650.

^{279.} *See id.* at 652 ("[T]he First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed.").

^{280.} See id. at 637 (noting that First Amendment protections for commercial speech are "somewhat less extensive than [those] afforded 'noncommercial speech'") (quoting Bolger v. Youngs Drug Products Corp., 463 U.S. 60, 64–65 (1982)).

^{281.} Id. at 651.

^{282.} Id. at 650.

^{283.} Id.

^{284.} Id. at 651.

^{285.} Id.

^{286.} Milavetz, Gallop & Milavetz, P.A. v. United States, 559 U.S. 229, 249 (2010).

^{287.} The Zauderer standard "is akin to rational-basis review." R. J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin., 696 F.3d 1205, 1212 (D.C. Cir. 2012), overruled on other grounds, Am. Meat Inst. v. U.S. Dep't of Agric., No. 13-5281, slip op. (D.C. Cir. July 29, 2014); see Spirit Airlines, Inc. v. U.S. Dep't of Transp., 687 F.3d 403, 411 (D.C. Cir. 2012) (describing Zauderer's standard as "reasonableness review").

valid,"²⁸⁸ and a court must "uphold regulation so long as it bears a rational relationship to a legitimate governmental purpose."²⁸⁹

To summarize, commercial speech receives limited First Amendment protection because of the value the information provides *consumers*; a corporation's entitlement to protection of its own free speech interests is thus merely "minimal."²⁹⁰ Given that corporations' interest in not providing relevant product information is "minimal," courts subject factual commercial disclosure requirements to rational-basis review. To do otherwise by heightening scrutiny of compelled commercial speech would impermissibly disfigure the First Amendment, giving preference to a company's interest in withholding important information about its products—which it is uniquely, and often unilaterally, positioned to access—above the public's right to obtain knowledge prior to purchase.

B. State Labeling of Genetically Engineered Foods Is Constitutional Under Zauderer

As numerous courts have recognized, *Central Hudson* applies to commercial *restrictions* and *Zauderer* applies to commercial *disclosures*.²⁹¹ Under the *Zauderer* rational-basis test, a commercial disclosure of "purely factual and uncontroversial information" is constitutional if it furthers a legitimate government interest.²⁹²

Here, state-mandated labels on genetically engineered foods are consistent with the First Amendment because they require disclosure only of factual information about the use of genetic engineering in food production that serves the legitimate government interests of informing

292. Zauderer, 471 U.S. at 651.

^{288.} *Cf.* Lawrence v. Texas, 539 U.S. 558, 579 (2003) (O'Connor, J., concurring) (quoting Cleburne v. Cleburne Living Ctr., Inc., 473 U.S. 432, 440 (1985)) (explaining the rational-basis test under the equal protection clause).

^{289.} Dist. of Columbia v. Heller, 554 U.S. 570, 687–88 (2008) (Breyer, J. dissenting) (internal quotation marks omitted).

^{290.} Zauderer, 471 U.S. at 651.

^{291.} See Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001) ("Zauderer, not Central Hudson Gas & Electric Corp v. Public Service Comm'n, describes the relationship between means and ends demanded by the First Amendment in compelled commercial disclosure cases. The Central Hudson test should be applied to statutes that restrict commercial speech." (emphasis in original) (internal citation omitted)); accord Spirit Airlines, 687 F.3d 403 at 412, 413 (D.C. Cir. 2012) ("Disclosure requirements . . . are not the kind of limitations that the Court refers to when invoking the Central Hudson standard of review."); Commodity Trend Serv., Inc. v. Commodity Futures Trading Comm'n, 233 F.3d 981, 994 (7th Cir. 2000) ("The government can impose affirmative disclosures in commercial advertising if these are reasonably related to preventing the public from being deceived or misled.").

consumers, preventing consumer confusion and deception, and promoting public health and environmental protection.²⁹³

1. Genetically Engineered Food Labeling Is Subject to Review Under Zauderer, not Central Hudson

Labeling opponents argue that genetically engineered food disclosures should be reviewed under *Central Hudson*'s intermediate scrutiny test rather than *Zauderer*'s rational-basis test. In essence, then, they suggest that labeling is more akin to a speech ban than a "purely factual and uncontroversial" disclosure requirement.²⁹⁴ However, the line between *Zauderer* and *Central Hudson* is clear: respectively, disclosures (i.e., compelled speech) versus prohibitions on speech.

Industry's *Central Hudson* alternative would instead severely erode *Zauderer*, applying that case only to compelled commercial disclosures designed to remedy corporate deceit. According to industry, applying *Central Hudson* is appropriate if a company is not directly misleading its customers.²⁹⁵ However, courts have unanimously rejected arguments so restricting *Zauderer*.²⁹⁶

Zauderer does not stand for the proposition that intermediate scrutiny applies to any compelled commercial speech that does not remedy overt deceit. Rather, *Zauderer* established that a government interest in preventing consumer deception or confusion is *sufficient* to satisfy rational-basis review—not that it is the *sin qua non* component for the rational-basis test ever to apply.²⁹⁷ In fact, no court that has considered the issue has limited *Zauderer*'s test only to the prevention of deception.²⁹⁸

297. Am. Meat Inst. v. U.S. Dep't of Agric., No. 13-5281, slip op. at 7 (D.C. Cir. July 29, 2014) (holding that *Zauderer* "sweeps far more broadly than the interest in remedying deception").

298. For example, the First Circuit rejected the argument that *Zauderer* applies only where a government seeks to prevent consumer deception, stating, "we have found no cases limiting *Zauderer* in such a way." Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 310 n.8 (1st Cir. 2005). In fact, the only circuit decisions that have limited *Zauderer* to preventing outright consumer deception have recently

^{293.} Id. (quoting In re R.M.J., 455 U.S. 191, 201 (1982)).

^{294.} See Complaint at 15, Grocery Mfrs. Assoc. v. Sorrell, No. 5:14-cv-117 (D. Vt. June 12, 2014) (arguing *Zauderer* does not apply).

^{295.} See, e.g., Zauderer, 471 U.S. at 650–51.

