

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT**

GROCERY MANUFACTURERS ASSOCIATION,
SNACK FOOD ASSOCIATION, INTERNATIONAL
DAIRY FOODS ASSOCIATION, and NATIONAL
ASSOCIATION OF MANUFACTURERS,

Plaintiffs,

v.

WILLIAM H. SORRELL, in his official capacity as the
Attorney General of Vermont; PETER E. SHUMLIN,
in his official capacity as Governor of Vermont;
TRACY DOLAN, in her official capacity as Acting
Commissioner of the Vermont Department of Health;
and JAMES B. REARDON, in his official capacity as
Commissioner of the Vermont Department of Finance
and Management,

Defendants.

Case No. 5:14-cv-117

**DEFENDANTS' REPLY BRIEF IN SUPPORT OF
THEIR MOTION TO DISMISS AND OPPOSITION TO
PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION**

STATE OF VERMONT

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- Exhibit A: Office of the Attorney General, Draft GE Food Labeling Rule, Oct. 15, 2014
- Exhibit B: Declaration of Dr. Michael Antoniou
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INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs stake out an extreme position, both legally and factually. As a matter of law, they say, Act 120 is not subject to rational-basis review under *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985), or even to intermediate scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). Instead, for a loose amalgam of reasons, Plaintiffs claim that both the GE-disclosure mandate and the prohibition on “natural” advertising warrant an exacting scrutiny that is “strict in theory, but fatal in fact.” *Fisher v. Univ. of Tex. at Austin*, 133 S. Ct. 2411, 2421 (2013) (quoting *Adarand Constructors, Inc. v. Pena*, 515 U.S. 200, 237 (1995)). As a factual matter, Plaintiffs continue, the debate about GE products is over: Vermont had “no basis whatsoever” (P.I. Mem. 6) to be concerned about health and safety issues; GE crops are indisputably “safe” (*id.* at 2); not a single contradictory study deserves scientific respect (*id.* at 6); and Vermont consumers have literally zero valid basis to care – and thus do not need to know – whether they may be purchasing GE foods every day. In short, insist Plaintiffs, Act 120 serves no interest other than to placate a vocal minority that opposes genetic engineering based on idiosyncratic prejudices worthy of climate-change deniers or the Flat Earth Society. *Id.* at 9.

Why do Plaintiffs advance such extreme positions? They do so because, as they well know, a faithful application of the *Zauderer* standard (or, for that matter, the standard of *Central Hudson*) would readily sustain the GE-disclosure mandate. They do so because the “natural” prohibition, especially as clarified by forthcoming regulations, in no way offends settled constitutional principles. Only by ratcheting up the level of scrutiny beyond what commercial speech regulations ordinarily receive can Plaintiffs characterize this as a close case.

Plaintiffs do not only misapply black-letter law. Their approach to Act 120 also requires them to ignore the detailed record before the Vermont Legislature, consisting of testimony from more than one hundred witnesses; dozens of scientific papers addressing the health, environmental, and religious implications of GE crops and technology; and fifty days of hearings and deliberations. Based on that evidence – not speculation or conjecture – the Legislature decided that uncertainty about the long-term impact of GE foods provides a sound basis to require labeling. Plaintiffs ask this Court to overturn that legislative judgment and enjoin the State from requiring manufacturers and retailers to inform Vermont consumers what they are buying and eating. And Plaintiffs seek such extraordinary relief, even though the state action they wish to enjoin will not take place until nearly *two years* from now, by which time this Court will have abundant time to actually reach the merits.

This Court should deny Plaintiffs' request. For the following reasons, as well as those set forth in the State's motion to dismiss, Plaintiffs fail to state a claim on which relief can be granted – much less show that they are entitled to a preliminary injunction.

A. Plaintiffs cloak their challenge to Act 120 in the raiment of the First Amendment, but their argument is threadbare. They argue that Act 120 deserves strict scrutiny simply because there has been public debate surrounding GE foods. But Plaintiffs – whose members have spent tens of millions of dollars challenging labeling initiatives around the country – are not, as they profess, “a politically unpopular group” (Opp. 13; P.I. Mem. 36) being forced to speak about a controversial service or product with which they disagree. They are representatives of some of the largest and most powerful corporations in the world, seeking to promote the sale of Twinkies, Pop Tarts, and Cheetos. They are, in short, commercial enterprises engaged in commercial activities. Act 120 requires them simply to make accurate factual disclosures about the products

they sell to Vermont consumers. Such compelled commercial disclosures are subject to rational-basis review, and Act 120 easily satisfies that standard.

B. Plaintiffs' challenge to Act 120's restriction on "natural" advertising fares no better. Not only are "natural" claims on GE foods inherently misleading, but evidence in the legislative record confirms that such claims actually mislead consumers. Such speech does not warrant First Amendment protection at all. Additionally, the Draft Rule released by the Office of the Vermont Attorney General on October 15, 2014 (Ex. A) clarifies the "natural" restriction, mooting Plaintiffs' vagueness challenge to that provision of the statute.

C. Plaintiffs' express-preemption argument rests on the proposition that any statement on a food product necessarily *changes* the "common or usual name" or "standard of identity" of a product or its ingredients. That sweeping proposition finds no support in the text of any federal statute or regulation. To the contrary, the principal regulatory authority on which Plaintiffs rely – the FDA's 2001 Draft Guidance for Industry – *permits* GE labeling because it does *not* alter the name of a product or its ingredients. Plaintiffs' conflict-preemption arguments are likewise without merit. Plaintiffs contend that Act 120 is preempted because it falsely conveys an "impression" or "legitimate[s]" the belief that GE foods are materially different from traditional foods, contrary to the position that the FDA has taken in non-binding policy statements. But that is not a ground for preemption; the non-binding policy statements that Plaintiffs cite have no preemptive effect; and, in any event, the FDA itself has stated that GE labels are *not* false or misleading.

D. Although their Amended Complaint alleges that Act 120 violates the dormant Commerce Clause, Plaintiffs do not even make a Commerce Clause argument in their motion for a preliminary injunction. And for good reason: The Second Circuit has squarely held that the

exact burdens Plaintiffs allege here – the cost of Vermont-specific labeling and distribution channels – are not burdens at all for purposes of the Commerce Clause. Plaintiffs therefore fail to state a claim under the Commerce Clause.

E. Finally, Plaintiffs cannot establish irreparable harm, and thus are not entitled to a preliminary injunction, irrespective of this Court’s view of the merits. Plaintiffs seek to “enjoin” a law that does not go into effect for nearly two years, by which time a final judgment on the merits is likely. Any preliminary relief will serve only as an advisory opinion, and will do nothing to alleviate the harms alleged by Plaintiffs.

This Court should grant Defendants’ motion to dismiss and deny Plaintiffs’ motion for a preliminary injunction.

BACKGROUND

A. Act 120’s GE-labeling mandate

Although Plaintiffs assert that GE crops do not vary from traditional crops in “any meaningful way,” the Vermont Legislature, after receiving conflicting evidence on the issue, reached a different conclusion. The Legislature found that “[g]enetically engineered foods potentially pose risks to health, safety, agriculture, and the environment.” Act 120, Sec. 1(4). The Legislature was properly concerned with each of those potential risks, and therefore required GE labeling because it “gives consumers information they can use to make decisions about what products they would prefer to purchase.” *Id.* Sec. 1(5)(E).

Genetic engineering is fundamentally different from natural plant breeding. *See* Ex. B, Antoniou Decl. ¶¶ 24-33; Ex. C, Benbrook Decl. ¶¶ 15-23. Indeed, numerous studies have shown that GE crops can have an unexpectedly different composition from their non-GE

counterparts – including differences in allergen levels, isoflavones, fats, proteins, and other nutrients. *See* Antoniou Decl. ¶ 28.

Plaintiffs argue that – differences aside – GE crops are indisputably “safe” and the Legislature had no basis for concluding otherwise. But an increasing number of studies, many of which were before the Legislature, have found that GE crops and associated pesticides may present significant health risks. For example, studies in animals suggest that GE foods may cause multiple organ damage, intestinal abnormalities, immune disturbances, liver and kidney toxicity, unexpected allergenicity, and other toxic effects. *See* Antoniou Decl. ¶¶ 39-47. All told, the Legislature considered dozens of scientific papers about the health risks associated with GE foods. Ex. J (materials considered by Legislature). The materials submitted to the Legislature included, for example, a study showing immune disturbances in mice fed GE corn, Ex. J at 252 & Antoniou Decl. ¶ 40 n.40; a study revealing signs of acute liver aging in mice fed GE soy, Ex. J at 328 & Antoniou Decl. ¶ 40 n.46; at least two surveys of the existing studies regarding the toxicity of GM foods, *see e.g.*, Ex. J at 194 and 207¹; and a 100-plus page examination of the available evidence that has raised red flags about the hazards of GE technology, including its impact on human health, *see* Ex. J at 18.² Those are legitimate studies showing that GE foods can be harmful to human health. *See* Antoniou Decl. ¶ 47.

And the health risks posed by human consumption of GE food are just part of the reason the State enacted Act 120. Studies show that GE foods have led to a massive increase in the use

¹ Artemis Dona, Ioannis S. Arvanitoyannis, *Health Risks of Genetically Modified Foods*, *Critical Reviews in Science and Nutrition*, 49(2): 164-75 (2009); Jose L. Domingo, *Toxicity Studies of Genetically Modified Plants: A Review of the Published Literature*, *Critical Review in Food Science and Nutrition* (2007).

² Michael Antoniou, Claire Robinson, John Fagan, *GMO Myths and Truths: An Evidence-Based Examination of the Claims Made for the Safety and Efficacy of Genetically Modified Crops*, Earth Open Source (June 2012).

of herbicides, the emergence and spread of herbicide-resistant plants and insecticide-resistant insects, the concomitant development of a new-generation of herbicide-resistant plants that are resistant to even more hazardous herbicides, gene flow (i.e., contamination) from GE crops to non-GE crops (with significant economic repercussions), and significant risks to biodiversity. *See* Benbrook Decl. ¶¶ 38-67; Antoniou Decl. ¶¶ 65-79. And once again, the Legislature reviewed studies about these very environmental and economic implications of GE technology and crops. *See, e.g.*, Ex. J at 620 & 673 (studies addressing gene flow),³ at 633 (addressing pesticide use),⁴ and at 753 (addressing risks to biodiversity).⁵

Just as importantly, the Legislature also recognized that the scientific literature lacked “long-term or epidemiologic studies in the United States that examine the safety of human consumption of genetically engineered foods.” Act 120, Sec. 1(2)(E). It heard testimony and reviewed papers addressing the lack of studies and the lack of adequate premarket testing and adequate federal regulation of GE foods. For example, Michael Hansen, Ph.D., Senior Staff Scientist with Consumers Union (who has worked on genetic engineering issues for more than 20 years) testified about the lack of premarket safety testing, the inadequacy of existing FDA regulations, and the general uncertainty in the field. *See* Ex. K at 1-50, Tr. of Hearings Before the H. Comm. on Agric. (Feb. 7, 2013). He provided a written submission summarizing the

³ A. Weiger, A. Pineyro-Nelson, J. Alarcon, A. Galvez-Mariscal, E.R. Alvarez-Buylla, D. Pinero, *Recent Long-Distance Transgene Flow Into Wild Populations Conforms to Historical Patterns of Gene Flow in Cotton (*Gossypium Hirsutum*) at its Centre of Origin*, *Molecular Ecology* (2011); Margaret Mellon, Jane Rissler, *Gone to Seed, Transgenic Contaminants in the Traditional Seed Supply*, Union of Concerned Scientists (2004).

⁴ Charles M. Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use in the U.S. – the First Sixteen Years*, Environmental Sciences Europe (2012).

⁵ John M. Pleasants, Karen S. Oberhauser, *Milkweed Loss in Agricultural Fields Because of Herbicide Use: Effect on the Monarch Butterfly Population*, *Insect Conservation and Diversity* (2012).

regulatory framework and highlighting recent studies showing unintended effects of genetic engineering, such as that GE plant material – including pesticides – is finding its way into the human body. Ex. J at 763;⁶ *see also* Ex. J at 260;⁷ Antoniou Decl. ¶¶ 48-64 (discussing flaws in studies purporting to show the safety of GE foods); Benbrook Decl. ¶¶ 68-74 (same).

The Legislature heard from many other witnesses. Scientists, traditional and organic farmers, manufacturers, consumers, attorneys, regulators, and lobbyists alike provided hours of testimony on *both* sides of the issues: The benefits and risks of GE foods and whether consumers should (or should not) be informed whether a product was made with GE technology or derived from GE crops. By way of example, the Legislature heard from Dave Rogers, Policy Advisory with Northeast Organic Farming Association, who spoke to the need for rigorous testing and the unintended consequences of GE technology, *see* Ex. K at 142-75, Tr. of Hearings Before the S. Comm. on Agric. (Jan. 10, 2014); from Gary Hirshberg, Founder and former CEO of Stonyfield Farm, who highlighted recent studies showing harms associated with increased pesticide and herbicide use, and who explained that the national “Just Label It” campaign is not “anti-GE” but has “concerns about the absence of independent, longer term, third party safety and health testing,” *see* Ex. K at 197-213, Tr. of Hearings Before the S. Comm. on Agric. (Jan. 15, 2014); and from Dr. Martin Donahue, of Oregon Physicians for Social Responsibility, who testified about increased pesticide use and associated health concerns, and who directed the Legislature to various sources for scientific studies, *see* Ex. K at 214-28, Tr. of Hearings Before the S. Comm. on Agric. (Jan. 16, 2014). These are but a few examples.

⁶ Michael Hansen, *Reasons for Labeling of Genetically Engineered Foods* (Mar. 19, 2012).

⁷ William Freese & David Schubert, *Safety Testing & Regulation of Genetically Engineered Foods*, *Biotechnology & Genetic Engineering Reviews* (Nov. 2004).

Plaintiffs nevertheless allege that the State ignored the findings of an “international consensus of scientists and regulators.” Am. Compl. ¶ 54. But the Legislature did not ignore opposing views about the safety or need for labeling of GE products; it considered them. For example, Robert Merker from the FDA testified that the FDA’s testing and regulatory procedures are sufficient to ensure the safety of GE foods. *See generally* Ex. K at 74-101, Tr. of Hearings Before the H. Comm. on Agric. (Feb. 19, 2013). Val Giddings, Senior Fellow at the Information Technology and Innovation Foundation, testified that the current science and regulatory regime raise no safety concerns. *See* Ex. K at 69, Tr. of Hearings Before the H. Comm. on Agric. (Feb. 15, 2013). And Karin Moore, Vice President and General Counsel, GMA, testified that the FDA and other scientific bodies have found no difference in the safety of foods produced with GE technology. *See* Ex. K at 134, Tr. of Hearings Before the H. Comm. on Judiciary (May 6, 2013).

The Legislature also considered written materials and testimony about how consumers’ religious beliefs may inform their decision to purchase GE foods. For example, the Legislature heard from Rabbi Elihu Gervitz, who explained that food labeling is important to the Jewish community in light of dietary restrictions that prohibit commingling, and that labeling of GE products will allow observant members of that community to avoid foods that may have been altered using genes from non-kosher sources. Ex. K at 231-34, Tr. of Hearings Before the H. Comm. on Agric. (Apr. 16, 2014). The Legislature also considered an article finding religion to be a factor that affects whether consumers purchase GE foods, and discussing how members of each of the three main monotheistic religions – Judaism, Christianity, and Islam – choose not to eat genetically engineered food for religious reasons. Ex. J at 776.⁸ Indeed, the question

⁸ Emmanuel B. Omobowale, Peter A. Singer, Abdallah S. Daar, *The Three Main Monotheistic Religions and GM Food Technology: An Overview of Perspectives*, BMC International Health and Human Rights (2009).

whether to consume genetically engineered food poses ethical challenges to constituents of numerous religious groups. *See* Ex. D, Brunk Decl. ¶¶ 15-16. And the Legislature considered statements from many such groups when considering Act 120. *See* Ex. J at 784-95.⁹

Significantly, the Legislature also heard evidence showing consumer confusion about the prominence of GE foods, including two national surveys showing that Americans are generally unaware that many of the products sold in supermarkets today have been genetically engineered. *See* Ex. J at 796, Allison Kopicki, *Strong Support for Labeling Modified Foods*, New York Times (July 27, 2013) (fewer than half those polled knew that many foods sold at supermarkets had been genetically engineered); Ex. J at 799, Thomson Reuters, *National Survey of Healthcare Consumers: Genetically Engineered Food* (Oct. 2010) (only 69.2% knew that food available in stores had been genetically engineered, and only 51.3% of those earning less than \$25,000 per year had such knowledge).

