UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

GROCERY MANUFACTURERS ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	Case No. 5:14-cv-00117-CR
WILLIAM H. SORRELL, in his official capacity as the Attorney General of Vermont, *et al.*,	)	
Defendants	)	

AMICI CURIAE
VERMONT PUBLIC INTEREST RESEARCH GROUP & CENTER FOR FOOD SAFETY'S
MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND
IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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ACT 120: A HISTORY

On February 6, 2013, Representative Kate Webb introduced H.112 to the Vermont House Committee on Agriculture and Forest Products. She explained that the "introduction of genetically engineered foods into our diet has come quietly without mandatory labeling," that genetically engineered (GE) foods "might increase the risk of long-term health impairment," and that "without our knowledge and consent, we are all participants in this grand experiment." Statement of Kate Webb 24 (Feb. 6, 2013) (Exhibit A at 3). Ms. Webb stated that Vermonters also deserve to know whether "the food they purchase poses potential risks to the environment and biodiversity." *Id.* at 24-25 (Exhibit A at 3-4). Over the next month, the Committee heard testimony from 35 individuals, including science and medical professionals, policy experts, attorneys, business owners, and agency personnel. *See* Vt. Legislative Bill Tracking System, H.112 Legislative History (Exhibit B to Defs.' Mot. Dismiss, Doc. 24-3, at 18-23). The House Committee on Judiciary then spent several days considering the bill and hearing from additional witnesses. *Id.* at 16-17. In the Senate the following year, the Committee on Agriculture worked with the bill for 19 days and heard testimony from 31 witnesses, plus an additional 53 members of the public who testified at a public hearing. *Id.* at 6-15. At its last major stop, the bill garnered testimony from 17 people in the Senate Committee on Judiciary.

During its review of H.112, the Vermont legislature made several important determinations, which it memorialized in the Findings section of Act 120. *See* 2014 Vt. Acts & Resolves No. 120 (Act 120), Sec. 1. First, the legislature found that federal law does not currently require GE foods to be labeled as such. *Id.* Sec. 1(1). This is correct. *See* Statement of Policy: Foods Derived from New Plant Varieties (1992 Policy Statement), 57 Fed. Reg. 22,984-01, 22,991 (May 29, 1992); U.S. Food & Drug Administration (FDA), DRAFT Guidance for

Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (Jan. 2001) ("The 1992 policy does not establish special labeling requirements for bioengineered foods as a class of foods.").

Second, the legislature found that federal law does not require independent testing of the safety of foods produced with genetic engineering. Act 120, Sec. 1(2). This also is true. There is no federal statute or regulation that requires either GE companies or the United States Food and Drug Administration (FDA) to test the safety of GE foods. *See id.* Sec. 1(2)(A); 1992 Policy Statement, 57 Fed. Reg. at 22,989-90 (providing guidance to industry for assuring safety of GE foods and encouraging "informal consultation"). FDA does not independently test the safety of GE foods, but rather reviews voluntarily submitted studies that have been financed or conducted primarily by the biotechnology companies themselves. *See* Act 120, Sec. 1(2)(B); Testimony of Robert Merker, Ph.D., 2, 11-12 (Feb. 19, 2013) (Exhibit A at 9, 18-19) (testing done by purveyor or manufacturer or labs with which they contract). FDA does not make safety determinations regarding these products, but instead informs the biotechnology companies that they (the companies) have made safety determinations. *See* Act 120, Sec. 1(2)(B); Testimony of Michael Hansen, Ph.D., 37-39 (Feb. 7, 2013) (Exhibit A at 48-50); Michael Hansen, Ph.D., *Reasons for Labeling of Genetically Engineered Foods* 2-3 (Mar. 19, 2012) (Exhibit B at 2-3); William Freese & David Schubert, *Safety Testing & Regulation of Genetically Engineered Foods*, 21 Biotech. & Genetic Eng'g Revs. 5 (2004) (Exhibit B at 19) ("The review process . . . makes it clear that, contrary to popular belief, the FDA has not formally approved a single GE crop as safe for human consumption. Instead, at the end of the consultation, the FDA merely issues a short note summarizing the review process and a letter that conveys the crop developer's assurances that the GE crop is substantially equivalent to its conventional counterpart."); FDA,

Biotechnology Consultations on Food from GE Plant Varieties (listing industry consultations with FDA and providing links to FDA memos and letters).

Additionally, FDA has no protocol for determining whether studies that are not industry-funded would produce different results than FDA's current process. *See* Act 120, Sec. 1(2)(C); Merker Testimony 16-17 (Exhibit A at 23-24). In fact, non-industry scientists often cannot conduct studies in the United States because industry has restricted use of patented GE crops in food safety research. *See* Act 120, Sec. 1(2)(F); Freese & Schubert at 1-2 (Exhibit B at 15-16); Michael Antoniou et al., *GM Soy: Sustainable? Responsible?* 5 (Sept. 2010) (Exhibit B at 43); Hansen, *Reasons for Labeling* 5-6 (Exhibit B at 5-6). Relatedly, there have been no long-term or epidemiologic studies in the United States demonstrating that GE foods are safe for human consumption. *See* Act 120, Sec. 1(2)(E); Michael Antoniou et al., *GMO Myths & Truths: An Evidence-Based Examination of the Claims Made for the Safety & Efficacy of Genetically Modified Crops* 37-40 (June 2012) (Exhibit B at 87-90); European Network of Scientists for Social & Environmental Responsibility, *Statement: No Scientific Consensus on GMO Safety* 2 (Oct. 21, 2013) (Exhibit B at 115).

Third, the legislature found a lack of consensus regarding the safety of GE foods, and that such foods pose potential risks to human health. Act 120, Sec. 1(2)(D), (4), (6). This too is well founded. The legislature heard testimony regarding potential health effects from credentialed professionals on multiple occasions. *See, e.g.*, Testimony of Michael Hansen, Ph.D. (Feb. 7, 2013 & Jan. 29, 2014) (Exhibit A at 38-87, 88-117); Hansen, *Reasons for Labeling* 7-12 (Exhibit B at 7-12) (describing multiple studies demonstrating unintended effects of genetic engineering); Letter from Michael Hansen to Carolyn Partridge (Feb. 25, 2013) (regarding follow-up questions including need to label "highly purified" GE foods); Testimony of David Rogers, Retired

Professor (Jan. 10, 2014) (Exhibit A at 118-48); Testimony of Martin Donohoe, M.D. (Jan. 16 & 29, 2014) (Exhibit A at 149-65, 166-80). The legislature also had before it at least 47 scientific studies and documents supporting the fact that there are potential health risks with consuming GE foods and, at the very least, that there is a lack of consensus regarding their safety. *See Table of Contents: Health Risks of GE Foods, Volume I* (MTD Exhibit B, Doc. 24-3, at 26-27); *Table of Contents: Health Risks of GE Foods, Volume II* (MTD Exhibit B, Doc. 24-3, at 28-29); *Table of Contents: GE Labeling-Additional Materials for Vermont Legislature Spring 2014* (MTD Exhibit B, Doc. 24-3, at 31). For example, according to various experts on GE foods:

> We feel compelled to issue this statement because the claimed consensus on GMO safety does not exist. The claim that it does exist is misleading and misrepresents the currently available scientific evidence and the broad diversity of opinion among scientists on this issue. Moreover, the claim encourages a climate of complacency that could lead to a lack of regulatory and scientific rigour and appropriate caution, potentially endangering the health of humans, animals, and the environment. European Network of Scientists for Social & Environmental Responsibility, *Statement: No Scientific Consensus on GMO Safety* 1 (Oct. 21, 2013) (Exhibit B at 114).
>
> Based on the scientific uncertainty surrounding both the molecular characterization of genetically engineered (GE) crops as well as the detection of potential allergenicity, there is more than enough uncertainty to decide to require labeling of foods produced via GE as a risk management measure as a way to identify unintended health effects that may occur post approval. If foods are not labeled as to GE status, it would be very difficult to even identify an unexpected health effect resulting from a GE food. Michael Hansen, *Reasons for Labeling of Genetically Engineered Foods* 1 (Mar. 19, 2012) (Exhibit B at 1).
>
> In the preceding paragraphs, we have described the US regulatory system for GE foods, and with specific examples pointed out serious deficiencies in both regulatory oversight and corporate testing procedures. It is clear that the US regulatory process must be made mandatory, as well as more stringent and transparent. William Freese & David Schubert, *Safety Testing & Regulation of Genetically Engineered Foods*, Biotech. & Genetic Eng'g Revs. 17 (Nov. 2004) (Exhibit B at 31).
>
> An increasing body of evidence shows the disruptive effect of the GM transformation process and clear signs of toxicity in well-controlled animal feeding studies even of a short-term nature. . . . Based on available evidence and

> inadequacy of the tests required by regulators, at present no GM crop and food can be categorically stated as safe to consume, especially on a long-term, life-long basis. Michael Antoniou, *Sources & Mechanisms of Health Risks from Genetically Modified Crops & Foods*, Biosafety Briefing-Third World Network 6 (Sept. 2013) (Exhibit B at 129).
>
> With the precautionary principle in mind, because GM foods have not been properly tested for human consumption, and because there is ample evidence of probable harm, the AAEM asks . . . [f]or a moratorium on GM food, implementation of immediate long term independent safety testing, and labeling of GM foods, which is necessary for the health and safety of consumers. American Academy of Environmental Medicine, *Genetically Modified Foods* 2 (May 8, 2009) (Exhibit B at 135).
>
> The results of most studies with GM foods indicate that they may cause some common toxic effects such as hepatic, pancreatic, renal, or reproductive effects and may alter the hematological, biochemical, and immunologic parameters. However, many years of research with animals and clinical trials are required for this assessment. Artemis Dona & Ioannis S. Arvanitoyannis, *Health Risks of Genetically Modified Foods*, 49 Critical Revs. Food Sci. & Nutrition 164, 164 (2009) (Exhibit B at 137).
>
> Taking into account the increased risk of human and animal exposures to significant levels of these toxins, especially through diet, our results suggest that further studies are required to clarify the mechanism involved in the hematotoxicity found in mice, and to establish the toxicological risks to non-target organisms, especially mammals, before concluding that these microbiological control agents are safe for mammals. Belin Poletto Mezzomo et al., *Hematotoxicity of Bacillus thuringiensis as Spore-crystal Strains Cry1Aa, Cry1Ab, Cry1Ac or Cry2Aa in Swiss Albino Mice*, J. Hematology & Thromboembolic Diseases 8 (2013) (Exhibit B at 156).

See National Research Council, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* 8-15 (2004) (making recommendations for better assessment of GE safety and stating that "there remain sizeable gaps in our ability to identify compositional changes that result from genetic modification of organisms intended for food; to determine the biological relevance of such changes to human health; and to devise appropriate scientific methods to predict and assess unintended adverse effects on human health").

Fourth, the legislature found that GE crops pose potential risks to the environment. Act 120, Sec. 1(4). In fact, there are documented harms. For example, cross-pollination by GE crops contaminates wild plants as well as organic and conventional crops. *See* Act 120 Sec. 1(4)(D)-(E). A 2004 report found that traditional varieties of seeds used by U.S. farmers are "pervasively contaminated with low levels of DNA sequences originating in genetically engineered varieties of those crops." Margaret Mellon & Jane Rissler, *Gone to Seed-Transgenic Contaminants in the Traditional Seed Supply* 1 (2004) (Exhibit B at 165); *see also* Doug Gurian-Sherman, *Contaminating the Wild? Gene Flow from Experimental Field Trials of Genetically Engineered Crops to Related Wild Plants* 2 (2006) (concluding that "it is virtually inevitable that gene flow from GE crop field trials to wild weedy relatives will occur unless additional steps are taken to prevent it"). A more recent study identified genetically modified cotton genes in wild populations in Mexico. A. Wegier et al., *Recent Long-Distance Transgene Flow into Wild Populations Conforms to Historical Patterns of Gene Flow in Cotton (Gossypium hirsutum) at Its Centre of Origin*, 20 Molecular Ecology 4182, 4188-92 (2011) (Exhibit B at 243-47). Another concluded that feral populations of canola were "large and widespread" based on a roadside survey of canola plants that found two GE varieties growing in the wild, as well as "novel combinations of transgenic forms." Meredith G. Schafer et al., *The Establishment of Genetically Engineered Canola Populations in the U.S.*, PLoS one 6(10): e25736.doi:10.1371/ journal. pone.0025736 (2011) 1 (Exhibit B at 250).

