IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

GROCERY MANUFACTURERS ASSOCIATION, SNACK FOOD ASSOCIATION, INTERNATIONAL DAIRY FOODS ASSOCIATION, and NATIONAL ASSOCIATION OF MANUFACTURERS, Plaintiffs, v. WILLIAM H. SORRELL, in his official capacity as the Attorney General of Vermont; PETER E. SHUMLIN, in his official capacity as Governor of Vermont; TRACY DOLAN, in her official capacity as Interim Commissioner of the Vermont Department of Health; and JAMES B. REARDON, in his official capacity as Commissioner of the Vermont Department of Finance and Management,[1] Defendants.	)	Case No. 5:14-cv-117-cr

MEMORANDUM OF POINTS AND AUTHORITIES
IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

[1] Pursuant to Fed. R. Civ. P. 25(d), Tracy Dolan is substituted for Harry L. Chen as Interim Commissioner of Health, in her official capacity.

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

Page

TABLE OF AUTHORITIES

Page(s)

CASES:

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

CONSTITUTION:

FEDERAL STATUTES:

TABLE OF AUTHORITIES—Continued

Page(s)

FEDERAL REGULATIONS:

FEDERAL ADMINISTRATIVE MATERIALS:

TABLE OF AUTHORITIES—Continued

Page(s)

VERMONT STATUTES:

TABLE OF AUTHORITIES—Continued

Page(s)

VERMONT STATUTES (CONT'D):

STATE LEGISLATIVE MATERIALS:

TABLE OF AUTHORITIES—Continued

Page(s)

OTHER AUTHORITIES

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

* For readability, Plaintiffs have included web site URLs in this Table of Authorities but not in the main text. URLs cited herein were last visited on September 11, 2014.

PRELIMINARY STATEMENT

To pacify a vocal segment of the population that opposes genetic engineering, the State of Vermont has waded into a political controversy and enacted Act 120, legislation that is both unconstitutional and preempted by federal law. Plaintiffs seek preliminary relief that enjoins the Defendants from implementing Act 120 until this litigation has run its course.

Act 120 establishes labeling requirements for "genetically engineered foods." These requirements are unique to Vermont. *See* Press Release, *Gov. Peter Shumlin Signs First-in-the-Nation Genetically Engineered Foods Labeling Law*, May 8, 2014. They will also affect most of the grocery products sold here, because genetically engineered varieties of corn and soybean account for more than 90% of the plantings of those commodity crops in the United States. Federal law does not require food labeling to also include plant labeling because there is no rational justification for such a regime. Act 120, however, is not concerned with rational justification. It caters to beliefs and biases that a government has no business endorsing.

Act 120 exceeds numerous constitutional limitations. Because it serves no legitimate governmental interest, Act 120 cannot withstand any flavor of First Amendment scrutiny. *See, e.g.*, *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011); *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996); *CTIA—The Wireless Ass'n v. City & Cnty. of S.F.*, 827 F. Supp. 2d 1054 (N.D. Cal. 2011), *aff'd* 494 F. App'x 752 (9th Cir. 2012); *see also Alexander v. Cahill*, 598 F.3d 79 (2d Cir. 2010). Act 120 also intrudes upon – and indeed outright violates – federal labeling requirements and so is preempted under the Supremacy Clause in both its particular applications, *see* 21 U.S.C. §§ 343-1(a); 467e; 678, as well its overall operation, *see Arizona v. United States*, 132 S. Ct. 2492 (2012), which undermines three decades of work by federal regulators across

four agencies, under five federal statutes. On these grounds, and others,[2] Plaintiffs are likely to prevail in this suit.

Plaintiffs request a preliminary injunction because their member companies will suffer irreparable injury without one. Manufacturers have no way to reliably distinguish ingredients derived from genetically engineered plant varieties from those that are not. The changes manufacturers would need to demand from their suppliers and initiate in their own facilities to segregate ingredients require money and time—much more time than the Act's July 1, 2016 effective date allows. But there are downstream changes required, too, in the form of building out Vermont-specific supply and distribution chains that do not exist. Plaintiffs' members will not be able recoup the cost of those efforts from the State if they prevail, nor could they easily return their businesses to the status quo ante. A preliminary injunction also is in the public interest because there is no public interest in an unconstitutional law that disrupts the U.S. food supply without rational justification.

For these reasons and those detailed below, Plaintiffs respectfully request that the Court enter a preliminary injunction against the implementation and enforcement of Act 120.

BACKGROUND

The foods produced from genetically engineered crops are safe. *See* Declaration of Dr. Alan R. McHughen in Support of Pls.' Mot. for a Prelim. Inj. (McHughen Decl.). Two decades of experience, thousands of studies, and close regulatory scrutiny all confirm as much. *Id.*, ¶¶ 69-74 (and sources cited therein). But vehement opposition to genetic engineering persists. Some individuals feel that it conflicts with their philosophical or religious beliefs; others have concerns about large-scale agriculture in general, or biases against certain companies in

[2] In the interest of expediting resolution of their Motion, Plaintiffs do not address their fact-intensive Commerce Clause arguments in this Memorandum.

particular. Vermont's law rests on those beliefs and biases; it regulates the labeling of food products for reasons that have nothing to do with the food itself.

A. Genetically Engineered Crops

"Genetic engineering" typically refers to the use of recombinant DNA (rDNA) techniques to transfer particular genes from one organism into the genome of another so that the second organism expresses a desired trait. McHughen Decl. ¶¶ 27-31. Over the past two decades, crop scientists have used genetic engineering to create hardier varieties of popular staple food crops. *Id.*, ¶¶ 34-40. These varieties are commercially popular: in 2014, 93% of the corn, 94% of the soybeans, and 96% of the cotton planted in the United States were from genetically engineered varieties. *See* USDA, *Genetically Engineered Varieties of Corn, Upland Cotton, and Soybeans, by State and for the United States 2000-2014*, USDA.gov.[3] In Vermont, the figures are similar: genetically engineered varieties account for 90% of the corn and an estimated 85-95% of the soybeans planted here. *See* Vt. Agency of Agric., Food & Markets, *Reported Genetically Engineered Seed Sales in Vermont 2002-2012*, Vermont.gov.

Genetically engineered crops enter the food supply in the same ways other crops do. The plant creates a food – say, an ear of corn – which can be sold at retail as a raw commodity or processed further into food ingredients like starches and oils. The ingredients may be sold as they are, or manufactured into multi-ingredient foods. *See* Declaration of Rick Blasgen in Support of Pls.' Mot. for a Prelim. Inj. (Blasgen Decl.) ¶¶ 7-9. None of these steps involves genetic engineering; that is a technology used on the plant. McHughen Decl., ¶ 78-79.

[3] The full URL for each Internet citation appears in the Table of Authorities.

B. Federal Regulation of Genetically Engineered Crops

The federal government regulates agricultural crops in the United States through a web of statutory schemes, including those under the federal Plant Protection Act (PPA), 7 U.S.C. §§ 7701-7772; the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y; the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301, *et seq.*; the Federal Meat Inspection Act (FMIA), 21 U.S.C. §§ 601, *et seq.*; and the Poultry Products Inspection Act (PPIA), 21 U.S.C. §§ 451, *et seq*. In addition, pesticide labeling is regulated under FIFRA, 7 U.S.C. § 136a, and food labeling is subject to detailed regulation and oversight under the FFDCA, FMIA, PPIA, the Nutrition Labeling and Education Act (NLEA), 21 U.S.C. § 343-1, and the Organic Foods Production Act, 7 U.S.C. §§ 6501-6522.

Under these numerous statutes, four federal agencies share principal authority over food crops: the U.S. Department of Agriculture's (USDA) Animal Plant and Health Inspection Service (APHIS) regulates to prevent the spread of plant pests and diseases under the PPA; the Environmental Protection Agency (EPA) oversees regulates pesticides under FIFRA and sets levels of pesticide tolerance in foods under the FFDCA; the Food and Drug Administration (FDA) regulates food safety and labeling under the FFDCA and NLEA; and the USDA's Food Safety Inspection Service (FSIS) regulates the safety and labeling of foods, including those with plant-based ingredients, that are produced at meat and poultry processing facilities, pursuant to the FMIA and PPIA.

Long-standing federal policy requires these four agencies (APHIS, EPA, FDA, FSIS) to regulate genetically engineered plants and plant products primarily through the frameworks established under those many statutes (PPA, FIFRA, FFDCA, FMIA, PPIA, etc.). *See* White House Office of Science and Technology Policy, *Coordinated Framework for Regulation of Biotechnology*, 51 Fed. Reg. 23302 (June 26, 1986). The policy emphasizes a product-based

approach, under which plants, foods, drugs, and pesticides derived in any way from genetic engineering are regulated "in essentially the same manner for safety and efficacy as products obtained by other techniques." *Id.* at 23304. The agencies coordinate and sequence review at each stage, so that "[b]y 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." *Id.*

The basic principle of the federal policy is that regulation attaches to the product, not the process of creating it. Under the FFDCA, for example, a food may not be sold in interstate commerce if it is adulterated or if it is misbranded, regardless of source. 21 U.S.C. § 331. FDA's focus in enforcing those prohibitions is the food, not the process: it will deem a food adulterated if *the food* contains a substance "injurious to health," *id.*, § 342, and FDA will deem a food misbranded if *the food* is materially different from *the food* identified on its label, *id.*, §§ 321(n), 343. These principles apply to foods derived from genetically engineered plant varieties just as they do to other foods.

FDA's policy is well established. From the beginning, the agency has emphasized that its regulations "must be based on the rational and scientific evaluation of products, not on *a priori* assumptions about certain processes" or on "generic concerns about biotechnology." FDA, *Statement of Policy for Regulating Biotechnology Products*, 51 Fed. Reg. 23309 (June 26, 1986). And FDA's specific policy with respect to food is that "[t]he regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food." FDA, *Statement of Policy: Foods Derived from New Plant Varieties*, 57 Fed. Reg. 22984, 22991 (May 29, 1992) (1992 Statement). FDA does not assign special regulatory status to foods produced from genetically engineered plant varieties, as a class, because there is no

evidence that they vary in their objective characteristics "in any meaningful or uniform way." *Id.*

C. The Safety of Foods Derived from Genetically Engineered Plants

There is no basis whatsoever for Act 120's claim that there is a "lack of consensus" about the "validity of the research and science" about the safety of foods derived from genetically engineered plant varieties. *See* Act 120, § 1(2)(D). To the contrary, "[t]he science is quite clear," the publisher of *Science* has declared, that "crops produced from modern methods of biotechnology are safe." Am. Ass'n for the Adv. of Science, *Statement of the Board of Directors on the Labeling of Genetically Modified Foods*, Oct. 20, 2012. *See* McHughen Decl., ¶¶ 71, 93-101 (and sources cited therein, including the National Academy of Science, the American Medical Association, the Royal Society of Medicine, the European Commission, and others).

There is also consensus within the federal government about the validity of the science. *See, e.g.*, 1992 Statement, at 22991 ("FDA is not aware of any information showing that . . . foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding."); CQ Cong. Transcripts, *House Appropriations Subcomm. on Agric., Rural Dev., FDA and Related Agencies Holds Hrg. on Pres. Obama's Proposed Fiscal 2015 Budget Request for the FDA*, Mar. 27, 2014, at 15 ("very credible scientific organizations . . . have looked hard at this issue over a long period of time," and FDA "ha[s] not seen evidence" of risks to health); Press Release, *USDA Secretary Vilsack Addresses American Farm Bureau Convention*, USDA.gov, Jan. 13, 2014 ("There are no studies that reflect that there is any safety concern" with genetically engineered crops); U.S. Trade Rep., *Executive Summary of the First U.S. Submission*, EC – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291, 292 and 293, at 8 (Apr. 30, 2004) ("[T]he safety of biotech

products has been confirmed by scientific reports under the auspices of renowned international institutions . . . , as well as independent scientists in the United States, Africa and Europe.")

As further assurance, FDA offers voluntary food-safety consultations to plant developers. *See* FDA, *Biotechnology Consultations on Food from GE Plant Varieties*, FDA.gov. Every commercialized, genetically engineered plant variety on the market has gone through this process and had its safety data recognized by the agency. McHughen Decl. ¶ 61.

D. The U.S. Policy Against Mandatory Labeling of Foods Derived from Genetically Engineered Plants

The past three decades have seen an increase in demand for foods produced with so-called "traditional" methods, but FDA does not require labeling of methods; its mandate is food. Accordingly, when Congress enacted the Organic Foods Production Act, it directed USDA—not FDA—to establish a program for certified organic labeling. 7 U.S.C. § 6503. Under that statute, a food may be designated as "certified organic" if the producer strictly observes methods USDA prescribes. *Id.*, § 6504. A certified organic label signifies the producer did not use genetically engineered seeds or plant materials, 7 C.F.R. §§ 205.2 (defining "excluded methods"); and it allows the producer to capture the value of consumer demand for food produced under that constraint. Dimitri & Greene, *Growth Patterns in the U.S. Organic Industry*, USDA Agric. Info. Bulletin No. 777 (2013) (reporting annual organic sales of $28 billion).

FDA has consistently rejected calls to mandate the opposite type of label—a required disclosure attached to foods and ingredients derived from genetically engineered plants. As FDA explained in 1992, and as it maintains today, failure to use special labeling for a food derived from a genetically engineered plant would constitute misbranding only "if a safety or usage issue exists," or if the food "differs from its traditional counterpart" to the extent that it should be identified with a different name. 1992 Statement, at 22991. There was (and is) no evidence to

support a labeling requirement because there was (and is) no evidence showing that foods derived from genetically engineered plants, as a class, "differ from other foods in any meaningful or uniform way" or "present any different or greater safety concern" compared to other foods. *Id.* In 2000, a federal district court upheld FDA's decision to reject mandatory labeling as a reasonable one. *See Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000).