Based on this wealth of testimony and scientific material, the Legislature might have banned GE foods altogether from Vermont, or severely restricted sales – but it did not. Conversely, the Legislature also did not conclude – as Plaintiffs insist it should have – that there is *no* basis for concern about the proliferation of GE foods. Although the Legislature did not “unearth incontrovertible proof that GE food is dangerous,” it “did come to the conclusion that there is enough uncertainty about the health and environmental consequences to grant Vermonters the right to make educated decisions when buying food.” *See* Ex. K at 130, Tr. of Hearings Before the H. Comm. on Judiciary (Statement of Representative Teo Zagar) (Apr. 18,

⁹ *Faith and GMOs: Christian, Jewish, and Hindu Congregations Urged to Vote Yes on 37*, Faith & GMOs, <http://www.faithandgmos.org/> (last visited Jan. 31, 2013); *Christian Faith Leaders, GMOs, and Prop 37/Food Labeling*, Faith & GMOs, <http://faithandgmos.org/content/christians-gmos-andprop-37food-labeling> (last visited Feb. 4, 2013); *Unitarian Universalist Association (UUA) of Congregations, Ethical Eating: Food and Environmental Justice – 2011 Statement of Conscience*.

2013); *see also* Ex. K at 103, Tr. of Hearings Before the H. Comm. on Agric. (Feb. 21, 2013) (Statement of Representative Kristina Michelsen) (“[T]he whole essence of what we have been hearing is that lack of consensus on the safety.”); Ex. K at 141, Tr. of Hearings Before the H. Comm. on Commerce and Econ. Dev. (May 8, 2013) (Statement of Representative Teo Zagar) (“[F]or multiple health, personal, cultural, religious, environmental and economic reasons, the State finds that GE foods should be labeled.”). That is what Act 120 accomplishes.

Plaintiffs ignore the lack of long-term studies and the conflicting scientific evidence presented to the Legislature. They suggest that the evidence confirming the safety of genetic engineering is “on par with that supporting climate change,” P.I. Mem. 9, and maintain that an absolute scientific consensus exists. They say that the Court should credit the views of “[p]restigious professional organizations” and the “editorial boards of prestigious American newspapers” that agree with them that mandatory labeling is unwarranted. P.I. Mem. 9. But not only is their claim about scientific consensus refuted by materials in the legislative record,¹⁰ surveys show that more than 90% of Americans – and the vast majority of Vermonters – support the mandatory labeling of GE foods. Ex. J at 796 (NY Times poll); Act 120, Sec. 1(5)(A). More than 60 countries around the world currently require GE labeling. Antoniou Decl. ¶ 24. Maine and Connecticut have passed GMO labeling laws (albeit laws that will not go into effect until certain conditions are triggered).¹¹ Vermont is not alone in deciding – based on overwhelming support – that a mandatory labeling regime is justified, and Plaintiffs’ assertion that the State is merely catering to outliers whose support for labeling stems from “irrational, baseless fears” (Am. Compl. ¶ 54) rings hollow.

¹⁰ *See, e.g.*, Ex I at 219 (European Network of Scientists for Social & Environmental Responsibility, *No Scientific Consensus on GMO Safety* (Oct. 21, 2013)).

¹¹ *See* 22 Me. Rev. Stat. tit. 22, Ch. 565, §§ 2591-2596 (2013); Conn. Pub. Act No. 13-183 (2013).

B. Act 120's ban on natural advertising for GE foods

Act 120 also restricts the ability of manufacturers and retailers to label GE foods “natural.” The Legislature’s decision to include that restriction was based on evidence that such advertising is deceptive. For example, the Legislature considered a summary of a 2010 survey conducted by The Hartman Group that showed that 61% of consumers believed that “natural” suggests the absence of genetically engineered food. Ex. J at 804;¹² Ex. E, Kolodinsky Decl. ¶ 9; *see also id.* ¶ 26 (results from 2013 Vermonter Poll “confirm that ‘natural’ labels on genetically engineered foods would be misleading to Vermont citizens in particular”). The Legislature also considered a 2012 Hartman Group report that concluded that the word “natural” on food products has become increasingly meaningful to consumers because they desire foods that are “less processed” with “clean ingredient lists” and “fresh, real foods,” characteristics decidedly not associated with GE foods. Ex. J at 806.¹³ And recent consumer surveys confirm the Legislature’s conclusion that consumers are, in fact, misled by “natural” advertising on GE foods. Kolodinsky Decl. ¶¶ 8-27.

C. The Attorney General’s draft rule

Plaintiffs insist that this Court should rule on the constitutionality of Act 120 immediately. But, as contemplated by the statute, the Office of the Attorney General is currently engaged in rulemaking to clarify the reach of the statute. As part of that process, the Attorney General released a preliminary draft rule for public comment on October 15, 2014 (“Draft Rule”). Ex. A. The Draft Rule addresses many of the aspects of Act 120 that Plaintiffs

¹² Cornucopia Institute, *Cereal Crimes: How “Natural” Claims Deceive Consumers and Undermine the Organic Label – A Look Down the Cereal & Granola Aisle* (Oct. 2011) (citing 2010 Hartman Group Poll).

¹³ Hartman Group, *Organic & Natural 2012* (2012).

challenge.¹⁴ For example, it makes clear that the definition of GE in the statute “does not encompass a change of genetic material through the application of traditional breeding techniques, conjugation, fermentation, traditional hybridization, in vitro fertilization, or tissue culture.” *Id.* § 1.6. It also makes clear that the animal products exemption, Sec. 2, § 3044(1), applies not just to foods “consisting entirely of or derived entirely from an animal that is itself not produced with genetic engineering,” but also “[p]ackaged, processed food containing meat or poultry, the label of which requires approval by the [USDA] under 21 U.S.C. §§ 451-472, 601-695, or the state equivalent, under 6 V.S.A. §§ 3301-3318.” Draft Rule § 3.1.

The Draft Rule further clarifies the scope of Act 120’s restriction on advertising GE foods as “‘natural,’ ‘naturally made,’ ‘naturally grown,’ ‘all natural,’ or any words of similar import that would have a tendency to mislead a consumer,’” Act 120, Sec. 2, § 3043(c). It limits “words of similar import” to “nature, natural, or naturally.” Draft Rule § 1.12. It restricts the use of these words in advertising only “(1) in advertising at or in the retail premises, (2) on signs identifying the product at the point of display in the retail premises, or (3) on the label of the food.” *Id.* § 2.3.1. It provides that the restriction “does not apply to a food’s trade, brand, or product name, or any information contained in the Nutrition Facts Label or Ingredient List required by the [FDA].” *Id.* And it confirms that Act 120 does not limit manufacturers or retailers from disclaiming on its packaging or signs that the FDA “does not consider food produced with genetic engineering to be materially different from other foods.” *Id.* § 2.3.2.

¹⁴ “Administrative interpretation and implementation of a regulation are, of course, highly relevant to our analysis, for in evaluating a facial challenge to a state law, a federal court must . . . consider any limiting construction that a state court or enforcement agency has proffered.” *Ward v. Rock Against Racism*, 491 U.S. 781, 795-96 (1989) (quotations omitted).

D. The proceedings in this case

Plaintiffs filed their initial Complaint on June 12, 2014 (Doc. 1), more than two years before Act 120 takes effect on July 1, 2016. Defendants filed a motion to dismiss the Complaint on August 8, 2014. Doc. 24 (referred to here as “MTD”).

Plaintiffs responded with several filings. First, they filed a motion for leave to file an Amended Complaint. Doc. 37.¹⁵ Second, they filed an opposition to Defendants’ motion to dismiss. Doc. 36 (referred to here as “Opp.”). Third, they filed a motion for a preliminary injunction, seeking to enjoin the enforcement of Act 120, even though it does not go into effect for nearly two years. Doc. 33 (referred to here as “P.I. Mem.”). Finally, Plaintiffs filed a request for judicial notice of various materials, including excerpts from the Legislature’s hearings on Act 120. Doc. 40 (Sept. 12, 2014).¹⁶

After a hearing on September 19, 2014, *see* Doc. 45, the parties filed a stipulated joint motion for a scheduling order, Doc. 50, which this Court issued on October 6, 2014, Doc. 51. Consistent with the Scheduling Order, this brief serves as (1) a reply in support of Defendants’ motion to dismiss and (2) an opposition to Plaintiffs’ motion for a preliminary injunction.

¹⁵ The State does not object to Plaintiffs’ motion to file an Amended Complaint. *See* Defendants’ Response to Plaintiffs’ Motion for Leave to File an Amended Complaint. As discussed below, however, Plaintiffs’ Amended Complaint – just like their original Complaint – fails to state a claim on which relief can be granted.

¹⁶ The State does not object to Plaintiffs’ request that this Court take judicial notice of legislative materials and public documents. *See* Defendants’ Request for Judicial Notice and Response to Plaintiffs’ Request for Judicial Notice. However, Plaintiffs’ request for judicial notice does not go far enough: They seek to have this Court take judicial notice of legislative hearing transcripts, on the one hand, while arguing on the other that this Court cannot take judicial notice of the numerous studies that were presented to the Legislature (*see* Opp. 9 n.3). The legislative record in this case consists of both hearing transcripts and documents presented to the Legislature, both of which can be considered by this Court on the State’s motion to dismiss and the Plaintiffs’ motion for a preliminary injunction. MTD 4 n.3.

ARGUMENT

As the State explained in its opening brief, Plaintiffs fail to state a claim on which relief can be granted. Their Amended Complaint, which does nothing to remedy the defects in their initial Complaint, should therefore be dismissed in its entirety.

This Court should also deny Plaintiffs' motion for a preliminary injunction. To obtain a preliminary injunction, a plaintiff "must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Because Plaintiffs have failed even to state a claim, they plainly have not shown that they are likely to succeed on the merits. Nor have Plaintiffs shown that they will suffer any irreparable harm, given that Act 120 does not go into effect until July 1, 2016, which is likely to be long after any final judgment from this Court.

I. PLAINTIFFS HAVE FAILED TO STATE A CLAIM THAT THE GE-DISCLOSURE REQUIREMENT VIOLATES THE FIRST AMENDMENT, AND ARE NOT LIKELY TO SUCCEED ON THE MERITS OF THAT CLAIM.

A. Act 120's GE disclosure requirement is not subject to strict scrutiny.

Only two months ago, the Second Circuit reiterated that the regulation of commercial speech is *not* subject to strict scrutiny. *Safelite Grp., Inc. v. Jepsen*, 764 F.3d 258, 261 (2d Cir. 2014);¹⁷ *see Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 623 (1995) ("We have always been careful to distinguish commercial speech from speech at the First Amendment's core."); *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 65 (1983) ("[T]he degree of protection afforded by the First Amendment depends on whether the activity sought to be regulated constitutes

¹⁷ *See Conn. Bar Ass'n v. United States*, 620 F.3d 81, 93 n.15 (2d Cir. 2010) ("[W]e are bound by precedent distinguishing commercial and noncommercial speech and applying different standards of review to laws mandating commercial speech disclosures and laws restricting commercial speech.").

commercial or non-commercial speech.”). The Second Circuit further confirmed that, within the rubric of commercial speech generally, “disclosure requirements about a company’s own products or services” – precisely what Act 120 calls for – are subject to rational-basis review under *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985). *Safelite*, 764 F.3d at 264.¹⁸ Plaintiffs offer a litany of reasons to ratchet up the level of scrutiny, but each is meritless.

1. Act 120 compels commercial – not political – speech.

Plaintiffs’ first pass – that Act 120 compels “political speech” (Opp. 8; *see also* P.I. Mem. 19) – borders on frivolous. Product labels are commercial speech in its most basic form: “part of a firm’s marketing plan to provide certain information to the consumer.” *Adolph Coors Co. v. Brady*, 944 F.2d 1543, 1546 (10th Cir. 1991). Through labels, manufacturers convey information that “relate[s] solely to the economic interests of the speaker and its audience,” *Conn. Bar Ass’n*, 620 F.3d at 94 (quoting *Central Hudson*, 447 U.S. at 561), and “do no more than propose a commercial transaction,” *Anderson v. Treadwell*, 294 F.3d 453, 460 (2d Cir. 2002) (quoting *Bolger*, 463 U.S. at 60). Plaintiffs’ declarants make that very point. *See* Adams Decl. ¶ 10 (“Product packaging and labeling is one of the ways [Coke] communicates with its

¹⁸ Plaintiffs hint throughout their papers that the *Zauderer* test and commercial speech doctrine have been eroded. But the Supreme Court has not overruled the well-settled framework established by *Central Hudson* and *Zauderer* – as evidenced by the Second Circuit’s recent application of that very framework in *Safelite*. The cases on which Plaintiffs rely do not alter that conclusion. In *Sorrell v. IMS Health Inc.* (P.I. Mem. 20), for example, the Court applied *Central Hudson* to evaluate a law restricting speech even though it was content-based, 131 S. Ct. 2653, 2667-68 (2011); *see Fleming, Inc. v. U.S. Dept. of Health & Human Servs.*, 854 F. Supp. 2d 192, 197 (D. Conn. 2012) (*IMS Health* “did not impact the traditional framework for evaluating commercial speech under the First Amendment”). And in *Milavetz, Gallop & Milavetz, P.A. v. United States* (P.I. Mem. 30; Opp. 12), the Court simply reaffirmed that *Zauderer* applies to disclosures directed at misleading speech – it did not purport to *limit* the *Zauderer* test to that context. 559 U.S. 229, 249 (2010). Finally, *Harris v. Quinn* (P.I. Mem. 20) was not a commercial speech case (made clear by the absence of any discussion of *Central Hudson*, *Zauderer*, or *IMS Health*). 134 S. Ct. 2618, 2639 (2014).

consumers”); Baxter Decl. ¶ 7 (same for Pepsi); Bradley Decl. ¶ 9 (same for General Mills); Hermansky Decl. ¶ 10 (same for Conagra). The Second Circuit treated speech on product labels as commercial in *National Electric Manufacturers Association v. Sorrell* (“NEMA”), 272 F.3d 104 (2d Cir. 2001). So did the D.C. Circuit in *American Meat Institute v. USDA*, 760 F.3d 18 (D.C. Cir. 2014).

Plaintiffs’ reliance on *Evergreen Association, Inc. v. City of New York* – a *political* speech case – is misplaced. In that case, pro-life centers that offered free pregnancy-related services to discourage abortions challenged an ordinance requiring them to disclose that they did not offer abortions. 801 F. Supp. 2d 197, 202 (S.D.N.Y. 2011), *aff’d in part, vacated in part*, 740 F.3d 233 (2d Cir. 2014). The district court held that the law did not regulate commercial speech because “the offer of free services such as pregnancy tests in furtherance of a religious belief does not propose a commercial transaction,” and the centers offered services *not* “in furtherance of their economic interests,” but as “charitable work . . . grounded in their opposition to abortion and emergency contraception.” *Id.* at 205. On appeal, the Second Circuit did not decide whether the law regulated commercial speech, finding the law unconstitutional under any standard and noting that the regulation “alter[ed] the centers’ *political speech* by mandating the manner in which the discussion of [abortion] issues [with potential clients] begins.” 740 F.3d at 249 (emphasis added). Whereas the ordinance in *Evergreen* operated in a political setting – forcing pro-life advocates to speak about services they fundamentally oppose and do *not* provide; Act 120 operates in a commercial setting – requiring sellers of food to convey on a product label an uncontroverted fact about a product they offer to consumers.

2. Act 120 is not a content-based or content-discriminatory regulation.

Relying on *Riley v. National Federation of the Blind of North Carolina, Inc.*, 487 U.S. 781 (1988), Plaintiffs next seek strict scrutiny on the ground that the GE-disclosure requirement is somehow content-based. But in *Riley*, the Court held that a regulation compelling commercial speech that was “inextricably intertwined” with *charitable* speech – which enjoys full First Amendment protection – was subject to strict scrutiny. *Id.* at 796. Along the way, however, the Court reiterated that purely commercial speech “is more susceptible to compelled disclosure requirements.” *Id.* at 796 n.9. Not surprisingly, courts have consistently declined to read *Riley* as mandating strict scrutiny for compelled commercial speech. *N.Y. State Rest. Ass’n v. N.Y.C. Bd. of Health* (“*NYSRA*”), 556 F.3d 114, 132 (2d Cir. 2009) (distinguishing *Riley*); *Conn. Bar Ass’n*, 620 F.3d at 94 (same); *Beeman v. Anthem Prescription Mgmt., LLC*, 315 P.3d 71, 86 (Cal. 2013) (same). For good reason: Plaintiffs’ interpretation of *Riley* would subject *thousands* of routine commercial disclosure requirements, including all standard federal nutrition labels, to strict scrutiny as content-based regulations. That is plainly not the law, and would gut the holding of *Zauderer*.¹⁹ Moreover, the Supreme Court has confirmed that, even outside the commercial speech context, compelled speech regulations do not automatically warrant strict scrutiny, but only where they compel speech “bearing a particular message.” *Turner Broad.*

¹⁹ *NEMA*, 272 F.3d at 116. (“Innumerable federal and state regulatory programs require the disclosure of product and other commercial information,” and subjecting them to “searching scrutiny” would be “neither wise nor constitutionally required”); *Pharm. Care Mgmt. Ass’n v. Rowe*, 429 F.3d 294, 316 (1st Cir. 2005) (“The idea that . . . thousands of routine regulations require an extensive First Amendment analysis is mistaken.”); see Jennifer M. Keighley, *Can You Handle the Truth? Compelled Commercial Speech and the First Amendment*, 15 U. Pa. J. Const. L. 539, 563-64 (2012) (discussing the “wide variety of disclosures policies” that “would be subject to searching judicial review” if *Zauderer* were deemed inapplicable).