As the courts have recognized, these types of contamination harms are irreparable and result in a critical loss of choice for farmers and, ultimately, consumers. *See, e.g., Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2756 (2010) (affirming that gene flow "injury has an environmental as well as an economic component"); *Ctr. for Food Safety v. Vilsack*, No. C08-

00484JSW, 2009 WL 3047227, at *9 (N.D. Cal. Sept. 21, 2009) (noting the "potential elimination of farmer's choice to grow non-genetically engineered crops, or a consumer's choice to eat non-genetically engineered food"); *Geertson Seed Farms v. Johanns*, No. C06-01075CRB, 2007 WL 518624, at *9 (N.D. Cal. Feb. 13, 2007) ("For those farmers who choose to grow non-genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop.").

The legislature also found that the use of GE crops in commodity agriculture production may contribute to a loss of biodiversity and increased vulnerability of crops to pests and other factors, which is borne out in the literature. *See* Act 120, Sec. 1(4)(C); *e.g.*, Rebecca J. Goldburg, *Environmental Concerns with the Development of Herbicide-Tolerant Plants*, 6 Weed Technology 647, 649 (1992) (Exhibit B at 257) (explaining how then-newer herbicides intended for herbicide-resistant GE plants "could lead to increased incidence of weeds," potentially toxic effects on fish fry, and glyphosate accumulation in plant foods); John M. Pleasants & Karen S. Oberhauser, *Milkweed Loss in Agricultural Fields Because of Herbicide Use: Effect on the Monarch Butterfly Population*, Insect Conservation & Diversity 1 (2012) (Exhibit B at 261) ("results strongly suggest that a loss of agricultural milkweeds is a major contributor to the decline in the monarch population"); Tanya E. Cheeke at al., *Evidence of Reduced Arbuscular Mycorrhizal Fungal Colonization in Multiple Lines of Bt Maize*, 99 Am. J. Botany 700, 706 (2012) (Exhibit B at 277) (finding reduced soil fungi colonization in roots of multiple Bt maize lines, potentially leading to "negative effect on the abundance or diversity" of soil fungi); Antoniou et al., *GM Soy*, at 18-19 (Exhibit B at 56-57) (reporting fewer bees and butterflies among GM crops, and concerns regarding non-target plant disease). Additionally, the use of GE crops in agriculture has substantially increased—not reduced—the use of pesticides. Charles M.

Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use in the U.S.—the First Sixteen Years*, Environmental Sciences Europe 1 (2012) (Exhibit B at 279) ("Contrary to often-repeated claims that today's genetically-engineered crops have, and are reducing pesticide use, the spread of glyphosate-resistant weeds in herbicide-resistant weed management systems has brought about substantial increases in the number and volume of herbicides applied.").

Juxtaposed against these harms, GE crops have not increased yields or provided relief for world hunger. *See, e.g.*, Antoniou et al., *GM Soy*, at 13-14 (Exhibit B at 51-52) (discussing studies and noting that "[a]t best, GM crops have performed no better than their non-GM counterparts, with GM [Roundup Ready] soy giving consistently lower yields"); Doug Gurian-Sherman, *Failure to Yield: Evaluating the Performance of Genetically Engineered Crops* 33 (2009) (studying thirteen years of GE crops and concluding that GE crops have not increased intrinsic agricultural yields while traditional breeding methods have); Antoniou et al., *Myths & Truths*, at 295-326 (explaining, among other things, that agroecological farming, not genetic engineering, is key to food security).

Fifth, the legislature found that labeling GE foods as "natural" is inherently misleading because genetic engineering does not occur in nature. Act 120, Sec. 1(5)(C). This conclusion is indisputable: both the World Health Organization and Monsanto agree that genetic engineering is not a "natural" process. *See* World Health Organization, 20 Questions on Genetically Modified (GM) Foods Q1 (2012) (MTD Exhibit B, Doc. 24-3, at 41) ("Genetically modified organisms (GMOs) can be defined as organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally. The technology is often called 'modern biotechnology' or 'gene technology,' sometimes also 'recombinant DNA technology' or 'genetic engineering.'"); Monsanto, Glossary (2002-2012) (MTD Exhibit B, Doc. 24-3, at 35) (defining genetically

modified organisms as "[p]lants or animals that have had their genetic makeup altered to exhibit traits that are not naturally theirs"). Comments from FDA staff during the development of the agency's 1992 policy statement also demonstrate that genetic engineering differs from traditional breeding and is not "natural." *See* Memo from Dr. Mitchell Smith, Ph.D., to Jim Maryanski, *Comments on Draft Federal Register Notice on Food Biotechnology* 1 (Jan. 8, 1992) (Exhibit B at 292) (stating that, with biotechnology, "natural biological barriers to breeding have been breached").

Additionally, use of the term "natural" on GE food products is deceptive in practice. For instance, a 2010 poll showed that "61% of consumers erroneously believed that the 'natural' claim implied or suggested the absence of genetically engineered foods." Cornucopia Institute, *Cereal Crimes: How "Natural" Claims Deceive Consumers and Undermine the Organic Label—A Look Down the Cereal & Granola Aisle* 29 (Oct. 2011) (Exhibit B at 295) (citing 2010 Hartman Group Poll).[1] In another poll, 85% of consumers replied that the "natural" label on packaged foods should indicate that all ingredients included occur naturally or in nature. Consumer Reports, *Food Labeling Poll* 16 (2007) (Exhibit B at 311). In a recent poll by the Consumer Reports National Research Center, 64% of consumers polled believed a "natural" label meant no GE organisms were used. Consumer Reports, *Food Labels Survey: 2014 Nationally-Represented Phone Survey* 8 (Apr. 2014). Nevertheless, recent findings show that foods produced with genetic engineering *have* been labeled as "natural." In October 2014, *Consumer Reports* released findings on tests of over 80 processed and packaged foods for the presence of GE corn or soy, finding that numerous products made "natural" claims on packaging but contained GE materials. Andrea Rock, *Where GMOs Hide in Your Food: New Consumer*

[1] The full report is available at http://www.cornucopia.org/cereal-scorecard/docs/Cornucopia_Cereal_Report.pdf.

Reports' Tests Find Genetically Modified Organisms in Many Packaged Foods, Including Those Labeled 'Natural' (Oct. 2014); Carey Gillam, *US Foods Labeled 'Natural' often Contain GMOs, Group Reports*, Reuters (Oct. 7, 2014). Polling and testing thus illustrate that consumers are currently deceived by foods with the "natural" label, thinking that those foods were not produced with genetic engineering when, in fact, they may well have been.

Finally, and perhaps most importantly, the Vermont legislature found that the absence of a GE label created not only the potential for, but also the reality of, consumer confusion and deception. *See* Act 120, Sec. 1(5)(A)-(B). The legislature found that polling "by the New York Times indicated that many consumers are under an incorrect assumption about whether the food they purchase is produced from genetic engineering." *Id.* Sec. 2(5)(B); *see* Allison Kopicki, *Strong Support for Labeling Modified Foods*, N.Y. Times (July 27, 2013) (Exhibit B at 315) (fewer than half polled said they knew large amount of processed foods they buy at supermarkets is GE; almost half said they thought most or a lot of their fruits and vegetables were GE); Thomson Reuters, *National Survey of Healthcare Consumers: Genetically Engineered Food* (Oct. 2010) 5 (Exhibit B at 322) (only 69.2% of those polled knew that some of the food available in stores had been genetically engineered; for those earning less than $25,000/year, only 51.3% were aware of this fact). As one University of Vermont professor testified, foods produced with genetic engineering are "credence goods," which means that "even after consumers use that product, they have no idea what they were eating . . . . [A]nd that's when labeling comes in and helps consume[r]s to understand what is in the product in the absence of no other way to know." Testimony of Jane Kolodinsky, Ph.D., 11-12 (Jan. 31, 2014) (Exhibit A at 192-93). In addition, "polls conducted by the Center for Rural Studies at the University of Vermont indicate that a large majority of Vermonters want foods produced with genetic

engineering to be labeled as such." Act 120, Sec. 2(5)(A); *see* Jane Kolodinsky, *Vermonter's Views on GMO Labeling* 2 (Jan. 29, 2014) (Exhibit B at 324) ("Over the 13 year period, on average 88.9 percent of Vermonters agree there should be GMO labeling.").

For all of these reasons and more, the State of Vermont determined that it is in the best interests of the State to require labels on foods produced with genetic engineering. Act 120, Sec. 1(6). And although Vermont is the first state in the nation to take this step, it is not alone: national polls consistently show that the great majority of Americans want to know whether the foods they buy are produced with genetic engineering. *See, e.g.*, Kopicki (93% of respondents say GE foods should be labeled); Emily Swanson, Huffington Post, *GMO Poll Finds Huge Majority Say Foods Should Be Labeled* (Mar. 4, 2013, 5:21pm) ("82% of Americans think GMO foods should be labeled"); Thomson Reuters, *National Survey,* (Exhibit B at 321) (93% of respondents said GE foods should be labeled). Two of Vermont's neighbors have passed GE labeling bills with contingency clauses. An Act To Protect Maine Food Consumers' Right To Know about Genetically Engineered Food and Seed Stock, 2014 Me. Laws 1; Conn. Gen. Stat. Ann. § 21a-92c (West 2013). Four other states have had ballot initiatives on GE labeling, with opponents spending over $100 million in efforts to defeat those initiatives. Annie Gasparro & Jacob Bunge, *Food Industry Wins Round in GMO-Labeling Fight*, Wall Street J. (Nov. 5, 2014). Approximately 20 additional states have introduced labeling bills. Rani Molla, Wall Street J., *Which States Are Considering Labels for GMO Foods?* (July 14, 2014, 1:02pm). Globally, 64 countries currently require some form of GE labeling. Just Label It, Labeling around the World.

Vermont's decision to give Vermonters the benefits of this information is sound, and Act 120 is constitutional. Plaintiffs' claims should be dismissed and their motion for a preliminary injunction should be denied.

ARGUMENT

I. ACT 120 IS CONSTITUTIONAL UNDER THE FIRST AMENDMENT

Supreme Court precedent on commercial speech is clear: its value lies in providing information to the public. *See, e.g.*, *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 561-62 (1980) ("Commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information."); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 763 (1976) ("As to the particular consumer's interest in the free flow of commercial information, that interest may be as keen, if not keener by far, than his interest in the day's most urgent political debate."). In furtherance of these goals, governments may prohibit misleading speech and require factual disclosures. *Cent. Hudson*, 447 U.S. at 563-64; *Zauderer v. Office of Disciplinary Council of the Sup. Ct. of Ohio*, 471 U.S. 626, 650-53 (1985). This is what Act 120 does.

In reviewing Act 120, the Court should grant significant deference to the judgments of Vermont's legislature, pursuant to guiding principles from the Supreme Court. First, courts afford great deference to legislative factual findings. *Walters v. Nat'l Ass'n of Radiation Survivors*, 473 U.S. 305, 330 n.12, 335 (1985) (upholding statutory fee limitation for veteran services under Fifth and First Amendments and stating: "When Congress makes findings on essentially factual issues . . . those findings are of course entitled to a great deal of deference, inasmuch as Congress is an institution better equipped to amass and evaluate the vast amounts of data bearing on such an issue.") (citing cases). Second, in the rational-basis context, courts must uphold a law "'so long as it bears a rational relation to some legitimate end.'" *Vacco v. Quill*, 521 U.S. 793, 799 (1997) (citation omitted). Under this standard, "any reasonably conceivable

state of facts" can provide that rational basis, *Fed. Commc'ns. Comm'n v. Beach Commc'ns, Inc.*, 508 U.S. 307, 313 (1993), and a "legislative choice" may be "rational speculation unsupported by evidence or empirical data," *id* at 315. Third, in the intermediate-scrutiny context, a court's "sole obligation" is to assess whether the legislature "has drawn reasonable inferences based on substantial evidence." *Turner Broad. Sys., Inc. v. Fed. Commc'ns. Comm'n*, 520 U.S. 180, 195 (1997); *Turner Broad. Sys., Inc. v. Fed. Commc'ns. Comm'n*, 512 U.S. 622, 666 (1994). In making this assessment, a court does not "reweigh the evidence *de novo*" nor "replace [the legislature's] factual predictions" with its own. 512 U.S. at 666. Instead, a court should order further factual development only where a particular record is insufficient to support a determination of whether relevant constitutional factors have been met. *See id.* at 668.[2] Under any of these scopes of review, Vermont's disclosure law satisfies constitutional requirements.

A. The *Zauderer* test applies to Act 120's disclosure requirement.

In this Circuit, it is well settled that *Zauderer* provides the standard for factual disclosure requirements absent two limited, inapplicable situations. *See, e.g., Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001) ("*Zauderer*, not [*Central Hudson*], describes the relationship between means and ends demanded by the First Amendment in compelled commercial disclosure cases."); *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 556 F.3d 114, 131-34 (2d Cir. 2009) (applying *Zauderer* to New York calorie disclosure law); *Conn. Bar Ass'n v. United States*, 620 F.3d 81, 92-93 (2d Cir. 2010) (rejecting strict scrutiny and applying *Zauderer* to bankruptcy disclosure law); *Safelite Grp., Inc. v. Jepsen*, 764 F.3d 258, 263 (2d Cir.