FDA has in fact gone further than rejecting mandatory labeling: it has urged caution in making claims about the *absence* of ingredients derived from genetically engineered plants. In 2001 guidance, FDA said its regulations permit "non-GMO"[4]-type claims only to the extent they are not misleading. FDA, *Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering*, Jan. 17, 2001, FDA.gov (2001 Guidance). The guidance identifies several examples of misleading claims, including any claim that implies a food has superior safety or nutritional value because it is "non-GMO." *Id.*

FDA is not the only U.S. agency to have weighed in on the matter. Over the past year, the Secretary of Agriculture, Tom Vilsack, has repeatedly stated that mandatory labeling is inappropriate. "GMO labeling doesn't fit," he told one reporter, because it has nothing to do with health or safety. Ball, *Want to Know If Your Food is Genetically Modified?*, TheAtlantic.com, May 14, 2014. The Secretary recently told European audiences the same thing. He explained that the U.S. does not require mandatory labeling because it would be misleading: "When you label something you are essentially conveying the message that there may be something that you need to know about with reference to this product that may be harmful to you." Inside U.S. Trade, *Vilsack Pokes At Major EU TTIP Red Lines at GMOs,*

[4] "GMO" stands for "genetically modified organism" and is often used to refer to foods and ingredients derived from genetically engineered plant varieties.

Hormone Beef, InsideUSTrade.com, June 19, 2014. He emphasized that food policy should be based on "sound science." *Id.*

Prestigious professional organizations agree that mandatory labeling is unwarranted. The American Medical Association has announced that "there is no scientific justification for special labeling of bioengineered foods, as a class." Policy H-480.958, *Bioengineered (Genetically Engineered) Crops and Food* (2012). The American Academy for the Advancement of Sciences warned that mandating labels "can only serve to mislead and falsely alarm consumers." *Statement of the Board of Directors*, *supra*. The editorial boards of prestigious American newspapers – institutions deeply invested in access to information – have similarly agreed that mandatory labeling is unjustified. *See Genetically Modified Crops Could Improve the Lives of Millions*, Wash. Post, June 1, 2014 (calling mandatory labeling "gratuitous"); *Editorial: Base Food Labeling on Fact, Not Fear*, L.A. Times, May 5, 2014 (mandatory labels "would serve mainly to frighten grocery shoppers . . . without making them better informed"); *Editorial: Why Label Genetically Modified Foods?*, New York Times, Mar. 14, 2013 ("Consumers can already find products free of genetically engineered ingredients, with labels voluntarily placed by the manufacturers."); *Food Labeling Initiative Would Sow Confusion: Editorial*, The Oregonian, Jul. 8, 2014 ("Mandatory food labels should display nutritionally relevant information, not ideology.").

The movement for labeling persists, however, because despite a scientific consensus on a par with that supporting climate change, many individuals still believe that genetic engineering simply *must be* wrong. But this is not a legitimate "lack of consensus," as the Act's findings would have it; it is instead a matter of personal belief, be it religious, philosophical, or political, or simply rooted in hostility to particular businesses or "big" business in general. There is no

denying, at this point, that "the political fight over GMOs" is "supercharged" and based in part on "distrust of big business." Ostrander, *Can GMOs Help Feed a Hungry World?*, The Nation, Sept. 1, 2014; *see also* Specter, *Seeds of Doubt*, The New Yorker 46, 57, Aug. 25, 2014 (noting an "all-encompassing obsession with [seed developer] Monsanto").

E. Vermont's Attempts to Regulate Genetically Engineered Products

The Vermont General Assembly has many times attempted to place burdens on companies that sell products connected in some way to genetic engineering. The General Assembly's attempts to regulate have failed, repeatedly, for lack of justification.

Its first misstep occurred in 1994, when the General Assembly passed a law requiring special labeling for milk produced from cows treated with recombinant bovine somatotrophin (rBST), a hormone produced using genetic engineering. 6 V.S.A. § 2754 ("rBST law"). Though FDA had rejected mandatory labels – rBST is identical to BST – Vermont thought it necessary to provide labels in light of "consumer concern" about safety and some consumers' "philosophical opposition" to rBST. Br. of Defendants-Appellees, *Int'l Dairy Foods Ass'n v. Amestoy*, No. 95-7819, 1995 WL 17049818, at 13 (2d Cir. Oct. 19, 1995). The rBST law was later ruled unconstitutional on the ground that consumer interest is not sufficient justification for compelling speech. *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 68 (2d Cir. 1996).

In 2004, Vermont enacted a law mandating labeling for genetically engineered seed. *See* 6 V.S.A. § 644(a)(4). The law was not enforced. In the view of the Agency of Agriculture, farmers did not need labeling to know when they were buying genetically engineered seed, and requiring labeling would be "onerous" and potentially violate the Commerce Clause. Meyers, *Advocates: GMO Label Law Not Enforced*, Times Argus, Feb. 2, 2006. Then, in 2006, the General Assembly made seed manufacturers liable for "damages" caused by the drift of genetically engineered seed onto neighboring farms. 2006 Vt. Bills & Resolutions S.18. The

law was vetoed by then-Governor Douglas because it "fail[ed] to find a middle ground" and would "dive[ ] into new legal territory that may only promote needless litigation." Rathke, *Genetically Engineered Seed Liability Bill Vetoed*, Times Argus, May 16, 2006.

In 2012, food labeling returned to the fore, with a bill introduced that would have declared a food misbranded if it failed to indicate whether it had been "produced with genetic engineering." 2012 Vt. Bills & Resolutions H.772. Governor Shumlin was "gun shy" about the legislation; he believed it to be "an identical bill" to the rBST law that failed in 1996. *See* Hallenbeck, *The Great GMO Debate*, Burlington Free Press, Apr. 23, 2012. The Attorney General agreed. *See* Moats, *GMO Labeling Bill Faces New Challenge*, Times Argus, Mar. 30, 2012. The bill did not make it to a vote.

F. "An Act to Regulate the Labeling of Genetically Engineered Foods"

On January 29, 2013, bill H.112 was introduced in the Vermont House of Representatives. The bill proposed to add a new chapter to the Vermont Statutes regarding the labeling of what it called "genetically engineered foods." 2013 Vt. Bills & Resolutions, H. 112. The Governor and Attorney General again publicly expressed their doubts about the law's constitutionality. The Governor once more noted that H.112 "resembled" the rBST law, and he said that law had been "called unconstitutional for some very good reasons." *See* Dritschilo, *Shumlin: GMO Labeling Good, Bill Bad*, Rutland Herald, Mar. 4, 2013. The Attorney General warned that "there's going to be a [legal] fight, and there's no certainty we're going to win." D'Ambrosio, *With Vermont in Front, GMO Fight Heats Up*, Burlington Free Press, June 9, 2013. All the same, H.112 passed the House.

In the Senate, an amended version of H.112 was introduced. *See* O'Grady, *H.112: Side by Side of House Passed Bill and Senate Proposal of Amendment*, Apr. 16, 2014, Vt.us. The Senate then held hearings, where much of the time was spent debating the constitutionality of the

law, rather than the justification for it. *See, e.g.*, Transcripts of Hearings Before the House Comm. on the Judiciary (Apr. 18, 2013; "Apr. 18 Tr."); Senate Committee on Agriculture, Food, and Markets (Feb. 7, 2014; "Feb. 7 Tr."); the Senate Committee on the Judiciary (Mar. 19, 2014; "Mar. 19 Tr.") (Apr. 3, 2014; "Apr. 3 Tr.") (to be filed with the court in the next day). In the end, the Senate's faith in the law was so shaky that an amendment was introduced to insulate taxpayers from having to fund the lawsuit (correctly) predicted to be imminent. H.112 passed both houses soon thereafter. On May 8, 2014, Governor Shumlin signed the bill into law.

1. Relevant Provisions

Act 120 requires a "food offered for sale by a retailer after July 1, 2016" to be labeled as "produced entirely or in part from genetic engineering if it is . . . entirely or partially produced with genetic engineering." 9 V.S.A. § 3043(a). The Act prescribes the text of the labels. *Id.*, § 3043(b). Raw commodities must be designated as "produced with genetic engineering," while processed foods may be designated as either "produced," "may be produced," or "partially produced" with genetic engineering. *Id.* The Attorney General, through rulemaking, may require alternate wording "in a manner consistent with requirements in other jurisdictions," or require a "disclaimer" that FDA "does not consider foods produced from genetic engineering to be materially different from other foods." Act 120, § 3. The Act further provides that "a manufacturer of a food produced entirely or in part from genetic engineering shall not label the product on the package, in signage, or in advertising as 'natural,' 'naturally made,' 'naturally grown,' 'all natural,' or any words of similar import that would have a tendency to mislead a consumer." 9 V.S.A. § 3043(c).

The General Assembly's several stated purposes for enacting Act 120 essentially boil down to one: to allow consumers to avoid labeled food based on their beliefs and biases about genetic engineering. The Act offers four variations on this theme, declaring the State's intent to

promote "informed" decisions based on "potential health risks," or "concern[ ] about the potential environmental effects of the production of food from genetic engineering," or based on "religious reasons," with those decisions made free from "deceptive" assertions that foods tied in some way to genetic engineering are "natural." 9 V.S.A. § 3041. Stated differently, the purpose of the Act is to facilitate the expression of personal beliefs and biases about genetic engineering by "informing" consumers when those beliefs and biases are implicated.

But only some of the time. The Act exempts many categories of food for which, in theory, the consumer's aversion to genetic engineering should be just as strong. 9 V.S.A. § 3044. The Act exempts processed food sold for immediate consumption and food sold at restaurants, regardless of content. *Id.*, § 3044(7). It exempts food produced "without the knowing or intentional use" of genetically engineered plant varieties, regardless of content. *Id.*, § 3044(2), (6). It exempts products derived entirely from an animal (i.e., meat and milk), even if the animal consumed feed from genetically engineered crops that allegedly "contribut[e] to "potential environmental effects." *Id.*, § 3044(1). There are many other exemptions in addition to these. *See id.* § 3044(3) (processing aids and enzymes); (4) (alcohol); (5) ("genetically engineered materials" no more than .9% by weight); (8) (medical food).

Act 120 has many other remarkable features. For one, its definition of "genetic engineering" is unheard-of in scope, extending far beyond established federal definitions and reaching many types of commonly used agricultural practices. McHughen Decl. ¶¶ 77-85; 7 C.F.R. Part 340. Act 120's definition is not just unique to Vermont, but unique *within* Vermont, which has codified two other definitions of genetic engineering that do not match Act

120—or each other.[5] Another notable feature is that the Act applies to food "offered for sale by a retailer," *id.*, § 3045, but assigns liability for processed foods to the manufacturer, for civil penalties and consumer "rights and remedies," *id.*, § 3048.

Then there is the funding: the Act *requires* the State to use private donations to defend and implement the law. Act 120, § 4. If that money runs out, then (and only then) the State may use settlement monies —but only to the extent of a surplus over budget, up to $1.5 million. *Id.*, § 4(c). As a result, the implementation of Act 120 will come to halt if private donors stop funding it, and the State hits its $1.5 million cap without further appropriations. *Id.*, § 4(b).

2. Rulemaking

Act 120's administrative provisions went into effect upon enactment, including the section authorizing Attorney General to adopt "requirements for the implementation of [the law]." Act 120, §§ 3, 7. In June, the Attorney General posted an online survey, on the site SurveyMonkey, asking for opinions on where and how the labels should appear on food packages. *See* Vt. Office of the Atty. Gen., *Vermont Attorney General's GE Food Labeling Rule Questionnaire*, Jul. 17, 2014, SurveyMonkey.com. The survey was not restricted to Vermont residents, or appear to verify that takers claiming to be in Vermont actually were. This means many people outside the State may influence the design of a label they will never see, and never use. *See* Vt. Office of the Atty. Gen., *GE Food Labeling Rule Questionnaire: Summary of Results*, Jul, 16, 2014, Vt.us; Herrick, *State Receives $78,000 Check for GMO Defense Fund*, Vermont Digger, Sept. 11, 2014, VTDigger.org (reporting that Vermonters account for just 5% of the $300,000 in the State's special fund, with the balance made up by nationwide advocacy groups, private corporations, and others outside the state).

[5] *Compare* 6 V.S.A. § 641 (incorporating USDA definition by reference); *id.*, § 1030 (defining "genetically modified organism" as one produced with "modern molecular methods").

The Attorney General has stated that his office is engaged in rulemaking, "with the goal of promulgating the rules by July 2015." Vt. Office of the Atty. Gen., *GE Food Labeling Rule: Frequently Asked Questions*, Aug. 4, 2014, Vt.us. But this gives manufacturers less than a year.

G. The Need for Preliminary Relief

Plaintiffs are trade associations representing food manufacturers. Plaintiffs' members will be subject to Act 120 because they sell products containing ingredients derived from corn, soybeans, and other crops for which virtually all of the U.S. supply comes from genetically engineered plant varieties. *See* Declarations of Cofi Adams, Alexander Baxter, Jeff Bradley, Steven Hermansky, and Michael Morgan, all In Support of Pls.' Motion for a Prelim. Inj. (collectively, "Company Decls.").

Plaintiffs filed this action on June 12, 2014 to declare invalid and enjoin Act 120. Yet, while this litigation is pending, Plaintiffs' member companies must endeavor to come into compliance with the law. As described below, this requires product-by-product review, followed by fundamental changes in manufacturers' supply chains (which are not adapted to segregate the products of genetically engineered plants) and their distribution chains (which are not adapted to segregate products bound for Vermont). Some companies could choose instead to exit from the Vermont market entirely. Whatever path they choose, the companies must start down that path now, devoting substantial time, money, and employee resources to the effort.