Sys., Inc. v. FCC, 512 U.S. 622, 642 (1994).²⁰ By merely requiring an informational disclosure, Act 120 does no such thing.

Plaintiffs also contend that Act 120 discriminates by content in practice because it burdens only manufacturers of GE foods, not manufacturers of non-GE foods. P.I. Mem. 17. The plaintiffs in *NYSRA* similarly tried to invoke heightened scrutiny, claiming that New York’s calorie disclosure rule forced only a “targeted group of private restaurant[s]” – large national chains – to post calories. Appellant Brief, *NYSRA*, 556 F.3d 114, 2008 WL 6513103, at *40-41. The Second Circuit applied *Zauderer*, rejecting precisely the argument that plaintiffs make here. 556 F.3d at 133.

3. Act 120 does not discriminate by viewpoint.

Tweaking just slightly their “content-based” contention, Plaintiffs next assert that Act 120 is “viewpoint-based” – an attempt to “tilt public debate” about genetic engineering “in a preferred direction.” P.I. Mem. 17-18. Not so. Act 120 simply recognizes risks associated with certain foods, and evenhandedly requires *all* manufacturers selling those foods in Vermont (exemptions aside)²¹ to label them, “without reference to the ideas or views” held by a particular manufacturer or consumer about genetic engineering. *Turner*, 512 U.S. at 643. Manufacturers and consumers of GE and non-GE foods alike can speak publicly about the benefits or risks of

²⁰ *Turner* was not a commercial speech case, and thus the Court’s finding that the law at issue was content-neutral led it to apply the intermediate scrutiny standard applicable to content-neutral restrictions that pose incidental burdens on speech. 512 U.S. at 662.

²¹ Plaintiffs argue that Act 120 discriminates by viewpoint in “practical operation” because it requires only manufacturers who “knowingly or intentionally” genetically engineer foods to label them. But the exemptions for foods produced “without the knowing or intentional use” of GE material (Act 120, Sec. 2, §§ 3044(2), (6)) merely protect manufacturers and retailers who inadvertently violate Act 120 by failing to label food they thought was produced without genetic engineering. That has nothing to do with anyone’s viewpoint. *See Hill v. Colorado*, 530 U.S. 703, 722-25 (2000) (finding a law content- and viewpoint-neutral despite a “knowing” requirement that protected speakers from inadvertently violating statute).

genetic engineering; Act 120 does not purport to regulate that speech. And the mere fact that there is public debate about the wisdom of genetic engineering does not confer protected status to what is otherwise garden-variety commercial speech. *Bolger*, 463 U.S. at 68; *Central Hudson*, 447 U.S. at 562 n.5; *Conn. Bar Ass’n*, 620 F.3d at 95. “[W]hether a disclosure is scrutinized under *Zauderer* turns on whether the disclosure conveys factual information or an opinion, not on whether the disclosure emotionally affects its audience or incites controversy.” *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 569 (6th Cir. 2012).²² “Facts can disconcert, displease, provoke an emotional response, spark controversy, and even overwhelm reason, but that does not magically turn such facts into opinions.” *Id.*; see *Safelite*, 764 F.3d at 263-64 (*Zauderer* applies to fact disclosures about a product).²³

Moreover, the text of the required labels is not “advocacy” (P.I. Mem. 21), nor does it require any manufacturer or retailer to validate a point of view. *Compare Pac. Gas & Elec. Co v. Public Utils. Comm. of Cal.* (“*PG&E*”), 475 U.S. 1, 13-15 (1986) (P.I. Mem. 18) (invalidating law that required utility companies that sent political mailings to reserve space for third-parties to express opposing views); *Hurley v. Irish-Am. Gay, Lesbian and Bisexual Grp. of Boston*, 515

²² The cases cited in footnote 13 of Plaintiffs’ preliminary injunction brief, in addition to having been overruled by *American Meat*, all involved disclosures that were *themselves* controversial, not just related to purportedly “controversial” subject matters. See, e.g., *Nat’l Ass’n of Mfrs. v. SEC*, 748 F.3d 359, 371 (D.C. Cir. 2014) (“The label ‘conflict free’ is a metaphor that conveys moral responsibility for the Congo war.”); *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205, 1216-17 (D.C. Cir. 2012) (“Images of a woman crying, a small child, and the man wearing a T-shirt emblazoned with the words I QUIT . . . are unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting [smoking].”). See MTD 12 & n.8.

²³ Plaintiffs misconstrue the Ninth Circuit’s decision in *CTIA-The Wireless Ass’n v. City & Cnty. of S.F.*, 494 F. App’x 752 (9th Cir. 2012), when they suggest that the required disclosures were held “controversial” based solely on the existence of a “debate” in the scientific community about the health effects of cell phone usage. Opp. 8; P.I. Mem. 32. As the Court of Appeals explained, the ordinance required the disclosure of “more than just facts,” and indeed included “San Francisco’s recommendations as to what consumers should do if they want to reduce exposure to radiofrequency energy emissions.” *CTIA*, 494 F. App’x at 753.

U.S. 557, 574-76 (1995) (P.I. Mem. 17) (parade organizer could not be compelled to permit gay rights group to march because participation would likely be viewed as organizer's endorsement of group's message); *Harris v. Quinn*, 134 S. Ct. 2618, 2639 (2014) (P.I. Mem. 20) (home-care assistants could not be forced to contribute dues to a union who advocated for views the assistants did not support). Cases like these involved speakers forced to carry or associate with "the messages of third parties, where *the messages themselves* are biased against or are expressly contrary to the corporation's views.'" *Am. Meat*, 760 F.3d at 27 (quoting *PG&E*, 475 U.S. at 15-16 n.12) (emphasis added); see *Beeman*, 315 P.3d at 83-84 (distinguishing *PG&E*, *Hurley*, and similar cases). Act 120's required disclosure expresses no view about genetic engineering, nor would a consumer reasonably believe otherwise, especially because Act 120 permits Plaintiffs to add a disclaimer expressing their own, or the FDA's, views, a fact that Plaintiffs wholly fail to address in their papers. Draft Rule § 2.3.2; MTD 13.

* * *

"In resolving disputes, [courts] should follow the case which directly controls." *Clear Channel Outdoor, Inc. v. City of New York*, 594 F.3d 94, 108 (2d Cir. 2012). Here, those cases are *Zauderer*, *NEMA*, and *NYSRA*. Plaintiffs cannot escape those cases by trying to convert a routine informational disclosure law into one about controversial beliefs and superstitions. The plaintiffs in *NYSRA* tried the same tactic, arguing that heightened scrutiny should apply because New York's calorie-posting law "force[d] restaurant owners to espouse a controversial view about whether their customers should be required to look at calorie counts before buying a meal." Appellant Brief, *NYSRA*, 556 F.3d 114, 2008 WL 6513103, at *48. The Second Circuit rejected that argument outright and applied *Zauderer*. *NYSRA*, 556 F.3d at 134. This Court should too.

B. Under the *Zauderer* rational-basis standard, the compelled disclosure provision is plainly constitutional.

Zauderer establishes that “an informational disclosure law . . . [is] subject to *rational review*, that is, a determination of whether the required disclosure is reasonably related to the state’s interest.” *Safelite*, 764 F.3d at 262 (emphasis added). Plaintiffs doubtless realize that Act 120 satisfies that standard, so they insist that “rational review” does not actually mean “rational review,” and that *Zauderer* imports the “substantial interest” requirement of *Central Hudson*’s intermediate-scrutiny test. Opp. 9-12; P.I. Mem. 33-35. But they cite no case in which a court has reached that conclusion.²⁴ Worse yet, Plaintiffs ask this Court to disregard settled Second Circuit precedent,²⁵ not to mention cases from three other circuits,²⁶ holding that informational disclosure laws are subject to rational-basis review. They premise that curious request on the Second Circuit’s use of the term “substantial” to describe the interests at stake in *NEMA* and *NYSRA*. Opp. 11; P.I. Mem. 34. But that passing description was scarcely a holding *requiring* a substantial interest, or establishing, as Plaintiffs contend, that the Second Circuit was somehow

²⁴ In *American Meat*, the D.C. Circuit declined to decide what level of interest was required under *Zauderer* because “the government’s interest in country-of-origin labeling for food” was a “substantial” one. 760 F.3d at 23. And *Ysursa v. Pocatello Education Ass’n*, 555 U.S. 353 (2009), and *City of Los Angeles v. Preferred Communications, Inc.*, 476 U.S. 488 (1986), which Plaintiffs cite (P.I. Mem. 30), do not even discuss *Zauderer*, let alone the First Amendment test for commercial speech disclosures.

²⁵ See MTD 9-16; *Safelite*, 764 F.3d at 263-64; *Conn. Bar Ass’n*, 620 F.3d 81 at 95-96.

²⁶ *King v. Governor of New Jersey*, 767 F.3d 216, 236 (3d Cir. 2014) (“In the context of commercial speech, the Supreme Court has treated compelled disclosures of truthful factual information differently than prohibitions of speech, subjecting the former to rational basis review and the latter to intermediate scrutiny.”); *Pharm. Care Mgmt. Ass’n*, 429 F.3d at 316 (“This is a test akin to the general rational-basis test governing all government regulations under the Due Process Clause.”); *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1212 (describing *Zauderer* as “akin to rational-basis review”), *overruled on other grounds by Am. Meat*, 760 F.3d at 23 n.1.

“errant” (Opp. 10) in characterizing the governing standard as “rational basis review.”²⁷

Plaintiffs denigrate Act 120 as a mere sop to “consumer curiosity” – and thus invalid even under rational-basis review under *International Dairy Foods Association v. Amestoy* (“*IDFA*”), 92 F.3d 67 (2d Cir. 1996) (a case decided not under *Zauderer*, but under *Central Hudson*, see MTD 26-27) – because the State itself supposedly has not taken a position on the risks of GE foods. P.I. Mem. 24. But Vermont *has* taken a position: The legislative findings declare *the State’s* determination that there is no consensus about the validity of the research and science surrounding GE foods, Act 120, Sec. 1(2)(D), and that “[g]enetically engineered foods potentially pose risks to health, safety, agriculture, and the environment,” *id.* Sec. 1(4). Each of those findings suffices to uphold the labeling requirement under *Zauderer*.

Plaintiffs maintain that those findings are “false.” Opp. 9 & n.3. But legislative findings “on essentially factual issues . . . are of course entitled to a great deal of deference, inasmuch as [the legislature] is an institution better equipped to amass and evaluate the vast amounts of data bearing on such an issue.” *Walters v. Nat’l Ass’n of Radiation Survivors*, 473 U.S. 305, 330 n.12, 335 (1985) (citing cases); *Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 195 (1997) (Courts “must accord substantial deference” to legislative judgments). Legislatures are tasked with weighing conflicting evidence presented during the legislative process, and the Court’s “sole obligation is to assure that, in formulating its judgments, [the legislature] has drawn reasonable inferences based on substantial evidence.” *Turner*, 520 U.S. at 195.

Here, the Legislature reasonably relied on a wealth of scientific studies and testimony. In that regard, this case is unlike *IDFA*, where an “extensive record . . . contain[ed] *no scientific evidence* from which an objective observer could conclude that rBST has any impact at all on

²⁷ The State has by no means conceded that its interests here are not “substantial” (Opp. 12), assuming any such standard applies. As explained in Section I(C), *infra*, they plainly are.

dairy products.” 92 F.3d at 73 (emphasis added). No doubt Plaintiffs have many scientists on their side, each of whom may well believe that genetic engineering carries no more risk than other food production methods. Perhaps, in the fullness of time, Plaintiffs’ scientists will be proved right. But the Legislature found, based on dozens of studies and articles and weeks of testimony, that the current state of the science is uncertain; that reasonable minds differ on this issue; and that there are legitimate reasons for consumers to avoid genetically engineered foods. Plaintiffs’ insistence that there is *no* evidence supporting Act 120 is simply inaccurate, especially in light of the Legislature’s careful consideration of the evidence before it.

Indeed, while Plaintiffs focus their attention on the risks associated with human consumption, they mention only in passing the State’s equally legitimate interests in protecting against the *environmental* risks of GE technology and crops. In particular, Plaintiffs ignore studies showing that the increased use of genetically engineered plants has led to a dramatic increase in herbicide use; the emergence and spread of herbicide-resistant weeds; gene flow from GE crops to non-GE crops, contaminating conventional or organic crops (often with devastating effects on commerce and international trade); alterations in soil microbial communities; and reductions in biodiversity. *See* Benbrook Decl. ¶¶ 24-67; Antoniou Decl. ¶¶ 65-79.

In the single paragraph Plaintiffs devote to that state interest (P.I. Mem. 26), they simply ask the Court to deem the environmental implications of GE technology and crops speculative – and to again disregard numerous studies, *see* Ex. J at 612-762, and witness statements considered by the Legislature on this issue, *see* Ex. K at 142-75, 214-28. And they assert that any environmental concerns are outweighed by the numerous benefits of genetically engineered crops. But the Legislature is entitled to weigh that balance differently, and, more importantly, to require that manufacturers label their products so that consumers can make that choice for

themselves. Just as New York City was justified in passing a disclosure law “to promote informed consumer decision-making” about restaurant foods that might lead to obesity, *NYSRA*, 556 F.3d at 134, so too is Vermont justified in promoting informed consumer decision-making about whether to purchase products that might negatively impact the environment and organic crops.

Plaintiffs likewise dismiss the other purposes of Act 120 (prevention of consumer confusion and accommodation of religious beliefs), addressing them in but a single sentence. P.I. Mem. 27. But the question whether to consume GE foods poses ethical challenges to members of numerous religious groups to which Vermont citizens belong. Brunk Decl. ¶¶ 15-16, 19. And contrary to Plaintiffs’ assertion, facilitating dietary choices based on those religious beliefs is a legitimate state interest. *See Cutter v. Wilkinson*, 544 U.S. 709, 713 (2005) (“This Court has long recognized that the government may . . . accommodate religious practices” (quotation omitted)). So too is remedying consumer confusion. *Zauderer*, 471 U.S. at 651. Plaintiffs argue that the confusion at issue here “is nothing more than the *absence* of information.” P.I. Mem. 27. But all informational disclosure laws start from a place of “absence of information,” because a lack of information can confuse just as readily as inaccurate information. Indeed, *Zauderer* itself involved a regulation compelling attorneys to disclose potential costs because the absence of that information deceived consumers. 471 U.S. at 651.

Any one of these state interests would be sufficient. Even were this Court to conclude (as Plaintiffs urge) that GE foods pose no human health risks, Act 120 is reasonably related to such other state interests as preventing consumer confusion about what is in their foods, protecting against environmental risks, and accommodating the religious beliefs of Vermont citizens. Nor is it true that Act 120 irrationally discriminates against a “politically unpopular group.” Opp. 13;

P.I. Mem. 36. It comes with ill grace for these plaintiffs to don the mantle (P.I. Mem. 35-36) of *U.S. Department of Agriculture v. Moreno*, 413 U.S. 528, 533 (1973), which accords more searching rational-basis review for laws subjecting minorities to disparate treatment. Plaintiffs, after all, represent the “world’s largest beverage company” (Coca-Cola) (Adams Decl. ¶ 6), a “global food company” (General Mills) (Bradley Decl. ¶ 5), “one of North America’s largest packaged food companies” (ConAgra Foods, Inc.) (Hermansky Decl. ¶ 4), Kraft Foods, a company whose “products are found in 98% of US households,” (Morgan Decl. ¶ 1), and large food manufacturers such as Monsanto that have spent tens of millions of dollars opposing labeling laws throughout the country.²⁸ They are not exactly “discrete and insular minorities.” *United States v. Carolene Prods. Co.*, 304 U.S. 144, 152 n.4 (1938).

C. The disclosure requirement satisfies intermediate scrutiny under *Central Hudson*.

If the Court nevertheless determines that *Zauderer* does not apply, Act 120 easily meets the intermediate-scrutiny test under *Central Hudson*. See *Safelite*, 764 F.3d at 264-65 (applying *Central Hudson* to compelled speech regulation where *Zauderer* did not govern).²⁹

The State’s interests are plainly “substantial”: The Legislature reasonably concluded that a mandatory labeling law would inform consumers about the prevalence of GE material in food

²⁸ Annie Gasparro and Jacob Bunge, *Food Industry Wins Round in GMO-Labeling Fight*, Wall Street Journal (Nov. 5, 2014), available at <http://online.wsj.com/articles/colorado-voters-defeat-proposal-to-require-gmo-labeling-of-foods-1415206857>; Julie Jargon and Ian Berry, *Dough Rolls Out To Fight ‘Engineered’ Label on Food*, Wall Street Journal (Oct. 25, 2012), available at <http://online.wsj.com/articles/SB10001424052970203400604578073182907123760>.