[2] In *Turner*, a First Amendment intermediate-scrutiny case, the Supreme Court remanded for further development of the record, noting that the district court had not made factual findings. 512 U.S. at 665, 668. On a second appeal, the Court upheld the must-carry provisions of a federal cable act and found that the evidence before Congress and on remand confirmed the reasonableness of congressional judgment. *Turner*, 520 U.S. at 195-225.

2014) (recognizing core rationale for drawing "distinction between 'standards of review [to be applied] to laws mandating commercial speech disclosures and laws restricting commercial speech'") (citation omitted). The first situation does not apply because Vermont's interests in passing Act 120 are substantially more significant than the gratification of consumer curiosity. *See Nat'l Elec. Mfrs.*, 272 F.3d at 115 n.6 (*Central Hudson* applies if state interest in disclosure requirement is "supported by no interest other than the gratification of 'consumer curiosity'") (citation omitted). The second situation does not apply because Act 120 plainly requires manufacturers and retailers to label food products that *those* manufacturers and retailers are producing or offering for sale. Act 120, Sec. 2, § 3043; *cf. Safelite*, 764 F.3d at 264 (*Central Hudson* applies if disclosure requirement "compels speech that goes beyond the speaker's own product or service").

1. Act 120's disclosure requirement is factual and uncontroversial.

a. "Produced with genetic engineering" is factual.

Plaintiffs cannot dispute that the label "produced with genetic engineering" states a fact. Instead, they claim that Act 120's label does not accurately describe GE products. Am. Compl. (Doc. 37-2) ¶ 43; Pls.' Mem. Mot. Prelim. Inj. (Doc. 33-1), at 31. But Plaintiffs are wrong: the term "genetic engineering" has a common and consistent meaning. For instance, FDA uses Act 120's terminology in public educational materials. *See, e.g.*, FDA, Questions & Answers on Food from Genetically Engineered Plants (July 22, 2014) ("While these technique[s] are sometimes referred to as 'genetic modification,' FDA considers 'genetic engineering' to be the more precise term."); FDA, FDA's Role in Regulating Safety of GE Foods (May 9, 2013) ("Since people have been modifying plants for thousands of years through breeding and selection, FDA uses the term 'genetically engineered,' or 'GE,' to distinguish plants that have

been modified using modern biotechnology from those modified through traditional breeding."). Additionally, the definition of "genetic engineering" in Act 120 is coextensive with accepted international guidelines. *Compare* Codex Alimentarius, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, *CAC/GL 44-2003* § 2(8) *with* Act 120, Sec. 2, § 3042(4). And the term "produced" accurately describes a food product's relation to the method through which it was made. *See, e.g.*, FDA, Foods Derived from Genetically Engineered Plants (Apr. 8, 2013) ("We recognize and appreciate the strong interest that many consumers may have in knowing *whether a food was produced using genetic engineering*.") (emphasis added).

Plaintiffs' claim that Act 120's label might "confuse" or "frighten" consumers is pure speculation. *See* Am. Compl. (Doc. 37-2) ¶ 43. To the contrary, FDA has already opined that such labels are "not likely to be misleading." FDA, DRAFT Guidance for Industry ("genetically engineered" and "[t]his product contains cornmeal that was produced using biotechnology" are the "kind[s] of simple statement[s]" that would not be misleading). More significantly, Plaintiffs offer no indication of how their speculative allegations of "confusion" and "fear" are legally relevant. *See Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 251 (2010) (claim that disclosure term "debt relief agency" was "confusing and misleading" amounted to "little more than a preference" that lacked "any constitutional basis" where statute "by its terms applied only to debt relief agencies"). Also, nothing in Act 120 prevents Plaintiffs from providing additional truthful information about their products. *See Conn. Bar Ass'n*, 620 F.3d at 98-100 (holding that required disclosure was not misleading and reasoning that "[n]othing in [the required disclosures] limits or impedes a debt relief agency's ability to communicate its own views on public issues associated with the bankruptcy system"); Irradiation in Food, 51 Fed. Reg. 13,376-01, 13,388-89 (Apr. 18, 1986) (in rulemaking for labeling of irradiated foods,

stating, "manufacturers may want to use additional labeling statements as part of a consumer education effort" and "any confusion created by the presence of a retail label requirement can be corrected by proper consumer education programs"); *see also Va. State Bd. of Pharmacy*, 425 U.S. at 769-70 (rejecting argument that disclosure of drug prices would somehow harm "unwitting customers" and calling approach "highly paternalistic").

b. "Produced with genetic engineering" is uncontroversial.

Though Plaintiffs suggest that *Zauderer* does not apply because genetic engineering is "controversial" and subject to "public debate," Pls.' Mem. Opp. Mot. Dismiss (Doc. 36), at 8; PI Mem. (Doc 33-1), at 31, this is not the test. Rather, under *Zauderer*, it is the factual nature of the required disclosure that must be uncontroversial, not the subject matter itself. Indeed, when the Second Circuit addressed this element, it declined to find a disclosure requirement controversial based on some restaurants' desire to avoid disclosing factual information because they "d[id] not want to communicate to their customers that calorie amounts should be prioritized among other nutrient amounts." *NYSRA*, 556 F.3d at 132-33, 134 (treating as irrelevant that "the significance of the facts [plaintiffs] were being asked to disclose" was in "dispute"). Further, courts have repeatedly declined to treat the "uncontroversial" language from *Zauderer* as important. *See Milavetz*, 559 U.S. at 248-53 (applying *Zauderer* and not mentioning "uncontroversial" language); *Conn. Bar Ass'n*, 620 F.3d at 95-102 (same); *Nat'l Elec. Mfrs.*, 272 F.3d at 113-16 (reciting "uncontroversial" language but focusing on "factual" nature of information).

Plaintiffs severely misconstrue the cases they attempt to cite in their favor. *See* MTD Opp. (Doc. 36) at 8; PI Mem. (Doc. 33-1) at 31-33. First, Act 120 does not regulate political speech, the type of speech at issue in *Evergreen.* In *Evergreen*, the court reviewed three disclosure requirements that New York City had placed on "pregnancy services centers" (PSCs).

Evergreen Ass'n, Inc. v. City of New York, 740 F.3d 233, 244-51 (2d Cir. 2014). The court did not analyze the disclosure requirements as commercial speech, but rather subjected them to intermediate and strict scrutiny. *Id.* at 245. Under strict scrutiny, the court *upheld* the first disclosure requirement—that PSCs must disclose whether they have a licensed medical provider on staff. *Id.* at 246-49.[3] The court determined that the City's interest in informing consumers about PSC services was served by this "brief, bland, and non-perjorative" disclosure. *Id.* at 247, 250 (citation omitted). It is difficult to imagine how *Evergreen* could be relevant to this case, other than to note that Act 120's "produced with genetic engineering" requirement is even more "brief, bland, and non-pejorative" than the disclosure requirement that was upheld under strict scrutiny in *Evergreen*. Act 120 does not require Plaintiffs to disclose whether they provide services or referrals for services that they oppose or to recommend competing companies.

Similarly, the *CTIA* court did not hold that San Francisco's required disclosure about cell phone emissions was "controversial" because cell phone safety was subject to scientific debate. *See* MTD Opp. (Doc. 36) at 8. Rather, the court found that the required disclosure "contain[ed] more than just facts" and therefore was not "'purely factual and uncontroversial.'" *CTIA—The Wireless Ass'n v. City & Cnty. of S.F.*, 494 Fed. Appx. 752, 753-54 (9th Cir. 2012) (citation omitted). Unlike Act 120, the San Francisco law required the disclosure to contain not just facts about cell phone emissions, but also San Francisco's recommendations on how to reduce exposure to those emissions. *Id.* at 753.

[3] The Court struck down the other two requirements because they were not narrowly tailored—not because they were "controversial." *Evergreen*, 740 F.3d at 249-51. In the footnote cited by Plaintiffs, MTD Opp. (Doc. 36) at 8, the court opined that, assuming the City's law regulated commercial speech, the second and third disclosure requirements would not regulate "purely factual and uncontroversial information." *Id.* at 245, n.6. One disclosure forced the PSCs to convey the City's health recommendation and the other required them to mention controversial services (e.g., abortions) that the plaintiffs opposed. *Id.* Neither is the case here.

Plaintiffs also mischaracterize the other cases they cite. *See* PI Mem. (Doc. 33-1) at 33 n.13. None of those cases focused on whether the content of a disclosure requirement was "controversial;" instead, the key inquiry was whether the disclosure required a statement of facts or of something else. *See Nat'l Ass'n of Mfrs. v. U.S. Secs. & Exch. Comm'n*, 748 F.3d 359, 371 (D.C. Cir. 2014), *overruled by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (in dicta, noting it was not clear that label "conflict free" was "factual and non-ideological" because it was "a metaphor that conveys moral responsibility for the Congo war"); *R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 696 F.3d 1205, 1216-17 (D.C. Cir. 2012), *overruled by Meat Inst.*, 760 F.3d 18 (D.C. Cir. 2014) (where images did not "convey *any* warning information at all, much less make an 'accurate statement' about cigarettes," they were not "purely factual, accurate, or uncontroversial") (emphasis in original); *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) (where State's idea of "sexually explicit" was "far more opinion-based than the question of whether a particular chemical is within any given product," label conveyed a "subjective and highly controversial message"); *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 966-67 (9th Cir. 2009) (similar). "Produced with genetic engineering" is none of these things. It is not a metaphor. It is not an image. It is not an opinion. It is a fact.

2. Strict scrutiny does not apply to Act 120's disclosure requirement.

Plaintiffs make the remarkable and unprecedented argument that strict scrutiny applies to Act 120's disclosure requirement. *See* MTD Opp. (Doc. 36) at 6; PI Mem. (Doc. 33-1) at 16-22. Strict scrutiny does not apply in the commercial speech context, period. Even if it did, Act 120's disclosure requirement would not qualify for strict scrutiny: it is neither content based nor viewpoint discriminatory.

a. Act 120 regulates commercial speech and strict scrutiny is inapplicable.

Commercial speech occupies a "'subordinate position in the scale of First Amendment values.'" *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 477 (1989) (citation omitted). It "occurs in an area traditionally subject to government regulation," *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 455-56 (1978), and receives "less protection . . . than . . . other constitutionally safeguarded forms of expression," *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 64-65 (1983) (citation omitted). Consequently, courts have consistently rejected pleas to apply strict scrutiny to regulations of commercial speech. *See, e.g.*, *Cent. Hudson*, 447 U.S. at 566 (articulating lesser form of scrutiny for commercial speech regulations); *Bolger*, 463 U.S. at 65-68 (rejecting appellee's request to treat mailed contraceptive advertisements as "fully protected speech" and applying *Central Hudson* instead); *Alexander v. Cahill*, 598 F.3d 79, 88-90 (2d Cir. 2010) (applying *Central Hudson* to ban on certain attorney advertising despite content-based restrictions); *Nat'l Elec. Mfrs.*, 272 F.3d at 113-14 (applying *Zauderer* to calorie disclosure requirement where district court had "misperceived the proper standard to apply").[4]

Despite Plaintiffs' strange and unsupported assertion otherwise, *see* PI Mem. (Doc. 33-1) at 22, the speech that Act 120 regulates—food labels—is undeniably commercial. Commercial speech is speech that "does no more than propose a commercial transaction." *Bolger*, 463 U.S. at 66 (quotation marks and citations omitted). A label is a quintessential means of proposing a commercial transaction: it gives information to the consumer, who uses the information to make purchasing decisions. Unsurprisingly, then, it is settled that "information on . . . labels constitutes commercial speech." *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481 (1995); *see*

[4] In *Riley v. National Federation of the Blind of North Carolina*, the Supreme Court did apply strict scrutiny to compelled disclosures regarding charitable contributions, but only because the state's mandated commercial disclosures were "inextricably intertwined" with fully protected expression—namely charitable solicitation. 487 U.S. 781, 796 (1988).

Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth., 134 F.3d 87, 97 (2d Cir. 1998) (information on label is "conveyed in the context of a proposal of a commercial transaction"); *Adolph Coors Co. v. Brady*, 944 F.2d 1543, 1546 (10th Cir. 1991) ("[p]roduct labels . . . also constitute commercial speech"). The simple fact that an advertisement "links a product to a current public debate" does not "entitle[]" it to "the constitutional protection afforded non commercial speech." *Bolger*, 463 U.S. at 68 (quotation marks and citation omitted); *see Cent. Hudson*, 447 U.S. at 562 n.5 (rejecting argument that would "grant broad constitutional protection to any advertising that links a product to a current public debate," as "many, if not most, products may be tied to public concerns with the environment, energy, economic policy, or individual health and safety").

b. Act 120 is not content based.