Plaintiffs tried to avert the need for this Motion by seeking relief directly from the Attorney General. Those discussions, though cordial and informative, did not yield an agreement. Accordingly, Plaintiffs respectfully request that implementation of Act 120 be enjoined during the pendency of this litigation.

STANDARD OF REVIEW

To obtain a preliminary injunction, a plaintiff "must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Natural Res. Defense Council, Inc.*, 555 U.S. 7, 20 (2008).

ARGUMENT

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS.

Plaintiffs are likely to succeed on the merits of their claims because Act 120 violates the First Amendment, *see Amestoy*, 92 F.3d at 73, suffers from insoluble vagueness, and runs afoul of federal statutes and policy that comprehensively regulate the products of genetic engineering.

A. Act 120's Labeling Requirement Violates the First Amendment.

Plaintiffs are likely to succeed in their First Amendment challenge to Act 120's labeling requirement because it is a politically motivated speech regulation that does not serve a legitimate governmental interest. There is no standard of First Amendment scrutiny – not even the "reasonable-relationship" review the State has urged – under which this law passes muster.

1. Act 120 Burdens Speech According to Content, Speaker, and Viewpoint.

Though Act 120 straightforwardly fails under the intermediate scrutiny applied in *Amestoy*, *see infra* at 22, more recent Supreme Court and Second Circuit decisions confirm that strict scrutiny is the standard Vermont must actually surmount. A law burdening speech based on its content is " 'presumptively invalid' " and "can stand only if it satisfies strict scrutiny." *United States v. Playboy Entm't Grp., Inc.*, 529 U.S. 803, 813, 817 (2000) (quoting *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992)). A law may not stand under any circumstance, however, if it "goes even beyond mere content discrimination, to actual viewpoint discrimination." *Sorrell*, 131 S. Ct. at 2663 (quoting *R.A.V*, 505 U.S. at 391). Act 120 discriminates in favor of

particular viewpoints. The Supreme Court told Vermont that it may not burden speech "to tilt public debate in a preferred direction," *id.* at 2671, but the State did not heed that warning here.

Act 120's labeling requirement, to begin, is a content-based regulation because it mandates speech about genetic engineering that manufacturers would not otherwise make. The "content" of speech includes what is said and what the speaker chooses "not to say." *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557, 573 (1995). That principle flows from the "general rule" that "the speaker has the right to tailor the speech," a rule that "applies not only to expressions of value, opinion, or endorsement, but equally to statements of fact the speaker would rather avoid." *Id.* A disclosure requirement that "[m]andat[es] speech the speaker would not otherwise make necessarily alters the content of the speech," and thus amounts to "content-based regulation." *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1989).

Act 120 is also content *discriminatory*. Instead of applying even-handedly, and requiring *every* label to indicate whether the food has or has not been produced with genetic engineering, the Act compels only the affirmative designations ("produced," "partially produced, "may be produced"). 9 V.S.A § 3403(b). It does not compel the corresponding negative ("produced without genetic engineering"). Manufacturers of products requiring an affirmative declaration are placed at a disadvantage under Act 120 because they must use valuable space on their packaging to speak on the issue. Other manufacturers have the choice to use the space as they see fit. Act 120 is discriminatory because it applies burdens according to the "particular content" of the speech that has been omitted, *Sorrell*, 131 S. Ct. at 2663.

Act 120 then "goes even beyond mere content discrimination, to actual viewpoint discrimination," because it singles out Plaintiffs' members for special burdens in order "to tilt

public debate in a preferred direction." *Id.* at 2663 (citation omitted), 2671. The Act declares that some consumers hold negative opinions of genetic engineering, perhaps because they distrust the federal government's review policies, *see* Act 120, § 1(1), (2) (describing perceived FDA omissions and oversights); or because they oppose "commodity agricultural production practices" for environmental policy reasons, *id.*, 2(E); or because they subscribe to the unidentified religious beliefs to which the Act alludes, *id.*, 5(D). But all of these beliefs are just that—beliefs. And the Act compels Plaintiffs' members to accommodate them.

It is not enough to respond that the disclosure is factual (which it is not, *see* pp. 27-28, *infra*); the Scarlet Letter was factual, too. Act 120's required labeling, interpreted in light of the legislative findings and purpose as it must be, cannot be other than a poster for the personal beliefs and policy preferences of individuals opposed to genetic engineering. Forcing companies to put that poster on many thousands of products for the sake of a protest movement is viewpoint discrimination. A state may not "force [a speaker] to respond to views that others may hold," or "abridge its own rights in order to enhance the relative voice of its opponents." *See Pac. Gas & Elec. Co. v. Public Util. Comm'n*, 475 U.S. 1, 11 (1986) (plurality).

The Act also discriminates by viewpoint "in its practical operation" without regard to legislative intent, because its onerous burdens fall uniquely on speakers taking a particular position. *Sorrell*, 131 S. Ct. at 2663. If Act 120 were truly even-handed, its requirement would apply to *all* foods "entirely or partially produced with genetic engineering." 9 V.S.A. § 3043(a). It does not. A manufacturer can obtain amnesty from the Act's requirements if it certifies (or has someone verify) that it has not "knowingly or intentionally" used ingredients that come from genetically engineered plants. *Id.*, § 3044(2), (6) (similar). Thus, the burdens of the Act are reserved for the manufacturers who knowingly and intentionally use genetically engineered

ingredients. This *mens rea* distinction has nothing to do with the content of the food. Yet it determines which manufacturers will be spending the next two years meticulously revising their labeling, and which will not.

The Vermont statute struck down in *Sorrell* had the same fatally defective design. It prohibited drug marketers from purchasing "prescriber-identifying information"—but it permitted research institutions and consumer-interest groups to purchase the same data, because they would use it for ends the State deemed to be benevolent. *See* 131 S. Ct. at 2663. The law burdened the marketers, because of the message they would promote, and, thus, "in its practical operation," discriminated by viewpoint. *Id*. That was confirmed by the Act's findings, which indicated that the General Assembly wanted to end data-based marketing altogether. *Id.*

Act 120 follows this same pattern. It burdens the speech of manufacturers who have not yielded to personal and political sentiments against genetic engineering. The Act ties the hands of these "knowing" beneficiaries of genetic engineering while allowing those who certify their opposition to continue unimpeded. *They* may keep their labeling as-is, without deploying their workforce to shoulder the onerous burdens of revising each label to make room to accommodate the new statements, or the variants and disclaimers the Attorney General might authorize. And that is viewpoint discrimination. Vermont has no authority "to license one side of a debate to fight freestyle, while requiring the other side to follow Marquis of Queensberry rules." *R.A.V.*, 505 U.S. at 392.

In both intent and practical operation Act 120 is viewpoint discriminatory, and viewpoint discrimination is something "the State cannot do." *Sorrell*, 131 S. Ct. 2672.

2. Strict Scrutiny Applies.

"In the ordinary case it is all but dispositive to conclude that a law is content-based and, in practice, viewpoint-discriminatory." *Sorrell*, 131 S. Ct. at 2667. And so the State can be

counted upon to argue that this is not an "ordinary case" because it involves commercial speech. *Id*. That, however, is a distinction without a difference.

The Supreme Court has not recognized a lesser standard of scrutiny for commercial speech when a law is viewpoint-discriminatory. In *Sorrell*, after finding viewpoint discrimination, the Supreme Court found "no need to determine" whether the burdened speech was commercial speech. 131 S. Ct. at 2667. Nor did the Court hold that intermediate scrutiny would apply if the speech were commercial. *See id.* Rather, assuming both propositions to be true, the Court held that Vermont's restriction on prescriber-identifying information could not survive even intermediate scrutiny: "the outcome is the same" no matter which standard applied. *Id.* (citing *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 184 (1999)).

That has also been true in cases involving compelled speech: the commercial-noncommercial distinction has simply not been relevant when a law is viewpoint-discriminatory. In the context of compelled speech, the commercial-speech distinction is inapplicable because the speech that is burdened is what the speaker has chosen "*not* to say." *Hurley*, 515 U.S. at 573 (emphasis added). A court must therefore assess the nature of the speech that is being compelled to assess the nature of the "speech" being burdened. The Supreme Court confirmed just that in *Harris v. Quinn*, 134 S. Ct. 2618 (2014). There, applying strict scrutiny, the Court concluded that certain "partial-public employees" could not be compelled to pay fees to a union bargaining representative. *Id.* at 2638-2644. The Court rejected calls for intermediate scrutiny because the

unions' speech – "the speech *compelled* in th[at] case" – was advocacy in support of particular viewpoints. *Id.* at 2639 (emphasis added).[6]

The Second Circuit recently confronted the commercial-noncommercial question in *Evergreen Association, Inc. v. City of New York*, and found the distinction immaterial there, too. 740 F.3d 233 (2d Cir. 2014). In that litigation, pro-life counseling centers challenged a New York law requiring them to tell clients that their centers do not offer abortion-related services or referrals. *Id.* at 238 (describing "services disclosure"). The centers argued that strict scrutiny should apply, while the City predictably argued for intermediate scrutiny, on the ground that the centers' speech was commercial. *Id.* at 244-245. The court of appeals' opinion, though it did not resolve the question, strongly suggested that a commercial-speech analysis was inappropriate. "When evaluating compelled speech," the court explained, "we consider the context in which the speech is made," and the services disclosure was being compelled in "the context of a public debate over the morality and efficacy of contraception and abortion." *Id.* at 249. Thus, the court concluded, the disclosure "alter[ed] the centers' *political* speech." *Id.* (emphasis added).[7] And the law failed intermediate scrutiny anyway. *Id.* at 250.

There are hints of this issue in *Amestoy*, as well, involving the rBST law. 92 F.3d at 71. There, the court wrestled with the question whether strict or intermediate scrutiny should apply

[6] The only decision to look at the nature of the speaker's message *before* the compulsion is *PG&E*, a plurality opinion that pre-dated *Riley*. 475 U.S. 1 (1986). There, in addressing a compelled insert in a utility's monthly newsletter, the Court focused on the political aspects of the newsletter in concluding the law did not regulate commercial speech. *Id.* at 8-9. However, the compelled speech was also political, so the analysis would have been the same under the *Riley*/*Harris* formulation. *Id.* at 15-16.

[7] The court held that the law failed intermediate scrutiny because another disclosure (that the center does not have "a licensed medical provider on staff") supplied "a more limited alternative regulation." *Evergreen*, 740 F.3d at 249-250. The plaintiffs have filed a petition for certiorari with respect to the ruling that this "status disclosure" satisfies strict scrutiny. Pet. No. 13-1462, 82 U.S.L.W. 3724 (U.S. June 5, 2014).

to the mandatory disclosure of the use of rBST, and the court held intermediate scrutiny would apply if the rBST law compelled businesses "to *engage in* purely commercial speech." *Id.* (emphasis added). The nature of the added speech would set the standard. Just as in *Sorrell* and *Evergreen*, though, the court found it unnecessary to decide whether the rBST disclosures were commercial or political because the law failed even intermediate scrutiny. *Id.*

Act 120 fails intermediate scrutiny, too. Therefore it does not satisfy strict scrutiny. But to the extent the distinction is found to make a difference, a commercial-speech discount should not apply because the disclosure *compelled* by Act 120 is not commercial speech. It is made in "the context [of] a public debate over the morality and efficacy" of certain practices, *Evergreen*, 740 F.3d at 249, and it has nothing to do with "propos[ing] a commercial transaction." *Harris*, 134 S. Ct. at 2639 (internal quotation marks and citation omitted). Indeed, the General Assembly confirmed that these statements would help consumers "*avoid*" a transaction with the manufacturer, 9 V.S.A. § 3041(1) (emphasis added). They cannot properly be called commercial speech.

3. Act 120 Does Not Withstand Strict or Intermediate Scrutiny.

Strict scrutiny requires Vermont to show that Act 120's labeling mandate is "justified by a compelling government interest and narrowly drawn to serve that interest." *Brown v. Entm't Merchants Ass'n*, 131 S. Ct. 2729, 2738 (2011). This requires Vermont to "specifically identify 'an actual problem' in need of solving, . . . and the curtailment of free speech must be actually necessary to the solution." *Id.* Vermont has not made this showing. The only problems it has identified are "potential" (and fictional "potentials" at that), and burdening speech is not necessary to achieve any of them. Here, in any event, Act 120 fails strict scrutiny because it cannot survive even the intermediate scrutiny *Amestoy* applied. As in *Amestoy*, *Evergreen*, and *Sorrell*, this standard provides an adequate basis for deciding this case against the State.

a. *Amestoy* Compels That Act 120 Be Enjoined For Lack of a Substantial Interest.

Because Act 120 imposes a "targeted, content-based burden" on protected speech, "the State must show at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest," with "a 'fit between the legislature's ends and the means chosen to accomplish those ends.'" *Sorrell*, 131 S. Ct. at 2667-68 (citing *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980), and quoting *Board of Trustees of SUNY v. Fox*, 492 U.S. 469, 480 (1989)). The State cannot satisfy thus burden with "mere speculation or conjecture; rather it must demonstrate that the harms it recites are real and that its restrictions will in fact alleviate them to a material degree." *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993).

Vermont cannot make the required showing here because the harms recited in Act 120 are not "real." They consist of speculation and conjecture about speculation and conjecture. See, for example, the repeated references to "risks" that are "potential" or that only "may" exist. *E.g.*, Act 120, § 1(4) ("[g]enetically engineered foods potentially pose risks"); *id.*, § 1(6) ("potential risks to human health"). But a risk by definition is a mere potentiality. Act 120's "findings" thus describe a risk of a risk.[8] If that were enough to compel speech, there would be "no end" to what a government could mandate. *Amestoy*, 92 F.3d at 74.