^{296.} Zauderer, 471 U.S. at 650–51; R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin., 696 F.3d 1205, 1227 n.6 (D.C. Cir. 2012) (Rogers, J., dissenting) (citing Zauderer, 471 U.S. at 650–51; Disc. Tobacco City & Lottery v. United States, 674 F.3d 509, 556 (6th Cir. 2012); N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health, 556 F.3d 114, 133 (2d Cir. 2009)), overruled by, Am. Meat Inst. v. U.S. Dep't of Agric., No. 13-5281, slip op. (D.C. Cir. July 29, 2014)); see also Disc. Tobacco City, 674 F.3d at 556 ("Zauderer's framework can apply even if the required disclosure's purpose is something other than or in addition to preventing consumer deception.").

2. State Labeling for Genetically Engineered Foods Is a Factual and Uncontroversial Disclosure

Because the simple factual disclosure that a product is "produced through genetic engineering" is not controversial, the Zauderer standard applies. In contrast, industry's argument is that a manufacturer's bare desire not to disclose a fact of production makes that fact "controversial." This argument misleadingly conflates the express disclosure requirement with desire to withhold information. However, industry's Zauderer's requirement that a description be "purely factual and uncontroversial" concerns the *language* of a required disclosure (i.e., expressly, "information"); it does not consider whether industry wants consumers to have access to specific information. Labeling opponents' argument has no stopping point: Under it, any statement of fact industry wants to withhold would fail to qualify for *Zauderer* analysis because it would be allegedly "controversial," allowing industry to create its own controversy.

In reality, however, a straightforward statement of facts becomes "controversial" only if it contains *opinions*. Here, labeling on foods produced through genetic engineering is not "controversial" under *Zauderer* because industry cannot dispute that such a label describes a simple fact. It is not an opinion that can be disputed; that a product is produced through genetic engineering or not is an ascertainable fact. And that fact is no less pure and uncontroversial simply because the industry prefers to keep consumers in the dark. Accurate factual statements, such as "produced through genetic engineering" easily satisfy *Zauderer*'s requirement for disclosures, regardless of whether industry would prefer to withhold that information about production.

Recently, in a similar and instructive case, industrial food groups were unsuccessful in making this same argument about facts being "controversial." The case challenged USDA's country-of-origin labeling (COOL) as violative of industry's commercial speech rights.²⁹⁹ As with labeling on genetically engineered foods, COOL requires producers to label basic facts of food production in the form of the three major steps of meat

been overruled. *See* Nat'l Ass'n Mfrs. v. Sec. & Exch. Comm'n, 748 F.3d 359, 372 (D.C. Cir. 2014), *overruled by, Am. Meat Inst.*, slip op. at 16–17 (limiting *Zauderer* to preventing consumer deception); *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1212, 1217 (*"Zauderer . . .* establish[es] that a disclosure requirement is only appropriate if the government shows that, absent a warning, there is a self-evident—or at least 'potentially real'—danger that an advertisement will mislead consumers." (citation omitted)).

^{299.} Am. Meat Inst., slip op. at 9, 16-17.

production: where an animal was born, raised, and slaughtered.³⁰⁰ With COOL, industry contended that *Zauderer*'s rational-basis review should be limited only to commercial disclosure requirements "where the company has no objection to the message conveyed by the compelled speech"³⁰¹—i.e., where it consents to the existence of the disclosure. However, the D.C. Circuit, sitting *en banc*, disagreed, concluding instead that COOL is purely factual and uncontroversial because it mandates disclosure only of facts that are not disputed as untrue.³⁰²

As with COOL, industrial food groups do not—and indeed cannot contend that a statement acknowledging the way a food was produced is somehow untrue. Consequently, state labeling of genetically engineered foods satisfies *Zauderer*'s requirement that a disclosure be purely factual and uncontroversial.

3. State-Mandated Labeling of Genetically Engineered Foods Furthers Important Government Interests

States have plainly legitimate interests in mandating disclosures that, among other things, promote public health and environmental protection, as courts have long recognized. For example, following *Zauderer*, the Second Circuit held as legitimate a state interest in protecting public health via nutrition disclosures that "promote informed consumer decision-making so as to reduce obesity and the diseases associated with it."³⁰³ Similarly, the First Circuit applied *Zauderer* in holding that Maine has legitimate interests in promoting human health by "ensuring that its citizens receive the best and most cost-effective health care possible" and "increasing public access to prescription drugs."³⁰⁴ And the D.C. Circuit recently held *en banc* that COOL satisfies *Zauderer* because it advances, *inter alia*, a "substantial"

^{300.} *See id.* at 3–4 (describing Congress' definition of "country of origin" for the purpose of COOL labeling).

^{301.} Brief for Nat'l Ass'n of Mfrs. et al., as Amici Curiae Supporting Appellants at 15, Am. Meat Inst. v. Dep't Agric., 746 F.3d 1065 (2014) (No. 13-5281) (requesting that *Zauderer* be "limited to '*purely* factual *and* uncontroversial' disclosures, where the company has no objection to the message conveyed by the compelled speech").

^{302.} Am. Meat Inst., slip op. at 14-15.

^{303.} N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health, 556 F.3d 114, 133–34 (2d Cir. 2009); *see also* Entm't Software Ass'n v. Blagojevich, 469 F.3d 641, 651 (7th Cir. 2006) ("[T]he Constitution permits the State to require speakers to express certain messages without their consent, the most prominent examples being warning and nutritional information labels.").