Plaintiffs do not cite—nor are *amici* aware of—any case in which a court has found that a commercial disclosure requirement was "content based" and therefore subject to strict scrutiny. Under Plaintiffs' expansive theory, every compelled disclosure—be it a safety warning, ingredient list, or nutrition panel—would be subject to strict scrutiny because every compelled disclosure contains "content." This is not the law.

Plaintiffs begin with the misguided conclusion that compelled speech is automatically content based and therefore worthy of strict scrutiny review. MTD Opp. (Doc. 36) at 6; PI Mem. (Doc 33-1) at 16-20. However, whether a statement is compelled has no bearing on whether it is content based. Rather, "laws that by their terms distinguish favored speech from disfavored speech on the basis of the *ideas or views expressed* are content based." *Turner*, 512 U.S. at 643 (emphasis added). For example, in *R.A.V. v. City of St. Paul*, the Supreme Court held that St. Paul's "fighting words" ordinance applied to expression that provoked only "on the basis of race, color, creed, religion or gender" but not "in connection with other ideas," such as "political

affiliation, union membership, or homosexuality." 505 U.S. 377, 391 (1992). Accordingly, the ordinance imposed "special prohibitions on those speakers who express views on disfavored subjects." *Id.* Unlike that content-based law, Act 120 does not impose ideas or views on any speaker. *See* Act 120, Sec. 2, § 3043(b) (requiring "produced with genetic engineering" label).

Similarly, the cases that Plaintiffs cite for the proposition that Act 120 infringes on a speaker's right to choose what "not to say" are inapposite. PI Mem. (Doc. 33-1) at 17, 20-21. In *Hurley v. Irish-American Gay, Lesbian & Bisexual Grp. of Bos.*, the Court considered whether a Massachusetts law requiring a privately sponsored parade to include a group expressing a message contrary to that of the sponsors violated the First Amendment. 515 U.S. 557, 566 (1995). The Court held that Massachusetts could not require the parade sponsors to "propound a particular point of view" by mandating that the group (GLIB) be allowed to participate in the parade because, among other things, the parade sponsors "may object to unqualified social acceptance of gays and lesbians or have some other reason for wishing to keep GLIB's message out of the parade." *Id.* at 574-75. Likewise, in *Harris v. Quinn*, the Court struck down a law that required non-union members to pay dues to a union because "no person in this country may be compelled to subsidize speech by a third party that he or she does not wish to support." 134 S. Ct. 2618, 2644 (2014). There absolutely is no parallel here. Act 120 does not require companies to state the view that, for instance, "GE foods are bad for the world"—only that they disclose their products' method of production.

c. Act 120 is not viewpoint discriminatory.

The crux of Plaintiffs' viewpoint argument is that Vermonters have concerns about GE foods and therefore want to know which foods are GE. *See* MTD Opp. (Doc. 36) at 7; PI Mem.

(Doc 33-1) at 17-19.[5] Essentially, Plaintiffs ask this Court to rule that a state's interest in passing a disclosure requirement is *per se* invalid if the regulated entities dislike the state's interest. No case has ever held this. A state's substantial interest in enacting a factual disclosure requirement does not equate to viewpoint discrimination. *See, e.g., Evergreen*, 740 F.3d at 239-41 (exhaustively listing reasons for City's substantial interest in having pregnancy services centers disclose factual information about their services to patients). If it did, every label currently required by state and federal law might rise to the level of viewpoint discrimination. Rather, under Supreme Court precedent, a government must "favor one speaker over another" and discriminate against speech "because of its message." *Rosenberger v. Rector & Visitors of Univ. of Va.*, 515 U.S. 819, 828 (1995). Again, the label required by Act 120 is not a message; it is a fact.

Plaintiffs similarly misconstrue *Sorrell v. IMS Health, Inc.*, MTD Opp. (Doc. 36) at 6-8; PI Mem. (Doc 33-1) at 18-20, in which a state law prevented pharmacies from selling patient prescription data to pharmaceutical manufacturers. In *IMS*, the Second Circuit struck down the statute because it was not sufficiently tailored; i.e., all but one group of speakers—the disfavored speakers—could still obtain access to doctors' prescribing information. 131 S. Ct. 2653, 2668, 2672 (2011). Essentially, the State did not agree with the message that the disfavored speakers were promoting, which was a matter of opinion: that doctors should prescribe name-brand drugs instead of generic brands. *Id.* at 2671-72. Here, there is no burden on the expression of any opinion by Plaintiffs; as noted, under Act 120, Plaintiffs are free to express opinions about their products. In the realm of factual disclosures such as Act 120, there is no government

[5] Attempting to have it both ways, Plaintiffs argue that *Vermont* has no interest in GE labeling, but that *Vermonters* have an illegitimate interest in GE labeling. As explained above, Vermont has a deep interest in GE labeling. And, as explained here, that interest does not make the law viewpoint discriminatory.

endorsement of a particular "viewpoint" or suppression of contrary ideas, and thus no threat to the freedom of expression. Consequently, Plaintiffs' reliance on non-commercial, non-disclosure cases such as *IMS* is misplaced.

Finally, Plaintiffs' idea that Act 120 impermissibly distinguishes between groups based on viewpoint—i.e., because manufacturers are exempt from Act 120's labeling requirement if they do not sell GE foods—is illogical. *See* MTD Opp. (Doc. 36) at 7; PI Mem. (Doc. 33-1) at 18-19. Act 120 does not require food manufacturers to label their products because of a message they convey; they must label their products because those products are produced with genetic engineering.

B. Act 120's disclosure requirement meets the *Zauderer* test.

1. Vermont's interests in passing Act 120's disclosure requirement are legitimate and substantial.

Plaintiffs' main argument here is that Vermont does not have a "substantial interest" in Act 120, *see* MTD Opp. (Doc. 36) at 9-12; PI Mem. (Doc. 33-1) at 23-27, 34-36, but they fail to note that the Second Circuit has repeatedly characterized the *Zauderer* interest as "legitimate." *Natl'l Elec. Mfrs.*, 272 F.3d at 115 (referring to "legitimate and significant public goal"); *Conn. Bar Ass'n*, 620 F.3d at 101 (applying *Zauderer* and dismissing plaintiffs' claims where government had "legitimate" interest). Regardless, in this case Plaintiffs' purported distinction is irrelevant, because Vermont's interests in Act 120 are both legitimate and substantial.

One of Act 120's primary purposes is to "[r]educe and prevent consumer confusion and deception by . . . promoting the disclosure of factual information on food labels to allow consumers to make informed decisions." Act 120, Sec. 2, § 3041(3). Time and again, courts have upheld this governmental interest as both legitimate and substantial. *See, e.g.*, *Zauderer*, 471 U.S. at 650-52 n.15 (upholding disclosure requirement and noting "the reasonableness of the

decision that appellant's omissions created the potential for deception of the public"); *Milavetz,* 559 U.S. at 253 (upholding bankruptcy disclosure where government interest was in preventing consumer deception); *Evergreen,* 740 F.3d at 248 (upholding medical provider disclosure under strict scrutiny where disclosure "support[ed] the state interest in informing consumers and combating misinformation"); *Conn. Bar Ass'n,* 620 F.3d at 96 ("The government's significant interest in avoiding confusion and deception in the operation of [the bankruptcy] system is self-evident."). Given that so many Vermonters need this information, that they do not currently have it, and that polls show consumers often have *inaccurate* assumptions about whether their foods are GE, Vermont's interest in preventing consumer confusion and deception is especially well founded. *See supra* Act 120: A History; *Meat Inst.,* 760 F.3d at 23 (citing "demonstrated consumer interest" in country-of-origin labeling as factor contributing to government's substantial interest).[6]

Another primary interest of Act 120 is in "[p]ublic health and food safety." Act 120, Sec. 2, § 3041(1). In particular, the Act seeks to "[e]stablish a system by which persons may make informed decisions regarding the potential health effects of the food they purchase and . . . if they choose . . . avoid potential health risks of food produced from genetic engineering." *Id.* Like preventing consumer confusion and deception, promoting public health and food safety is a valid state interest. *See, e.g., Nat'l Elec. Mfrs.,* 272 F.3d at 115; *NYSRA,* 556 F.3d at 134; *Rubin,* 514 U.S. at 485 (concluding that promoting "health, safety, and welfare" is "substantial" interest under *Central Hudson*). Though Plaintiffs make much of the fact that Act 120 seeks to address

[6] Plaintiffs are incorrect that Vermont's interest in labeling must share all of the characteristics of the government's interest in *Meat Institute. See* PI Mem. (Doc. 33-1) at 35 n.15. On the contrary, the *Meat Institute* court drew on a variety of factors to conclude that the government had a sufficient interest, but did not establish an exclusive set of factors. The case establishes that many factors may combine to make an interest "substantial," not that many factors are required. 760 F.3d at 23.

health "risks" rather than proven health harms, PI Mem. (Doc. 33-1) at 23 & n.8, the very case they cite for support actually concluded that a local government *could* require factual disclosures regarding cell phone emissions on the basis of a potential health risk. *CTIA*, 827 F. Supp. 2d at 1061. The court noted that "[w]hether or not cell phones cause cancer is a debatable question" and held that "[a] government may impose, out of caution, at least some disclosure requirements based on nothing more than the possibility that an agent may (or may not) turn out to be harmful."[7] *Id.* at 1060-61. Here, Vermont has a substantial interest in enabling consumers to optimize their health by avoiding foods that pose potential safety risks, not merely in allowing consumers to avoid foods that are known to be harmful.

Additionally, this case is not *Amestoy II*, despite Plaintiffs' best attempts to forever cabin Vermont's lawmakers within the confines of that narrow decision. In *Amestoy*, the court noted that "'Vermont [did] not claim that health or safety concerns prompted the passage of'" the labeling law, and that the record contained "no scientific evidence from which an objective observer could conclude that rBST has any impact at all on dairy products." *Int'l Dairy Foods Ass'n v. Amestoy,* 92 F.3d 67, 73 (2d Cir. 1996) (citation omitted). Here, health and safety concerns permeate Act 120, and substantial scientific evidence supports Vermont's determinations that GE foods pose potential health risks, and that no consensus of safety exists. *See supra* Act 120: A History.

[7] The court in *CTIA* pointed out that San Francisco used the word "risk" in a way "different from the usual way." 827 F. Supp. 2d at 1061. Vermont, in contrast, wisely used the words "potential health risks," which reflects the fact that there is a lack of consensus on whether GE foods pose health risks. Regardless, as with Act 120, San Francisco's ordinance addressed health risks that, though possible, had not yet been statistically proven (in contrast to, for instance, smoking), and the court held this was sufficient to sustain a fact sheet requirement (once revised). *Id.* at 1061-63.

Further, unlike FDA's decision on rBST in *Amestoy*—where the agency "concluded" after "'exhaustive studies'" that "'there are no human safety or health concerns'" with rBST-derived products, 92 F.3d at 73 (citation omitted)—with GE foods, FDA has never made a determination of safety. The agency also has not issued a rule, as it had in the rBST case. *See* Final Rule: Sterile Sometribove Zinc Suspension, 58 Fed. Reg. 59,946-02 (Nov. 12, 1993) (approving drug); Voluntary Labeling of Milk & Milk Products, 59 Fed. Reg. 6279-04, 6279 (Feb. 10, 1994) (explaining FDA had approved rBST because it "had determined after a thorough review" that product was safe). And, in the only document on GE foods that FDA *has* issued—i.e., a policy statement pre-public notice and comment—the agency raised several concerns regarding potential negative health effects. 1992 Policy Statement, 57 Fed. Reg. 22,985-88 (e.g., unexpected effects, toxicants, allergenicity, antibiotic resistance).

Plaintiffs' attempt to straightjacket the State through *Amestoy* also fails to recognize that public health is only *one* of the State's interests in Act 120. Another is to "[i]nform the purchasing decisions of consumers who are concerned about the potential environmental effects of the production of food from genetic engineering." Act 120, Sec. 2, § 3041(2). Precisely this type of interest was recently upheld by the D.C. Circuit. *See Meat Inst.*, 760 F.3d at 23-24. There, the court held that the history of country-of-origin disclosure requirements being used to "enable consumers to choose American-made products" was a factor in establishing the government's interest. *Id.* at 23. The court specifically referenced legislative statements that "identified the statute's purpose as enabling customers to make informed choices based on characteristics of the products they wished to purchase." *Id.* at 24. The court explained: "Even though the production steps abroad for food imported into the United States are to a degree subject to U.S. government monitoring . . . it seems reasonable for Congress to anticipate that

many consumers may prefer food that had been continuously under a particular government's direct scrutiny." *Id.* (citation omitted). Similarly here, the Vermont legislature recognized that consumers may prefer to avoid purchasing GE foods based on concerns about the environment. And unlike health risks and unknowns, the adverse environmental impacts of GE crops—transgenic contamination and massively increased pesticide use among them—are well documented. *See* Act 120: A History. Environmental protection is a well-established governmental interest. *See, e.g.*, *Nat'l Elec. Mfrs.*, 272 F.3d at 115; *Cent. Hudson*, 447 U.S. at 568 (noting that conserving energy is "substantial" interest); *Maine v. Taylor*, 477 U.S. 131, 148, 152 (1986) (upholding Maine law under dormant Commerce Clause where state had "a legitimate interest in guarding against imperfectly understood environmental risks, despite the possibility that they may ultimately prove to be negligible").