As this discussion indicates, Act 120 is the rBST law all over again. Act 120, like the rBST law, was motivated by "widespread and deeply felt consumer concern" about "potentially

[8] *See CTIA*, 827 F. Supp. 2d at 1061 ("the word 'risk' is being used by the City and County of San Francisco in a way different from the usual way. . . . [T]here is a statistical risk that smoking will lead to cancer for any given individual," but when "there is no statistical correlation," "the word 'risk' is being used in a different way, namely that there is a 'risk' that the 'possible' may turn out to be a 'definite.' This use of 'risk' in this way is a large step shy of the normal use").

harmful health effects" of a product of genetic engineering. Appellees' Br., *Amestoy*, at 7. The State has justified Act 120, just as it did the rBST law, by pointing to "on-going debate within the scientific community," and suggesting that consumers "have a legitimate basis for being skeptical" about FDA's safety determinations. *Id.* at 11. And in Act 120, just as in the rBST law, the State "[took] *no* position on whether [the targeted product] is beneficial or detrimental"; the State intended only to cater to "strong consumer interest and the public's right to know." 92 F.3d at 73 & n.1 (quoting district court). *Amestoy* declared those interests "insufficient" under intermediate scrutiny. *Id.* at 73.[9] The court found "no case" where "consumer interest alone was sufficient to justify requiring a product's manufacturers to publish the functional equivalent of a warning about a production method that has no discernable impact on a final product." *Id.*

Amestoy is dispositive here. That case involved the same "production method" that Act 120 targets, and two decades of study have yet to yield evidence that this method leads to a "discernable impact on a final product." *Id.* The State's asserted health interest in rBST labeling was nothing more than an interest in catering to consumer concern *about* health. So too here. As a co-sponsor of Act 120 put it: the General Assembly "couldn't say for sure that these products cause that harm," but in his view sufficiently "demonstrated enough concern." Apr. 18 Tr., pt. 1, at 20-21. Thus, just as in *Amestoy*, Act 120 fails because Vermont "has not adopted the concerns of consumers; it has only adopted that the consumers *are* concerned." 92 F.3d at 73. The First Amendment requires more than that double-derivative.

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[9] The Second Circuit later said that the *Amestoy* court "expressly limited" its ruling to disclosures "supported by no interest other than consumer curiosity," *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 n.6 (2d Cir. 2001), but the court appears to have quoted Judge Leval's dissenting opinion, 92 F.3d at 81. In any event, *Amestoy* makes clear that "gratification of 'consumer curiosity'" is the only function a label can be said to serve when it conveys information that does not "bear[] on a *reasonable* concern for human health or safety or some other sufficiently substantial governmental concern." *Id.* at 74, 78 (emphasis added).

The Attorney General knows this. On February 7, 2014, he testified to a Senate committee that unproven allegations of harm are not sufficient to justify mandatory labeling:

> If you've got half the expert community saying one thing, and half the expert community saying the other, then the question for the trier of fact is which is more credible, which studies are better . . . [¶]
>
> But at the end of the day, [if] it's roughly a fifty-fifty balance, then it would make it somewhat difficult for the government to say that we have this compelling interest to require the labeling when there's a relative lack of certainty of the harm, and that was the case in [*Amestoy*], where there were . . . arguments both ways.

Feb. 7 Tr. 13-14. Here, the State cannot come close to mustering a "fifty-fifty balance," *id.*; the scientific consensus is plain. And it says Act 120 is wrong. McHughen Decl. ¶¶ 71, 93-101 (and sources cited therein). It is therefore impossible, not just "somewhat difficult," for the State to surmount *Amestoy* here.

Nor can the State can find refuge in the Second Circuit's decisions in *New York State Restaurant Association v. New York City Board of Health*, 556 F.3d 114 (2d Cir. 2009) (*NYSRA*), and *National Electrical Manufacturers Association v. Sorrell*, 272 F.3d 104 (2d Cir. 2001) (*NEMA*). In those cases, the government enacted a disclosure requirement to *encourage* consumers to make particular choices that would serve the government's own interests. The aim of the mercury-labeling law in *NEMA*, was to "encourag[e] . . . changes in consumer behavior, " 272 F.3d at 115, and in *NYSRA*, the City's stated interest was to encourage "healthier food choices." 556 F.3d at 135. The State has claimed no such intent in Act 120. Though consumers may have beliefs about health, environmental, or religious concerns, the question is why the State cares, and here, as in *Amestoy*, the State has not taken a position on whether genetic engineering actually is "beneficial or detrimental," 92 F.3d at 73 n.1. That is fatal to the Act.

A word must be said about the State's asserted "environmental" interests. The findings make clear that the environmental concerns at issue are those associated with "commodity agricultural production practices" to which genetic engineering allegedly "contributes." Act 120, § 1(4)(C). This hand-waving in the general direction of harm does not come close to outweighing the many substantial environmental benefits that are *directly* tied to genetically engineered crop varieties – including dramatic reductions in the use of toxic pesticides, *see* Fernandez-Cornejo, et al., *Genetically Engineered Crops in the United States*, USDA Econ. Research Rept. No. 162, at 23-28 (2014). The State's other environmental findings fare no better. There is no evidence that genetically engineered plant varieties threaten to oust native flora and fauna. McHughen Decl. ¶ 104. And the speculative risk that pollen could spread to organic crops and make them less "marketable" is an economic concern, not an environmental one. In any event, the fact that 90% of the corn and soybean plants grown in the State are genetically engineered casts some doubt on whether the State really means what it says about the environment.

Contrary to the State's belated assertion in its Motion to Dismiss, ECF No. 24-1, at 16 (Defs.' Mem.), Act 120 is *not* framed as a measure to combat the risks-of-risks of genetic engineering. 9 V.S.A. § 3041. Indeed, such an intent was *deleted* from the statutory statement of purpose when the bill headed to the Senate. *See H112 Side by Side*, at 7 (Senate strike-out of "promot[ing] food safety and protect[ing] public health"). And the Senate Judiciary Committee only retained the "potential health effects" phrase because they thought *Amestoy* would dispose of the case if they did not. *See* Apr. 3 Tr. 4-9 (though health effects "could be argued both ways," omitting it would raise "a red flag" under *Amestoy*). The connection to the environment is just as specious. Act 120's lead sponsor testified herself that "labeling of foods *probably isn't*

going to have much to do with the environmental risks because it's a little too indirect." Tr. H. Jud., at 6 (Apr. 18, 2013) (emphasis added). The remaining articulated "purposes," to the extent either amounts to more than "a purpose to avoid *Amestoy*," fall flat just the same. The alleged confusion the State references is nothing more than the *absence* of information, rather than actual deception about a material fact, and the State surely cannot claim that promoting particular religious beliefs is a governmental interest. (If it does, Plaintiffs reserve the right to amend their Complaint to contain an Establishment Clause claim.).

Act 120 is framed – and must be assessed – as a purely informational measure for consumers. As the Governor said the day he signed it into law, Act 120 "isn't a judgment on whether GMOs are good or bad. All we're saying in Vermont is consumers have the right to know what they buy."[10] That places Act 120 squarely in *Amestoy*'s domain.

b. Act 120 Does Not Directly Advance or Bear a Reasonable Fit With The State's Asserted Interests.

Even if every speculative concern listed in the Act were taken, counterfactually, to be a "harm" that is "real," *Edenfield*, 507 U.S. at 771, and *Amestoy* were distinguishable, the remaining elements of intermediate scrutiny also suffice to dispatch Act 120's labeling requirement.

First, the labels do not directly advance the State's professed interest in informing consumers because the definition of "genetic engineering" used in the statute is misleading. Act

[10] The Tavis Smiley Show, *Interview with Peter Shumlin*, PBS (May 8, 2014). See also:

> [Host]: So if you're not taking a position on whether it's good or bad, why not give the industry the benefit of the doubt?
>
> [Governor]: Because there are many, many people who believe that it is not wise to be tampering with what nature has created. I'm not going to enter into that debate, who's right or wrong there.

120 defines genetic engineering as "the process by which a food is produced from an organism or organisms." 9 V.S.A. § 3042(4). That is not correct. One may genetically engineer a plant but one does not genetically engineer a food into existence. McHughen Decl. ¶ 79; FDA, *Biotechnology* (web site), FDA.gov (referring to "genetically engineered *plants* for use in food and feed" and "foods derived from genetically engineered *plants*") (emphasis added). Further, the "partially produced" label tells consumers little, and the "may be" qualifier tells them nothing. The Act does not specify when a manufacturer may or must use one of these qualifiers, which means even a diligent consumer will be unable to discern the difference. In fact, it is not even clear how the "may be" variation fits within the Act, which by its terms applies only to foods that *are* "produced with genetic engineering" either "entirely or partially." 9 V.S.A. § 3043(a). Act 120 does not serve the State's putative informational interest, directly, indirectly, or otherwise. *See, e.g.*, *Authentic Bevs. Co. v. Tex. Alcoholic Bev. Comm'n*, 835 F. Supp. 2d 227, 246 (W.D. Tex. 2011) (labels distinguishing "beer" from "ale" did not advance state interest because they "potentially conceal[ed] as much information as they provide[d]").

Second, Act 120's labeling requirement does not materially advance the State's informational interest because it exempts vast quantities of food that contain ingredients derived from genetically engineered plants. Food sold at restaurants and for immediate consumption are two large categories. Because of these exemptions, a label would appear on a pack of tortillas sold at retail, but there would be no label at a restaurant which uses those same tortillas to make burritos. Hot dogs sold at a convenience store might have to be labeled "partially produced with genetic engineering" because of the bun, but a food truck parked outside could sell hot dogs without that disclosure. The other exemptions carve out still more. With such moth-eaten coverage, Act 120 cannot be said to "materially" advance the goal of informing consumers. This

is an independently sufficient ground for invalidating it. *See Greater New Orleans*, 527 U.S. at 190 (choosing not to resolve whether government proved "interest" element "because the flaw in the [its] case is more fundamental: The operation of [the statute] and its regulatory regime is so pierced by exemptions and inconsistencies that the Government cannot hope to exonerate it.").

Third, the disclosure requirement does not have a reasonable fit with any interest. A State's obligation under the fit element is to show that that costs were "carefully calculated," *Fox*, 492 U.S. at 480, *and* that it considered less restrictive alternatives, *and* had an adequate justification for rejecting them. "If the First Amendment means anything, it means that regulating speech must be a last—not first—resort." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002). Mandatory labeling was Vermont's "first resort." The State could have promoted the existing, adequate voluntary labeling systems under USDA's organic program and other certification systems – which many consumers already use.[11] Or the State could have chosen to educate consumers through its own speech, or by directing consumers to free informational sources, for example, reviews by independent scientists, *see, e.g.*, BioFortified Blog, www.biofortified.org.

The State also could have – but has not – advocated for the proposed federal bill that it cites in its Motion to Dismiss– a bill which has GMA's full support, and would among other things, require labeling when there is a demonstrated health or safety issue. *See* Safe and Affordable Food Labeling Act of 2014, H.R. 4432, 113 Cong. (2014) (cited at Defs.' Mem. 42). Vermont appears not to have considered these non-intrusive measures for promoting consumers' informational interests.

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[11] *See* The Non-GMO Project, *Non-GMO Project Expands Verification Capacity*, Aug. 5, 2014, NonGMOProject.org (reporting 20,000 verified products with $7 billion in annual sales); *see also* Tr. Mar. 19, at 2-10 (Maroney) (advocating for state support of organic programs).

In view of the adequate voluntary labeling in the marketplace, the costs imposed by Act 120 on food manufacturers can only be seen as gratuitous and punitive, not tailored. Therefore, Act 120 cannot withstand even the modest demands of intermediate scrutiny.

4. Act 120 Fails the "Reasonable Relationship" Test.

a. The statements at issue are not factual and uncontroversial.

The State plans to defend this law by reference to *NEMA* and *NYSRA*. Defs.' Mem. 9-10.[12] In those decisions, the Second Circuit applied a "reasonable relationship" test, *NEMA*, 272 F.3d at 115, by which it meant the standard of review the Supreme Court applied to a compelled corrective disclaimer in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985). *See id.* at 651 (disclaimer requirements permissible if "reasonably related to the State's interest in preventing deception of consumers"). Since those decisions, *NEMA*'s extension of this standard beyond corrective disclaimers to prevent deception, and *NYSRA*'s characterization of the standard as rational basis review have been called into question. In *Milavetz, Gallop, & Milavetz, P.A. v. United States*, 559 U.S. 229 (2010), the Supreme Court made clear that an "essential feature" of a law subject to *Zauderer* is that it is "intended to combat the problem of inherently misleading advertisements" (not just to provide more information), and the Court called the *Zauderer* standard "less exacting scrutiny," *id.* at 249-250. And serious questions attend the application of pure rational-basis review to questions implicating First Amendment rights. *See Ysursa v. Pocatello Educ. Ass'n*, 555 U.S. 353, 359 (2009) (applying rational-basis review "[g]iven that the State has *not* infringed the [challengers'] First Amendment rights") (emphasis added); *City of Los Angeles v. Preferred Commc'ns, Inc.*, 476 U.S. 488, 496 (1986) (rational-

[12] The State also relies upon *Safelite Grp., Inc. v. Jepsen*, 988 F. Supp. 2d 199 (D. Conn. 2013), which was recently vacated, 2014 WL 4358418 (2d Cir. Sept. 4, 2014).

basis review "typically does not have the same controlling force" in First Amendment cases) (internal quotation marks and citation omitted).

Putting those serious questions to the side, though, one thing is for certain under Second Circuit precedent: is that the *Zauderer*/*NEMA*/*NYSRA* standard, however it might be characterized, applies only to mandated speech that is "purely factual and uncontroversial, *id.* at 651. *See Evergreen*, 740 F.3d at 245 n.6. Neither trait can be ascribed to Act 120.