^{304.} Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 310 (1st Cir. 2005).

government interest in protecting consumers' right to choose foods that they reasonably perceive as the safest.³⁰⁵

Public health is intimately related to—and directly influenced by—the environment. Both health and environmental disclosure information are legitimate government interests served by labeling. As the Second Circuit has held, under *Zauderer*, "Vermont's interest in protecting human health and the environment from mercury poisoning is a legitimate and significant public goal."³⁰⁶ And, in a somewhat different context, the Ninth Circuit recognized as "legitimate" and consistent with the First Amendment an agency's interest in requiring storm sewer providers to educate the public about impacts from stormwater discharge into water bodies and to inform the public about the hazards of improper waste disposal.³⁰⁷

Here, state labeling of genetically engineered foods furthers important government interests in promoting both human health and environmental protection. For example, Vermont's Act 120 finds that genetically engineered foods "potentially pose risks to health, safety, agriculture, and the environment."³⁰⁸ Accordingly, Vermont passed a law mandating labeling "to prevent inadvertent consumer deception, prevent potential risks to human health, protect religious practices, and protect the environment."³⁰⁹ Such interests are plainly legitimate under *Zauderer*. Further, courts must "assume that the objectives articulated by the legislature are actual purposes of the statute."³¹⁰

Labeling opponents try to undercut the state interests that support disclosures on genetically engineered foods by contending that health

^{305.} *Am. Meat Inst.*, slip op. at 9 ("[S]everal aspects of the government's interest in [COOL] for food . . . make the interest substantial: . . . [COOL] enable[s] consumers to choose American-made products; the demonstrated consumer interest in extending country-of-origin labeling to food products; and the individual health concerns and market impacts that can arise in the event of a food-borne illness outbreak."). Because the court held these interests were "substantial," it did not need to reach whether a lesser interest could suffice under *Zauderer. Id.* at 9.

^{306.} Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001).

^{307.} See Envtl. Def. Ctr., Inc. v. U.S. Envtl. Prot. Agency, 344 F.3d 832, 849 (9th Cir. 2003) (concluding that disclosure requirements did not require the conveyance of a specific message, but rather informational activities that may or may not take the form of speech); Dex Media W., Inc. v. City of Seattle, 793 F. Supp. 2d 1213, 1230–32 (W.D. Wash. 2011) (analyzing and approving under *Zauderer* a city's interests in reducing paper waste and maintaining resident privacy), *rev'd*, 696 F.3d 952 (9th Cir. 2012).

^{308.} Act 120, *supra* note 7, Sec. 1(4).

^{309.} Id. at Sec. 1(6).

^{310.} Minnesota v. Clover Leaf Creamery, 449 U.S. 456, 463 n.7 (1981); *accord* Am. Beverage Ass'n v. Snyder, 735 F.3d 362, 372 (6th Cir. 2013) ("Absent concrete evidence *from the statutory language* that the unique-mark requirement is purposefully discriminatory, Plaintiff cannot prevail on this claim." (emphasis added)).

concerns about these foods are invalid because harm to health has not been proven. But this argument falls flat. First, governments do not simply require labels on food products if they definitively know such foods are harmful; rather, they pull those foods off market shelves.

Second, the standard for evaluating the legitimacy of a government's public health interest is whether that interest protects consumers' reasonable perceptions of enhanced safety, not whether a product meets some baseline federal safety standard for human use or consumption. States have a legitimate interest in guarding against "imperfectly understood . . . risks, despite the possibility that they may ultimately prove to be negligible."³¹¹ In other words, states have a legitimate interest in allowing consumers to optimize their health by avoiding foods that potentially pose safety risks, not merely in allowing consumers to avoid foods that are known to be harmful. Federal food safety standards are thus a floor, not a ceiling, and states may legitimately require labeling that is reasonably likely to facilitate improved and informed human health decisions.

4. State-Mandated Labeling of Genetically Engineered Foods Prevents Consumer Confusion and Thus Satisfies Even Circumscribed *Zauderer* Review

Various government interests beyond preventing consumer deception are cognizable under *Zauderer*.³¹² However, even if *Zauderer* were so limited, state labeling of genetically engineered foods would still satisfy the rational-basis standard.

First, the *Zauderer* standard cannot logically be limited to interests in preventing outright deception because commercial speech that is "misleading" or "inherently likely to deceive" receives no First Amendment protection at all.³¹³ Instead, *Zauderer* applies to factual disclosures that remedy the "possibility of consumer confusion or deception."³¹⁴ Under *Zauderer*, a disclosure need only relate to a non-speculative "likelihood of

^{311.} Maine v. Taylor, 477 U.S. 131, 148 (1986); *see* Grocery Mfrs. of Am., Inc. v. Gerace, 755 F.3d 993, 1004 (2d Cir. 1985) (concluding that the existence of a "controversy" demonstrated that a state's concerns were not unreasonable); *see also* Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 313 (1st Cir. 2005) ("It matters not whether these benefits actually come into being at the end of the day.").

^{312.} See supra notes 296–98 (citing cases that have held that Zauderer is not limited to preventing deception).

^{313.} In re R.M.J., 455 U.S. 191, 202-03 (1982).

^{314.} Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985) (quoting *In re R.M.J.*, 455 U.S. at 201); *see* Spirit Airlines, Inc. v. U.S. Dep't of Transp., 687 F.3d 403, 413 (D.C. Cir. 2012) (recognizing that *Zauderer* requires merely "the *possibility* of deception").

deception," or a "tendency to mislead."³¹⁵ Thus a government may mandate a factual disclosure to address consumers' "confusion" about a product, including the possibility of confusion via omission of information.

For example, the Tenth Circuit held under *Zauderer* that a disclosure requirement remedied a possibility of consumers being misled when it required stock publicists to disclose that they receive consideration from the companies they promote.³¹⁶ That requirement remedied potential deception by mandating full disclosure of factual information that was relevant to consumer purchasing decisions. Similarly, in upholding a compelled commercial disclosure, the Second Circuit stated:

To be sure, the compelled disclosure at issue here was not intended to prevent "consumer confusion or deception" per se... but rather to better inform consumers about the products they purchase. Although the overall goal of the statute is plainly to reduce the amount of mercury released into the environment, it is inextricably intertwined with the goal of increasing consumer awareness of the presence of mercury in a variety of products.³¹⁷

The U.S. Supreme Court has similarly explained that a "warning or disclaimer might be appropriately required . . . in order to dissipate *the possibility of consumer confusion or deception.*"³¹⁸ In short, government-mandated factual disclosures are constitutional when they fill important informational gaps that otherwise would potentially confuse consumers.