Finally, all of these interests are *the State's.* Plaintiffs' last-gasp attempt to dump Act 120 into the *Amestoy* box by claiming that Vermont does not actually hold its expressly stated interests is wrong, and is belied by Plaintiffs' own prior briefing. In attempting to keep Amici on the sidelines, Plaintiffs previously argued that the "*State's* interest" in Act 120 was the same as Amici's. *See* Pls.' Opp. Mot. Intervene (Doc. 22) at 11 (citing Purpose section of Act 120 and stating that Applicants' interests were "the same as those the State has identified"). Plaintiffs are correct. Like Amici, the State of Vermont is concerned about consumer confusion and deception, potential health risks, and environmental harms, as well as protecting religious practices. *See* Act 120, Sec. 1. The Vermont legislature worked on H.112 for two years, held at least 52 committee meetings, and heard at least 136 testimonies. H.112 Legislative History (MTD Exhibit B at 1-23). These are not the actions of a disinterested legislature. As if this were not enough, Act 120 is explicit:

> For multiple health, personal, religious, and environmental reasons, *the State of Vermont finds* that food produced from genetic engineering should be labeled as such, as evidenced by the following . . . .
>
> Because both the FDA and the U.S. Congress do not require the labeling of food produced with genetic engineering, the State should require food produced with genetic engineering to be labeled as such *in order to serve the interests of the State*, notwithstanding limited exceptions, to prevent inadvertent consumer deception, prevent potential risks to human health, protect religious practices, and protect the environment.

Act 120, Sec. 1(5), (6) (emphases added); *see Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980) ("the starting point for interpreting a statute is the language of the statute itself"). Naturally, the legislature's interests reflect those of Vermonters. It is, after all, the legislature's job to promote the interests of Vermonters.

2. Act 120's disclosure requirement is reasonably related to Vermont's interests.

Plaintiffs' argument that rational-basis review does not apply in the First Amendment context has no support, and would require this court to ignore Second Circuit precedent. Their argument is based purely on the "interest" prong of *Zauderer*, and Plaintiffs do not even attempt to argue that Vermont's law would fail the "reasonable relationship" prong—likely because they cannot. MTD Opp. (Doc. 36) at 10-13; PI Mem (Doc. 33-1) at 33-36.

The "reasonable relationship" rule is the essence of rational-basis review, and it *does* apply in the First Amendment context. *Safelite*, 764 F.3d at 262 ("In *Zauderer*, however, the Court created an exception that an informational disclosure law—as opposed to a prohibition on speech—was subject to rational review, that is, a determination of whether the required disclosure is reasonably related to the state's interest."); *NYSRA*, 556 F.3d at 134 ("rational basis applies and NYSRA concedes that it will not prevail if we apply that test"); *Nat'l Elec. Mfrs.*, 272 F.3d at 115 ("The Amendment is satisfied, therefore, by a rational connection between the purpose of a commercial disclosure requirement and the means employed to realize that

purpose"); *Conn. Bar Ass'n*, 620 F.3d at 95 (subjecting disclosure mandate to rational basis review). Under this standard, and despite H.112's voluminous record, Vermont had "'no obligation to produce evidence or empirical data to sustain . . . rationality.'" *NYSRA*, 556 F.3d at 134 n.23 (citation omitted).

Because the goal of any disclosure requirement is to provide information to the public in order to achieve a certain purpose or purposes, disclosure requirements naturally lend themselves to meeting the "reasonable relationship" test. This is particularly true where, as here, a required label gives consumers information with which to make important decisions about the food they consume. As explained by the court in *Meat Institute*:

> The self-evident tendency of a disclosure mandate to assure that recipients get the mandated information may in part explain why, where that is the goal, many such mandates have persisted for decades without anyone questioning their constitutionality. In this long-lived group have been not only country-of-origin labels but also many other routine disclosure mandates about product attributes, including, for instance, disclosures of fiber content, 16 C.F.R. pt. 303, care instructions for clothing items, 16 C.F.R. pt. 423, and listing of ingredients, 21 C.F.R. § 101.4.

760 F.3d at 26. In addition, though Plaintiffs complain about Act 120's exemptions, PI Mem. (Doc. 33-1) at 28-29, the law's scope is perfectly logical. For example, labeling of certain exempted products is preempted by federal law; some other exempted products are typically not labeled at the federal level, either (e.g., restaurant food). *See* Letter from Laura Murphy to Senate Committee on Judiciary *and* Attachments (Mar. 28, 2014) (Exhibit B at 331-37). Further, Vermont is under no obligation to address all aspects of the GE disclosure issue at once. *See Zauderer*, 471 U.S. at 651 n.14 ("we are unpersuaded by appellant's argument that a disclosure requirement is subject to attack if it is 'under-inclusive'-that is, if it does not get at all facets of the problem it is designed to ameliorate"); *Nat'l Elec. Mfrs.*, 272 F.3d at 115-16 ("the Vermont statute is rationally related to the state's goal, notwithstanding that the statute may ultimately fail

to eliminate all or even most mercury pollution in the state. . . . States are not bound to follow any particular hierarchy in addressing problems within their borders"); *NYSRA*, 556 F.3d at 133 n.22 (regulation affecting only 10% of restaurants upheld even though "'it does not get at all facets of the problem it is designed to ameliorate'") (citation omitted).

C. Act 120's disclosure requirement also satisfies intermediate scrutiny.

Even if this Court applies *Central Hudson,* Act 120's disclosure requirement passes muster. First, the requirement "directly advances" Vermont's interests in preventing consumer confusion and deception and giving consumers critical information with which to make choices about the food they buy on the basis of health, environmental, and religious concerns. *See Cent. Hudson*, 447 U.S. at 566 (regulation should directly advance governmental interest). Vermont need not provide "a surfeit of background information" to show that its requirement directly advances its interest, but may rely on "reference to studies and anecdotes" and "on history, consensus, and 'simple common sense.'" *Fla. Bar v. Went for It, Inc.*, 515 U.S. 618, 628 (1995) (citation omitted); *see Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 509 (1981) (relying on "accumulated, common-sense judgments of local lawmakers"). Given that the purpose of any disclosure requirement is to provide information, the disclosure of said information satisfies the "directly advances" prong as a matter of "common sense." Information on food labels—e.g., nutrition facts, ingredient lists, or declarations of the presence or absence of specific ingredients—is an obvious method by which consumers receive information and make purchasing decisions. *See Bad Frog Brewery*, 34 F.3d at 96-97 (recognizing product labels as source of information about nature of product). The D.C. Circuit recently discussed this issue at length, finding that country-of-origin labeling directly advanced the government's interest in "informing consumers about a particular product trait" and that "the means-end fit is self-

evidently satisfied when" the government's interest is in "assuring that consumers receive particular information." *Meat Inst.*, 760 F.3d at 25-27 (discussing *Central Hudson* and *Zauderer* "reasonable fits" as one).

Second, Act 120's disclosure requirement is "not more extensive than necessary" to serve Vermont's interests. *See Cent. Hudson*, 447 U.S. at 566 (regulation should not be more extensive than necessary). In advancing its interests, a state need not adopt the "'least restrictive means,'" but must only ensure that the "'regulation not burden substantially more speech than is necessary.'" *Safelite*, 764 F.3d at 265 (citation omitted). If a requirement is "in proportion to the interest served," it satisfies this final prong of the *Central Hudson* test, *In re RMJ*, 455 U.S. 191, 203 (1982), and a court should "defer" to a "reasonable" government decision about regulation, *Clear Channel Outdoor, Inc. v. City of New York*, 594 F.3d 94, 104-05 (2d Cir. 2010).

Vermont's decision is reasonable, and Act 120's disclosure requirement is in proportion to the interests it serves. Like other food labeling requirements, Act 120 applies to the food products that the labels describe. The label will be on either the product package or a nearby shelf or bin. Act 120, Sec. 2, § 3043(b). This is the surest and easiest way for consumers to access the information—at the point of purchase. *See NYSRA*, 556 F.3d at 135 ("information . . . at the point-of-decision would help consumers make informed . . . food choices"). Options other than labeling either would not provide the needed information, or would not provide it in a way that is accessible to consumers at the point where they are making decisions. Further, Act 120 is focused because it applies to a particular category of food products; it is not a broad labeling requirement that applies to all entities regardless of their utilization of biotechnology in the production process.

Additionally, a state regulation generally must be "substantially excessive" to fail this prong. *Fox*, 492 U.S. at 479. For example, in *Lorillard Tobacco Co. v. Reilly*, the Court found that "the broad sweep" of Massachusetts' restrictions on tobacco advertising "would constitute nearly a complete ban on the communication of truthful information . . . to adult consumers." 533 U.S. 525, 561-62 (2001). According to the Court, those restrictions had a disproportionate effect in urban areas, unnecessarily applied to signs of all shapes and sizes, and created an onerous burden on small retailers. *Id.* at 562-65. The Court noted that "a speech regulation cannot unduly impinge on the speaker's ability to propose a commercial transaction and the adult listener's opportunity to obtain information about products." *Id.* at 565. Act 120's disclosure requirement, in contrast, falls far short of this threshold; it does not ban any speech, much less operate as a "complete ban on the communication of truthful information" to consumers. Nor does it "unduly impinge on the speaker's ability to propose a commercial transaction"—manufacturers are free to provide additional, truthful information about their products. All Act 120 requires is that food manufacturers include a disclosure on food products that are already subject to other disclosure requirements through the well-established delivery method of labeling. *See Safelite*, 764 F.3d at 266 (a "straight-forward disclosure" is a sufficiently tailored means of achieving state interest). This requirement is not "more extensive than necessary," and certainly not "substantially excessive."

II. ACT 120'S "NATURAL" PROHIBITION IS CONSTITUTIONAL

The Court also should reject Plaintiffs' challenge to Act 120's prohibition on use of the term "natural" because false, deceptive, or inherently misleading speech is not entitled to any First Amendment protection. *See, e.g.*, *Cent. Hudson*, 447 U.S. at 563; *Milavetz*, 559 U.S. at

250-51. Using the term "natural" to describe foods produced with genetic engineering is misleading because GE foods are, by definition, the antithesis of natural.

The New Oxford American Dictionary defines "natural" as "existing in or caused by nature; not made or caused by humankind." *New Oxford American Dictionary* 1167 (3d ed. 2010). In sharp contrast, genetic engineering is the process of fundamentally changing organisms via recombinant DNA vectors, injections, and techniques in a way that "does not occur by natural multiplication or natural recombination." *See* Act 120, Sec. 2, § 3042(4) (defining "genetic engineering"). This is not just Act 120's definition, but rather also that of the statute's source: the universally recognized, international definition of "genetic engineering" established by the Codex Alimentarius Commission—the world's leading food standards authority—which defines "modern biotechnology" as:

> the application of (a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) fusion of cells beyond the taxonomic family, that o*vercome natural physiological, reproductive or recombination barriers* and that are *not techniques used in traditional breeding and selection*.

Codex Alimentarius, *supra* Act 120: A History (emphases added). As described, the United Nations World Health Organization and even biotech giant Monsanto explain that being *un*natural is a defining characteristic of foods produced with genetic engineering. *See supra* Act 120: A History (quoting respective GE definitions as including genetic alteration "in a way that that does not occur naturally" to exhibit traits "that are not naturally theirs").

In other words, genetic engineering involves the insertion of foreign (often bacterial) genetic material into a food plant or crop by artificial means—i.e., through a gene "gun," a bacterial vector, or chemical or electrical treatment—without regard for natural species boundaries. *See, e.g.*, Michael K. Hansen, *Genetic Engineering Is Not an Extension of*

Conventional Plant Breeding: How Genetic Engineering Differs from Conventional Breeding, Hybridization, Wide Crosses & Horizontal Gene Transfer 1, 7, 11 Consumer Policy Institute/Consumers Union (2000). For example, biotechnicians may use promoters derived from genetic parasites, such as viruses, that have been designed to breach species barriers. *Id.* at 7. But neither vectors nor promoters are needed in traditional breeding. *Id.* at 6-7. Further, natural breeding can only occur between closely related life forms (e.g., rice with rice, corn with corn), *id.* at 2, and cannot add genes of an organism from a different phylum order (e.g., fish with plant, plant with bacteria), *id.* at 1-2.