As an initial matter, the statement that Act 120 prescribes is not factual. Vermont has defined "genetic engineering" as something it is not: a way to "produce food from an organism." *Supra* at 27. Moreover, the multiplicity of definitions of genetic engineering that appear in the Vermont Statutes confirm that "genetic engineering" is not a term with a fixed factual meaning. Rather, its scope depends on the idiosyncratic value judgments of the person defining it at any given point. In light of these fundamental definitional problems, Act 120's labels cannot be called factual. *See, e.g.*, *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) (invalidating mandatory age "18" stickers on violent video games as statements of opinion).

Zauderer review is also limited to disclosure requirements that are "uncontroversial." *Evergreen*, 740 F.3d at 245 n.6. It would be difficult to point to a current consumer issue *more* controversial than genetic engineering. One need not witness a "March Against Monsanto" to grasp the point; the controversy is right there on the face of Act 120. Its findings imply, among other things, that FDA is captured by industry; that industry cannot be trusted to report its own data; and that eating foods derived from genetically engineered plants offends God. Act 120, § 1. The Act is intended to *fuel* controversy. That takes it outside *Zauderer*'s limited domain.

Court after court has rejected *Zauderer* review in such circumstances. Right on point are the decisions on cell-phone disclosures in *CTIA—The Wireless Ass'n v. City & County of San Francisco*, 827 F. Supp. 2d. 1054 (N.D. Cal. 2011), *aff'd in part, rev'd in part*, 494 F. App'x 752 (9th Cir. 2012). This litigation involved San Francisco's "Cell Phone Right to Know" ordinance, which required retailers to inform customers that cell phones emit radiation, and that there are ways to "avoid" exposure. 827 F. Supp. 2d at 1057-58. Among other requirements, the retailers had to mark phones with stickers and hand out "fact-sheets." *Id.* The district court enjoined the sticker requirement because it would "unduly interfere with the retailers' own right to speak to customers." *Id*. at 1063-64. The court also ordered the fact-sheet to be revised, because "[a]lthough each factoid . . . may have an anchor in some article somewhere, . . . t]he overall impression left is that cell phones are dangerous and that they have somehow escaped the regulatory process. That impression is untrue and misleading, for all of the cell phones sold in the United States must comply with safety limits set by the FCC." *Id.* at 1062.

On appeal, the Ninth Circuit affirmed the sticker ruling *and* struck down the fact-sheet, as revised. 494 F. App'x at 754. The critical point for the court was that the legislative findings "acknowledge[d] that '[t]here is a debate in the scientific community about the health effects of cell phones.'" *Id.* at 753 (quoting record). The City had also conceded that there was no evidence showing cell phones cause cancer. *Id.* at 754. Based on this record the court "could not say" the fact sheet was "'purely factual and uncontroversial,'" and could not uphold it under *Zauderer*. *Id.* (quoting 471 U.S. at 651).

The reasoning in *CTIA* maps directly onto this case. Act 120 points to a "lack of consensus" and "conflicting studies" but the State will, and must, concede that none of these studies demonstrates that foods derived from genetically engineered plants are harmful to human

health. *See* Apr. 18 Tr. 20 (co-sponsor of bill: legislature "couldn't demonstrate" health effects); *see also* McHughen Decl. ¶¶ 72-74, 100. All that remains to justify the labeling requirement, then, is the Act's accounting of the policy preferences and religious reasons people may have for opposing genetic engineering and "commodity agricultural production practices." Those are controversies.[13]

As one witness put it, mandatory labeling is merely a "shibboleth, for a far larger issue" about modern agriculture. *See* Mar. 19 Tr. 2. Requiring speech from manufacturers to "tilt [that] public debate in a preferred direction" is viewpoint discrimination, *Sorrell*, 131 S. Ct. at 2671, and it has no claim to *Zauderer* review.

b. The Disclosures At Issue Fail The Rest of the *Zauderer* Test.

The *Zauderer*/*NEMA*/*NYSRA* test does not apply to Act 120 because it compels controversial, non-factual disclosures. Act 120 would not pass this test anyway.

As formulated in *NEMA*, 272 F.3d at 115 & n.6, the *Zauderer* test requires (1) a "substantial interest" and (2) a "rational connection between the purpose of a commercial disclosure requirement and the means employed to realize that purpose." Thus, to the extent *NEMA* holds that *Zauderer* involves review less searching than intermediate scrutiny, the court applied that discount only to the elements of advancement and fit. *See id.* at 115 (*Zauderer* "describes *the relationship* between the means and ends") (emphasis added); *id.* at 115 n.6 ("the

[13] Other decisions rejecting *Zauderer* for "controversial" disclosures include *Nat'l Ass'n of Mfrs. v. SEC*, 748 F.3d 359, 370-71 (D.C. Cir. 2014) ("conflict minerals" disclosures); *R.J. Reynolds Tobacco Co v. FDA*, 696 F.3d 1205, 1216 (D.C. Cir. 2012) (inflammatory graphic warnings); *Entm't Software Ass'n*, 469 F.3d at 652 ("18" stickers on video games); *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950 (9th Cir. 2009) (same), *aff'd sub nom. Brown v. Entm't Merchants Ass'n*, 131 S. Ct. 2729 (2011).

issue we face here" is "the proper *relationship* between a disclosure regulation's means and its ends") (emphasis added).

Much as the State might wish otherwise, the Second Circuit has not eliminated intermediate scrutiny's "substantial interest" requirement for compelled disclosures. The court did not do so in *NEMA*; it was undisputed in that case that the State's interest was substantial. *See Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 72 F. Supp. 2d 449, 451 (D. Vt. 1999) ("No one disputes Vermont has an interest in reducing the amount of mercury which finds its way to the environment. The only substantial dispute is whether [the law] furthers th[at] goal[.]"); 272 F.3d at 115 & n.6 (noting state's "substantial interest in protecting human health and the environment"). The court did not delete the substantial interest requirement in *NYSRA*, either; the plaintiffs "conced[ed]" New York had a "substantial interest" in combating obesity. 556 F.3d at 134. Therefore, even though the court *called* its analysis "rational basis review," *id.* at 138, that is not actually what the court employed because it did not discount the substantial-interest requirement. The D.C. Circuit recently reserved this question. *See American Meat Inst. v. USDA*, No. 13-5281, 2014 WL 373269, at *4 (D.C. Cir. Jul. 29, 2014) ("Because the interest motivating the 2013 Rule is a substantial one, we need not decide whether a lesser interest could suffice under *Zauderer*."). *See also, e.g., Ass'n of Nat'l Advertisers v. Lungren*, 44 F.3d 726, 732 (9th Cir. 1994) (upholding recycling-related disclosures where parties agreed environmental interests were substantial).[14]

[14] The Second Circuit referred to the pure Fifth Amendment rational-basis standard in a case involving the same statutory provisions upheld in *Milavetz* and decided the same year. *Connecticut Bar Association v. United States*, 620 F.3d 81 (2d Cir. 2010). But court determined that *Milavetz* "compelled" it to review those provisions under the "the rational basis test stated in *Zauderer*," because "each of those provisions [wa]s directed at misleading commercial speech," *id*. at 95-96. The court also referred to the standard in these terms in a dictum in *Safelite*, 2014

Act 120 fails the *Zauderer* test because the binding precedent in this circuit holds that *consumer* interest is not a substantial interest; indeed, consumer interest is not even a governmental interest. *Amestoy*, 92 F.3d at 74.[15] And even if consumer interest were sufficient on its own, mandatory labeling is an irrational response to that interest that would fail the reasonable-relationship test. *NYSRA*'s analysis of rational legislation is particularly instructive on this point. When it found that calorie disclosures have a "reasonable relationship" to promoting consumer health, the *NYSRA* court relied on the following sources: a federal statute, *id.* at 118, 135 (citing 21 U.S.C. § 343(q)(1)); a report commissioned by FDA, *id.*; a report commissioned by USDA, *id.* at 135-36; and a statement of policy by the American Medical Association, all in *favor* of calorie disclosures, *id.* at 136-138 & n.24. Here, those very authorities line up unanimously *against* mandatory labeling. *See* Background Part C, *supra*. There is no reasonable relationship here.

Rounding out the First Amendment defects in Act 120, true "rational basis" review would also defeat this statute. That standard demands a legitimate governmental interest, and catering to personal, political, and religious views that reject science is neither legitimate nor governmental, as interests go. It is not legitimate because it is politically motivated. *See U.S.*

WL 4358418, where the court held the standard did *not* supply the appropriate level of review for disclosures intended to affect competition in a market rather than to convey information about the inherent characteristics of a product.

[15] Defendants contend that the D.C. Circuit's *AMI* opinion recognizes consumer interest as a substantial interest. Defs.' Mem. 10. Not so. The court held that *three* "aspects" of the country-of-origin labeling rule for meat "combine[d]" to make the interest substantial: the history of country-of-origin labeling, consumer desire to extend that labeling to another class of products, and the government's interest in responding to health concerns (i.e., "Mad Cow" disease), and "potential market impacts" of an outbreak. 2014 WL 373269, at *4. Act 120's labeling requirement has no historical antecedent; it establishes a new labeling regime rather than extending an existing one to a new class of products; and there is no evidence of genetically engineered plant varieties causing harm to health.

Dep't of Agric. v. Moreno, 413 U.S. 528, 534 (1973) (regulations serving a "bare [legislative] desire to harm a politically unpopular group cannot constitute a legitimate governmental interest"). It is not governmental because it rests on consumer interest in the air rather than a prevention of a harm. *See Buffalo Teachers Fed'n v. Tobe*, 464 F.3d 362, 368 (2d Cir. 268) (legitimate public purpose is one 'aimed at remedying an important general social or economic problem rather than providing a benefit to special interests.' "). The State's refusal to put taxpayer money toward the enforcement of this statute suggests that the State does not truly believe it to be vested with the public interest.[16] Moreover, because the State has no monetary skin in the game, there is not even a *financial* interest in the enforcement of this flawed statute.

Under any and every available standard of review, Plaintiffs are likely to succeed on their First Amendment challenge to Act 120's labeling requirement.

B. Act 120's Ban On "Natural" And "Similar" Terms Violates the First Amendment and Is Void for Vagueness.

In addition to its unconstitutional labeling requirement, Act 120 contains a draconian labeling restriction: "a manufacturer of a food produced entirely or in part from genetic engineering shall not label the product on the package, in signage, or in advertising as 'natural,' 'naturally made,' 'naturally grown,' 'all natural,' *or any words of similar import that would have a tendency to mislead a consumer*." 9 V.S.A. § 3043(c) (emphasis added).

This "natural" ban is just another manifestation of viewpoint discrimination and is invalid on its face. *See* 131 S. Ct. 2671. The purpose of this restriction is to conform manufacturers' speech to the "general perception" that genetically engineered crops are not "natural." Act

[16] The Attorney General in fact put this argument squarely to legislators: "I can envision an argument coming from those attacking the statute to say, '[W]ell the government interest wasn't so important that the government put [its] own money up. It's only if individuals, whether wealthy or not, fund it, that the law even goes into effect. '" Tr. S. Agric. 14-40, at 12 (Feb. 7, 2014). But the General Assembly put the Special Fund in the law all the same.

120, § 1(5)(C). Perception is not fact, and the "general perception" at issue here is rooted in personal belief systems about "nature." Moreover, a state "may not . . . completely ban statements that are not actually or inherently misleading." *Peel v. Atty. Reg'n & Disciplinary Comm'n.*, 496 U.S. 91, 110 (1990). But that is precisely what the natural ban does. For that reason, and because its catch-all clause will chill even non-deceptive expression, Plaintiffs are likely to succeed on their First and Fifth Amendment challenges to it.

1. Vermont Has Not Shown That There Is a "Real" Risk of Deception.

Although it is invalid as viewpoint discrimination, the "natural" ban also fails intermediate scrutiny under *Central Hudson*.

The first question under *Central Hudson* is whether the speech that is restricted concerns lawful activity and is not misleading. *Ibanez v. Fla. Dep't of Bus. & Prof'l Reg., Bd. of Accountancy*, 512 U.S. 136, 143 (1994). It is true that the General Assembly "found" that the use of "natural" and "similar descriptors" on foods derived from genetically engineered plants is "inherently misleading." Act 120, § 1(5)(C). But a court exercises "independent judgment of the facts bearing on an issue of constitutional law," *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 666 (1994) (internal quotation marks and citation omitted), and the State's finding that "natural" claims are "inherently" deceptive does not pass the smell test. After all, the State has employed broad exemptions that *allow* the use of "natural" terms on many foods for which it would otherwise be forbidden. 9 V.S.A. § 3044. There is no reason why "inherently" deceptive speech would lose that "inherent" characteristic in certain circumstances or on certain foods, and the Act does not offer one.

Another finding that tests the bounds of independent judgment is the claim that "natural" terms "pose[ ] a risk of confusing or deceiving consumers." Act 120, § 1(5)(C). For that finding to carry the day, though, the State was required to develop an evidentiary record consisting of

more than just "rote invocation of the words 'potentially misleading.'" *Ibanez*, 512 U.S. at 146. The State must meet its burden to " 'demonstrate that the harms it recites are real and that its restrictions will in fact alleviate them to a material degree.'" *Id.* (quoting *Edenfield*, 507 U.S. at 771). That burden "is not slight." *Id.* at 143. As the Attorney General's staff knows, "[t]he way [deception] can be proven [is] through consumer studies that try to determine what consumers perceive when they see certain words on a label . . . ." Apr. 18 Tr., pt. 2, at 22 (statement of B. Asay). The legislative findings here, by contrast, rely upon "general perception," which Defendants can only evidence by reference to dictionary definitions. Defs.' Mem. 18-19.