With state labeling of genetically engineered foods, the requisite "common sense" review³¹⁹ demonstrates a possibility that consumers are confused or have been misled about whether a majority of processed foods are genetically engineered. Indeed, the federal government has thus far

^{315.} Milavetz, Gallop & Milavetz, P.A. v. United States, 559 U.S. 229, 251 (2010) (quoting *Zauderer*, 471 U.S. at 652–53); *Zauderer*, 471 U.S. at 652–53 (quoting FTC v. Colgate-Palmolive Co. 380 U.S. 374, 391–92 (1964)).

^{316.} United States v. Wenger, 427 F.3d 840, 849-50 (10th Cir. 2005).

^{317.} Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001) (internal citation omitted) (emphasis added) (quoting *Zauderer*, 471 U.S. at 651).

^{318.} In re R.M.J., 455 U.S. at 201 (emphasis added).

^{319.} See Spirit Airlines, 687 F.3d at 413 (citing Milavetz, Gallop & Milavetz, P.A., 559 U.S. at 249) (explaining that a "common sense" assessment of surrounding circumstances of a disclosure is sufficient to establish a possibility of deception). Similarly, a disclosure requirement is sufficient even if it is "under-inclusive" or "piecemeal." *Zauderer*, 471 U.S. at 651 n.14 (citing Zablocki v. Redhail, 434 U.S. 374, 390 (1978)).

refused to require such labeling, allowing corporations to withhold information that is highly relevant to consumers' purchasing decisions.

Further, and more generally, labeling production-method information on foods is especially critical where, as with genetically engineered foods, the market for conventional food products has failed to inform consumers about significant production criteria.³²⁰ For example, here, absent required labeling, consumers cannot determine whether conventional foods are created through use of genetic engineering, and are instead potentially misled into thinking they are natural—i.e., produced through traditional breeding. As Vermont's Act 120 found, polls show that "many consumers are under an incorrect assumption about whether the food they purchase is produced from genetic engineering."³²¹ Indeed, numerous class action lawsuits have been filed based on the theory that labeling genetically engineered food as "natural" is false and misleading.³²²

Without labeling, consumers who reasonably prefer traditional, nonengineered food cannot select products consistent with their values and food safety preferences unless they can afford to buy, and can access, organic foods. Since there is no federal standard for "natural" and genetically engineered foods are regularly labeled as "natural," consumers are continuously deceived and misled, absent mandatory labeling.³²³ Requiring labeling remedies such confusion and deception, correctly placing the burden on the corporations to disclose factual information about the foods from which they profit.

C. Courts Have Applied Zauderer and Upheld Similar Labeling Requirements

Under *Zauderer*, courts have upheld commercial disclosure requirements that are similar to state laws requiring disclosure of food produced with genetic engineering. In fact, in just the last five years, the Second, Sixth, and D.C. Circuits have concluded that various food labeling

^{320.} See Kysar, supra note 114, at 537 ("[P]roduct manufacturers not only remain generally free of mandates to disclose process information, but also are beginning to enjoy legal protections both from government efforts to introduce such mandates and from consumer efforts to obtain and act on process information through other means.").

^{321.} Act 120, supra note 7, Sec. 1(5)(B).

^{322.} Nicole E. Negowetti, *Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority*, GOVERNANCE STUDIES AT BROOKINGS (The Brookings Inst., Washington, D.C.), June 2014, at 1, *available at* http://www.brookings.edu/~/media/research/files/papers/2014/06/26-food-labeling-litigation/negowetti_food-labeling-litigation.pdf.

^{323.} Id. at 2.

requirements are consistent with the First Amendment.³²⁴ Under those cases, *Zauderer* governs review of compelled commercial speech, regardless of whether a government's interest lies in preventing deception or in furthering some other legitimate purpose.

In *New York State Restaurant Association v. New York City Board of Health*, the Second Circuit assessed the constitutionality of a New York City requirement that restaurants post calorie content information on their menus and menu boards.³²⁵ The court explained that "rules 'mandating that commercial actors disclose commercial information' are subject to the rational basis test" prescribed by *Zauderer*.³²⁶ The Second Circuit went on to hold that calorie labeling on menus was constitutional because it furthered a legitimate interest in preventing obesity—i.e., in promoting optimum human health.³²⁷ Despite industry's objections to the contrary, the court concluded that the calorie labeling requirement was purely factual and uncontroversial because it required only factually accurate text, and industry's preference for withholding that information failed to render the disclosure requirement controversial.³²⁸

In *International Dairy Foods v. Boggs*, the Sixth Circuit addressed the constitutionality of an Ohio regulation regarding the labeling of rBGH-free milk.³²⁹ The background and facts of the *Boggs* case are summarized *supra*³³⁰ in the context of that case's dormant Commerce Clause holding. As relevant here, Ohio also required that a factual disclosure be applied to any milk labeled as rBGH-free that would state that, according to the FDA, there is no difference between milk derived from rBGH-treated cows versus untreated cows.³³¹ The Sixth Circuit rejected the plaintiffs' argument that *Central Hudson* applied to that disclosure requirement, observing that Ohio "does not prohibit the use of production claims. It instead requires only the disclosure of accompanying information."³³² Thus, "[b]ecause the Ohio Rule regulates production claims by requiring them to be accompanied by a disclosure, *Zauderer* controls our review."³³³ Under *Zauderer*, the Sixth

- 330. See supra Part.III.B.
- 331. Boggs, 622 F.3d at 640.

^{324.} Am. Meat Inst. v. U.S. Dep't of Agric., No. 13-5281, slip op. at 17 (D.C. Cir. July 29, 2014); Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 641–42 (6th Cir. 2010); N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health, 556 F.3d 114, 117–18, 136 (2d Cir. 2009).

^{325.} N.Y. State Rest. Ass'n, 556 F.3d at 117-18.

^{326.} Id. at 132 (quoting Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 114 (2d Cir. 2001)).

^{327.} Id. at 134-36.

^{328.} Id. at 134.

^{329.} Boggs, 622 F.3d at 632.

^{332.} Id. at 642.

^{333.} Id. at 641.