Yet this is exactly what genetic engineering does in GE plants: it artificially inserts genes of various bacteria and animals into the genetic material of a plant to create organisms that would otherwise never be found in nature and cannot be rationally described as "natural." *Id.* at 12 ("GE, on the other hand, does away with all such barriers in the natural world, permitting scientists to manipulate genetic materials in a way that was inconceivable before."). The label "natural" connotes foods from plants and animals that have only their natural complement of traits, not entirely new ones never before exhibited by the species, such as the ability to produce bacterial insecticides or survive spraying with a powerful herbicide. *See* Antoniou *et al.*, *Myths & Truths*, at 42 (Exhibit B at 92) (most GE foods engineered to contain insecticides or be herbicide resistant). Moreover, there is no way for consumers to detect from a visual inspection alone whether a food was produced with genetic engineering. For these reasons, as the State found, it is inherently misleading to consumers to label GE foods with such highly unnatural characteristics as "natural." Act 120, Sec. 1(5)(c).

Despite this straightforward logic, Plaintiffs erroneously argue that Vermont had a burden to produce evidence of specific "instances" proving consumers were misled. MTD Opp. (Doc.

36) at 15; PI Mem. (Doc. 33-1) at 37-38. The Supreme Court has twice rejected that argument: there is no such burden, when, as here, the misleading nature of the advertisement is "self-evident." *See Milavetz*, 559 U.S. at 251 ("Milavetz makes much of the fact that the Government in these consolidated cases has adduced no evidence that its advertisements are misleading. *Zauderer* forecloses that argument: When the possibility of deception is as self-evident as it is in this case, we need not require the State to conduct a survey of the . . . public before it [may] determine that the [advertisement] had a tendency to mislead.") (quotation marks and citation omitted); *see also 1-800-411-Pain Referral Serv., LLC v. Otto*, 744 F.3d 1045, 1062 (8th Cir. 2014) ("As in *Zauderer* and *Milavetz*, we view 411–Pain's advertisements as *inherently misleading on their face without requiring proof of actual deception*.") (emphasis added). Instead, it is sufficient if the "particular content" of the speech "suggests it is inherently misleading," as here. *In re R.M.J.*, 455 U.S. 191, 203 (1982) ("Misleading advertising may be prohibited entirely" when "the particular content or method of the advertising suggests that it is inherently misleading *or* when experience has proved that in fact.") (emphasis added); *Farrin v. Thigpen*, 173 F. Supp. 2d 427, 437 (M.D.N.C. 2001) ("[E]vidence is only required where the ad at issue *contains a truthful statement* that is nonetheless misleading and is *not required* where the ad is inherently misleading.") (citing *Zauderer*, 471 U.S. at 652) (emphases added). As explained, labeling GE foods as "natural" is not a truthful statement.

In any event, Vermont *did* have evidence to support its conclusion. As discussed *supra* at Act 120: A History, polls repeatedly have shown that a majority of consumers believe that the "natural" label means a food was not derived from genetic engineering, and recent testing shows that many foods labeled "natural" are actually produced with genetic engineering, deceiving consumers.

Plaintiffs further argue that using a "natural" label on GE foods is not misleading because not every food produced with genetic engineering is covered by Act 120, MTD Opp. (Doc. 36) at 15; PI Mem. (Doc 33-1) at 37, but the *Zauderer* Court rejected this "under-inclusive" argument. *Zauderer*, 471 U.S. at 651 n.14 ("As a general matter, governments are entitled to attack problems piecemeal, save where their policies implicate rights so fundamental that strict scrutiny must be applied."); *see Clear Channel Outdoor, Inc. v. City of New York*, 608 F. Supp. 2d 477, 515 (S.D.N.Y. 2009), *aff'd* 594 F.3d 94 (2d Cir. 2010) ("The few exceptions to the ban on off-site commercial arterial advertising that remain along the City's roads do not undermine the constitutionality of the Zoning Resolution."). Plaintiffs also cite inapposite caselaw. PI Mem. (Doc. 33-1) at 38-39. Unlike this case, *Alexander v. Cahill* dealt with speech that was "not inherently false, deceptive or misleading." 598 F.3d at 89. Neither was the product symbol in *Bad Frog* inherently deceptive or misleading. *Bad Frog Brewery*, 134 F.3d at 98. Those cases are thus irrelevant here, and in any event, could not trump the Supreme Court's holdings that such deception can be self-evident. Plaintiffs' remaining arguments regarding the application of the *Central Hudson* factors, PI Mem. (Doc. 33-1) at 39-40, are similarly irrelevant because labeling GE foods as "natural" does not pass the threshold *Central Hudson* requirement, which is that commercial speech "not be misleading." 447 U.S. at 566; *see, e.g.*, *Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1108 (9th Cir. 2004) ("Because the plaintiffs' use of 'board-certified' is inherently misleading, it is not protected speech.").

III. ACT 120'S DISCLOSURE REQUIREMENT IS NOT PREEMPTED BY FEDERAL LAW

Several fundamental principles guide all preemption analysis. First, "'the purpose of Congress is the ultimate touchstone in every preemption case.'" *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (citation omitted). Second, courts "start with the assumption that the historic police

powers" should not be superseded "unless that was the clear and manifest purpose of Congress." *Id.* (quotation marks and citation omitted). This "presumption against preemption" is particularly strong here because Act 120 concerns areas traditionally within the province of state regulation. *NYSRA*, 556 F.3d at 123 (presumption is "heightened" in fields of traditional state regulation); *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3d Cir. 2009) ("Health and safety issues have traditionally fallen within the province of state regulation. This is true of the regulation of food and beverage labeling and branding."); *Plumley v. Massachusetts*, 155 U.S. 461, 472 (1894)) ("If there be any subject over which it would seem the states ought to have plenary control . . . it is the protection of the people against fraud and deception in the sale of food products."). This presumption applies not only to the question of whether Congress expressly or impliedly intended any preemption at all, but also to the question of "the scope of [Congress's] intended invalidation of state law." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Where Congress includes an express preemption provision, it normally evinces congressional intent that no other area be impliedly preempted. *Cipollone v. Ligget Grp., Inc.*, 505 U.S. 504, 517 (1992). Further, any presumption aside, if a preemption clause is susceptible to an interpretation against preemption, a court "ha[s] a duty to accept the reading that disfavors preemption." *Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005) ("In areas of traditional state regulation, [courts] assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest'") (citation omitted); *accord Riegel v. Medtronic, Inc.*, 552 U.S. 312, 335 (2008).

A. Act 120's disclosure requirement is not expressly preempted by the Nutrition Labeling & Education Act.

Plaintiffs assert that Act 120's disclosure requirement is expressly preempted by three provisions of the Nutrition Labeling and Education Act (NLEA). *See* MTD Opp. (Doc. 36) at

21; PI Mem. (Doc. 33-1) at 44-50. However, Plaintiffs fail to moor their sprawling interpretation to the actual words of the NLEA, which is the touchstone of congressional intent and the basis for determining express preemption. *In re WTC Disaster Site*, 414 F.3d 352, 372 (2d Cir. 2005) ("'If the statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent.'") (citation omitted). They also ignore the presumption against preemption, which applies with special force here. In essence, Plaintiffs ask this Court to hold, as no court ever has, that all food labeling information constitutes part of the food's standard of identity or common or usual name. This would strain the NLEA far beyond its terms: under Plaintiffs' reading, states would be unable to require *any* food labeling beyond what the NLEA already mandates. As explained below, this is not the case. Act 120's disclosure requirement comes nowhere near infringing on federal territory because it does not regulate, much less change, federal requirements regarding food identity and naming.

1. Federal standard of identity provisions do not preempt Act 120's disclosure requirement.

The NLEA preempts state law that (1) establishes a "standard of identity" for a food that is not identical to the federal "standard of identity" for the food, or (2) provides that a food may not be labeled in accordance with its federally defined standard of identity. 21 U.S.C. §§ 343-1(a)(1), 343(g). The federal standards of identity for food products are provided in federal regulations and include standards for fruit pies, canned vegetables, frozen desserts, macaroni, etc. 21 C.F.R. §§ 131-169. Basically, a standard of identity specifies the types and quantities of ingredients in a particular food product. *See id.* § 130.8.

Act 120 does not establish any standard of identity for any food product; nor does it impose any requirement that conflicts with federal identity standards. For example, the federal

"standard of identity" for bread specifies that it shall contain "not less than 62 percent total solids." *Id.* § 136.110(a). "Produced with genetic engineering" does not require that "bread" contain "not less than 12 percent total solids" instead. *See Vt. Pure Holdings, Ltd. v. Nestle Waters N. Am., Inc.*, No. civ.A.03-11465DPW, 2006 WL 839486, at *7 (D. Mass. Mar. 28, 2006) (state law not preempted where plaintiff "d[id] not seek either to challenge or add to the FDA's definition of 'spring water"). Nor does Act 120 require a food that qualifies as "bread" under the federal identity standard to be labeled as something else (e.g., "ketchup"). Thus, under Plaintiffs' example, "enriched corn meal" would still be "enriched corn meal." *See* PI Mem. (Doc. 33-1) at 49.

The two cases that Plaintiffs cite on the standard of identity issue are unpersuasive. *See* PI Mem. (Doc. 33-1) at 44-45, 49-50. In *PepsiCo*, the court found that a state consumer fraud action regarding the source of bottled water was preempted because the federal standard of identity for bottled water specifically exempted "purified water" from disclosing source information. *In re PepsiCo, Inc. Bottled Water Mktg. & Sales Practices Litig.*, 588 F. Supp. 2d 527, 534-39 (S.D.N.Y. 2008). There is no parallel here. Federal identity standards do not exempt any food product from bearing the information "produced with genetic engineering" on its label. Additionally, the court in *PepsiCo* held that "[w]here federal requirements *address* the subject matter that is being challenged through state law claims, such state law claims are preempted to the extent they do not impose identical requirements." *Id.* at 538 n.10 (noting that state law claims could survive preemption where they concern "subject matter that the FDA *has not endeavored to regulate* [such as claims regarding] purified water's ability to clear up the drinker's acne") (emphases added); *see Red v. Kraft Foods, Inc.*, 754 F. Supp. 2d 1137, 1140-41 (C.D. Cal. 2010) (so interpreting *PepsiCo*). Act 120 falls under this category because nothing in

federal identity standards addresses, much less regulates, foods produced with genetic engineering.

The second case Plaintiffs rely on, *Mills v. Giant of Md., LLC*, 441 F. Supp. 2d 104 (D.D.C. 2006), is easily distinguishable and also poorly reasoned. First, the court in *Mills* reviewed a precise identity standard for a particular food—milk. *Id.* at 106-10. Because the identity standard for "milk" specified various labels for various circumstances, a state law action for failure to include an additional milk-specific label was preempted. *Id.* at 108. "Produced with genetic engineering," in contrast, is not a milk-specific label and is not even required for the milk-only products that were at issue in *Mills*. *See* Act 120, Sec. 2, § 3044(1). Second, the *Mills* court ignored the language and structure of the express federal preemption provision, seeming to reason that if there is a standard of identity for a food product, any other state labeling requirement for the food product—whether it has to do with standard of identity or not—is preempted. *See* 441 F. Supp. 2d at 108.

If the reasoning in *Mills* were correct, Congress's decision to list specific labeling categories where state law is preempted would have been utterly unnecessary, because *every* non-identical state labeling requirement would be preempted, regardless of its category. *See* 21 U.S.C. § 343-1(a); *e.g.*, *United States v. Aleynikov*, 676 F.3d 71, 80-81 (2d Cir. 2011) (explaining and applying basis statutory interpretation canon that statutes not be interpreted in way that creates surplusage). Instead, the NLEA is clear that state law is not preempted unless expressly so. Pub. L. No. 101-535, Sec. 6(c)(1) (21 U.S.C. § 343-1 note) (NLEA "shall not be construed to preempt any provision of state law, unless such provision is expressly preempted under Section 403A of the Federal Food, Drug, and Cosmetic Act"). Additionally, the Supreme Court has recently affirmed that only state laws "of the type" in the NLEA's express preemption provision

are preempted. *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2238 (2014) ("It is significant that the complex pre-emption provision distinguishes among different FDCA requirements. It forbids state-law requirements *that are of the type but not identical to only certain FDCA provisions* with respect to food and beverage labeling.") (citing NLEA) (emphasis added).