The State's *ipse dixit* falls far short of what the Second Circuit requires. For example in *Alexander v. Cahill*, 598 F.3d 79 (2d Cir. 2010) the Second Circuit invalidated a New York bar rule prohibiting certain attorney advertising gimmicks because there was a "a dearth of evidence" showing that consumers "have, in fact, been misled by the sorts of names and promotional devices targeted by [the rule]." *Id.* at 95. In the court's view, these gimmicks were "akin to, and no more than, the kind of puffery that is commonly seen, and indeed expected, in commercial advertisements generally." *Id.* The government defendants thus "failed to meet their burden for sustaining this prohibition under *Central Hudson*." *Id.*

Similarly, in *Bad Frog Brewery Inc.. v. New York State Liquor Authority*, 134 F.3d 87 (2d Cir. 1998), the court invalidated a ruling that prohibited a brewery's use of a crude image on its beer labels. Though recognizing the State's interest in shielding children from vulgarity, the court held that the ban did not "materially advance" those interests because of the "wide currency of vulgar displays throughout contemporary society." *Id.* at 98, 99. Nor did the court countenance the argument that the labels would encourage consumers to "defy authority," as this proposition was "not so self-evident as to relieve the state from its burden of marshalling some

empirical evidence to support its assumptions." *Id.* The State had none, so this justification failed, too.

Natural claims are "commonly seen, and indeed expected" in food advertising and labeling generally, *Alexander*, 598 F.3d at 95, and to impugn them, the State has offered nothing other than its own "rote invocation of the words 'potentially misleading,'" *Ibanez*, 512 U.S. at 146. The State had a burden to "marshal[ ] some empirical evidence to support its assumptions," *Bad Frog*, 134 F.3d at 100, and it did not. The natural ban fails right out of the gate.

2. Vermont Has Not Shown Material Advancement or Fit.

The natural ban also fails First Amendment scrutiny because Vermont cannot possibly show that its all-out ban "directly and materially advances" its interest in preventing deception "in a manner no more extensive than necessary to serve that interest." *Ibanez*, 512 U.S. at 142.

The exemptions doom the natural ban just as they doom the labeling mandate. The State cannot say that "natural" terms present an unacceptable risk of deception when the State is perfectly willing to tolerate them for exempted foods. The exemptions certainly raise a doubt as to whether the State has any true interest, let alone a "substantial" one, in protecting the "general perception" of "natural" foods it has asserted. As has been the case for other unconstitutional speech regulations, broad exemptions greatly "diminish the credibility of the government's rationale for restricting speech in the first place." *City of Ladue v. Gilleo*, 512 U.S. 43, 52 (1994). *See, e.g., Rubin v. Coors Brewing, Inc.*, 514 U.S. 476, 489 (1995) (invalidating restrictions on beer labeling that did not apply to other categories of liquor).

The natural ban is also "substantially excessive, disregarding far less restrictive and more precise means," *Rockwood v. City of Burlington*, 21 F. Supp. 2d 411, 423 (D. Vt. 1998) (citing *Fox*, 469 U.S. at 479). Without apparent justification or tailoring, Act 120's natural ban on its face covers *all forms of advertising*, within and outside the store, on television and radio, in the

press, and online. The natural ban is not even proportional to the labeling requirement, which applies only to product packaging and displays. The element of "fit" also requires the "costs to be carefully calculated" before a state restricts speech. *Fox*, 469 U.S. at 480. The ban here fails to take into account the costs of the rule, for example with respect to trademarks and brand names that include the prohibited terms or words that may be "of similar import."

Moreover, Act 120 reflects no consideration of whether the information on the labels it targets " 'may be presented in a way that is not deceptive.'" *Peel*, 496 U.S. at 110 (citation omitted). That is a box the State must check *before* it bans speech that is only "potentially" misleading. *Id.* *See also Hairston v. S. Beach Bev. Co.*, No. 12-1429, 2012 WL 1893818 (C.D. Cal. May 18, 2012) (dismissing complaint alleging that "all natural" was deceptive, where complaint failed to take into account label's contextual claims about vitamin and fruit content).

Act 120's "natural" ban is also just unnecessary: Vermont law provides a remedy for misleading speech. *See* 9 V.S.A. § 2461. And perhaps that is why the State did not muster record support, carved out expansive categories of food in the exemptions, and broadly phrased the law to impose liability—not tailored to reserve it. The only additive purpose served by Act 120, then, is to amplify the message of those who oppose genetic engineering by codifying *their* "general perception" of what is "natural" and what is not. Act 120, § 1(5)(C). Accordingly, Act 120's ban on "natural" claims violates the First Amendment.

3. The Natural Ban is Void for Vagueness.

A law can be challenged as vague on its face if it implicates First Amendment rights, either under the First Amendment's "fit" requirement, *see, e.g.*, *Reno v. ACLU*, 521 U.S. 844 (1997), or under the Fifth Amendment's due process clause, *see, e.g.*, *FCC v. Fox Television Stations*, 132 S. Ct. 2307 (2012). "Words of similar import that have a tendency to mislead a

consumer" defeats the fit element for the natural ban under the First Amendment, as explained above, and it is void for vagueness in violation of due process.

Under the Fifth Amendment, a law violates due process if it "fails to provide a person of ordinary intelligence fair notice of what is prohibited or is so standardless that it authorizes or encourages seriously discriminatory enforcement." *Holder v. Humanitarian Law Project*, 561 U.S. 1, 18 (2010). *See also Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). When, as here, the law also implicates First Amendment rights, and threatens to chill speech, "rigorous adherence" to fair notice requirements is necessary. *Fox Television*, 132 S. Ct. at 2317. Accordingly, due process and the First Amendment together require the government to draft speech regulations with "narrow specificity." *NAACP v. Button*, 371 U.S. 415, 432-433 (1963).

Act 120's natural ban does not regulate with "[n]arrow specificity," *id.* The statute does not define or qualify the term "natural," so a manufacturer has no guidance as to which words are "of similar import." In fact, the lead sponsor of Act 120's testified that "natural" "*doesn't mean anything.*" Apr. 18 Tr. at 15 (emphasis added). That means it has no "import" at all. A person of even extraordinary intelligence would thus have great difficulty assessing the outer bounds of the Act 120 prohibition. Consider the dilemma of a manufacturer's general counsel at this very moment. Which words are "of similar import" to natural? "Pure"? "Wholesome"? "Country"? What about a brand name that includes the word "Farm" or "Earth?" That such "questions . . . so readily come to mind means that it is not sufficiently clear to a manufacturer or distributor of ordinary intelligence, what exactly the statute prohibits." *Ass'n of Nat'l Advertisers, Inc. v. Lungren*, 809 F. Supp. 747, 762 (N.D. Cal. 1992) (invalidating as vague restriction limiting use of "recyclable" label to packages that were "conveniently recyclable"), *aff'd*, 44 F.3d 726 (9th Cir. 1994).

Act 120's qualification that there must be "[a] tendency to mislead a consumer" only exacerbates the flaws in the prohibition. Though a law may sometimes overcome a vagueness challenge if it makes reference to "a standard . . . developed and accepted in actual practice." *A.B. Small Co. v. Am. Sugar Ref. Co.*, 267 U.S. 233, 241 (1925), a law may be voided for vagueness when it ties liability to "wholly subjective judgments without statutory definitions, narrowing context, or settled legal meanings," *United States v. Williams*, 553 U.S. 285, 306 (2008). Act 120's natural ban fits that bill to a tee.

Act 120's "tendency to mislead a consumer" test is so subjective as to be meaningless. It has no precedent in the law of consumer protection, and it has no discernible limits. By contrast, there are boundaries to the "*reasonable* consumer" test – i.e., the standard "accepted in actual practice," *A.B. Small*, 267 U.S. at 241; it permits liability only when a seller has made a misrepresentation that would be "material" for a purchaser "interpreting a message reasonably under the circumstances." *Peabody v. P.J.'s Auto Vill., Inc.*, 153 Vt. 55, 57, 569 A.2d 460, 462 (1989). *See also FTC Policy Statement on Deception*, appended to *In re Cliffdale Assocs.*, 103 F.T.C 110, 174 (1984) (adopting reasonable consumer test); FDA, *Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements*, 67 Fed. Reg. 78,002, 78,003 (Dec. 20, 2002) (same). Act 120 does not contain that limitation.

The qualification that the word must have a "tendency" to mislead doubles down on the problem. This phrasing expands the scope of liability rather than explaining it, and it puts the manufacturer in the position of having to guess when any one consumer, somewhere, might "tend[ ]" to be misled by a particular "word." But "[t]he fact that a person only violates [an] ordinance if his or her action evokes a particular response from a third party" fails to provide fair notice, and it is "especially problematic" when a law chills First Amendment rights. *Stahl v. City*

of St. Louis, 687 F.3d 1038, 1041 (8th Cir. 2012). *See, e.g.*, *Coates v. City of Cincinnati*, 402 U.S. 611, 614 (1971) (invalidating ban on groups congregating in a way that is "annoying" to others because violation "may entirely depend upon whether or not a policeman is annoyed"). Act 120 is problematic in just this way: it requires a manufacturer to guess at a third-party's "tendency" to have a particular subjective state of mind in particular circumstances, when that third party is *not* a "reasonable consumer." 9 V.S.A. § 3043(c). Worse, the penalty for guessing incorrectly is severe, with daily-multiplying civil liability and potentially punitive damages. *See infra* at 57-58.

Act 120 also creates an unacceptable risk of arbitrary and ad-hoc enforcement – an independent ground for invalidity. *Grayned*, 408 U.S. at 108. Act 120 delegates the identification of "words of similar import" to juries, judges, the attorney general, and private plaintiffs, and it tells those individuals that they need only find a "tendency to mislead" lurking within a "word" that they could find to be "of similar import" to a set of words that are not themselves defined. This doubly subjective determination invites arbitrary application and enforcement that due process forbids. *See, e.g.*, *Hayes v. N.Y. Atty. Grievance Comm.*, 672 F.3d 158, 169 (2d Cir. 2012) (invalidating attorney-advertising requirement that disclaimers be "prominently made" because it granted "unfettered discretion" to disciplinary committee); *Cunney v. Bd. of Trustees of the Vill. of Grand View, N.Y.*, 660 F.3d 612, 622, 625 (2d Cir. 2011) (invalidating zoning provision that "provide[d] no standard that c[ould] be objectively applied," thus granting enforcement officers "unfettered latitude in making compliance determinations").

Plaintiffs' members should not be left to guess in the dark about what is and is not permissible under Act 120, given that it applies to all labeling, signage, *and advertising.* Nor can Plaintifs' wait for guidance to be issued in July of 2015, because that does not afford them

enough time to make changes. *See* Part II, *infra*. The natural ban is void for vagueness, and Plaintiffs' are likely to succeed in showing it to be invalid under the First and Fifth Amendments.

C. Act 120 Is Preempted By Federal Law and the Comprehensive Federal Policy Governing the Products of Genetic Engineering.

Plaintiffs are also likely to succeed on the merits of their claim that Act 120 is preempted either in whole or in part, by the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Nutrition Labeling and Education Act (NLEA), 21 U.S.C. § 343-1(a)(2); the Federal Meat Inspection Act (FMIA), 21 U.S.C. §§ 601 *et seq.*, and the Poultry Products Inspection Act (PPIA), 21 U.S.C. §§ 451 *et seq.*

1. Act 120's Labeling Requirement Is Expressly Preempted by the Federal Food, Drug and Cosmetic Act.

As amended by the NLEA, the FFDCA preempts state-law requirements that are "not identical to" the federal labeling standards and requirements FDA promulgates under various subsections of 21 U.S.C. § 343. *See* 21 U.S.C. § 343-1(a)(1-5) (addressing federal standards of identity under § 343(g) and requirements under § 343(b), (c), (d), (e), (f), (g), (h), (i)(1), (i)(2), (k), (q), and (r)(1)). The FFDCA thus preempts "[a] multitude of state laws, state regulations, state administrative agency rulings, and state-court decisions." *POM Wonderful LLC v. The Coca-Cola Co.*, 134 S. Ct. 2228, 2239-40 (2014). As FDA later explained, NLEA preemption is intended to promote "national uniformity in certain aspects of food labeling, so that the food industry can market its products efficiently in all 50 States in a cost-effective manner." *State Petitions Requesting Exemption from Federal Preemption*, 58 Fed. Reg. 2462, 2462 (Jan. 6, 1993). Accordingly, FDA has clarified that a state law is "not identical" to a federal requirement if it "directly or indirectly imposes obligations or contains provisions concerning . . . the labeling of food" that are "not imposed by" or "[d]iffer from those specifically imposed by" federal regulation. 21 C.F.R. § 100.1(c)(4). *See also In re Pepsico, Inc.*, 588 F.Supp.2d 527, 538-39

(S.D.N.Y. 2008) ("not identical" language in NLEA preempts requirements that "go beyond federal law").

Act 120 is expressly preempted by the FFDCA, as amended, because the Act imposes a labeling requirement that is "not identical" to the federal requirements for ingredient disclosures and product naming promulgated by FDA pursuant to subsections (g) and (i) of 21 U.S.C. § 343. *See id.*, § 343-1(a)(1),(2).

a. Ingredient Labeling Under § 343(i)(2)

Section 343, subsection (i) declares a food misbranded "[u]nless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient." 21 U.S.C. § 343(i). The section further provides, as relevant here: "To the extent that compliance with the requirements of clause (2) of this paragraph . . . results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary." *Id.* Requirements under clause (2) expressly preempt "not identical" state law. *Id.*, § 343-1(a)(1).

Act 120 is expressly preempted because it requires that a label on a multi-ingredient food bear *more* than the "common or usual name of each such ingredient," § 343(i)(2). Act 120 mandates that a processed food be labeled to indicate that it is "produced with genetic engineering," or "partially" or potentially so. 9 V.S.A. § 3043(b)(3). Act 120 thus requires the label of a multi-ingredient food to indicate that it contains an ingredient derived from genetically engineered crops. *See* Act 120 Leg. Summ., Vt.us, at 1 (subsection (b)(3) applies to "any processed food that contains a product of genetic engineering"). Act 120 is expressly preempted because federal regulation does not include that requirement for the ingredients in a multi-ingredient food.