Circuit upheld Ohio's disclosure requirement as reasonably related to that state's interests.³³⁴

Most recently, the D.C. Circuit heard *American Meat Institute v. U.S. Department of Agriculture*, which concerned the constitutionality of country-of-origin labeling (COOL) on raw meat.³³⁵ Pursuant to COOL, meat processors must label meat products with information regarding where the animal was born, raised, and slaughtered.³³⁶ The American Meat Institute (AMI) filed suit to challenge COOL as, among other things, a compelled commercial disclosure that contravened the First Amendment.³³⁷ The D.C. District Court disagreed, applying *Zauderer* and concluding that COOL was reasonably related to the government's interest in preventing consumer confusion.³³⁸ AMI appealed, and the D.C. Circuit affirmed.³³⁹ The circuit court then decided to rehear the appeal *en banc* specifically to address the scope of *Zauderer*. In its July 2014 *en banc* decision, the D.C. Circuit held both that *Zauderer* is the appropriate standard of review and that "*Zauderer* in fact does reach beyond problems of deception."³⁴⁰

According to the D.C. Circuit, COOL is constitutional because it mandates disclosure of "purely factual and uncontroversial" information and is reasonably related to legitimate government interests.³⁴¹ As an initial matter, COOL is purely factual and uncontroversial because AMI could not dispute the truth of the mandated text.³⁴² Further, the court held that COOL furthers a "substantial" government interest in allowing consumers to choose American products and allowing consumers to purchase products that they reasonably perceive to be safest.³⁴³ Finally, COOL satisfies *Zauderer*'s rational-basis test because, "by acting only through a reasonably crafted disclosure mandate, the government meets its burden of showing that the mandate advances its interest in making the 'purely factual and uncontroversial information' accessible" to consumers.³⁴⁴ Given those

343. Id. at 9.

344. Id. at 14-15.

^{334.} Id. at 640, 642.

^{335.} Am. Meat Inst. v. U.S. Dep't of Agric., No. 13-5281, slip op. at 17 (D.C. Cir. July 29, 2014).

^{336.} Id. at 5.

^{337.} Id.

^{338.} Am. Meat Inst. v. U.S. Dep't of Agric., 968 F. Supp. 2d 38, 48-52 (D.D.C. 2013).

^{339.} Am. Meat Inst. v. U.S. Dep't of Agric., 746 F.3d 1065, 1069 (D.C. Cir. 2014), vacated as moot by Am. Meat Inst. v. U.S. Dep't of Agric., No. 13-5281, slip op. (D.C. Cir. Apr. 4, 2014).

^{340.} Am. Meat Inst. v. U.S. Dep't of Agric., No. 13-5281, slip op. at 3 (D.C. Cir. July 29, 2014). 341. *Id.* at 15.

^{342.} Id. at 16.

conclusions, the D.C. Circuit upheld COOL as consistent with the First Amendment. $^{\rm 345}$

These recent food labeling cases confirm that *Zauderer*, not *Central Hudson*, governs review of compelled commercial disclosures,³⁴⁶ and the same will apply to state labeling of genetically engineered foods. These cases also demonstrate that labeling genetically engineered foods is "purely factual and uncontroversial" under *Zauderer* because labeling opponents do not, and cannot, dispute that such labeling requires purely accurate factual disclosures.³⁴⁷ The industry's preference for withholding information about the use of genetic engineering fails to render state labeling controversial under *Zauderer*.³⁴⁸ Finally, these cases affirm that *Zauderer* extends to legitimate interests beyond preventing consumer deception, including states' legitimate interest in promoting consumers' ability to make choices that improve their own health.³⁴⁹

D. State Laws Requiring the Labeling of Genetically Engineered Foods Also Pass Muster Under Central Hudson

As explained above, *Zauderer*, not *Central Hudson*, provides the controlling standard for factual disclosures in commercial speech, such as the labeling of GE foods. Nevertheless, even under *Central Hudson*'s intermediate scrutiny test, state-mandated labeling of genetically engineered foods is constitutional.

In *Central Hudson*, the U.S. Supreme Court established intermediate scrutiny for analyzing bans on commercial speech. For a ban on non-misleading commercial speech to be constitutional, it must (1) further a "substantial" governmental interest; (2) directly advance that interest; and

^{345.} Id. at 17.

^{346.} See id. at 6 (applying Zauderer to government mandates requiring "disclosure of 'purely factual and uncontroversial information' appropriate to prevent deception in the regulated party's commercial speech" (quoting Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985)); Int'l Dairy Foods v. Boggs, 622 F.3d 628, 641 (6th Cir. 2010) (applying Zauderer to a state law compelling the disclosure of information regarding rbGH in milk); N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health, 556 F.3d 114, 133 (2d Cir. 2009) (quoting Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 105, 115 (2nd Cir. 2001)) (applying Zauderer to a state law compelling commercial disclosures of information).

^{347.} Am. Meat Inst., slip op. at 16 (quoting Zauderer, 471 U.S. at 651).

^{348.} See N.Y. State Rest. Ass'n, 556 F.3d at 133–34 (finding that the food industry's preference to provide complete nutrition information instead of calorie information was invalid).

^{349.} Am. Meat Inst., slip op. at 9; see also N.Y. State Rest. Ass'n, 556 F.3d at 133–34 (holding that compelled commercial disclosure for the sake of combatting obesity was a legitimate state interest).

(3) be no more extensive than necessary to serve that interest.³⁵⁰ The Court has never applied *Central Hudson* to a commercial disclosure requirement, rather than a ban on speech. Furthermore, the few circuit cases that have expressly applied *Central Hudson*, rather than *Zauderer*, to a compelled commercial disclosure case have been limited only to their facts³⁵¹ or directly overruled.³⁵²

Nevertheless, even if *Central Hudson* applied, state labeling laws would still pass constitutional muster. First, state labeling of genetically engineered foods promotes "substantial" state interests such as promoting human health and environmental protection, and preventing consumer confusion.³⁵³ Under the Supreme Court's *Central Hudson* jurisprudence, any of those interests is sufficient.³⁵⁴

Second, state labeling of genetically engineered foods directly advances those state interests because there is an "immediate connection"³⁵⁵ between disclosing whether foods are produced through genetic engineering and allowing consumers to avoid foods with questionable health and environmental impacts. State labeling also informs consumers who may otherwise be confused about whether unlabeled foods (e.g., "natural" foods) are genetically engineered.