2. Federal common or usual name provisions do not preempt Act 120's disclosure requirement.

FDA's common or usual name provisions come into play for naming ingredients and, if there is no identity standard for a food product, for naming the food product. *See* 21 U.S.C. § 343(i). For ingredients, FDA's regulations require that ingredients "shall be listed by common or usual name in descending order of predominance." 21 C.F.R. § 101.4(a)(1). For food products, the common or usual name "shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients [and] shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name." *Id.* § 102.5(a). The percentage of a "characterizing" component or ingredient must be included in the common or usual name if the characterizing ingredient or component has a "material bearing on price or consumer acceptance," or if consumers would otherwise believe that the characterizing ingredient or component was present in larger amounts. *Id.* § 102.5(b) (e.g., "contains X percent X"). The common or usual name may derive from common usage or may be specified in the regulations. *Id.* § 102.5(d). As with identity standards, states cannot establish a different requirement for a common or usual name than that already required under federal law. 21 U.S.C. § 343-1(a)(3).

Act 120 does not affect the common or usual names of either food products or ingredients. For instance, it does not require GE corn to be named "Bt corn" instead of "corn," or GE zucchini to be named "grucchini" instead of "zucchini." And, Act 120 does not require a can of soda to bear the name "carbonated soft drink partially produced with genetic engineering," as Plaintiffs suggest. *See* PI Mem. (Doc. 33-1) at 48. Nor does Act 120 require any disclosure of percentages of characterizing ingredients or components, much less with a common name different from a federal common name (e.g., "carbonated soft drink containing X% corn syrup produced with genetic engineering"). Rather, the Act requires a can of soda that has been partially produced with genetic engineering to indicate that fact on "the package." Act 120, Sec. 2, § 3043(b)(3). The common name of the can of soda will remain the same. Plaintiffs' reading of common name requirements would severely frustrate congressional intent, as there would be no need for Congress to list the specific categories of state labeling that are expressly preempted if everything were part of a product's name. *See, e.g.*, *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1123-24 (N.D. Cal. 2010) (state law action regarding use of term "wholesome" on package—which necessarily referred to product—not preempted by NLEA).

Similarly, Act 120 does not require changes to the common or usual names of ingredients in the ingredient list of a product, so Plaintiffs' references to FDA guidance documents do not help them. *See* PI Mem. (Doc 33-1) at 46. First, as explained *infra* Part III.B, guidance documents do not have preemptive effect. Second, even if they did, they would not present a problem. For instance, it is true that FDA's 2001 Draft Guidance advises manufacturers that they may not use optional terms to describe ingredients "in the ingredient list." FDA, DRAFT Guidance for Industry. However, the guidance offers no opinion on state labeling requirements

and, in any case, Act 120 is consistent with the guidance: the Act does not require labels to state information in the ingredient lists (e.g., "corn produced with genetic engineering, sugar produced with genetic engineering"). Further, FDA's 1993 request for data lacks any reference to state labeling requirements or any suggestion that a "produced with genetic engineering" label would change the common or usual name of an ingredient. *See* Food Labeling; Foods Derived from New Plant Varieties, 58 Fed. Reg. 25,837-03 (Apr. 28, 1993); *see also* 1992 Policy Statement, 57 Fed. Reg. at 22,991 (similar). Rather, the guidance simply explained that the agency might require a change to a common or usual name of an ingredient in order to adequately describe the basic nature of the ingredient (e.g., "hydrolyzed soy protein" instead of "hydrolyzed vegetable protein"). *See* 58 Fed. Reg. at 25,838.

Finally, the cases Plaintiffs rely on are unpersuasive. *See* PI Mem. (Doc. 33-1) at 50. First, Plaintiffs use the *Turek* quote out of context: in that case, the label *did* fall under one of the expressly preempted categories for which Congress had expressed a desire for uniformity. *See Turek v. General Mills*, 662 F.3 423, 426-27 (7th Cir. 2011) (state action fell under nutrient labeling category). Here, however, Congress has expressed no such desire for GE foods, either in the NLEA or elsewhere. *See infra* Part III.B. Second, the *Briseno* case hurts Plaintiffs rather than helps them. In that case, the court held that a state lawsuit against ConAgra for using the term "100% natural" on vegetable oils from GE plants was not preempted by the NLEA's common or usual name express preemption provisions. *Briseno v. ConAgra Foods, Inc.*, No. 11-05379, at *8 (C.D. Cal. Nov. 23, 2011) (Exhibit C). The court determined that those preemption provisions were "inapplicable" because the plaintiff did not argue "that ConAgra cannot use the common or usual names of canola oil, vegetable oil or corn oil, or that ConAgra must modify the list of ingredients on its labels." *Id.* Likewise, here: Act 120 does not forbid Plaintiffs from

using the common or usual names of their products, nor mandate that they modify ingredient lists. To the contrary, the Act expressly states the opposite. *See* Act 120, Sec. 2, § 3043(d). *Briseno's* reluctance to impose an order regarding "the manner in which ingredients must be listed on packages" is consistent with the NLEA and poses no difficulty here. *Briseno* at 13 (Exhibit C). Act 120 imposes no requirements regarding "the manner in which ingredients must be listed on packages."

B. Act 120 does not conflict with federal law.

The Court should also reject Plaintiffs' implied "conflict" preemption arguments. Conflict preemption can take two forms: "impossibility" preemption and "obstacle" preemption. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992). As with all preemption analyses, the touchstone of obstacle preemption is Congress's purposes. *Geier v. Am. Honda Motor Co*., 529 U.S. 861, 873 (2000) (state laws must "'stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives *of Congress*'") (emphasis added) (citation omitted). Obstacle preemption does "not justify a 'freewheeling judicial inquiry into whether a state statute is in tension with federal objectives,'" since "'such an endeavor would undercut the principle that it is Congress rather than the courts that preempts state law.'" *Chamber of Commerce of U.S. v. Whiting*, 131 S. Ct. 1968, 1985 (2011) (citation omitted). Rather, the Court's "precedents 'establish that a high threshold must be met if a state law is to be preempted for conflicting with the purposes of a federal Act.'" *Id.* (citation omitted).

1. The Federal Food, Drug, & Cosmetic Act does not impliedly preempt Act 120.

Plaintiffs first claim that it is impossible to comply with both federal labeling law and Act 120 because the Federal Food Drug and Cosmetic Act (FFDCA) prohibits the use of false and misleading labeling, but Act 120 purportedly "conveys an opinion about their products that is

false and misleading." MTD Opp. (Doc. 36) at 24; PI Mem. (Doc. 33-1) at 51. However, as explained, Act 120's disclosure is indisputably factual, not opinion-based; it is not false and misleading, but rather a verifiable, statutorily defined, fact of production. *See supra* Part I.A.1. Plaintiffs next allege that it is impossible to comply with both Act 120 and the FFDCA's labeling requirements for food product names. MTD Opp. (Doc. 36) at 24; PI Mem. (Doc. 33-1) at 53. This argument is similarly baseless, since Act 120 does not require changing the name of any food or ingredient: it only requires additional labeling as to whether a food was produced with genetic engineering. *See supra* Part III.A. Because it is plainly not a "physical impossibility" to comply with both Act 120 and the FFDCA's requirements, Vermont's law is not conflict preempted. *See Fla. Lime & Avocado Growers v. Paul*, 373 U.S. 132, 142-43 (1963).[8]

Plaintiffs next argue that Act 120 is impliedly preempted because it is an alleged obstacle to "nationally uniform food and ingredient" requirements. MTD Opp. (Doc. 36) at 24. Yet this argument is just a reformulation of Plaintiffs' previous express preemption arguments regarding food and ingredient labeling. It should be similarly rejected in the implied preemption context because Act 120 does not require changes to common names or ingredients—an area in which Congress *actually* requires uniform labeling. Further, to the extent that Plaintiffs' implied preemption arguments rest on the NLEA's requirements and objectives, *there can be no implied preemption at all*, as the statute helpfully points out; NLEA preemption is either express or non-existent. *See* Pub. L. No. 101-535, Sec. 6(c)(1); *Holk*, 575 F.3d at 336. Additionally, Congress has not expressed a purpose contrary to the labeling of GE food either in the FFDCA or any other law. If anything, Act 120's objectives resound with those of the FFDCA. *See United*

[8] Plaintiffs themselves cite a 2001 FDA guidance document discussing voluntary labeling, which further demonstrates that companies can comply with federal law and still label GE foods under Act 120. FDA, DRAFT Guidance for Industry.

States v. Bacto-Unidisk, 394 U.S. 784, 798 (1969) ("overriding purpose" to "protect the public health"); 136 Cong. Rec. H5836-01 (July 30, 1990) (Rep. Emerson) ("meeting consumer food information needs").

2. Federal policy on genetic engineering is not law and thus cannot preempt.

Plaintiffs also argue that Act 120 is an obstacle to federal "policy" on genetic engineering. MTD Opp. (Doc. 36) at 24; PI Mem. (Doc. 33-1) at 53-54. In so doing, they rely heavily on the 1986 Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986), claiming that Act 120 creates a purported obstacle to the framework's purposes and execution. Setting aside the belying fact that the *framework does not discuss labeling at all, let alone attempt to preempt states from requiring labeling*, the more fundamental flaw with Plaintiffs' argument is that policy documents like the framework are not laws or regulations, they do not have the force of law and they *cannot* be sources of preemption. *See, e.g., Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 243 (3d Cir. 2008) ("[W]e must reiterate, lest the analysis become unmoored, that it is federal *law* which preempts contrary state law; nothing short of federal law can have that effect.") (emphasis in original). The framework is a nearly thirty-year-old executive branch policy document. *See* 51 Fed. Reg. at 23,302 ("Announcement of [P]olicy"). Contrary to Plaintiffs' descriptions, the framework is not a regulation, and agencies do not regulate "under" it. *See, e.g., Found. on Econ. Trends v. Johnson*, 661 F. Supp. 107, 109 (D.D.C. 1986) ("The Framework and definitions contained therein are set forth to guide policymaking, not to regulate.").[9] The *Holk* case is on-point,

[9] Plaintiffs also cite two FDA guidance documents. *See* PI Mem. (Doc. 33-1) at 52; FDA, DRAFT Guidance for Industry (providing "nonbinding recommendations"); 1992 Policy Statement. Again, their reliance is misplaced, because guidance documents do not have the force of law and hence cannot preempt. *See, e.g., United States v. Mitchell*, 39 F.3d 465, 470 (4th Cir. 1994) ("For regulations to have the force and effect of law they must first be 'substantive' or

rejecting a similar argument in the "natural" label context and holding that FDA's mere policy on "natural" could not preempt state-law claims. *Holk*, 575 F.3d at 340.

In addition to not possibly serving as a source of preemption, agency policies are only even relevant as supplemental indicators of preemptive intent to the extent that they reflect *Congress's* "purposes and objectives." *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000) (referencing importance of congressional intent). The framework, in contrast, is an executive branch document; it was not established pursuant to any congressional purpose or directive, and has nothing to do with Congress's purposes; the framework's "objectives" and "aims" therefore are completely irrelevant for conflict preemption purposes. Plaintiffs struggle to couple existing statutes like the FFDCA to the framework in order to infuse it with preemption relevance, PI Mem. (Doc. 33-1) at 53, but Congress has never enacted a single word about GE foods, in the FFDCA or otherwise, or ever mentioned the framework or its alleged purposes and objectives, or suggested that states are preempted from requiring GE labeling. *P.R. Dep't of Consumer Affairs v. Isla Petroleum Corp*., 485 U.S. 495, 503 (1988) ("There is no federal pre-emption in vacuo, without a constitutional text or a federal statute to assert it."); *Wyeth*, 555 U.S. at 600-01 (Thomas, J., concurring) ("no agency or individual Member of Congress can pre-empt a State's judgment by merely musing about goals or intentions not found within or authorized by the statutory text"). Finally, even FDA does not have specific regulations applying the FFDCA to GE foods. There simply is no federal "law"

'legislative-type' rules, as opposed to 'interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice.'") (citation omitted); *Barnes v. Campbell Soup Co.*, No. C12-05185JSW, 2013 WL 5530017, at *7 (N.D. Cal. July 25, 2013) (deferral of regulatory action through use of "general and unrestrictive policy" not preemptive). Additionally, and as explained *supra*, nothing in these guidance and policy documents conflicts with Vermont's labeling requirement.

regarding labeling of GE foods that could potentially preempt state law, and certainly none expressing the requisite "clear and manifest" congressional intent.