To the contrary, in fact: FDA has stated that "terms that describe an ingredient of a multi-ingredient food as [genetically engineered] should *not* be used in the ingredient list of a multi-ingredient food." *See* 2001 Guidance (emphasis added). FDA has repeatedly framed the question whether food labels must disclose the presence of such ingredients as one that falls under the identification requirements in Section 343(i); each time it has done so it has concluded that no additional disclosures are necessary. *See* FDA, *Food Labeling: Foods Derived from New Plant Varieties*, 58 Fed. Reg. 25,837, 25,838 (Apr. 28, 1993) (necessity of disclosures related to whether foods contain "one or more ingredients developed by 'genetic engineering,'" is informed by whether the "common or usual name" of those ingredients continue to "describe adequately the basic nature of the ingredient"); 1992 Statement, at 22991 ("labeling requirements" related to genetic engineering are tied to "common or usual name" requirement, but labeling disclosures not required). These interpretations, which are entitled to deference, confirm that FDA requirements for ingredient labeling under § 343(i)(2) preempt state law requiring a label to disclose the presence of ingredients derived from genetically engineered crops. *NYSRA*, 556 F.3d at 126 (deferring to FDA's interpretation of NLEA preemption).

Act 120 is not saved by the proviso that it "shall not be construed to require: (1) the listing or identification of any ingredient or ingredients that were genetically engineered; or (2) the placement of the term genetically engineered' immediately preceding any common name or primary product descriptor of a food." 9 V.S.A. § 3043(d). The preemption inquiry "does not end at the text of the statute." *Entergy Nuclear Vermont Yankee, LLC v. Shumlin*, 733 F.3d 393, 416 (2d Cir. 2013). Rather, the court considers the statute "as it affects" the speaker. *Vango Media, Inc. v. City of New York*, 34 F.3d 68, 74 (2d Cir. 1994) (holding advertising ban was preempted despite purportedly curative statement of legislative intent). *See also, e.g.*, *23-34 94th*

St. Grocery Corp. v. N.Y.C. Bd. of Health, 685 F.3d 174, 183 (2d Cir. 2012) (examining "the practical effect the [regulation] has on the manufacturer's promotional activity at the retail location"); *Greater N.Y. Metro. Food Council v. Giuliani*, 195 F.3d 100, 108 (2d Cir. 1999) (dismissing legislative-disclaimer argument as "sophistry"), *abrogated on other grounds by Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001). *See also, e.g.*, *Association of Int'l Auto. Mfrs. v. Abrams*, 82 F.3d 602, 611 (2d Cir. 1996) (vacating summary judgment to government based on triable issue of fact as to whether state statute in effect amounted to preempted performance standard). These precedents all make clear that "because I said so" is no response to a preemption argument, and that is all this subsection of the Act contains.

The FFDCA's allowance for exemptions in § 343(i) further confirms that Act 120 is expressly preempted. There, Congress expressly established a mechanism for FDA to create exemptions from federal ingredient-labeling requirements "[t]o the extent compliance . . . results in deception." 21 U.S.C. § 343(i). One of the asserted premises for the Act 120 labeling requirement is to "[r]educe and prevent consumer confusion and deception." 9 V.S.A. § 3041(3). Act 120 thus requires additional disclosures about ingredients based on a finding that compliance with the federal requirements "results in deception." Congress has granted that power exclusively to FDA.

The purpose and practical effect of Act 120 is to require manufacturers to make characterizations about one or more ingredients in a multi-ingredient food. Act 120's mandate is a requirement for identifying ingredients that is "not identical to" the federal requirements for identifying ingredients and is therefore preempted under 21 U.S.C. § 343-1(a)(2).

b. Product Labeling

Act 120's labeling requirement is also a requirement for product labeling that is not identical to the federal requirements for the names that must be used on the label of foods

pursuant to subsections (g) and (i)(1) of 21 U.S.C. § 343. It is therefore preempted by 21 U.S.C. § 343-1(a)(1) and (3), as well.

So that consumers can readily understand the type of food they are buying, the FFDCA requires that the food product as a whole, as well as each ingredient, with a few exceptions, be identified by "the common or usual name" of the food or ingredient. 21 U.S.C. § 343(i)(1), (2). Under FDA regulations, the "common or usual name" must identify "in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients," and be "uniform among all identical or similar products." 21 C.F.R. § 102.5(a). Thus, a box of cereal must identify itself as "cereal" (the common or usual name of the product as a whole), and it must identify its ingredients as oats, flour, sugar, and so on (the common or usual name of these ingredients). FDA has also specified the names manufacturers *must* use for particular foods. *See* 21 C.F.R. Part 102 (mandated "common or usual names"); *id.*, Parts 131 to 169 (mandated "standards of identity" containing naming requirements). Just as with ingredient labeling, state law requirements that are "not identical to" the federal requirements for naming, or prescribed names for foods subject to standards of identity or other "common or usual" name prescriptions, are expressly preempted. 21 U.S.C. § 343-1(a)(1), (3).

Act 120 runs straight into these federal prohibitions as well, because it imposes new names on food products and their ingredients. Under federal law, the common or usual name of a soda is "carbonated soft drink," without regard to whether that soda contains, for example, sugar derived from genetically engineered sugar beets or caramel color derived from genetically engineered corn. Under Act 120, however, a soda that contains one or both of those ingredients would be identified as "carbonated soft drink partially produced with genetic engineering." 9 V.S.A. § 3043(b)(3). This requirement is "not identical to" federal "common or usual" name

requirements because those requirements do *not* designate the use (or potential use, or partial use) of ingredients derived from genetically engineered crops as affecting "the basic nature" of the food or as a "characterizing propert[y]" justifying a different identification scheme under 21 C.F.R. § 102.5(a). *See* 1992 Statement, at 22991; 2001 Guidance. Because Act 120 requires a different identifier, it is expressly preempted.

The same logic applies to foods subject to an FDA-mandated standard of identity under 21 U.S.C. § 343(g) or a common or usual name prescription under § 343(i)(1). A standard of identity establishes the recipe for the ingredients in a product, the procedure typically used to make the food, and the naming that is required. *See id.*, § 341. FDA has established standards of identity for dozens of foods, including cheeses, milk, breads, grain flours, corn derivatives, cacao products, sweeteners, food dressings and many other foods. *See* 21 C.F.R. Parts 131 to 169. All other food products must be named by a common or usual name consistent with the requirements of 21 C.F.R. Part 102.5(a) or comply with one of the specific common or usual name regulations codified by FDA. None of these standards or regulations requires a product to disclose the presence of ingredients derived from genetic engineering.

Act 120 would. Take enriched corn meal, a product for which FDA has established a standard of identity. *See* 21 C.F.R. § 137.260. The standard of identity makes no distinction between corn meal produced from genetically engineered corn and corn meal produced from non-genetically engineered corn. But under Act 120, the label effectively tells consumers that the name of the product is "enriched corn meal made from genetically engineered corn" – a designation that is clearly "different from" the product's mandated standard of identity. *Mills v. Giant of Md., LLC*, 441 F. Supp. 2d 104, 108 (D.D.C. 2006) (NLEA preemption of claim purporting to require additional disclosures regarding effects of lactose for "milk" because such

disclosures "would far exceed the labeling requirements mandated by the standard of identity"), *aff'd on other grounds by* 508 F.3d 11 (D.C. Cir. 2007). So too for a product, such as vegetable oil, covered by an FDA-mandated "common or usual name." *See Briseno v. ConAgra Foods, Inc.*, No. 11-5379, ECF No. 54 , at 13 (C.D. Cal. Nov. 23, 2011) (striking request for court order compelling manufacturer to label vegetable oil "genetically engineered" as preempted by common or usual name prescription in 21 C.F.R. § 101.4(b)(14)).

Act 120 and other proposed state-law regulations make "[i]t . . . easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide. Manufacturers might have to print 50 different labels, driving consumers who buy food products in more than one state crazy." *Turek v. General Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011). Act 120 is one large step toward that unpalatable scenario, and the FFDCA preempts it.

2. Act 120 Is Expressly Preempted with Respect to Products Covered by the FMIA and PPIA.

Congress has expressly preempted state-law "marking, labeling, packaging, or ingredient requirements in addition to, or different than, those" promulgated by USDA under the Federal Meat Inspection Act and Poultry Products Inspection Act. 21 U.S.C. § 678; *id.*, § 467e. If a product is made at an FSIS-inspected processing facility, USDA has the sole authority to review, approve, and dictate the mandatory content of the labeling of that product. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977); *Grocery Mfrs. of Am., Inc. v. Gerace*, 755 F.2d 993, 997 (2d Cir. 1985). Many products that include meat, poultry, and eggs but would not qualify as "derived entirely from an animal" within the meaning of Act 120's exemption, are produced at FSIS-inspected facilities, such as canned meat or poultry products and pre-made frozen meals

containing meat or poultry. *See* FSIS, Meat, Poultry, and Egg Product Inspection Directory, USDA.gov (listing brands produced at FSIS-inspected facilities).

Act 120 is a "marking, labeling, packaging [and] ingredient requirement[ ]" that applies to meat and poultry products produced at FSIS-inspected facilities that are not derived entirely from an animal. Act 120, including both labeling requirement and natural ban, is therefore expressly preempted by the FMIA and PPIA with respect to those products. *See, e.g., Grocery Mfrs.*, 755 F.2d at 997 (FMIA and PPIA preempted New York law adopting different requirements for labeling products as "imitations"); *National Broiler Council v. Voss*, 44 F.3d 740, 747 (9th Cir. 1994) (PPIA preempted state law prohibiting the word "fresh" on labels for poultry chilled below 26 degrees where federal law set floor at 24 degrees); *American Meat Inst. v. Leeman*, 180 Cal. App. 4th 728 (4th Dist. 2009) (FMIA preempted warnings under Prop. 65).

3. Act 120 is Conflict-Preempted.

Finally, Act 120 is preempted because "state laws are preempted when they conflict with federal law." *Arizona v. United States*, 132 S. Ct. 2492, 2501 (2012). Conflict preemption reaches "cases where 'compliance with both federal and state regulations is a physical impossibility, and those instances where the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (internal quotation marks and citations omitted). Act 120 is preempted in both respects.

a. Act 120 Compels Manufacturers to Use Labels That Conflict With Federal Requirements for Truthfulness and Naming.

Act 120 puts manufacturers squarely in conflict with federal law. The core of the FFDCA's misbranding provision is subsection § 343(a), which prohibits the use of labels that are "false or misleading in any particular." 21 U.S.C. § 343(a). Act 120's labels are misleading because they designate a food as entirely or partially "produced with genetic engineering," using

a definition of "genetic engineering" that far exceeds the meaning of that term in federal law, McHughen Decl. ¶ 77, and even in other Vermont laws, *see* 6 V.S.A. §§ 641; 1030 (discussed *supra* 14 n.5). Further, even if genetic engineering had been defined to be consistent with these definitions – focused on rDNA techniques – Act 120's compelled labels are misleading because a processed food is not "produced," to any degree, "with genetic engineering," however that term is defined. It is manufactured by the manufacturer.

Further, labeling these foods conveys an overall impression that, contrary to FDA's findings, these foods are different in some "meaningful or uniform way." 1992 Statement, at 22991. They are not. The labels also convey the impression that these foods are not adequately regulated by FDA; indeed, that is the entire point of Finding 1 and its subsections in the Act, and it would be the point of any disclaimer the Attorney General might require through rulemaking. *See* Act 120, § 3. *See also CTIA*, 872 F. Supp. 2d at 1062. FDA has cautioned that "a label statement that expresses or implies that a food is superior (e.g., safer or of higher quality) because it is not bioengineered would be misleading," *see* 2001 Guidance; by the same token, a label implying that a food is *inferior* (e.g., less safe or of lower quality) because it does come from a genetically engineered crop would also be misleading.

Even if they are not found to convey this opinion directly, Act 120's labels nonetheless *legitimate* some individuals' opinion that foods produced with ingredients from genetically engineered crops are not as safe as other foods. *See* 9 V.S.A. § 3041(a). *See also* Defs.' Mem. 41 (characterizing Act 120 label as equivalent to a "warning"). By implying there may be validity to those opinions, which are not supported by the evidence, Act 120's labels are misleading and in conflict with federal law.

Act 120 also brings manufacturers into conflict with FDA common or usual name regulations, which require a common or usual name to be "uniform among all identical or similar products." 21 C.F.R § 102.5(a). FDA has concluded that genetic engineering results in no material difference, meaning the foods that would be labeled under Act 120 are "identical or similar" to the foods that would not be labeled. Yet, Act 120 requires different naming: corn, or "corn produced with genetic engineering." It requires that labeling shall *not* be uniform. That is, in fact, the very purpose of the Act.

Act 120 thus is conflict-preempted.

b. Act 120 Stands as an Obstacle to the Federal Policy of Coordinated Objective Review of Genetically Engineered Products.