Finally, state-mandated labeling on genetically engineered foods is no more extensive than necessary to serve state interests. A state need not choose the "least restrictive means" of achieving a goal; rather, there must simply be a "reasonable" fit between means and ends.³⁵⁶ As the Supreme

^{350.} Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980).

^{351.} Nat'l Elec. Mfrs. v. Sorrell, 272 F.3d 104, 115 n.6 (2d Cir. 2001) (limiting Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996), to its facts).

^{352.} See Nat'l Ass'n of Mfrs. v. Sec. & Exch. Comm'n, No. 13-5252, 2014 WL 1408274, at *9 (D.C. Cir. Apr. 14, 2014), overruled by, Am. Meat Inst., slip op. at 3; R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin., 696 F.3d 1205, 1212 (D.C. Cir. 2012) (applying *Central Hudson* to a compelled commercial disclosure requirement, but this opinion has been overruled); cf. Amestoy, 92 F.3d at 71 (applying *Central Hudson* to a compelled commercial disclosure where the state failed to even mention *Zauderer*).

^{353.} Cent. Hudson, 447 U.S. at 566.

^{354.} *See id.* at 568 (noting that conserving energy is a "substantial" interest); Rubin v. Coors Brewing Co., 514 U.S. 476, 485 (1995) (concluding that "promoting health, safety, and welfare" are "substantial" interests under *Central Hudson* (quoting Posadas de P.R. Assocs. v. Tourism Co., 478 U.S. 328, 341 (1986))); *see also* Edenfield v. Fane, 507 U.S. 761, 767, 769 (1993) (concluding that ensuring the "accuracy of commercial information in the market-place" is a "substantial" interest under *Central Hudson*).

^{355.} *Cent. Hudson*, 447 U.S. at 569 (concluding that a speech ban directly advanced the state's interest in energy conservation).

^{356.} Bd. of Trs. v. Fox, 492 U.S. 469, 480 (1989) (citing *In re* R.M.J., 455 U.S. 191, 203 (1982)).

Court has explained, "we do not think it appropriate to strike down such requirements merely because other possible means by which the State might achieve its purposes can be hypothesized."³⁵⁷ With genetically engineered food labeling, there is a reasonable fit between the means—a plainly worded, factual label indicating that a particular food product was "produced through genetic engineering"³⁵⁸—and the ends—informing consumers of the fact that foods were produced using genetic engineering.³⁵⁹ Consequently, labeling also satisfies this third factor, satisfying the *Central Hudson* standard.

E. Amestoy *Is Inapplicable to State Labeling of Genetically Engineered Foods*

As purported support for First Amendment challenges to food labeling laws, labeling opponents have clung with nostalgia to *International Dairy Foods Association v. Amestoy*, a 1996 case in which the Second Circuit overturned a commercial disclosure requirement under *Central Hudson*.³⁶⁰ In *Amestoy*, industry challenged a Vermont law requiring disclosures on milk from cows treated with a genetically engineered, bovine growth hormone, asserting, among other things, that the law violated the First Amendment.³⁶¹ In response, Vermont argued that its disclosure requirement passed muster under *Central Hudson*'s intermediate scrutiny test, without arguing that *Zauderer*'s rational-basis test applied.³⁶²

Given Vermont's framing, the Second Circuit applied *Central Hudson* and concluded that the disclosure requirement was unconstitutional because Vermont had failed to establish a "substantial" interest.³⁶³ According to the panel majority, Vermont "d[id] not claim that health or safety concerns" prompted the disclosure requirement, "but instead defend[ed] the statute on the basis of strong consumer interest and the public's right to know."³⁶⁴

^{357.} Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 652 (1985).

^{358.} See, e.g., Act 120, supra note 7, § 3043(b)(1) (requiring that genetically engineered foods be labeled with specifically worded language to alert customers of the contents of their food).

^{359.} See, e.g., *id.* (outlining the purpose behind labeling foods which contain genetically modified ingredients).

^{360.} Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73 (2d Cir. 1996).

^{361.} Id. at 69-70.

^{362.} Brief for Defendants-Appellees at 29, Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996) (No. 95-7819), 1995 WL 17049818, at *29–30.

^{363.} Amestoy, 92 F.3d at 73.

^{364.} *Id. But see id.* at 74 (Leval, J., dissenting) ("Vermont's regulation requiring disclosure of use of [the GE growth hormone] rBST in milk production was based on substantial state interests, including worries about rBST's impact on human and cow health, fears for the survival of small dairy

Infamously, the court explained that "consumer curiosity alone" did not promote a "substantial" state interest under *Central Hudson*.³⁶⁵ That is, manufacturers cannot be compelled to disclose information absent "some indication" that the information "bears on a reasonable concern for human health or safety or some other sufficiently substantial governmental concern."³⁶⁶

However, *Amestoy* is entirely inapposite. First, unlike current labeling laws, *Amestoy* concerned only review under *Central Hudson*, because the government in that case failed to argue that *Zauderer* provided the proper standard of review for commercial disclosure requirements.³⁶⁷ Accordingly, the Second Circuit simply assumed that *Central Hudson* applied rather than *Zauderer*.³⁶⁸ This begs the question of how that case would have turned out under *Zauderer*. In sharp contrast, challenges to any state labeling of genetically engineered foods will proceed under the *Zauderer* standard of review.

Second, the Second Circuit itself has subsequently held (1) that *Zauderer*, not *Central Hudson*, applies to factual commercial disclosure requirements, and (2) that *Zauderer* extends beyond preventing deception.³⁶⁹ Since *Amestoy*, the Second Circuit has expressly and repeatedly stated that where "regulations compel disclosure without suppressing speech, *Zauderer*, not *Central Hudson*, provides the standard of review."³⁷⁰ Further, the court has recognized as "legitimate" under *Zauderer* various state interests beyond preventing deception, including

farms, and concerns about the manipulation of nature through biotechnology." (internal quotation marks omitted) (quoting Int'l Dairy Foods Ass'n v. Amestoy, 98 F.Supp. 246, 249 (D. Vt. 1995))).

^{365.} Id. at 73-74.

^{366.} Id. at 74.