²⁹ The Court can determine at the motion to dismiss stage that Act 120 satisfies *Central Hudson*. See *Anheuser-Busch, Inc. v. Schmoke*, 63 F.3d 1305, 1313 (4th Cir. 1995) (affirming dismissal of Complaint under *Central Hudson* based on studies in legislative record), *vacated on other grounds*, 517 U.S. 1206 (1996), *readopted*, 101 F.3d 325, 327 (4th Cir. 1996), *cert. denied*, 520 U.S. 1204 (1997).

products and encourage informed purchasing choices.³⁰ With ample record support, the State found that the potential health and environmental risks of GE technology, crops, and resulting food products are real, and that the lack of long-term or epidemiological studies confirming the safety of GE foods is a basis for concern and, accordingly, for more transparency in labeling. Act 120, Sec. 1(2)(E), (4). These legislative judgments were based not on “mere speculation or conjecture,” *Edenfield v. Fane*, 507 U.S. 761, 770 (1993), but on a plethora of studies and testimony. *See Fla. Bar*, 515 U.S. at 620 (substantial state interest demonstrated by study in legislative record that included surveys, reports, and public testimony).

The disclosure mandate also “directly advances” the State’s objective of promoting informed consumer choice based on those concerns. *Metromedia Inc. v. City of San Diego*, 453 U.S. 490, 507 (1981). Indeed, it is hard to imagine a way to achieve the State’s interests *more* directly than by requiring disclosure to consumers, who can thereby make informed purchasing choices. That is doubtless why “many such mandates have persisted for decades without anyone questioning their constitutionality.” *Am. Meat*, 760 F.3d at 26.

Finally, where “the government acts only through a reasonably crafted mandate” that, as here, does not burden or chill more commercial speech than is necessary, “the means-end fit is self-evidently satisfied.” *Id.* Indeed, the Supreme Court has repeatedly described disclosure requirements as a “less restrictive” alternative to suppression of speech. *Citizens United v. FEC*, 558 U.S. 310, 369 (2010); *Zauderer*, 471 U.S. at 651.

Plaintiffs nevertheless contend that Act 120 fails to satisfy *Central Hudson*. First, they argue that the Act does not “directly advance” the State’s interests because Act 120’s definition

³⁰ Studies before the Legislature demonstrated that GE labeling facilitates consumer purchasing decisions. *See, e.g.*, Ex. J at 799 (*Reuters Poll*) (only 60% of consumers would be willing to eat GE vegetables, fruits, and grains).

of “genetic engineering” misleadingly refers to a “process by which food is produced,” rather than a method of growing plants. P.I. Mem. 28. But, as explained below, there is nothing wrong or misleading about Act 120’s definition: A food made from plants produced with genetic engineering is itself produced, at least in part, with genetic engineering. And the very FDA policy statement that Plaintiffs repeatedly cite authorizes labels stating that a food was “*produced* using biotechnology.” 2001 Draft Guidance for Industry (emphasis added).³¹

Plaintiffs also claim that the “partially produced” and “may be produced” labels are uninformative (P.I. Mem. 28),³² – but certainly Vermonters can understand what it means that a product was “partially” or “may” have been produced with genetic engineering, much the same way that consumers with peanut allergies can understand what it means that a product “may” have been produced with peanuts. Plaintiffs offer no explanation why consumers would not be assisted by Act 120’s labels.

Second, Plaintiffs describe Act 120 as a “moth-eaten” (P.I. Mem. 28) regulation, defeated by its exemptions. The premise of this argument is flawed: A “statute is not invalid under the Constitution because it might have gone farther than it did,” and it is well-recognized that legislative “reform may take one step at a time.” *Jana-Rock Constr., Inc. v. N.Y. State Dep’t of Econ. Dev.*, 438 F.3d 195, 211 (2d Cir. 2006). Further, a regulation does not run afoul of *Central Hudson* simply because it contains exemptions (as most laws do), but only where it “draws arbitrary distinctions” or where no “logical connection” exists between the overall regulatory scheme and the State’s interests. *Clear Channel*, 594 F.3d at 106-08. Here, the exemptions

³¹ U.S. Food and Drug Administration, Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, (2001) <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm059098.htm>.

³² Plaintiffs complain (P.I. Mem. 28) that Act 120 does not specify when the “partially” and “may be” produced qualifiers may be used, but the Draft Rule clarifies that issue (at § 2.2.2).

make perfect sense and do not render Act 120 insubstantial. Certain of the exemptions (animal products, processing aids, alcohol, and medical food, Act 120, Sec. 2, §§ 3044(1), (3)-(4), (8)) reflect the State’s attempt to avoid the very preemption challenges asserted by Plaintiffs and to ensure that Act 120 complements – rather than conflicts with – existing federal labeling regulations.³³ The restaurant exemption (*id.* at § 3044(7)) takes into account the impracticability of requiring labeling in the restaurant environment (the Nutrition Labeling and Education Act similarly exempts certain restaurants from its mandatory nutritional labeling regime, 21 C.F.R. § 101.9(j)(2)). The *de minimis* exemption (*id.* at § 3044(5)) reflects the State’s effort to achieve national and global consistency where possible; the 0.9% threshold requirement is based on the standards set by other countries and states, and thus allows for consistent labeling (and may help avoid the type of patchwork legislation Plaintiffs protest). And the purpose of the limited “knowingly or intentionally” exemptions (*id.* at §§ 3044(2), (6)) is to avoid penalizing traditional farmers (and the manufacturers they supply) whose crops were, unbeknownst to them, contaminated by gene flow from GE-crops.³⁴ *See* Benbrook Decl. ¶¶ 51-59. Act 120 directly advances the State’s interests by requiring labeling on the vast majority of foods sold in grocery stores, and the well-reasoned exemptions do not render it unconstitutional.

Third, Plaintiffs argue that Act 120 fails the “reasonable fit” prong because the State did not have an adequate justification for rejecting less restrictive alternatives, such as a voluntary labeling system. P.I. Mem. 29. But the State considered that alternative, and had reasons for

³³ These exemptions also reflect the Legislature’s recognition that there may be a difference between the direct human consumption of GE plant material and indirect human consumption of a food product derived from an animal that was fed GE plant material, or made with a GE processing aid that does not ultimately remain in the final product. Ex. K at 145.

³⁴ *See* Ex. K at 192-95, Tr. of Hearings Before the S. Comm. on Agric. (Jan. 9, 2014) (discussing exemptions) at 108-17, Tr. of Hearings Before the H. Comm. on Agric. (Feb. 27, 2013) (same), and at 143-45, Tr. of Hearings Before the H. Comm. on Commerce and Econ. Dev. (May 8, 2013) (same).

rejecting it. It heard testimony that a voluntary labeling would “leave most of the grocery store in the dark for consumers,” Ex. K at 181, Tr. of Hearings Before the S. Comm. on Agric. (Jan. 10, 2014) (testimony of Dan Barlow, public policy manager with Vermont Businesses for Social Responsibility), and that it is far easier to test whether a product contains GE material than to test to ensure that a product is GE-free, Ex. K at 57-59, Tr. of Hearings Before the H. Comm. on Agric. (Feb. 13, 2013) (testimony of Andrea Stander, Executive Director of the community farming group Rural Vermont). Plaintiffs also contend that the State should have undertaken a campaign to inform consumers about the proliferation of GE foods. P.I Mem 29. But such a campaign would not inform consumers whether a *particular* food at the grocery store contains GE materials. Only product manufacturers know and can provide that information. *See Evergreen*, 740 F.3d at 250 (advertising campaign was a viable alternative where – unlike here – the intended message did “not require knowledge of discrete information available only to individual [manufacturers]”). The Legislature is entitled to deference on its decision, after careful consideration of these alternatives, that a factual, mandatory product label – itself a minor and not “substantially excessive” burden on speech, *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 479 (1989) – fit the State’s interests underlying Act 120.

II. PLAINTIFFS HAVE FAILED TO STATE A CLAIM THAT ACT 120’S PROHIBITION ON THE USE OF “NATURAL” VIOLATES THE FIRST AMENDMENT, AND ARE NOT LIKELY TO SUCCEED ON THE MERITS OF THAT CLAIM.³⁵

Speech that is “inherently” or “actually” misleading does not enjoy First Amendment protection and can be banned outright. *Peel v. Att’y Registration & Disciplinary Comm’n of Ill.*,

³⁵ The Amended Complaint remedies Plaintiffs’ failure to allege standing to challenge the restrictions on “natural” advertising. Am. Compl. ¶ 59. But notably, and not surprisingly, in the numerous declarations submitted by Plaintiffs, none of their members is willing to identify any specific products that contain GE ingredients but are which nevertheless (mis)labeled as “natural.”

496 U.S. 91, 111 (1990) (Marshall, J., concurring). When used to advertise GE foods, the word “natural” and terms like it are inherently misleading and may be forbidden without violating the Constitution.³⁶ MTD 18-19; *see* Antoniou Decl. ¶ 23 (genetic engineering “results in the creation of particular combinations of genes that would not otherwise occur in nature”); Benbrook Decl. ¶¶ 15-23. Plaintiffs contend that, because Act 120 contains certain reasonable exceptions, the word “natural” on the remaining GE products cannot be inherently misleading. Opp. 15. It is hard to see why that is so. Even if Act 120 does not resolve *all* possible confusion, it remains constitutional for Act 120 to regulate misleading commercial speech as much as it does. *See, e.g., Jana-Rock Constr.*, 438 F.3d at 211-12. And, even though a small number of GE products are exempted, the word “natural” remains misleading when used to advertise what Plaintiffs concede to be “[t]he vast majority of foods sold in grocery stores in the United States today.” Am. Comp. ¶ 23. By prohibiting “natural” advertising for those GE foods, Act 120 reduces the degree of misleading claims.

“Natural” advertising on GE foods is also “actually” misleading. *Joe Conte Toyota, Inc. v. La. Motor Vehicle Comm’n*, 24 F.3d 754, 756 (5th Cir. 1994) (“commercial speech is ‘actually’ misleading when there is evidence of deception”). Although Plaintiffs insist that there is no evidence of deception in the legislative record (P.I. Mem. 38), they are mistaken. The Legislature considered surveys showing that consumers have, in fact, been deceived by “natural” advertising on GE foods, *see* Background, Section II, *supra*, and recent surveys confirm the Legislature’s finding that such “natural” claims are misleading. Kolodinsky Decl. ¶¶ 8-27. This record of consumer deception suffices to remove “natural” advertising from the protections of

³⁶ Plaintiffs’ attempts to characterize this as a regulation that discriminates by viewpoint (P.I. Mem. 36-37) fail for the same reasons set forth Section I(A) as to the disclosure requirement. This is a regulation of misleading commercial speech that has nothing to do with anyone’s “political beliefs” or views about genetic engineering.

the First Amendment, *see Bronco Wine Co. v. Jolly*, 29 Cal. Rptr. 3d 462, 476 (Ct. App. 2005) (deeming speech on wine labels misleading under *Central Hudson* based on survey in legislative history); *Milavetz*, 559 U.S. at 251 (evidence in congressional record sufficient to establish deception).³⁷

Plaintiffs argue that “natural” advertising is, at worst, only *potentially* misleading, and thus Act 120’s restriction on that speech is subject to *Central Hudson*’s balancing test. Even if that were true, Plaintiffs’ challenge should be dismissed. There can be no doubt that the State has a substantial interest in preventing misleading advertising, *Edenfield*, 507 U.S. at 769 (state has a substantial interest “in ensuring the accuracy of commercial information in the marketplace”), or that the risk of deception is “real” here in light of the evidence before the Legislature of consumer deception. Plaintiffs contend that the regulation is insufficiently narrowly-tailored because it covers “*all forms of advertising,*” trademarks, and words of “similar import” to natural. P.I. Mem. 39-40. But the Draft Rule released by the State on October 15, 2014, obviates those concerns. It limits “words of similar import” to “nature, natural, or naturally.” Draft Rule § 1.12. It restricts the use of those words only on (a) GE product labels; and (b) advertisements and signs at retail premises in Vermont. *Id.* § 2.3.1. And it makes clear that the “natural” advertising restrictions do not apply to trade, brand, or product names. *Id.* Under this rule, the natural restriction is “proportional to the labeling requirement” (P.I. Mem. 40) –

³⁷ Based on the evidence of deception in the legislative record, of which the Court can take judicial notice, MTD 3 n.4, the Court can determine at the motion to dismiss stage that the “natural” ban regulates not just “inherently” but “actually” misleading speech. The cases cited by Plaintiffs (P.I. Mem. 38) do not compel a different conclusion. In *Alexander v. Cahill*, the court expressly found that defendants, unlike here, “failed to provide evidence that consumers have, in fact, been misled” by the regulated speech. 598 F.3d 79, 95 (2d Cir. 2010). And in *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, NYSLA conceded that it was not regulating misleading speech. 134 F.3d 87, 98 (2d Cir. 1998).

specifically tailored to advertising on packaging and displays that consumers see when making purchasing decisions.

III. PLAINTIFFS FAIL TO STATE A CLAIM THAT ACT 120’S RESTRICTION ON “NATURAL” ADVERTISING IS UNCONSTITUTIONALLY VAGUE, AND ARE NOT LIKELY TO SUCCEED ON THE MERITS OF THAT CLAIM.

Plaintiffs challenge Act 120’s limits on the use of “natural” as facially vague, but they can prevail on a facial vagueness challenge only by showing that Act 120’s restriction on natural advertising is vague in all its applications. *Vt. Right to Life Comm., Inc. v. Sorrell*, 758 F.3d 118, 128 (2d Cir. 2014).³⁸ They do not argue that the natural restriction meets that standard, but instead conjure up “entirely hypothetical” labels, *Holder v. Humanitarian Law Project*, 561 U.S. 1, 25 (2010), that might fall within the reach of the statutory text. P.I. Mem. 41. But “speculation about possible vagueness in hypothetical situations not before the Court will not support a facial attack on a statute” where, as here, it is clear what the statute as a whole prohibits. *Hill v. Colorado*, 530 U.S. 703, 733 (2000); *see Nat’l Ass’n of Mfrs. v. Taylor*, 549 F. Supp. 2d 33, 62 (D.D.C. 2008) (rejecting facial vagueness challenge that rested on possible vagueness in hypothetical situation).

That principle is of particular importance here, where the State is still fine tuning Act 120 through the very rulemaking that the statute requires. Federal courts “must . . . consider any limiting construction that a state court or enforcement agency has proffered,” and cannot “hold a vague statute unconstitutional if a reasonable interpretation by a state court could render it

³⁸ Plaintiffs suggest that the facial nature of their claims has no bearing on their pleading obligations. Opp. 5. But courts routinely dismiss facial vagueness claims where the allegations do not meet the standard for a facial challenge. *See, e.g., Ctr. for Individual Freedom v. Madigan*, 697 F.3d 464 (7th Cir. 2012); *Wag More Dogs Ltd. Liab. Corp. v. Cozart*, 680 F.3d 359, 371 (4th Cir. 2012); *Am. Ass’n of People with Disabilities v. Herrera*, CIV 08-0702, 2010 WL 3834049 (D.N.M. July 28, 2010); *Gaughan v. City of Cleveland, Ohio*, 05-180, 2005 WL 3216269 (N.D. Ohio Nov. 29, 2005), *aff’d*, 212 F. App’x 405 (6th Cir. 2007).

constitutional in some application.” *Gresham v. Peterson*, 225 F.3d 899, 907-08 (7th Cir. 2000). Here, the Draft Rule limits “words of similar import” (the very phrase Plaintiffs challenge as unconstitutionally vague) to “nature, natural, and naturally.” Draft Rule § 1.12.³⁹ And it specifies precisely what forms of advertisement are restricted. *Id.* § 2.3.1. The “limiting construction” offered by the State addresses the precise vagueness concerns raised by Plaintiffs and confirms that this provision of Act 120 can – and will – be applied constitutionally within this core meaning.⁴⁰ Thus, Plaintiffs’ facial vagueness challenge fails as a matter of law.

³⁹ This portion of the Draft Rule also resolves Plaintiffs’ vagueness challenge (P.I. Mem. 42) to the phrase “tendency to mislead.” Even so, that phrase is not unconstitutionally vague because, in Plaintiffs’ own words, it “makes references to a standard developed and accepted in actual practice.” P.I. Mem. 42; see *Tiffany (NJ) Inc. v. eBay Inc.*, 600 F.3d 93, 112-13 (2d Cir. 2010) (showing that “tendency to mislead” is a developed standard in Lanham Act false advertising cases). Whether an advertisement satisfies the “tendency to mislead” standard is the type of question courts “pass [upon] every day.” *United States v. Williams*, 553 U.S. 285, 306 (2008). Moreover, although an advertisement’s “tendency to mislead” may turn on evidence of consumer perception, see *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 40-42 (D.C. Cir. 1985), liability under Act 120 does not arbitrarily turn – as Plaintiffs suggest – on a particular consumer’s reaction to an advertisement. *Compare Stahl v. City of St. Louis, Mo.*, 687 F.3d 1038, 1041 (8th Cir. 2012) (cited at P.I. Mem. 42) (law criminalizing only speech that had “the consequence of obstructing traffic” did not provide “people with fair notice of when their actions are likely to become unlawful”); *Coates v. City of Cincinnati*, 402 U.S. 611, 611-12, 614 (1971) (cited at P.I. Mem. 43) (ordinance prohibiting conduct that was “annoying to persons passing by” provided no standard because lawfulness depended entirely “upon whether or not a policeman is annoyed”).