Act 120 is also preempted because it stands as an obstacle to the full accomplishment of Congress's objectives and purposes in delegating regulatory authority to APHIS, EPA, FDA, and FSIS under the health and safety statutes they administer. With respect to genetically engineered plants, the agencies coordinate review from one link to the next pursuant to the 1986 *Coordinated Framework*. *See* Background Part B. Act 120 is premised on a finding that these federal agencies are not providing sufficient oversight of genetically engineered crops and foods derived from them. *See generally* Act 120, § 1(1). And the Act, in its operation, goes further. It adds an additional layer of regulation that is not coordinated with the federal government's review, or consistent with the principles reflected in it. Act 120 presents a very real obstacle to the accomplishment and execution of the federal policy reflected in the *Framework.*

The *Coordinated Framework* was adopted to require adequate safeguards for consumer health and safety while giving companies regulatory certainty that would facilitate the development of innovative products. 51 Fed. Reg. at 23303. The *Framework* is rooted in congressional enactments (PPA, FIFRA, FFDCA, PPIA, FMIA), and *all* of these statutes have

provisions that preempt state-law requirements. *See, e.g.*, 7 U.S.C. § 7756 (regulation of plant pests); *id.*, § 136v (pesticide labeling); 21 U.S.C. § 343-1 (food and ingredient labeling)); *id.*, § 467e (poultry product labeling); *id.*, § 678 (meat product labeling). The congressional intent in those preemption provisions extends to the *Coordinated Framework.* In thirty years, Congress has not abrogated the *Framework*, or FDA's food-labeling policy pursuant to it. That is significant: "Congress' failure . . . to alter the relevant statutory language or to otherwise condemn the regulatory definition, while not a failsafe guide, allows [a court] at least to infer that it has acquiesced in the FDA's construction." *Grocery Mfrs.*, 755 F.2d at 1000.

Act 120, in and of itself – as well as the patchwork of state-by-state regulation it invites – together threaten to undermine the guarantees of regulatory certainty and uniformity in the *Coordinated Framework*. Act 120 imposes significant burdens on the use of ingredients derived from genetically engineered crop varieties, and the 50-state patchwork it heralds would exponentially amplify those burdens. *See* Part II, *infra*. Congress could not possibly countenance such a result, and so Act 120 must give way. *See Jones*, 430 U.S. at 542-43 (holding that unique-to California net-weight labeling rule stood as obstacle to Congress's purpose in enacting uniform packing and labeling requirements); *Freeman v. Burlington Broadcasters, Inc.*, 204 F.3d 311, 325 (2d Cir. 2000) (invalidating town's zoning restriction on radio interference because it stood as an obstacle to Congress's purpose "in delegating regulatory power to the FCC for uniform regulation of broadcast technologies).

For all of the reasons above, Plaintiffs are likely to succeed on the merits of their claim that Act 120 is preempted, as well as their First Amendment and Fifth Amendment claims.

II. PLAINTIFFS WILL BE IRREPARABLY INJURED IN THE ABSENCE OF A PRELIMINARY INJUNCTION.

Plaintiffs also satisfy the injury element of the preliminary-injunction test because their members are "likely to suffer irreparable harm in the absence of preliminary relief." *Winter*, 555 U.S. at 20. Irreparable harm is measured by "the injury the plaintiff will suffer if he or she loses on the preliminary injunction but ultimately prevails on the merits, paying particular attention to whether the remedies available at law, such as monetary damages, are inadequate to compensate for that injury." *Salinger v. Colting*, 607 F.3d 68, 80 (2d Cir. 2010) (internal quotation marks and citation omitted).

If Act 120 is not enjoined for the duration of this litigation and Plaintiffs later prevail, the harm done to their businesses cannot be repaired. It is therefore irreparable.

A. Plaintiffs' Members Will Be Injured During the Pendency of This Litigation.

Plaintiffs' member companies will be severely injured by Act 120 before this Court renders final judgment in this litigation. Act 120 goes into effect in 22 months. Litigating this case to its conclusion may take longer than that, given the timing in similar cases.[17]

The changes required by Act 120 can be summarized concisely: Labeling according to particular distinctions requires segregating products according to those distinctions at every stage of the supply chain, and manufacturers typically do not segregate products by whether or not they contain ingredients derived from genetically engineered plant varieties, or whether they are bound for Vermont. *See* Company Decls.; Blasgen Decl. ¶¶ 13-14.

[17] *Amestoy*, 28 months (filed Apr. 25, 1994; 2d Cir. Aug. 8, 1996); *NEMA*, 40 months (filed Jul. 19, 1999; 2d Cir. Nov. 6, 2001); *Evergreen*, 34 months (filed Mar. 24, 2011; 2d Cir. Jan.17, 2014); *NYSRA*, 20 months (filed June 15, 2007; 2d Cir. ruling Feb. 17, 2009). None of these cases was litigated to trial. The trial-time benchmark may be *Sorrell v. IMS Health*, 20 months for trial (filed Aug. 29, 2007; judgment, Apr. 24, 2009), 39 months through appeal (2d Cir. Nov. 23, 2010), and 46 months through Supreme Court review (June 23, 2011). *See also* Act 120, § 4(d) (contemplating litigation extending potentially to 2018).

Creating this new system requires many stages of work. First, a manufacturer must conduct a review of its supply chain to determine which products are covered and which are not, and among those covered, which are exempted and which are not, of those that are not, which will be reformulated, and which will be relabeled. *Id.*, ¶¶ 16-19, 22. Then, unless reformulation or certification is possible, the manufacturer must design and implement new labeling, creating a separate stock-keeping unit (SKU) for tracking its Vermont-bound products. *Id.*, ¶¶ 24-27. Last but far, far from least, the manufacturer must build out a Vermont-specific distribution chain to carry those Vermont-only products. *Id*. This will be a monumental change from the status quo, and a costly one, as manufacturers typically do not distinguish the labeling or formulation of particular products for particular states. *Id.*, ¶¶ 28-33. The burden associated with redesigning labeling is substantial, *id.*, ¶¶ 34-38, but in operational terms, it is just the last phase of a multi-year process to accommodate a distinct Vermont-only product stream. *See* Declaration of Thomas Dempsey in Support of Pls.' Motion (Dempsey Decl) ¶¶ 10-19; Declaration of Richard Michaud in Support of Pls.' Motion (Michaud Decl.).

Complicating the situation for manufacturers further, Act 120's mandate is overlapping with ongoing FDA rulemaking to revise the Nutrition Facts panel. *See* FDA, Proposed Rule, *Food Labeling: Revision of the Nutrition and Supplemental Facts Panel*, 79 Fed. Reg. 11880 (Mar. 3, 2014). That means at some point in the next few years, manufacturers will need to redesign their labels as part of that regulatory change. Right now, though, they must start preparing labels for Act 120. Absent a preliminary injunction staying enforcement of Act 120 during this litigation, the sequencing of the two sets of regulations could force manufacturers to incur many of the injuries above—*twice.* *See* Dempsey Decl. ¶ 16.

Cost aside, the State has given manufacturers essentially no time to conduct the intensive review and restructuring that would need to occur to facilitate this regime. Act 120 appears to impose liability as of the date products appear on store shelves. But retailers are immune under the Act, 9 V.S.A. § 3045, so they have no incentive to clear out products with "old" labels on July 1, 2016. It therefore falls to the manufacturer to modulate the stream of its products into commerce so those "old" products cannot possibly be on the shelf on July 1, 2016. Blasgen Decl. ¶¶ 40-43. This obligation walks back the effective date by months and even years for some products. *Id.*

Despite the rapidly approaching "effective" effective date, manufacturers cannot even start to redesign their labels until the Attorney General has issued rules establishing where the mandatory statements should appear on the package of a food. The options are, quite literally, all over the place. *See Labeling Questionnaire, supra* (suggesting labels on front, back, side, and bottom of package, near Nutrition Facts panel or elsewhere). At this point the Attorney General has only set a "goal" of adopting regulations by July 1, 2015. But by that date, manufacturers of longer-shelf-life products like oils would need to have *already* put their products with the new labels into commerce to ensure compliance by the 2016 effective date. *See* Blasgen Decl. ¶¶ 40-43; Company Decls.

The dilemma facing manufacturers is an urgent one. Compliance by the effective date is highly unlikely, and probably impossible for many, but the penalties for non-compliance by the effective date are *severe*. Assume a manufacturer has a portfolio of 100 products, and a retail chain lets ten days go by before it swaps out the products with the "old" labels. That delay will, unbeknownst to the manufacturer, subject it to a potential *$1 million civil penalty* ($1,000 penalty * 100 products * 10 days). 9 V.S.A. § 3048(a). Even if the Attorney General were to

stay his hand on civil penalties, the manufacturer might still be sued under the private right of action the Act contemplates. *See id.*, § 3048(b) (providing "the same consumer rights and remedies as provided under" 9 V.S.A. ch. 63, subchapter 1).[18] In an action brought on behalf of a putative class of 10,000 plaintiffs, , who each paid an average of $1 for the manufacturer's product, the manufacturer's potential liability could include another $1 million in damages ($1 * 100 products * 10,000 plaintiffs), plus $3 million in punitive damages (statutory damages * 3), and attorneys' fees on top of that.

Consider the risk assessments taking place within Plaintiffs' member companies at this moment. In the example above, the manufacturer would face over *five million dollars* in potential penalties and liability because *the retailer* left the manufacturer's products on the shelf for ten days too long. Nor does the liability risk dissipate over time. At any point in the future a rogue retailer might purchase the manufacturer's products from a distributor in a neighboring state and resell them in Vermont, thereby subjecting the manufacturer to still more litigation and liability. This regime starts in less than two years.

B. The Injuries to Plaintiffs' Members Are Irreparable.

Plaintiffs' member companies do not have an adequate remedy at law for the compliance costs and other losses they will suffer if Act 120 is not enjoined. Their harm will be irreparable in four distinct respects:

First, the abridgement of manufacturers' freedom of expression constitutes irreparable injury. *Elrod v. Burns*, 427 U.S. 347, 373 (1976). Act 120 both bans speech and compels speech by Plaintiffs' member companies, each a distinct irreparable injury. *Id.* (restriction); *Evergreen*, 740 F.3d at 246 (compulsion). In particular, "[t]he wrong done by [a] labeling law to [Plaintiffs'

[18] Though Act 120 does not specify which provision affords the right of action to consumers, for the sake of illustration (and illustration only), we assume it is 9 V.S.A. § 2461.

members'] constitutional right *not* to speak is a serious one," and must be "given proper weight." *Amestoy*, 92 F.3d at 71. This First Amendment harm will occur while this case is being litigated, for Plaintiffs' members will be forced to revise the speech on their labels, on signage, and in advertising, and start putting products with the revised speech into commerce well before the Act's effective date, when they could not disagree more with the idea that speech conveys. *See* Company Decls. Those expressive injuries are irreparable.

Second, Plaintiffs' members' monetary costs are irreparable because the Eleventh Amendment precludes Plaintiffs from recovering money damages from the State. Those harms are, by definition, "irreparable." *See Entergy*, 733 F.3d at 423 (finding irreparable harm where plaintiff could not recover damages from State due to Eleventh Amendment immunity).

Third, the member companies' non-pecuniary losses are incalculable. The changes Act 120 forces go to the heart of manufacturers' operations. Blasgen Decl. ¶¶ 28-30, 44. Money damages (even if they were available) could not compensate manufacturers for those efforts. *See American Frozen Food Inst. v. United States*, 855 F. Supp. 388, 394 (CIT 1994) (packager would be irreparably injured by labeling rule requiring it to "re-engineer its inventory management process to track the source of the vegetables from delivery to packaging to ensure that the various labels will correctly reflect the countries of origin for the vegetables"). The losses of employee time and energy, and the diversion of staff and resources to compliance issues instead of new business opportunities, are also severe irreparable harms to Plaintiffs' members. Blasgen Decl. ¶ 41. *See Nordic Windpower USA, Inc. v. Jacksonville Energy Park, LLC*, No. 5:12-cv-5, 2012 WL 1388357, at *13 (D. Vt. Apr. 19, 2012) (recognizing "lost opportunities" as irreparable harm because "[i]rreparable harm may be found where damages are difficult to quantify").

Fourth, the costs imposed by Act 120 may cause some manufacturers to exit from the Vermont market entirely – which itself would entail severe financial and reputational penalties. Dempsey Decl. ¶¶ 16, 29-31; Michaud Decl. ¶¶ 11-12; Blasgen Decl. ¶ 45

The losses described above are irreparable. They are also unavoidable. For Plaintiffs' member companies, all roads lead to severe, irreparable injuries that could not be compensated if Plaintiffs later prevail on the merits. Accordingly, this element of the preliminary-injunction test is satisfied.

III. THE OTHER PRELIMINARY INJUNCTION FACTORS FAVOR RELIEF.

The balancing of hardships and public interest factors of the preliminary-injunction test merge into one for purposes of this Motion because the government is the party opposing relief. *Nken v. Holder*, 556 U.S. 418, 435 (2009). These combined factors weigh in favor of a preliminary injunction because Act 120 violates the Constitution, *see supra* Part I, and the State "does not have an interest in the enforcement of an unconstitutional law." *N.Y. Progress & Prot. PAC v. Walsh*, 733 F.3d 483, 488 (2d Cir. 2013) (internal quotation marks and citation omitted). That is particularly so here where consumer may suffer. *See* Dempsey Decl. ¶ 35.

Plaintiffs members' loss of First Amendment freedoms and other irreparable injuries also easily outweigh the costs of an injunction to Vermont – which would *prevent* the State from spending money to implement the law. The reality is that Act 120's main benefit to the State is its symbolic value. That symbolic value is not affected by a preliminary injunction. A preliminary injunction would preserve the status quo, and under the status quo, consumer interests are amply served by existing labeling.

CONCLUSION

For all of the foregoing reasons, Plaintiffs' Motion for a Preliminary Injunction should be granted.

DATE: September 11, 2014

Respectfully submitted,

/s/ Catherine E. Stetson

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CERTIFICATE OF SERVICE

I, Catherine E. Stetson, counsel for Plaintiffs, hereby certify that on September 11, 2014, I electronically followed the foregoing Document by the CM/ECF system, which will send notification of such filing to all registered participants.

Dated: September 11, 2014

/s/ Catherine E. Stetson
Catherine E. Stetson