^{367.} Brief for Defendants-Appellees, *supra* note 362, at 29–30.

^{368.} See Amestoy, 92 F.3d at 73 (applying *Central Hudson* to compelled commercial speech but not mentioning *Zauderer*).

^{369.} Conn. Bar Ass'n v. United States, 620 F.3d 81, 96 (2d Cir. 2010) (quoting Nat'l Elec. Mfrs. v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001)); N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health, 556 F.3d 114, 133 (2d Cir. 2009); *Sorrell*, 272 F.3d at 115.

^{370.} Conn. Bar Ass'n, 620 F.3d at 93; accord N.Y. State Rest. Ass'n, 556 F.3d at 133 (quoting Sorrell, 272 F.3d at 115); Sorrell, 272 F.3d at 115 ("Zauderer, not Central Hudson, describes the relationship between means and ends demanded by the First Amendment in compelled commercial disclosure cases.").

increasing consumer awareness of harmful substances in products,³⁷¹ reducing pollution,³⁷² and reducing obesity.³⁷³

Finally, the Second Circuit has expressly narrowed *Amestoy*, limiting its precedential effect to instances "in which a state disclosure requirement is supported by *no interest other than the gratification of 'consumer curiosity.*"³⁷⁴ But state labeling of genetically engineered foods does not meet this narrow criterion. Given the myriad substantial state interests and purposes that are expressly identified in the text of such state labeling, including preventing consumer confusion and deception and promoting human health and environmental protection, *Amestoy* is simply inapplicable.

CONCLUSION

Food industry lobbyists realize that it is a losing proposition to outright oppose the labeling of genetically engineered foods. Indeed, as noted, polls consistently conclude that over 90% of U.S. consumers favor such labeling because it provides the transparency that industry already grants its customers in scores of other countries.³⁷⁵ However, instead of consenting to consumers' reasonable preferences and simply labeling genetically engineered foods in the United States, labeling opponents—i.e., agrochemical companies and the multinational industries they serve—use their economic largesse to broadcast purported policy, economic, or legal flaws in state labeling legislation.

Industry says that state labeling will raise its costs, even though it regularly changes food labels as a natural course of business for marketing or regulatory reasons.³⁷⁶ Further, these multinational companies already label genetically engineered food all over the world. State laws are allegedly uneven in their scope, despite being consistent with international

^{371.} *Sorrell*, 272 F.3d at 115 (concluding that the state's goal of reducing mercury pollution was "inextricably intertwined with the goal of increasing consumer awareness of the presence of mercury in a variety of products," and that "the compelled disclosure at issue here was... [intended] to better inform consumers about the products they purchase" (internal citation omitted)).

^{372.} Id. (concluding "the state's goal of reducing mercury contamination" was legitimate).

^{373.} N.Y. State Rest. Ass'n, 556 F.3d at 136.

^{374.} Sorrell, 272 F.3d at 115 n.6 (quoting Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73 n.1 (2d Cir. 1996)) (emphasis added).

^{375.} *See, e.g., U.S. Polls on GE Food Labeling, supra* note 10 (presenting polling results that indicate a high level of support for the labeling of GMO foods).

^{376.} Kai Robertson, *Independent Study: Why Label Changes Don't Affect Food Prices*, JUST LABEL IT! 5 (Sept. 11, 2013), http://justlabelit.org/wp-content/uploads/2013/09/Kai-Roberston-Food-Labeling-Study-2013.pdf.

labeling standards. Opponents also argue that disclosure labeling infringes on their speech rights, even though their constitutional right to withhold factual commercial information is minimal, and the protection of commercial speech is predicated on the value such speech has for *consumers*. Industry groups claim that federal law supersedes state labeling laws, even though there is no federal law that directly addresses genetically engineered organisms, let alone the labeling of these organisms. Finally, according to industry, state laws will create a patchwork of different requirements, even though there is no evidence of that in practice.

Yet, while struggling against the rising tide of state-mandated labeling, these agrochemical companies have not supported federal legislation that would require nationwide labeling, thereby solving their "patchwork" problem. Instead, industry has aggressively lobbied Congress to expressly preempt states from requiring labeling, without asking for any meaningful federal labeling in return. These actions reveal industry's true goal: protecting their opaque status quo.³⁷⁷

All Americans have the right to know if their food is produced with genetic engineering, and labeling proponents have toiled for such action for nearly two decades, at both the congressional and federal agency level.³⁷⁸ However, facing a lack of leadership in Washington, D.C., labeling advocates have simultaneously worked to improve oversight and to require labeling at the state level, too. This state-level approach is the natural course in our federal system, and labeling opponents' objections disregard history and civics. For example, the USDA organic label similarly began at the state level, in Oregon in 1973,³⁷⁹ followed by California in 1979,³⁸⁰ and

^{377.} Press Release, Ctr. for Food Safety, supra note 172; see also Wilce, supra note 25.

^{378.} Ctr. for Food Safety, *supra* note 142, at 2–3, 18–19; *About GE Food Labeling*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/about-ge-labeling (last visited Dec. 9, 2014). Bills introduced regarding the labeling of genetically engineered food include: Genetically Engineered Foods Act, S. 2546, 108th Cong. (2004); S. 3095, 107th Cong. (2002); S. 3184, 106th Cong. (2000); H.R. 713, 107th Cong. (2002); Genetically Engineered Food Safety Act, H.R. 3554, 112th Cong. (2011); Genetically Engineered Food Right to Know Act, H.R. 3553, 112th Cong. (2011); Genetically Engineered Food Safety Act, H.R. 5578, 111th Cong. (2010); H.R. 5268, 109th Cong. (2006); Genetically Engineered Food Safety Act, H.R. 2917, 108th Cong. (2003); H.R. 4813, 107th Cong. (2021); S. 2080, 106th Cong. (2000); Genetically Engineered Food Right to Know Act, H.R. 1699, 113th Cong. (2013); S. 809, 113th Cong. (2013); Genetically Engineered Food Right to Know Act, H.R. 5577, 111th Cong. (2010); H.R. 6636, 110th Cong. (2008); Genetically Engineered Food Right to Know Act, H.R. 2916, 108th Cong. (2003); H.R. 4814, 107th Cong. (2002); A Bill to Amend the Federal Food, Drug, and Cosmetic Act to Require Labeling of Genetically Engineered Fish, S. 248, 113th Cong. (2013); H.R. 584, 113th Cong. (2013); S. 229, 112th Cong. (2011); H.R.520, 112th Cong. (2011).