⁴⁰ Plaintiffs assert that the restriction on natural advertising threatens to chill hypothetical, protected speech “across all forms of communications media.” Opp. 16; see P.I. Mem. 41-42. That assertion is also foreclosed by the Draft Rule and really is an overbreadth, not a vagueness, challenge. *Holder*, 561 U.S. at 19-20. The Supreme Court has squarely held that the overbreadth doctrine has no place in the commercial speech arena. *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 496-97 (1982); see also *United States v. Krikheli*, 08-CR-528, 2009 WL 4110306, at *4 (E.D.N.Y. Nov. 24, 2009) (“restraint on free speech – the evil which the overbreadth doctrine was designed to combat – is less likely where the expression is linked to ‘commercial well-being’ and therefore . . . not as easily deterred”). Thus, to the extent Plaintiffs’ facial vagueness challenge rests on allegations that a substantial amount of speech will be chilled, it fails as a matter of law. *Farrell v. Burke*, 449 F.3d 470 (2d Cir. 2006); *United States v. Taleb-Jedi*, 566 F. Supp. 2d 157, 183-84 (E.D.N.Y. 2008) (rejecting facial vagueness challenge). Moreover, in the commercial speech context, a statute need not be as precise as in noncommercial speech cases, *Vill. of Hoffman Estates*, 455 U.S. at 498, and

IV. PLAINTIFFS FAIL TO STATE A CLAIM UNDER THE SUPREMACY CLAUSE, AND ARE NOT LIKELY TO SUCCEED ON THE MERITS OF THAT CLAIM.

Plaintiffs have abandoned any claim that the “natural” restriction is preempted by federal law. Opp. 21 n.7. And rightly so: Courts have consistently held that state-law restrictions on the use of “natural” – including on foods made with genetic engineering – are not preempted by the Federal Food, Drug, and Cosmetic Act (“FDCA”). See MTD 34-36. Plaintiffs apparently recognize as much. But as the State made clear in its opening brief, Plaintiffs also fail to state a claim that Act 120’s GE-labeling requirement is preempted. Indeed, that claim fails for the same reasons that their “natural” claim fails.

A. Act 120’s GE-disclosure requirement is not expressly preempted by the Nutrition Labeling and Education Act (“NLEA”).

Plaintiffs contend that Act 120’s GE-disclosure requirement is expressly preempted by the NLEA. They offer two theories of express preemption. First, they assert that Act 120 is preempted because it imposes “ingredient labeling” requirements that are not identical to those required by the FDCA. Opp. 21; P.I. Mem. 45-47. Second, they contend that Act 120 is preempted because it imposes “product labeling” requirements that are not identical to those required by the FDCA. Opp. 21-22; P.I. Mem. 47-50.

Both arguments rest on a single fallacious premise: that the addition of a GE label “effectively” changes the name of the food product or its ingredients. P.I. Mem. 49. That argument finds no support in the text of the NLEA or FDA regulations. To the contrary, the only regulatory authority that Plaintiffs cite – the FDA’s non-binding guidance on GE labeling – states that a GE label does *not* alter the name of a food or its ingredients. Plaintiffs therefore fail to state a claim of express preemption under the NLEA.

Plaintiffs’ assertion that Act 120 should have been drafted with “narrow specificity” (P.I. Mem. 41) is likewise misplaced.

1. Act 120 does not impose requirements for “ingredient” labeling at all, and thus does not run afoul of 21 U.S.C. § 343(i)(2).

Section 343(i)(2) of the FDCA provides that a food without a federal standard of identity shall be deemed to be misbranded “[u]nless its label bears, . . . in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient.” 21 U.S.C. § 343(i).

Section 343-1(a)(2) of the NLEA, in turn, provides that states may not establish “any requirement for the labeling of food of the type required by section . . . 343(i)(2)” that is “not identical” to the requirements of that section. Plaintiffs contend that Act 120 is expressly preempted by section 343-1(a)(2) because it “is a state law requirement for ingredient disclosure ‘not identical’ to the requirements” for multi-ingredient foods set forth in section 343(i)(2). Opp. 21; *see also* P.I. Mem. 45.

Plaintiffs misread the statute. The FDCA requires manufacturers to list a food’s ingredients in the familiar information panel located on the side or back of food packages. What section 343(i)(2) says is that the list of ingredients on a multi-ingredient food product cannot use anything other than the “common or usual name” for each ingredient. Otherwise, the food will be deemed misbranded. Thus, the ingredient list for a box of breakfast cereal must state something along the following lines: “INGREDIENTS: oats, enriched flour (wheat flour, malted barley flour, niacin), leavening (baking soda and calcium carbonate), sugar, almonds, vegetable oil (canola or sunflower oil).” *See* 21 C.F.R. § 101.4. The ingredient list cannot call sugar “sucrose,” it cannot call almonds “*Prunus dulcis* seeds,” and it cannot place any intervening material between “sugar” and “almonds” in the ingredient list.⁴¹ Further, by operation of section 343-1(a)(2)’s express-preemption clause, a state cannot pass a law requiring manufacturers to

⁴¹ *See* FDA, Guidance of Industry: A Food Labeling Guide (Jan. 2013), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064880.htm>.

use the term “sucrose” instead of the common name “sugar” in the ingredient list, because such a law would impose an ingredient-labeling requirement contrary to section 343(i)(2)’s “common or usual name” requirement.

But that is not what Act 120 does. Act 120 does not require any ingredient to be called anything other than its common or usual name. It just requires a statement, elsewhere on the food “package,” that the food was “produced with genetic engineering.” Act 120, § 3043(b)(1). That is not an “ingredient” requirement at all, and is therefore not preempted by section 343-1(a)(2).

Plaintiffs’ only theory of preemption is therefore that the statement that a food was “produced with genetic engineering” changes the common or usual name of each ingredient listed in the ingredient statement. Imagine, for example, a label that describes a food product as “king size,” “fair trade,” or “from Canada.” According to Plaintiffs, those descriptions would all render the food misbranded (and thus be preempted, if required by state law) because they change the common or usual name of each ingredient to “fair-trade oats,” “king-size almonds,” or “Canadian flour.” In other words, *any* description on a food label implicitly modifies the names of the food’s ingredients and is therefore expressly preempted. Plaintiffs provide no support for such a far-reaching theory of preemption.

To the contrary, the principal authority Plaintiffs cite (P.I. Mem. 46) – the FDA’s 2001 draft guidance regarding voluntary labeling of GE foods – expressly *rejects* Plaintiffs’ theory.⁴²

The 2001 guidance states:

FDA reminds manufacturers that the optional terms that describe an ingredient of a multi-ingredient food as bioengineered should not be used *in the ingredient list* of the multi-ingredient food. Section [343](i)(2) of

⁴² Plaintiffs’ opposition to Defendants’ motion to dismiss does not cite a single case or regulatory authority in support of its cursory “ingredient labeling” argument. *See* Opp. 21.

the act requires each ingredient to be declared in the ingredient statement by its common or usual name. Thus, any terms not part of the name of the ingredient are not permitted in the ingredient statement. In addition, 21 CFR 101.2(e) requires that the ingredient list and certain other mandatory information appear in one place without other intervening material. FDA has long interpreted any optional description of ingredients in the ingredient statement to be intervening material that violates this regulation.

2001 Draft Guidance for Industry (emphasis added).⁴³

As the guidance makes clear, section 343(i)(2) forbids manufacturers from adding the term “genetically engineered” – or any other optional description of ingredients – “*in the ingredient list.*” 2001 Draft Guidance for Industry (emphasis added). But that does not mean that food cannot be labeled as genetically engineered elsewhere on the food packaging. To the contrary, the same guidance specifically states that manufacturers may label their food products as “[g]enetically engineered” or containing “cornmeal that was produced using biotechnology.” 2001 Draft Guidance for Industry.

Plaintiffs therefore draw exactly the wrong conclusion from the FDA’s guidance. That guidance shows that such labels, so long as they are not used as intervening material “in the ingredient list,” do *not* run afoul of section 343(i)(2)’s “common or usual name” requirement for ingredients. And Act 120 does not require manufacturers to change the common or usual name of any ingredient in a food’s ingredient list. Rather, it requires an *additional statement*, outside the ingredient list, that the food was produced with genetic engineering. That additional statement does nothing to alter the “common or usual” name of any ingredient listed.⁴⁴

⁴³ U.S. Food and Drug Administration, Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (2001), <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm059098.htm>.

⁴⁴ Plaintiffs muddy the waters by arguing that the FDA has “framed the question whether food labels *must* disclose the presence of such ingredients as one that falls under the

Plaintiffs nevertheless complain (P.I. Mem. 46) that Act 120 cannot be “saved” by the provision that it “shall not be construed to require: (1) the listing or identification of any ingredient or ingredients that were genetically engineered; or (2) the placement of the term ‘genetically engineered’ immediately preceding any common name or primary product descriptor of a food.” Act 120, § 3043(d). Plaintiffs miss the point of that provision. That provision is not, as Plaintiffs assume, a bare assertion that “Act 120 is not preempted.” Rather, it is an instruction that manufacturers should *not* use (and are *not* required to use) the term “genetically engineered” as intervening material in the ingredient list – consistent with section 343(i)(2) and the FDA’s guidance.

Briseno v. ConAgra Foods, Inc., No. 11-5379 (C.D. Cal. Nov. 23, 2011), the unpublished decision Plaintiffs cite in their motion for a preliminary injunction (P.I. Mem. 50), is therefore inapposite. In that case, the plaintiff sought an order requiring a manufacturer to change the manner in which it listed genetically engineered *ingredients*. The court stated that such an ingredient-listing requirement would violate section 343(i)(2), which, as discussed above, requires manufacturers to list ingredients according to their “common or usual name.” *Id.*, Doc. 54, at *13 (citing 21 U.S.C. § 343(i)(2)). But as noted, Act 120 does not require that specific ingredients in a food’s ingredient list use the term “genetically engineered”; indeed, it instructs manufacturers *not* to use the term “genetically engineered” in the ingredient list.

identification requirements of Section 343(i).” P.I. Mem. 46 (emphasis added). But the question whether the “common or usual name” provision *requires* manufacturers to disclose the presence of ingredients produced with genetic engineering says nothing about Plaintiffs’ theory here, which is that a GE label outside a food’s list of ingredients somehow changes the common or usual name of the food’s ingredients such that the food would be misbranded. None of the authorities Plaintiffs cite remotely supports that argument.

2. Act 120 does not impose requirements for “product” labeling at all, and thus does not run afoul of 21 U.S.C. §§ 343(g) and 343(i)(1).

Plaintiffs’ “product labeling” theory of preemption relies on two other FDCA misbranding provisions. First, Plaintiffs cite 21 U.S.C. § 343(g), which provides that a food that is subject to a federal standard of identity shall be deemed misbranded “unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard.” *See* P.I. Mem. 47-48. Second, Plaintiffs cite 21 U.S.C. § 343(i)(1), which requires a food to be identified by its “common or usual name” if it is not subject to a federal standard of identity. *See* P.I. Mem. 48. Sections 343-1(a)(1) and (3) of the NLEA, in turn, prohibit states from imposing requirements that are not identical to section 343(g)’s “standard of identity” requirement and section 343(i)(1)’s “common or usual name” requirement, respectively. 21 U.S.C. § 343-1(a)(1), (3).

Plaintiffs argue that Act 120 violates section 343(g)’s “standard of identity” requirement because a GE label “*effectively*” changes the name of corn meal (which has a standard of identity) to “enriched corn meal made from genetically engineered corn.” P.I. Mem. 49 (emphasis added). They likewise contend that Act 120 violates section 343(i)(1)’s “common or usual name” requirement because it changes the common or usual name of carbonated soft drink (which does not have a standard of identity) to “carbonated soft drink partially produced with genetic engineering.” *Id.* at 48.

As noted in the State’s opening brief (at 36-39), however, Act 120 does nothing of the sort: Act 120 doesn’t say that peanut butter (which has a federal standard of identity) *cannot* be called “peanut butter” if it is made with genetically engineered crops, and it doesn’t say that peanut butter *can* be called “peanut butter” if it does not conform to the federal standard of identity. It just requires peanut butter made with genetic engineering to be labeled as such.

Thus, to use Plaintiffs' examples, carbonated soft drink products will still be called "carbonated soft drink," and corn meal products will still be called "corn meal." They will just have an additional label that explains that they were produced with genetic engineering.

Plaintiffs' "product labeling" argument is therefore just a variation of their "ingredient labeling" argument – *i.e.*, it assumes that *any* phrase, anywhere on a food label, necessarily changes the name of the product. *See* P.I. Mem. 48 ("Act 120 . . . imposes new names on food products and their ingredients."). But "[a] disclosure requirement of this type would not force manufacturers to call 'honey' something other than 'honey.' Rather, it would require merchants . . . to *supplement* their product's label with additional information that is not part of the product's name." *Brod v. Sioux Honey Ass'n, Coop.*, 927 F. Supp. 2d 811, 824 (N.D. Cal. 2013) (holding that a state law mandating disclosure that pollen had been removed from honey is not preempted as inconsistent with the FDCA's "common or usual name" requirement).⁴⁵

In addition, Plaintiffs' argument once again proves too much: It would prevent manufacturers from adding – and states from requiring – nearly any food labels whatsoever. For example, Plaintiffs tout that manufacturers can voluntarily label food as "produced with genetic engineering" or as "GMO free." P.I. Mem. 29 & n.11. They also allege that their members currently label their products as "natural." Am. Compl. ¶ 59. But, by Plaintiffs' logic, those labels would *necessarily* render their food misbranded. After all, according to their theory, an "all natural" description on the front of a food package would "effectively" change the name of "carbonated soft drink" to "all natural carbonated soft drink."⁴⁶ And a "GMO free" label on corn

⁴⁵ In *Briseno*, the court similarly explained that a state-law requirement pertaining to a "100% Natural" label does not implicate the "common or usual name" requirement, because such a label does not change the name of a product. No 11-5379, Doc. 54, at *8.

⁴⁶ The State's position of course is that the use of the term "natural" is false and misleading as applied to GE products. But that is not because the term "natural" modifies the product's

meal would likewise “effectively” change the name of “corn meal” to “GMO-free corn meal.”

That theory is not just wrong; it would have profound consequences far beyond the circumstances of this case. Plaintiffs’ theory would preempt virtually *all* consumer-protection laws based on misleading food labels. Thus, according to Plaintiffs, a consumer could not sue a manufacturer for *falsely* claiming that its products are “from Canada,” “GMO free,” or “fair trade,” because such a lawsuit would be based on state tort law that establishes “common or usual name” or “standard of identity” requirements that differ from those imposed by federal law. The NLEA provides absolutely no support for that sweeping theory of express preemption – a theory that would upend states’ traditional role in regulating food and beverage labeling.

And, as noted, Plaintiffs argument is foreclosed by the FDA’s own 2001 guidance, which *permits* GE labeling and therefore shows that GE labels do *not* modify a product’s standard of identity or common or usual name. Indeed, the guidance makes clear that a manufacturer may, without running afoul of the FDCA, state that a food contains “cornmeal that was produced using biotechnology” – the exact hypothetical given by Plaintiffs here (at P.I. Mem. 49) as a supposedly impermissible modification of a food’s standard of identity. 2001 Draft Guidance for Industry.