IV. ACT 120 IS VALID UNDER THE COMMERCE CLAUSE

Plaintiffs allege that Act 120 violates the Commerce Clause by either imposing an excessive burden in violation of *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970), or impermissibly regulating commerce occurring solely outside Vermont. *See* MTD Opp. (Doc. 36) at 17. Neither claim is cognizable. First, pursuant to *Pike*, Plaintiffs must show that Act 120's alleged burdens are "clearly excessive" compared to its putative benefits, 397 U.S. at 142, but they fail to demonstrate a legally cognizable burden or even address Act 120's benefits, much less make a plausible argument that any legitimate burden vastly outweighs the law's substantial purposes and benefits. Second, to establish excessive extraterritorial effects, Plaintiffs must demonstrate that Act 120 "'regulates commercial activity that takes place wholly beyond the state's borders.'" *E.g.*, *Town of Southold v. Town of East Hampton*, 477 F.3d 38, 50 (2d Cir. 2007) (citation omitted). However, they fail to offer facts to show that Act 120's requirements so govern commercial activity in other states, or fall exclusively on out-of-state companies.

Plaintiffs cite *Ass'n of International Automobile Manufacturers v. Abrams*, 84 F.3d 602 (2d Cir. 1996), for the proposition that Commerce Clause allegations often raise issues of fact, MTD Opp. (Doc. 36) at 18-19. However, Plaintiffs do not themselves put forth facts creating a triable issue on either a *Pike* violation or impermissible extraterritoriality, so that case in inapposite. To the contrary, where, as here, plaintiffs fail to state viable Commerce Clause claims, courts dismiss those claims. *See, e.g.*, *SPGGC, LLC v. Blumenthal*, 505 F.3d 183, 192-93 (2d Cir. 2007) (dismissing claims where plaintiff "failed to plead facts sufficient to support

either theory"); *accord Automated Salvage Transp., Inc. v. Wheelabrator Envtl. Sys., Inc.*, 155 F.3d 59, 81 (2d Cir. 1998).

A. Plaintiffs fail to allege cognizable burdens from Act 120 that are clearly excessive compared to benefits.

First, the burdens Plaintiffs allege are not legally cognizable under *Pike*, 397 U.S. at 142, but rather are normal, non-discriminatory business compliance costs. *See, e.g.*, Amend. Compl. ¶ 73 (lamenting "the cost of implementing the regulation"). While Act 120 might cause incidental burdens in the form of increased business costs or lost profits for Plaintiffs, those types of alleged burdens are legally insufficient. The dormant Commerce Clause protects "the interstate market, not particular interstate firms" or a firm's "particular structure or methods of operation." *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 127 (1978). Whether implementation costs prompt companies to withdraw from Vermont is irrelevant, as "any regulation may drive some or all producers or distributors from the regulating state." *Nat'l Elec. Mfrs.*, 272 F.3d at 111. In addition, courts recognize that packaging and labeling costs are minimal. *See Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 472 (1981) ("the inconvenience of having to conform to different packaging requirements in Minnesota and the surrounding States should be slight"); *Int'l Dairy Foods Ass'n v. Amestoy*, 898 F. Supp. 246, 252 (D. Vt. 1995), *rev'd on other grounds by* 92 F.3d 67 (holding that rBST labeling law did not violate commerce clause and noting "cost of compliance seems minimal" where law did not prohibit use of rBST or require change to methods of production).

Essentially, an alleged burden must do much more than affect a company's bottomline in order to be cognizable. *See Exxon Corp.*, 437 U.S. at 127-28; *Nat'l Ass'n of Optometrists & Opticans v. Harris*, 682 F.3d 1144, 1154 (9th Cir. 2012) ("We conclude that Supreme Court precedent establishes that there is not a significant burden on interstate commerce merely

because a non-discriminatory regulation precludes a preferred, more profitable method of operating in a retail market."); *Energy & Env't Legal Inst. v. Epel*, No. 11-CV-00859-WJM-BNB, 2014 WL 1874977, at *6 (D. Colo. May 9, 2014) ("The dormant Commerce Clause neither protects the profits of any particular business, nor the right to do business in any particular manner."). Further, the alleged burden of reformulating food products, Amend. Compl. ¶¶ 74, 76, is *not* mandated by Act 120. Rather, reformulation is a voluntary option that Plaintiffs might choose in order to avoid disclosing that their products are produced with genetic engineering; it is not legally cognizable as a burden imposed by the statute.

Second, even if, *arguendo*, Plaintiffs' purported burdens *were* legally cognizable, Plaintiffs have failed to allege facts showing that such burdens could be "clearly excessive," *Pike*, 397 U.S. at 142, as compared to the important benefits Act 120 provides. In fact, Plaintiffs entirely fail to balance Act 120's purported burdens against its benefits, beyond conclusorily stating that the benefits of Act 120 are "non-existent," MTD Opp. (Doc. 36) at 18, and "effectively zero," Amend. Compl. ¶ 77. This is not plausible, because if Plaintiffs *had* tried to balance Act 120's purported burdens against its benefits, they would have been forced to confront that the law promotes critically important state purposes. Act 120, Secs. 1-2; *supra* Act 120: A History & Part I.B.1. For over a century, the Supreme Court has emphasized the importance of allowing states to protect their citizens from deception, particularly in the area of foods. *See Plumley*, 155 U.S. at 472; *Gen. Motors Corp. v. Abrams*, 897 F.2d 34, 41 (2d Cir. 1990) ("consumer protection law is a field traditionally regulated by the states"). And furthering public health and safety are also venerable state interests, as are promoting conservation and environmental protection. *See, e.g.*, *Hughes v. Oklahoma*, 441 U.S. 322, 337 (1979); *Maine*, 477 U.S. at 151 (state retains "broad regulatory authority to protect the health and safety of its

citizens and the integrity of its natural resources"); *Oxygenated Fuels Ass'n, Inc. v. Pataki*, 158 F. Supp. 2d 248, 253 (N.D.N.Y. 2001) ("Regulation and control of matters related to public health and safety are within the police powers of the states.") (citing *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985)). For example, in upholding a cheese labeling requirement under the dormant Commerce Clause, the Second Circuit has validated just these types of interests, including state concerns about nutrition (where the "very existence of the controversy" persuaded the court that the state's concerns were reasonable), preventing deception, promoting honesty, and allowing consumers to discern which products they were buying. *Grocery Mfrs. Ass'n of Am., Inc. v. Gerace*, 755 F.2d 993, 1004 (2d Cir. 1985).

Finally, despite Plaintiffs' request that this Court disregard Vermont's legislative conclusions as unwise or unfounded, *see* MTD Opp. (Doc. 36) at 18, the Commerce Clause does not permit second-guessing of legislative judgments. Rather, states "are not required to convince the courts of the correctness of their legislative judgments," *Clover Leaf Creamery*, 449 U.S. at 464, and courts do not "'second-guess the empirical judgments of lawmakers concerning the utility of legislation.'" *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 92 (1987) (citation omitted). Instead, Plaintiffs must "'convince the court that the legislative facts on which the classification is apparently based could not reasonably be conceived to be true by the governmental decisionmaker.'" *Clover Leaf Creamery*, 449 U.S. at 464 (citation omitted). Plaintiffs do not come close to meeting this burden.

B. Plaintiffs fail to show that Act 120 regulates extraterritorially.

Plaintiffs also have not shown that Act 120 "'regulates commercial activity that takes place wholly beyond the state's borders.'" *Town of Southold*, 477 F.3d at 50 (citation omitted). Act 120 does not mandate that GE foods be labeled outside the state, nor require other states to

adopt reciprocal labeling standards, nor force out-of-state companies to seek regulatory approval in one state before undertaking a transaction in another state. Plaintiffs also misconstrue the meaning of "practical effect." *See* MTD Opp. (Doc. 36) at 18. In the case that Plaintiffs cite on this point, the court held that the state laws in question might have the practical effect of "*control[ling] prices outside of the enacting states*." *Grand River Enters. Six Nations, Ltd., v. Pryor*, 425 F.3d 158, 173 (2005) (emphasis added). Act 120 is not a price-parity statute of the type at issue in *Grand River* and other cases of that line. *See id.* at 170-73. And, in *National Electrical Manufacturers Ass'n*, the Second Circuit held that Vermont's law requiring labeling of mercury-containing lamps did not practically control out-of-state commerce because it did not "inescapably require manufacturers to label all lamps wherever distributed," and "manufacturers could arrange their production and distribution processes to produce labeled lamps solely for the Vermont market." 272 F.3d at 110. As in *National Electrical Manufacturers Ass'n*, Act 120 is "indifferent" to whether foods "sold anywhere else in the United States are labeled or not." *Id.* If manufacturers label GE foods in other states, "it is only because the manufacturers are unwilling to modify their production and distribution systems to differentiate between Vermont-bound and non-Vermont-bound lamps." *Id.*

The Sixth Circuit recently rejected an identical argument in *International Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 647 (6th Cir. 2010). In *Boggs*, food companies argued that an Ohio regulation regulated extraterritorially by forcing them to create a "nationwide label" consistent with Ohio's requirements because of their "complex national distribution channels." *Id.* The Court disagreed:

> [H]ow the Processors label their products in Ohio has no bearing on how they are required to label their products in other states (or vice versa). Nor does compliance with the Ohio Rule raise the possibility that the Processors would be

> in violation of the regulations of another state. . . . The Rule accordingly does not purport to "regulate conduct occurring wholly outside the state."

Id. (quoting *Brown-Forman Distillers Corp. v. N.Y.S. Liquor Auth.*, 476 U.S. 573, 582 (1986).[10]

Finally, Plaintiffs' assertion that Act 120 regulates extraterritorially because "virtually all of Plaintiffs' member companies are based outside Vermont," MTD Opp. (Doc. 36) at 19-20, is unavailing. Plaintiffs cite no case for this proposition, and the Supreme Court has already held that the fact that a law "falls solely on interstate companies" does not mean that it violates the dormant Commerce Clause. *Exxon Corp.*, 437 U.S. at 125 (analyzing impact on interstate companies under discriminatory factor and finding no Commerce Clause violation). Regardless, like out-of-state manufacturers, Vermont manufacturers must label their GE food products under Act 120. Act 120, Sec. 2, § 3043(a)-(b). If Plaintiffs move their companies to Vermont, they will still be subject to the same requirements. And, unlike out-of-state retailers, Vermont retailers are the *only* retailers with obligations to label unpackaged foods. *Id.* Sec. 2, 3043(a), (b)(2). Thus, though Plaintiffs' out-of-state companies are free of this requirement for now, they too must label unpackaged foods if they decide to come to Vermont to set up a corner store. The requirements of Act 120 follow the manufacturer, not the contours of other states, and the Act does not regulate extraterritorially.

CONCLUSION

The interests at the heart of Act 120 are legitimate, substantial, and significant. Acting on behalf of the public it is charged with representing, the State of Vermont determined, based upon

[10] Plaintiffs' allegation regarding conflicting state labeling standards, Amend. Compl. ¶ 78; MTD Opp. (Doc. 36) at 19-20 n.5, is irrelevant, because no other state has a labeling law for genetically engineered food that has gone into effect. *Nat'l Elec. Mfrs.*, 272 F.3d at 112 ("It is not enough to point to a risk of conflicting regulatory regimes in multiple states; there must be an actual conflict between the challenged regulation and those in place in other states."). Further, any "patchwork" concern is remedied by Act 120's provision for accepting out-of-state labels if necessary. Act 120, Sec. 3(2).

a compelling body of evidence, that it is in the best interests of the State and its people to require labels on genetically engineered foods. The purposes of the law are rooted in the public interest—to prevent confusion and deception among consumers in the marketplace, to enable Vermonters to make informed decisions regarding potential health effects and to avoid those potential harms if they choose, to enable Vermonters who are concerned about the negative environmental impacts of genetically engineered foods to choose whether to buy those foods, and to allow persons to practice in conformity with their religious beliefs. Vermonters overwhelmingly support this law, and their interests in the information it provides are profound. For these reasons, a preliminary injunction against Act 120 would not be in the public interest. *See Winter v. Natural Res. Defense Council, Inc.*, 555 U.S. 7, 20 (2008) (preliminary injunction may be granted only if it is "in the public interest"); *Reckitt Benckiser, Inc. v. Motomco Ltd.*, 760 F. Supp. 2d 446, 457 (S.D.N.Y. 2011) ("'public interest is served by preventing consumer confusion or deception' [and] there is certainly public interest in the flow of information") (citation omitted).

Act 120 does not violate the First Amendment, is not preempted by federal law, and does not create an impermissible burden on interstate commerce. The Court should grant the State's Motion to Dismiss and deny Plaintiffs' Motion for a Preliminary Injunction.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2014, I electronically filed with the Clerk of Court the following document:

> Amici Curiae Vermont Public Interest Research Group and Center for Food Safety's Memorandum in Support of Defendants' Motion to Dismiss and in Opposition to Plaintiffs' Motion for a Preliminary Injunction

using the CM/ECF system. The CM/ECF system will provide service of such filing via Notice of Electronic Filing (NEF) to the following NEF parties:

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