^{379.} Act of July 6, 1973, 1973 Or. Laws 374.

^{380.} Act of Sept. 21, 1979, 1979 Cal. Stat. 3143.

then dozens of other states. In fact, no fewer than twenty-two states had their own organic standards before Congress finally passed the Organic Foods Production Act of 1990, which established a national organic labeling standard.³⁸¹ The organic example illustrates a basic federalist principle: Where there is a federal void of leadership, states step into the breach. As Justice Brandeis famously explained over eighty years ago, and as quoted by Justice O'Connor, "[o]ne of federalism's chief virtues, of course, is that it promotes innovation by allowing for the possibility that 'a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."³⁸² The organic label is but one closely analogous instance where states have led the way and the federal government has eventually followed. Other notable examples include ending slavery,³⁸³ ending child labor,³⁸⁴ establishing minimum wage laws,³⁸⁵ and regulating global

^{381.} S. REP. NO. 101-357, at 289 (1990); ALASKA STAT. § 03.58.010 (1989); IOWA CODE § 190B.1 (1989); MINN. STAT. § 31.92 (1985); Act of July 6, 1973, 1973 Or. Laws 374; An Act Concerning the Labeling of Natural and Organic Foods, 1978 Conn. Acts. 790 (Reg. Sess.); 1979 Cal. Stat. 3143; Act to Define What Foods May be Labeled or Advertised as Natural or Organic, sec. 1, 1979 Me. Laws 294; An Act Defining "Organic Food" and Requiring Accurate Labeling of Organic Food, 1985 Mont. Laws 605; An Act Concerning the Labeling of Natural and Organic Foods, Act of May 10, 1985, ch. 247, 1985 Wash. Sess. Laws 860-62 (establishing labeling standards for organic food products); Act of Apr. 17, 1986, 1986 Neb. Laws 1713; Act of Mar. 20, 1987, ch. 94, 1987 N.D. Laws 246-47; An Act to Provide for Standards and Compliance Requirements for Organic Foods, 1987 N.D. Laws 246; Act to Establish Minimum Standards for Food Products Which are Labeled as Organic Food, 1988 S.D. Sess. Laws 439; Act of Apr. 14, 1988, 1987 Wis. Sess. Laws 1014; Organic Certification Act, ch. 302, sec. 1, § 35-11.5, 1989 Colo. Sess. Laws 1376; Act No. 825, 1989 La. Acts 2362-63; Oklahoma Organic Food Act of 1989, 1989 Okla. Sess. Laws 1095; Grown in Texas, Natural, Lean, or Organic Certification, 1 Tex. Sess. Laws 1028 (1989); Act of Mar. 27, 1990, 1990 Idaho Sess. Laws 325; Virginia Organic Food Act, 1990 Va. Acts 475; An Act Relating to Organic Food, Enacting the Organic Commodity Act, 1990 N.M. Laws, 875; OHIO ADMIN. CODE 901:3-8-01 (1990).

^{382.} Gonzales v. Raich, 545 U.S. 1, 42 (2005) (O'Connor, J., dissenting) (quoting New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting)); *see also* Oregon v. Ice, 555 U.S. 160, 171 (2009) ("We have long recognized the role of the States as laboratories for devising solutions to difficult legal problems. This Court should not diminish that role absent impelling reason to do so." (internal citation omitted)); United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483, 502 (2001) (Stevens, J., concurring) (explaining that there is "a duty on federal courts, whenever possible, to avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a State have chosen to 'serve as a laboratory' in the trial of 'novel social and economic experiments without risk to the rest of the country."" (quoting *New State Ice Co.*, 285 U.S. at 311 (Brandeis, J., dissenting))).

^{383.} See Slavery Timeline, HARPER'S WEEKLY, http://blackhistory.harpweek.com/2Slavery/ SlaveryLevelOne.htm (select "View the Slavery Timeline") (last visited Dec. 9, 2014) (showing the progression of the abolition of slavery prior to the passage of the Thirteenth Amendment).

^{384.} See, e.g., Child Labor in U.S. History, CHILD LABOR PUB. EDUC. PROJECT, https://www.continuetolearn.uiowa.edu/laborctr/child_labor/about/us_history.html (last visited Dec. 9,

warming-causing emissions.³⁸⁶ Opponents of state labeling thus struggle against the great weight of our democratic process.

If we want to know whether our food contains high fructose corn syrup or trans-fats, we can simply read the label. This information has empowered millions of Americans to take control of what we eat and feed our families, for health, religious, environmental, or ethical reasons. However, these freedoms are being denied to the more than 90% of Americans who want to know if their food is genetically engineered. Since the federal government has so far failed the public, it is up to individual states to lead the way, and the U.S. Constitution provides this path, rather than preventing it. Eventually, all Americans will receive the labeling they seek and deserve, just as a rising tide lifts all boats. It is not a matter of *if*, but of *when*.

^{2014) (}showing that the child labor reform movement began in 1836 as a patchwork of state laws until the federal government regulated the minimum age of workers in the Fair Labor Standards Act of 1938).

^{385.} See Howard D. Samuel, *Troubled Passage: The Labor Movement and the Fair Labor Standards Act*, MONTHLY LABOR REV., Dec. 2000, at 32, 33, *available at* http://www.bls.gov/opub/mlr/2000/12/art3full.pdf (outlining the history of the Fair Labor Standards Act of 1938 and noting that in 1913, Massachusetts passed the first state minimum wage law for women, and that by 1923, minimum wage laws for women had been enacted in sixteen states).

^{386.} See State Legislation from Around the Country, CTR. FOR CLIMATE AND ENERGY SOLUTIONS, http://www.c2es.org/us-states-regions/key-legislation (last visited Dec. 9, 2014) (listing various state climate change laws).