Plaintiffs cite *Mills v. Giant of Maryland, LLC*, 441 F. Supp. 2d 104, 108 (D.D.C. 2006). P.I. Mem. 49. There, the district court found that a consumer lawsuit alleging that milk should contain a lactose warning was preempted on the ground that it imposed a requirement not identical to the standard of identity for milk. But the D.C. Circuit expressly declined to affirm the decision on that ground or address the preemptive scope of the standard-of-identity requirement. *Mills v. Giant of Md., LLC*, 508 F.3d 11 (D.C. Cir. 2007). For good reason: By

name or its ingredients. Rather, it is because the term “natural” falsely tells consumers that a food is not produced with genetic engineering.

the district court's logic, *any* statement on a label for a food with a standard of identity, even if that statement has nothing to do with that standard of identity, would be preempted. Thus, for example, a state law requiring recycling labels on beverage containers (including milk bottles) would be preempted as conflicting with the standard of identity for milk – even though such a law says nothing about what foods may or must be called “milk.” That is far too sweeping an interpretation of the standard-of-identity requirement. As the State explained in its opening brief (at 39 n.28), Act 120 does not run afoul of the standard-of-identity requirement because “[n]o federal standards of identity for [GE labeling] exist.” *Vt. Pure Holdings, Ltd. v. Nestlé Waters N. Am., Inc.*, No. 03-11465, 2006 WL 839486, at *9 (D. Mass. Mar. 28, 2006); *see Pepsico, Inc., Bottled Water Mktg. & Sales Pracs. Litig.*, 588 F. Supp. 2d 527, 538 & n.10 (S.D.N.Y. 2008) (states can impose requirements “concerning subject matter that the FDA has not endeavored to regulate”); *see also POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2235, 2238 (2014) (explaining that the NLEA forbids state law requirements that are “of the type” required by the FDA’s misbranding provisions).⁴⁷

B. Act 120’s GE-labeling requirement is not conflict-preempted by the Federal Food, Drug, and Cosmetic Act (“FDCA”).

Plaintiffs next contend that, even if Act 120 is not expressly preempted by the NLEA, it is conflict-preempted because (1) it is a “physical impossibility” to comply both with Act 120

⁴⁷ In their opposition to the State’s motion to dismiss, Plaintiffs try out another express preemption argument: that Act 120 “*endorses the premise* that foods derived from genetically engineered plants differ in some uniform and meaningful way from identical foods, derived from other plants,” contrary to the FDA’s “opposite view” that there is no difference between GE plants and non-GE plants. Opp. 22 (emphasis added). That is not an *express* preemption argument; Plaintiffs do not even attempt to point to any statutory provision that expressly prohibits states from “endorsing a premise.” In any event, Act 120 does no such thing: If a GE label necessarily “endorsed the premise” that GE foods are different from non-GE foods, why would the FDA nevertheless allow GE labelling? And, as noted in the State’s opening brief (at 13), Act 120 permits manufacturers to state that the FDA has *not* endorsed such a premise.

and with the FDCA, and (2) because Act 120 stands as an obstacle to federal law. P.I. Mem. 51. Plaintiffs fail to state a claim under either theory.

1. Act 120's GE-disclosure requirement is not "impossibility"-preempted.

The FDCA's misbranding provisions prohibit manufacturers from using food labels that are "false or misleading in any particular." 21 U.S.C. § 343(a). Plaintiffs contend that it is physically impossible to comply with Act 120 and with federal law because Act 120 requires manufacturers to use a label that "is false or misleading." Their theory is that Act 120's GE-disclosure requirement "conveys an *overall impression*" that GE foods are different from traditional foods in some meaningful way, contrary to the FDA's statement, in non-binding guidance, that GE and traditional foods are not materially different. P.I. Mem. 52 (emphasis added). Even if GE labels do not "convey this opinion directly," Plaintiffs say, "Act 120's labels nonetheless *legitimate* some individuals' opinion that foods produced with ingredients from genetically engineered crops are not as safe as other foods." *Id.*

To begin, an Act 120 label does not convey any "opinion." Opp. 24. It conveys a fact: that a food is produced using genetic engineering. Plaintiffs' entire premise is therefore flawed. If Plaintiffs are really worried about conveying such an opinion, there's a surefire way to refrain from doing so: They can include the disclaimer, expressly contemplated by Act 120, that the FDA does *not* consider GE foods to be materially different from traditional foods. *See* Draft Rule § 2.3.2.

Plaintiffs' argument is doomed for another reason: It assumes that the FDA, in fact, considers GE labels to be false or misleading because they convey the "opinion" that GE foods differ from non-GE foods. But, as noted, the nonbinding agency guidance that Plaintiffs cite *permits* GE labels. Indeed, that guidance expressly notes that statements such as "Genetically

engineered” or “This product contains cornmeal that was produced using biotechnology” “can be made *without being misleading*.” 2001 Draft Guidance for Industry (emphasis added).

Further, if Plaintiffs’ novel theory were correct (it is not), then some of its own members would already be in violation of federal law. For instance, one of Plaintiffs’ declarants, General Mills, sells Cheerios boxes that draw the very distinction that Plaintiffs claim the FDA forbids, by noting that Cheerios are “Not made with genetically modified ingredients.”⁴⁸ General Mills obviously does not believe this violates federal law.



In any event, Plaintiffs’ entire argument rests on the fact that the FDA stated, in non-binding guidance, that GE foods are not meaningfully different from traditional foods. Even if that guidance did not directly refute Plaintiffs’ argument (which it does), it nevertheless does not have preemptive force. As the State explained in its opening brief (at 34-35), “it is federal *law* which preempts contrary state law; nothing short of federal law can have that effect.” *Fellner v.*

⁴⁸ http://www.amazon.com/Cheerios-Cereal-21-Ounce-Pack/dp/B00L1KPV7U/ref=sr_1_2?ie=UTF8&qid=1415886685&sr=8-2&keywords=cheerios; *see also* <http://www.generalmills.com/Home/Brands/Cereals/Cheerios/Brand%20Product%20List%20Page.aspx> (click on “Cheerios”) (last visited Nov. 13, 2014).

Tri-Union Seafoods, LLC, 539 F.3d 237, 243 (3d Cir. 2008); see *Altria Grp., Inc. v. Good*, 129 S. Ct. 538 (2008). Thus, courts have consistently held that the “FDA’s policy statement regarding use of the term ‘natural’ is not entitled to preemptive effect.” *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 340 (3d Cir. 2009).

Although Plaintiffs have abandoned any preemption challenge to Act 120’s “natural” requirement, the same principle compels the conclusion that the FDA’s non-binding guidance on GE labeling also lacks preemptive effect. As with the term “natural,” the FDA has not promulgated *any* regulations regarding GE labeling. At most, it has decided *not* to regulate GE labeling. But as the State explained in its opening brief (at 35-36), “mere deliberate agency inaction – an agency decision *not* to regulate an issue – will not alone preempt state law.” *Fellner*, 539 F.3d at 247.⁴⁹ Indeed, in *Briseno*, one of the few cases Plaintiffs cite in support of their preemption argument (P.I. Mem. 50), the court held that the plain terms of the FDA’s 2001 draft guidance itself “makes clear” that “it is merely a non-binding draft distributed for comment purposes” that “cannot be said to have the force of federal law.” No 11-5379, Doc. 54, at *12 (citing *Holk*, 575 F.3d at 342). Plaintiffs have no answer. They just continue to cite the FDA’s non-binding guidance on GE labeling *as if it were law*. It’s not.

Moreover, Plaintiffs do not dispute (although they wholly ignore) that this case is governed by the presumption against preemption, under which courts must assume ““that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress.”” *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516

⁴⁹ Although courts will find implied preemption if the state law “regulates conduct in a field that Congress intended the Federal Government to occupy exclusively,” *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990), Plaintiffs do not allege field preemption. Nor could they: Congress has not “regulated so comprehensively in either the food and beverage or juice fields that there is no role for the state.” *Holk*, 575 F.3d at 337 (no field preemption of “all natural” labeling requirements).

(1992) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). They do not dispute that that presumption is heightened where, as here, “federal law is said to bar state action in fields of traditional state regulation.” *NYSRA*, 556 F.3d at 123 (quoting *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)). They do not dispute that “[t]he case for federal pre-emption is particularly weak where,” again, as here, “Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.” *Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009). And they do not dispute that the Supreme Court has cautioned that “impossibility pre-emption is a demanding defense.” *Id.* at 1199.

In spite of all that, Plaintiffs nevertheless assert that it is a “physical impossibility” (P.I. Mem. 51) to comply with Act 120 and federal law because Act 120 requires a purely factual disclosure that might “*legitimate*” someone’s personal beliefs in a way that is at odds with statements made in nonbinding agency guidance that has no preemptive effect (P.I. Mem. 52). That is a strained argument even in a vacuum. It is all the more tenuous in light of the fact that the non-binding guidance Plaintiffs cite *permits* GE food labeling – and expressly states that such labels do not render a food misbranded.

Finally, Plaintiffs suggest that Act 120’s definition of genetic engineering is misleading (and therefore preempted) because it “far exceeds the meaning of that term in federal law” and in other Vermont laws, which, they say, limit genetic engineering to “rDNA techniques.” P.I. Mem. 52. But the definitions of genetic engineering in the Vermont law Plaintiffs cite and the federal rule to which they allude go beyond “rDNA techniques” to include “cell fusion, microencapsulation and macroencapsulation.” 7 C.F.R. § 205.2; *see* 6 V.S.A. § 641(9). The FDA’s

1992 policy statement cited by Plaintiffs likewise includes “cell fusion” as a type of genetic engineering, just as Act 120 does. There is therefore no merit to Plaintiffs’ suggestion that “genetic engineering” is universally limited to “rDNA techniques.”⁵⁰

Plaintiffs also state that Act 120’s definition of genetic engineering is false because “a processed food is not ‘produced’” with genetic engineering. P.I. Mem. 52. Rather, they say, “[i]t is manufactured by the manufacturer.” *Id.* That is a non-sequitur. There is no dispute that manufacturers “manufacture” food. The point is that they do so from plants that are unquestionably “produced” with genetic engineering – which means that the finished product is necessarily produced, at least in part, with genetic engineering.

The McHughen declaration provides more context to Plaintiffs’ argument. It states that “genetic engineering . . . is not ‘a process by which food is *produced* from an organism or organisms’” because “[g]enetic engineering *often* has nothing to do with food or food production.” McHughen Decl. ¶ 78 (emphasis added). Indeed, the declaration continues, genetic engineering is in fact often used “to produce drugs for medical use” – including a “promising treatment for Ebola virus.” *Id.* That argument is logically flawed. Of course genetic engineering is not *exclusively* used to produce food, but that does not mean that it is *never* used to produce food. A statement that a book was “edited using computer software” is likewise not false simply because computer software “often has nothing to do with” editing books.

⁵⁰ The declaration of Plaintiffs’ expert suggests that Act 120’s definition of genetic engineering would encompass traditional agricultural techniques. *See* McHughen Decl. ¶¶ 81-82. The Draft Rule makes clear, however, that “[t]he term ‘genetic engineering’ does *not* encompass a change of genetic material through the application of traditional breeding techniques, conjugation, fermentation, traditional hybridization, in vitro fertilization, or tissue culture.” Draft Rule § 1.6 (emphasis added). That is consistent with the analogous provision in the USDA’s organic-labeling regulations. *See* 7 C.F.R. § 205.2 (“Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.”).

In any event, one need not resort to logic or linguistics to dispose of Plaintiffs' quarrel with the term "produced." The FDA's own Draft Guidance for Industry, which Plaintiffs repeatedly cite, specifically authorizes labels that state that a food was "*produced* using biotechnology." 2001 Draft Guidance for Industry (emphasis added). More recently, the FDA has reiterated that it recognizes "the strong interest that many consumers have in knowing whether a food was *produced using genetic engineering*." FDA, Questions & Answers on Food from Genetically Engineered Plants, <http://www.fda.gov/food/foodscienceresearch/biotechnology/ucm346030.htm> (emphasis added).⁵¹ Plaintiffs' bald assertion that the FDA would nevertheless consider it misleading to state that a food is "produced" with genetic engineering is without merit.

2. Act 120's GE-disclosure requirement is not obstacle-preempted.

Plaintiffs also contend that Act 120 is preempted because it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." P.I. Mem. 51 (quoting *Arizona v. United States*, 132 S. Ct. 2492, 2501 (2012)). In support, they rely on the "Coordinated Framework for Regulation of Biotechnology," a 1986 statement of policy by the Office of Science and Technology Policy. 51 Fed. Reg. 23,302, 23,302 (June 26, 1986). The Framework reviews the regulatory policies of several federal agencies and states that those agencies "will seek to operate their programs in an integrated and coordinated fashion" and make

⁵¹ The labeling laws in Maine and Connecticut (which do not go into effect until at least four other states or states with a population of more than 20,000,000 adopt similar legislation) use identical language. See 22 Me. Rev. Stat. tit. 22, Ch. 565, § 2593.1 (requiring label stating "Produced with Genetic Engineering"); Conn. Pub. Act No. 13-183, Sec. 3 (requiring label stating "Produced with Genetic Engineering"). Thus, the FDA and every state to consider the issue *agree* that the label "produced with genetic engineering" is *not* false or misleading in any way.

“[s]pecial efforts” to “improve public understanding of various aspects of rDNA technology.” 51 Fed. Reg. at 23,303, 23,308.

As noted above, however, “it is federal *law* which preempts contrary state law”; mere policy statements have no preemptive force. *Fellner*, 539 F.3d at 243. The Framework is just such a policy statement: “The Framework and definitions contained therein are set forth to guide policymaking, *not to regulate.*” *Found. on Econ. Trends v. Johnson*, 661 F. Supp. 107, 109 (D.D.C. 1986) (emphasis added). Thus, like the “FDA’s policy statement regarding use of the term ‘natural,’” the Framework is “not entitled to preemptive effect.” *Holk*, 575 F. 3d at 341.

Even if the Framework’s statement of policy somehow had preemptive force (and it does not), nothing in Act 120 even remotely presents an obstacle to the policies of inter-agency cooperation announced in the Framework. The Framework does not even *mention* food labeling. And why would it? It was written six years *before* the first genetically modified food was submitted to the FDA for approval in 1992. *See* 57 Fed. Reg. 22,984, 22,985 (May 29, 1992). And in the three decades since the Framework was drafted, the FDA has not promulgated a *single* regulation related to the labeling of GE food. Simply put, nothing in the Framework – a policy statement that focuses on inter-agency cooperation *within the federal government* – even hints at a congressional intent to preempt *state* food-labeling laws.

At its core, Plaintiffs’ argument is that state regulation of GE labeling is obstacle-preempted on the ground that multiple federal agencies have an interest in biotechnology, and seek to coordinate their own activities in that field. That is not a basis for federal preemption. If it were, then nearly every field implicating multiple federal agencies – environmental policy, transportation policy, law enforcement, and innumerable others – would be entirely off limits for any state regulation. As the Second Circuit has explained:

To infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence.

Gen. Motors Corp. v. Abrams, 897 F.2d 34, 42 (2d Cir. 1990) (quoting *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985)). Of course, as noted above, the Framework does not address GE labeling at all – much less comprehensively. It merely reflects an effort to coordinate biotechnology policy by multiple federal agencies and does nothing to preempt state laws relating to GE labeling.

That is particularly true in light of the presumption against preemption: Plaintiffs have not pointed to *any* statute demonstrating a “clear and manifest purpose of Congress” to supersede “the historic police powers of the States” in this field. *Cipollone*, 505 U.S. at 516 (quotation omitted). To the contrary, when Congress enacted the NLEA – which, unlike the Framework, actually addresses food labeling – it expressly left room for the states to regulate food labeling. Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364 (1990) (providing that the NLEA “shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343–1(a)] of the [FDCA]”); see *Wyeth*, 129 S. Ct. at 1200 (2009) (“The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.”). The regulation of food labeling has “traditionally fallen within the province of state regulation.” *Holk*, 575 F.3d at 334. Nothing in the Framework – a statement of policy relating to inter-agency cooperation written nearly 30 years ago – does anything to alter that bedrock principle.

C. Act 120's GE-labeling requirement is not preempted by the Federal Meat Inspection Act ("FMIA") and the Poultry Products Inspection Act ("PPIA").

Finally, Plaintiffs contend that Act 120 is expressly preempted by the FMIA and PPIA, which prohibit states from imposing labeling requirements for meat and poultry produced at USDA-inspected facilities. *See* Opp. 22-23; P.I. Mem. 50-51. Plaintiffs do not dispute that Act 120 contains an exemption for food products "consisting entirely of or derived entirely from an animal." Act 120, Sec. 2, § 3044(1). They argue, however, that "many products produced at [USDA]-inspected facilities," such as pre-made frozen meals, "contain ingredients other than those 'consisting entirely of' or 'derived entirely from' an animal." Opp. 23; *see* P.I. Mem. 50.

But the Draft Rule on "Animal Products and USDA Approved Labels" makes clear that Act 120's GE-disclosure requirement does *not* apply to "[p]ackaged, processed food containing meat or poultry, the label of which requires approval by the United States Department of Ag., under [the FMIA or PPIA]." Draft Rule § 3.1.2. Because Plaintiffs' sole allegation is that Act 120 impermissibly establishes labeling requirements for meat and poultry products that are subject to USDA inspection, they fail to state a claim that Act 120 is expressly preempted by the FMIA or PPIA.

As the State noted in its opening brief (at 42-43), moreover, Plaintiffs lack standing for their FMIA and PPIA challenges to Act 120. If Plaintiffs' members produce products that are covered by the FMIA or PPIA, "the proper recourse is for the aggrieved individuals themselves to bring suit" as to those particular products. *Rent Stabilization Ass'n of City of New York v. Dinkins*, 5 F.3d 591, 595 (2d Cir. 1993). Thus, any as-applied challenge must be brought by a member company that actually produces such products – not by trade groups comprising members that may or may not produce such products.

V. PLAINTIFFS FAIL TO STATE A CLAIM UNDER THE COMMERCE CLAUSE.

Plaintiffs do not even bother arguing their Commerce Clause claim in their preliminary injunction motion.⁵² And in response to the Defendants’ motion to dismiss, Plaintiffs do not make any claim that Act 120 “clearly discriminate[s]” against interstate commerce. *SPGGC, LLC v. Blumenthal*, 505 F.3d 183, 193 (2d Cir. 2007). Instead, they argue that Act 120 fails under the *Pike* balancing test because it imposes a burden on interstate commerce that “is clearly excessive in relation to the putative local benefits,” and impermissibly regulates commerce extraterritorially. Opp. 17 (quoting *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)). Plaintiffs fail to state a claim under either theory.

A. Plaintiffs fail to allege that Act 120 burdens interstate commerce.

The burdens to which *Pike* refers “are the burdens on interstate commerce that exceed the burdens on intrastate commerce.” *USA Recycling, Inc. v. Town of Babylon*, 66 F.3d 1272, 1287 (2d Cir. 1995). “Under *Pike*, if no such unequal burden be shown, a reviewing court need not proceed further.” *NEMA*, 272 F.3d at 109; *see also Automated Salvage Transp., Inc., v. Wheelabrator Env’tl. Sys., Inc.*, 155 F.3d 59, 75 (2d Cir. 1998) (“The minimum showing required to succeed in a Commerce Clause challenge to a state regulation is that it have a disparate impact on interstate commerce.”).

Here, the sole burden alleged by Plaintiffs is that Act 120 would require manufacturers to establish Vermont-specific distribution channels and food-packaging labels. As the State explained in its opening brief (at 27-28), however, the Second Circuit held in *NEMA* that *those exact burdens* – the need for manufacturers to “arrange their production and distribution processes to produce labeled [products] solely for the Vermont market” – are not burdens at all

⁵² This section of the brief therefore serves only as a reply in support of Defendants’ motion to dismiss.

for Commerce Clause purposes. *NEMA*, 272 F.3d at 110. That should end the matter.

Plaintiffs nevertheless seek to evade *NEMA*'s clear holding on the ground that it "was decided at the preliminary injunction stage, where the court assessed the plaintiffs' likelihood of success on the merits on the basis of the record available at that point." Opp. 18. But the fact that *NEMA* was decided at the preliminary injunction stage is a distinction without a difference. The rule articulated by the Second Circuit was in no way qualified by the particular context in which the case arose. The court simply held, point blank, that these kinds of burdens do not count for Commerce Clause purposes. So too here.

And in their haste to distinguish *NEMA*, Plaintiffs misread the case altogether. Plaintiffs contend that in *NEMA*, "the state's substantial interest in protecting health and the environment was undisputed." Opp. 18 (citing *NEMA*, 272 F.3d at 115). Thus, according to Plaintiffs, the burden in *NEMA* simply did not suffice "to offset the benefits in that case." *Id.* (emphasis added).

Not so. As noted, the threshold requirement under *Pike* is the existence of a disparate burden on interstate commerce. Accordingly, once the court in *NEMA* held that the cost of Vermont-specific labeling is *not* a cognizable burden under *Pike*, it did "not proceed further." 272 F.3d at 109. Thus, contrary to Plaintiffs' suggestion, the court in *NEMA* did not determine that the burdens of Vermont-specific labeling were insufficient to "offset the benefits." Opp. 18. The court did not even *mention* the local benefits when conducting its Commerce Clause analysis, much less weigh those benefits against the burdens.⁵³

⁵³ The court in *NEMA* discussed the State's interests only in the context of the plaintiff's First Amendment challenge. See *NEMA*, 272 F.3d at 115; Opp. 18 (citing to *NEMA*'s First Amendment analysis).

Plaintiffs' reliance on *Association of International Automobile Manufacturers v. Abrams*, 84 F.3d 602 (2d Cir. 1996), is therefore misplaced. Citing *Abrams*, Plaintiffs suggest that there is a *per se* rule that a *Pike* claim must survive a motion to dismiss. Opp. 18-19. But the Second Circuit has repeatedly upheld dismissals of *Pike* claims.⁵⁴ The issue, then (as for any motion to dismiss), is whether the facts alleged *in this case* state a claim. In *Abrams*, the court held that there was a factual dispute about the "degree" of the burdens and benefits of the statute at issue – and that that factual dispute was material to the *Pike* inquiry. 84 F.3d at 613. Here, the costs alleged by Plaintiffs, *even if accepted as true*, are simply not cognizable burdens under Second Circuit precedent. Given that fatal flaw, this Court "need not proceed further." *NEMA*, 272 F.3d at 109.

Plaintiffs, moreover, do not even argue in their brief that the alleged burdens on interstate commerce (which *NEMA* says are not cognizable in any event) actually "exceed the burdens on intrastate commerce," as required under *Pike*. *Babylon*, 66 F.3d at 1287. The closest they come is their statement that Vermont contains small manufacturers, and that such small manufacturers "may have more modest ingredient demands" than large manufacturers (and therefore may be able to switch to non-GE foods more readily than large manufacturers). Opp. 20 (emphasis

⁵⁴ See, e.g., *SPGGC*, 505 F.3d at 192-93 (affirming dismissal of dormant Commerce Clause claim on the ground that the plaintiff "failed to plead facts sufficient" to show that the challenged law "impacts interstate commerce"); *Freedom Holdings, Inc. v. Spitzer*, 357 F.3d 205, 218 (2d Cir. 2004) (affirming dismissal of Commerce Clause claim on the ground that "Appellants cannot and do not identify any in-state commercial interest that is favored" at "the expense of out-of-state competitors"); *Automated*, 155 F.3d at 77 (affirming dismissal of Commerce Clause claim on the ground that the settlement agreement at issue "has not imposed any 'incidental burdens' on interstate commerce that 'are clearly excessive in relation to the putative local benefits'" (quoting *Pike*, 397 U.S. at 142)); *Omya, Inc., v. Vermont*, 33 F. App'x 581, 583 (2d Cir. 2002) (affirming dismissal of Commerce Clause claim on the ground that the challenged law "does not have a disparate effect on interstate commerce," and noting that even if the law did impose such a burden, that burden is not "clearly excessive in relation to the putative local benefits" (quoting *Pike*, 397 U.S. at 142)).

added). But saying in a brief that something “may” come to pass is not even an allegation – much less an allegation that has any bearing on whether Plaintiffs stated a claim in their Amended Complaint. *Cf. Jones v. Schneiderman*, 974 F. Supp. 2d 322, 351 (S.D.N.Y. 2013) (explaining that an allegation that a law “could” or “may” affect commerce is mere “speculation” that is “insufficient to state a plausible claim”). Plaintiffs must allege that the costs of relabeling do, in fact, disproportionately burden interstate commerce. They do not do so.

Nor do Plaintiffs argue that *all* out-of-state manufacturers would be unable to change their ingredients. As explained in the State’s opening brief (at 27 n.20), the dormant Commerce Clause “protects the interstate market, not particular interstate firms.” *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127 (1978). Thus, “interstate commerce is not subjected to an impermissible burden simply because an otherwise valid regulation causes some business to shift from one interstate supplier to another.” *Id.* It is therefore irrelevant whether, as Plaintiffs contend, *some* out-of-state manufacturers may be unable to switch to non-GE ingredients, since they do not allege that *all* out-of-state firms would be unable to do so.

In any event, Plaintiffs take aim at the wrong target. Their entire disparate-burden argument is that some manufacturers can comply with Act 120 by refraining from using GE foods, while others cannot. In other words, Plaintiffs assume that the only way to comply with Act 120 is to switch to GE-free products. But Act 120 does not regulate the *use* of GE foods – *e.g.*, it does not require manufacturers to switch to GE-free products. Rather, it regulates the *labeling* of food. And Plaintiffs do not allege that in-state manufacturers would not incur the exact same burdens of labeling.

Finally, Plaintiffs complain that Act 120 exempts certain industries “without justification.” Opp. 17. As the State explained in its opening brief, however, the “exemptions”

Plaintiffs cite in their Amended Complaint (¶ 73) apply equally to in-state and out-of-state producers. MTD 24-25. As a matter of law, then, those exemptions do not implicate the Commerce Clause. Plaintiffs have no response.

Nor, for that matter, are Act 120's exemptions "without justification." What Plaintiffs call a "dairy" exemption is not a dairy exemption at all; it is an exemption for food consisting entirely of, or derived from, animal products. *See* MTD 25 n.17. As Plaintiffs themselves argue (Opp. 22-23), that exemption is necessary to comport with the Federal Meat Inspection Act and the Poultry Products Inspection Act. Plaintiffs cannot seriously contend that compliance with federal law is an insufficient "justification" for an exemption.⁵⁵

B. Any burdens on interstate commerce are not clearly excessive in relation to the putative local benefits.

Because Act 120 does not burden interstate commerce, this Court need not proceed to the second step of the *Pike* balancing test. *NEMA*, 272 F.3d at 109; *Automated*, 155 F.3d at 75. Even if Plaintiffs *had* alleged cognizable burdens on interstate commerce, however, those burdens are not excessive in relation to Act 120's putative local benefits.

Even after amending their Complaint, Plaintiffs' only allegation related to the Act's putative local benefits under *Pike* is that those benefits are "effectively zero" because consumers "can already avoid GE foods if they wish by buying certified organic or other voluntarily labeled products." Am. Compl. ¶ 77. As the State explained in its opening brief (at 30), that allegation misses the point of the law, which the Legislature enacted so that consumers would know whether any *particular* food product was produced with genetic engineering – not just the small

⁵⁵ Plaintiffs' reference to an "organic" exemption (Am. Compl. ¶ 73) is equally disingenuous. Act 120 contains no "organic" exemption. What Plaintiffs are alluding to is the fact that organic producers, as a rule, do not use GE ingredients and thus would not need to label their products as produced with genetic engineering. Organic producers are not *exempted* from Act 120; they *comply* with Act 120.

proportion of products that manufacturers *choose* to label. Plaintiffs fail to address that fundamental flaw, which renders their sole allegation regarding the Act's putative local benefits insufficient to state a claim under *Pike*.

Indeed, in the single sentence they devote to the issue of local benefits, Plaintiffs simply cite the portion of their Amended Complaint that discusses the *Zauderer* standard of review for compelled speech under the First Amendment and argue that Act 120 does not serve any "substantial" "government interest." Opp. 18 (citing Am. Compl. ¶¶ 53-54). As explained above, that assertion is facially implausible: The Legislature reviewed dozens of scientific studies on both sides of the issue and, based on those studies, determined that GE foods may present risks to human health and the environment. Plaintiffs' allegation that the State "ignore[d] the findings of an international consensus of scientists and regulators" (Am. Compl. ¶ 54) is therefore belied by the legislative record, which shows that the Legislature expressly considered those findings.

In any event, Plaintiffs misstate the showing required under *Pike*. As the State explained in its opening brief (at 31), "under *Pike*, it is the *putative* local benefits that matter." *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 313 (1st Cir. 2005). States therefore have an interest in guarding against "imperfectly understood risks" – even if those risks "ultimately prove to be *negligible*." *Maine v. Taylor*, 477 U.S. 131, 148 (1986) (emphasis added); *see Rowe*, 429 F.3d at 313 ("It matters not whether these benefits actually come into being at the end of the day."); *Grocery Mfrs. of Am., Inc. v. Gerace*, 755 F.2d 993, 1004 (2d Cir. 1985) (the existence of a "controversy" is sufficient to show that the State's concerns were not unreasonable). Plaintiffs fail to acknowledge that line of authority, which is fatal to their *Pike* claim.

The Legislature found that GE foods "potentially pose risks to health, safety, agriculture,

and the environment,” and that genetic engineering “may cause unintended consequences.” Act 120, Sec. 1(4). As a matter of law, those putative local benefits outweigh any burdens on interstate commerce imposed by Act 120 (which, in any event, are non-existent). *See Maine v. Taylor*, 477 U.S. at 148. Plaintiffs nevertheless ask this Court to declare that the Legislature had no basis whatsoever to conclude that GE foods present such “potential” risks to human health and the environment – even though, by Plaintiffs’ own admission, the Legislature reviewed studies and heard testimony saying just that. This Court should decline Plaintiffs’ extraordinary invitation “to second-guess the empirical judgments of lawmakers.” *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 92 (1978); *see Brown & Williamson, Tobacco Corp. v. Pataki*, 320 F.3d 200, 209 (2d Cir. 2003).

C. Plaintiffs fail to state a claim that Act 120 impermissibly regulates commerce extraterritorially.

A statute that “directly controls commerce occurring wholly outside the boundaries of a State” may be invalid under the Commerce Clause. *NEMA*, 272 F.3d at 110; *see SPGGC*, 505 F.3d at 193 (quoting *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989)). Plaintiffs contend that Act 120 impermissibly controls commerce occurring wholly outside the state, in two ways.

First, they allege that, to comply with Act 120, “manufacturers may ‘have to revise their labeling on a regional or even nationwide basis, no matter where in the country [their] products may be sold.’” Opp. 18 (quoting Compl. ¶ 74). But as the State explained in its opening brief, the Second Circuit addressed – and rejected – that exact claim in *NEMA*. *See* MTD 29. In that case, the plaintiffs argued (just like Plaintiffs here) that they would be forced “as a practical matter to label lamps sold in every other state.” *NEMA*, 272 F.3d at 110. The Second Circuit squarely rejected the argument that such nationwide labeling constitutes unconstitutional extraterritorial regulation:

NEMA's extraterritoriality contention fails because the statute does not inescapably require manufacturers to label all lamps wherever distributed. The Vermont statute, by its terms, is "indifferent" to whether lamps sold anywhere else in the United States are labeled or not. Unlike the restrictions involved in the Supreme Court's price-regulation cases, the statute here makes no mention of other states for any purpose. To the extent the statute may be said to "require" labels on lamps sold outside Vermont, then, 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. (internal citations omitted).

So too here. Act 120, like the Vermont labeling statute at issue in *NEMA*, is "indifferent" to whether GE food sold in other states is also labeled; the "manufacturers are not required to adhere to the Vermont rule in other states." *Id.* at 111. If Plaintiffs' members *choose* to label regionally or nationally, that's their choice to make. But "[c]ourts have held that when a defendant chooses to manufacture one product for a nationwide market, rather than target its products to comply with state laws, defendant's choice does not implicate the commerce clause." *Nat'l Fed. of the Blind v. Target Corp.*, 452 F. Supp. 2d 946, 961 (N.D. Cal. 2006); *see NEMA*, 272 F.3d at 110

As discussed above, *NEMA* also makes clear that, if Plaintiffs' members instead choose to label products for the Vermont market only, that too would not present any disproportionate burden on interstate commerce. "[M]anufacturers could arrange their production and distribution processes to produce labeled [products] solely for the Vermont market and then pass much of the increased costs along to Vermont customers in the form of higher prices." *NEMA*, 272 F.3d at 110. Whether Plaintiffs choose to comply with Act 120 by "relabel[ing] for Vermont only" or "relabel[ing] nationally" (Opp. 19), Plaintiffs have failed to state a Commerce Clause violation.

Second, Plaintiffs allege that they cannot comply with "the advertising restrictions in the Act without changing their nationwide and regional advertising, as well as their Internet

advertising and web sites.” Compl. ¶ 75. Thus, they argue, “Plaintiffs have stated a claim that the natural ban’s regulation of national media is a *per se* violation of the Commerce Clause.” Opp. 17 (citing *Am. Booksellers Found. v. Dean*, 342 F.3d 96, 104 (2d Cir. 2003)).

Act 120 provides that a manufacturer of a food produced with genetic engineering “shall not label the product on the package, in signage, or in advertising” as “natural.” Act 120, Sec. 2, § 3043(c). The Draft Rule clarifies the scope of the “natural” restriction:

The manufacturer of a food that is produced entirely or partially with genetic engineering and offered for retail sale in Vermont shall not make any statement about the food that contains the word natural or any words of similar import: (1) *in advertising at or in the retail premises*, (2) on signs identifying the product at the point of display in the retail premises, or (3) on the label of the food. This prohibition does not apply to a food’s trade, brand, or product name, or any information contained in the Nutrition Facts Label or Ingredient List required by the United States Food and Drug Administration in 21 C.F.R § 101.9.

Draft Rule 2.3.1 (emphasis added).

Thus, as the Draft Rule makes clear, Act 120’s “advertising” restriction does not regulate the “national media.” Opp. 17. Rather, it applies only to advertisements “at or in the retail premises” in Vermont. Draft Rule § 2.3.1. Because the advertising restriction applies only to in-state advertising, it plainly does not “directly control[] commerce occurring wholly outside the boundaries of a State.” *Healy*, 491 U.S. at 336.⁵⁶ Plaintiffs have therefore failed to state a claim that Act 120’s advertising restrictions impermissibly regulate commerce extraterritorially.

In a footnote, Plaintiffs state that their Amended Complaint “alleges that Act 120 is inconsistent with the regimes in other states.” Opp. 19 n.5. But what their Amended Complaint actually alleges is that there are “bills and ballot measures *pending*” in other states – specifically,

⁵⁶ *American Booksellers*, 342 F.3d 96, which addressed Internet regulations that applied *outside* of Vermont, is therefore inapposite. The Second Circuit, moreover, has described *American Booksellers*’ discussion of state regulation of the Internet as “dicta.” *SPGGC*, 505 F.3d at 195.

ballot measures “pending in Oregon and Colorado.” Am. Compl. ¶ 78 (emphasis added). Both those measures failed on Election Day. As the State explained in its opening brief (at 29), the Second Circuit has repeatedly made clear that, to even implicate the Commerce Clause, “there must be an *actual conflict* between the challenged regulation and those *in place* in other states” – not a potential conflict with laws that do not even exist. *NEMA*, 272 F.3d at 112 (emphases added); *accord SPGGC*, 505 F.3d at 196. Plaintiffs have not alleged – because they cannot – that Act 120 conflicts with any labeling law in effect in any state.⁵⁷

VI. PLAINTIFFS HAVE FAILED TO ESTABLISH THE REMAINING PREREQUISITES FOR A PRELIMINARY INJUNCTION.

A. Plaintiffs fail to show irreparable harm.

“A showing that irreparable harm is likely in the absence of preliminary relief is ‘the single most important prerequisite for the issuance of a preliminary injunction.’” *Entergy Nuclear Vt. Yankee, LLC v. Shumlin*, No. 11-99, 2011 WL 2811317, at *2 (D. Vt. July 18, 2011) (quoting *Rodriguez v. DeBuono*, 175 F.3d 227, 233-34 (2d Cir. 1999)). The threatened harm must be “imminent,” and must be a harm that “could be remedied by a preliminary injunction.” *Dexter 345 Inc. v. Cuomo*, 663 F.3d 59, 63 (2d Cir. 2011). “[T]he question is not whether the plaintiff has suffered irreparable harm, but whether it will be irreparably harmed *in the absence of an injunction*.” *Nat’l Elevator Cab & Door Corp. v. H & B, Inc.*, No 07-1562, 2008 WL 207843, at * 6 (E.D.N.Y. Jan. 24, 2008), *aff’d*, 282 F. App’x 885 (2d Cir. 2008) (quoted in *Entergy*, 2011 WL 2811317, at *2). Plaintiffs cannot make that showing here.

⁵⁷ Plaintiffs also fail to acknowledge that Act 120 expressly authorizes the Attorney General to require that GE labels be imposed “in a manner consistent with requirements in other jurisdictions for the labeling of food.” Act 120, Sec. 3(2).

Plaintiffs seek an injunction against “the implementation and enforcement of Vermont Act 120.” P.I. Mem. 1. But Act 120 does not go into effect *until July 1, 2016, at the earliest*.⁵⁸ Until that time, there is simply no State action for this Court to enjoin – and thus no imminent injury that “could be remedied by a preliminary injunction.” *Dexter 345 Inc.*, 663 F.3d at 63. This Court will have ample opportunity to resolve this case on the merits by then.⁵⁹ And only such a decision on the merits can prevent the harm that Plaintiffs allege.

This Court held as much in *Entergy*. In that case, the plaintiffs filed for a preliminary injunction in April 2011 to challenge Vermont laws that were scheduled to take effect fully eleven months later, in March 2012 (and which required plaintiffs to close one of their nuclear power plants in March 2012). The plaintiffs argued that they needed an immediate ruling on the constitutionality of the state laws so that they could decide whether to close their nuclear plant or invest around \$100 million in refueling the plant’s reactor that fall. *Entergy*, 2011 WL 2811317, at *4. Plaintiffs submitted evidence that they could not make that money back if they had to close the following spring (which they would have to do if the state laws went into effect). *Id.*

This Court recognized that the plaintiffs faced “a dilemma” of either closing down an operating nuclear power plant or spending \$100 million that could not be recouped if the law withstood constitutional challenge. *Id.* But it held that that dilemma did “not constitute

⁵⁸ The State is currently engaging in the rulemaking process, but Plaintiffs do not suggest that that process burdens their members’ rights in any way (nor can they). To the contrary, Plaintiffs’ only complaint about the rulemaking process is that it is not happening *fast enough*. See P.I. Mem. 57.

⁵⁹ Plaintiffs’ claim that this litigation “may take longer than” 22 months warrants little discussion. P.I. Mem. 55 & n.17. In support of that argument, Plaintiffs cite several cases that took longer than 22 months *through appeal*. But it is the merits ruling, not a preliminary injunction, that governs during the pendency of an appeal. And Plaintiffs’ list of cases conspicuously omits *Entergy*, which took just 9 months between the complaint and the merits ruling. If this case survives the State’s Motion to Dismiss, the Court can hold a trial during the summer of 2015, which would leave adequate time for a merits ruling before July 2016.

irreparable harm that can be resolved by a preliminary injunction.” *Id.* at *5. Rather, the plaintiffs’ “claimed harms [we]re only likely to be alleviated by a favorable final decision on the merits.” *Id.* at *3. Accordingly, this Court “decline[d] to order short-term drastic and extraordinary injunctive relief” that would “have no operative effect on state actions before trial.” *Id.* at *2.

That is exactly the case here. Any preliminary relief would have “no operative effect on state actions before trial,” because there are no state actions to enjoin until July 1, 2016. *Id.*; *see also Rodriguez*, 175 F.3d at 235 (preliminary relief unavailable where plaintiffs can “wait[] until the end of trial”). And plaintiffs do not allege any costs – none – that would be alleviated by a preliminary injunction. For example, Plaintiffs note a number of business decisions they might choose to make before July 1, 2016, such as relabeling products, substituting ingredients, or creating new distribution lines. But even if all of Plaintiffs’ contentions were true (and they are not), those alleged costs are not a basis for preliminary relief. That is because, as in *Entergy*, Plaintiffs’ “claimed harms are only likely to be alleviated by a favorable final decision on the merits.” *Id.* at 3. Indeed, Plaintiffs themselves allege that they must start preparing labels for Act 120 “right now.” P.I. Mem. 56. Thus, even if Plaintiffs obtained a preliminary injunction, they would still have to decide whether to change their labels now in anticipation of a loss on the merits.

Plaintiffs, in other words, seek an advisory ruling. They want to take this Court’s temperature on how it will ultimately rule on the merits. But that is not a proper ground for a preliminary injunction. As this Court explained in *Entergy*:

The Court will be in a better position to tailor injunctive relief, if it is warranted, as part of a final determination of the merits. While it is understandable that Entergy wishes relief from the dread of future enforcement of allegedly preempted statutes, where the preliminary injunctive relief – which would be of

very limited duration in this case – does not operate to enjoin any acts before trial, and cannot redress or ameliorate any harm, *it serves only as a preview of the Court's views of the merits and is unwarranted*. Preliminary injunctive relief does not guarantee permanent injunctive relief following trial on the merits.

Entergy, 2011 WL 2811317, at *3 (emphasis added). Here, too, a preliminary injunction would “not operate to enjoin any acts before trial,” and would therefore serve “only as a preview of the Court’s views of the merits.” *Id.*

Plaintiffs’ strained argument that Act 120’s “‘effective’ effective date” is before its *actual* effective date is therefore beside the point. *See* P.I. Mem. 57. Because any costs they allegedly would incur at that “‘effective’ effective date” would not be “vitiating by an interim injunction,” preliminary relief is unwarranted. *Am. Postal Workers Union, AFL-CIO v. U.S. Postal Serv.*, 766 F.2d 715, 722 (2d Cir. 1985); *see also Nat’l Elevator*, 2008 WL 207843, at *6 (plaintiffs must show that they “will be irreparably harmed *in the absence of an injunction*”). Indeed, any preliminary injunction itself would not be effective until July 1, 2016 (*i.e.*, the first date on which Act 120 could be enforced) – at which point it will likely have been superseded by a ruling on the merits.⁶⁰

Even apart from Plaintiffs’ *Entergy* problem, they cannot show irreparable harm for two additional reasons. First, “ordinary compliance costs are typically insufficient to constitute irreparable harm.” *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005); *see also*

⁶⁰ This highlights yet another fatal flaw that prevents the Court from granting Plaintiffs’ requested relief. Rule 65 limits the injunctive power of the federal courts to “specific legal violations.” *City of N.Y. v. Mickalis Pawn Shop, LLC*, 645 F.3d 114, 144 (2d Cir. 2011) (noting the “specificity provisions of Rule 65(d) are no mere technical requirements”); Fed. R. Civ. P. 65(d)(1)(C) (injunction must “describe in reasonable detail . . . the act or acts restrained or required”). Plaintiffs concede, as they must, that any preliminary relief would be in place only “until a final judgment on the merits has been rendered in this case.” P.I. Mem. 1. Yet Plaintiffs fail to allege any “specific legal violations” to be enjoined before that time. Nor could they, since no action will be taken by any state official to enforce Act 120 until July 1, 2016 at the earliest.

Am. Hosp. Ass'n v. Harris, 625 F.2d 1328, 1331 (7th Cir. 1980) (“[I]njury resulting from attempted compliance with government regulation ordinarily is not irreparable harm.”); *A.O. Smith Corp. v. FTC*, 530 F.2d 515, 527 (3d Cir. 1976) (“Any time a corporation complies with a government regulation that requires corporation action, it spends money and loses profits; yet it could hardly be contended that proof of such an injury, alone, would satisfy the requisite for a preliminary injunction.”). The ordinary business costs to Plaintiffs’ members for complying with Act 120 therefore do not justify a preliminary injunction. *See IMS Health Inc. v. Sorrell*, 631 F. Supp. 2d 429, 432 (D. Vt. 2009) (rejecting argument that harm is irreparable when, “under the Eleventh Amendment, the government is immune from damage suits and the expenses cannot be recouped,” and concluding that “[s]pending money to comply with the law is simply a fact of doing business”).⁶¹

⁶¹ Plaintiffs contend that any amount spent on compliance, no matter how small, is irreparable because the Eleventh Amendment bars recovery against the State. If this were the case, the irreparable injury requirement for a preliminary injunction would be met, by default, for any state regulation. The Second Circuit has not held as much. The Second Circuit cases addressing this Eleventh Amendment question in the context of irreparable injury are limited to state regulations that directly terminate or cause major disruptions to a business. *See e.g.*, *Entergy Nuclear Vt. Yankee, LLC v. Shumlin*, 733 F.3d 393, 423 (2d Cir. 2013) (act would require business to shut down); *United States v. State of New York*, 708 F.2d 92, 93 (2d Cir. 1983) (per curiam) (act imposed nighttime ban on use of an airport). That is consistent with the case law suggesting that irreparable injury cannot simply be a loss of profits, but rather must be “of such magnitude as to threaten the viability of the[] businesses” or cause “[m]ajor disruption.” *Petereit v. S.B. Thomas, Inc.*, 63 F.3d 1169, 1186 (2d Cir. 1995); *cf. C-B Kenworth, Inc. v. Gen. Motors Corp.*, 675 F. Supp. 686, 687-88 (D. Me. 1987) (cited by the Second Circuit in *Petereit* as finding no irreparable harm when harm amounted to less than five percent of total gross profits); *Lafayette Beverage Distribs., Inc. v. Anheuser-Busch, Inc.*, 545 F. Supp. 1137, 1151 (D. Ind. 1982) (cited by the Second Circuit in *Petereit* as finding no irreparable harm where the terminated relationship constituted 28% of plaintiff’s total sales). Complying with the requirements of Act 120 would not cause a major disruption to the business of food manufacturers. *See* Dyke Decl. ¶ 20 (average relabeling cost per-SKU is just .01% of the average per-SKU annual sales in the United States); Miller Decl. ¶ 17 (Act 120’s requirements would not “put anyone out of business or cause an overwhelming logistical hurdle”); Greenfield Decl. ¶ 14 (changes for complying with Act 120 can be folded into normal costs or passed along to consumers); Glidden Decl. ¶ 12 (same). In fact, as noted earlier, some of Plaintiffs’ own

Second, the harms complained of by Plaintiffs are not required by Act 120. Although Plaintiffs insist that they must identify subject products, reformulate or relabel them, create a Vermont-specific stock-keeping unit (SKU), and create Vermont-specific distribution lines, that is just one option for compliance. Plaintiffs' members could also comply with Act 120 by relabeling their products nationally, placing a sticker on products requiring labeling, or withdrawing from the market in Vermont. *See* Ex. F, Dyke Decl. ¶ 5 (identifying manufacturer options for compliance); Ex. G, Greenfield Decl. ¶ 13 (explaining that companies can communicate on packaging through labels, stickers, and "laser-jetting" information onto existing packages) & ¶ 15 (listing compliance options other than creating new distribution lines); Ex. H, Miller Decl. ¶¶ 9-11 (describing a number of ways to implement the change required by Act 120).⁶² Plaintiffs cannot create irreparable harm by virtue of their *choice* to comply with Act 120 by creating Vermont-specific labeling and distribution channels.

Finally, Plaintiffs contend that Act 120's impact on their members' "freedom of expression" satisfies the test for irreparable injury. P.I. Mem. 58. But "[t]he Second Circuit has 'not consistently presumed irreparable harm in cases involving allegations of the abridgement of First Amendment rights.'" *Mullins v. City of New York*, 634 F. Supp. 2d 373, 387 (S.D.N.Y.

members, such as General Mills, already label some of their products as not being made with genetic engineering, so adding the opposite label to other products cannot be as onerous as Plaintiffs claim. *See supra* 44; *see also* AdWeek, *Diet Coke Prints 2 Million Unique Labels in Latest Stroke of Packaging Genius*, <http://www.adweek.com/adfreak/diet-coke-prints-2-million-unique-labels-latest-stroke-packaging-genius-161042> (last visited Nov. 13, 2014) (noting that another one of Plaintiffs' declarants, Coca-Cola, recently set up a system to print 2 million unique labels in a single run).

⁶² Plaintiffs note that manufacturers will one day be required to comply with the FDA's final rule, when issued, revising the Nutrition Facts panel. P.I. Mem. 56. This FDA compliance is a cost unrelated to Act 120, and is certainly not an injury that Plaintiffs' members suffer as a result of Act 120. If anything, compliance with the FDA final rule may reduce the cost of compliance with Act 120; if the final rule is issued before compliance with Act 120 is required, businesses can make all changes to the labels during one redesign process. Miller Decl. ¶ 15.

2009) (quoting *Bronx Household of Faith v. Bd. of Educ. of City of N.Y.*, 331 F.3d 342, 349 (2d Cir. 2003)). Rather, “where a plaintiff alleges injury from a rule or regulation that may only potentially affect speech, the plaintiff must establish a causal link between the injunction sought and the alleged injury, that is, the plaintiff must demonstrate that the injunction will prevent the feared deprivation of free speech rights.” *Bronx Household of Faith*, 331 F.3d at 350; *see also Am. Postal Workers Union*, 766 F.2d at 722 (any “theoretical chilling of protected speech” could not “logically be thawed by the entry of an interim injunction”). Here, the injunction Plaintiffs seek would not prevent the “feared deprivation” of their members’ rights, because no speech at all is required until July 1, 2016.⁶³

B. Plaintiffs fail to show that “hardship” or the “public interest” warrant an injunction.

Plaintiffs contend that the “hardship” and “public interest” factors “merge into one” for purposes of their motion. P.I. Mem. 60. But Plaintiffs offer nothing but speculation on those factors. Plaintiffs claim that “consumer[s] *may* suffer” from Act 120 if it is not enjoined – presumably because manufacturers will pass their costs of compliance on to consumers. *Id.*

⁶³ The cases cited by Plaintiffs are distinguishable because they involved a restriction on or compulsion of speech that was in effect. *See Elrod v. Burns*, 427 U.S. 347, 351 (1976) (presuming irreparable harm where plaintiffs had been discharged or threatened with discharge because of their political affiliation); *Evergreen*, 740 F.3d at 238 (2d Cir. 2014) (finding a presumption of irreparable harm from law compelling speech that was in effect at the time); *Safelite*, 764 F.3d at 266 n.4 (2d Cir. 2014) (same). Here, a decision on the merits even six months before the July 1, 2016, effective date would provide manufacturers ample time to comply with Act 120. *See Greenfield Decl.* ¶ 8 (it would require six weeks to produce new packaging for compliance); *Miller Decl.* ¶ 15 (adding the statement required by Act 120 outside of regularly scheduled packaging windows could take one to six months); *Glidden Decl.* ¶ 11 (estimating that company could “easily” comply with labeling requirements within three to four months). While Plaintiffs contend that products with long shelf-lives would need to ship a full year in advance of July 1, 2016, because “Act 120 appears to impose liability as of the date products appear on store shelves” (P.I. Mem. 57), the Draft Rule addresses that concern by providing that for the first six months after Act 120 goes into effect, manufacturers “shall not be liable” unless they “*distributed*” their products on or after July 1, 2016. Draft Rule § 4.4.1 (emphasis added).

(emphasis added). But such costs – if any – are minimal. Dyke Decl. ¶¶ 16-20 (cost of national relabeling of \$1,966 per-SKU, representing only 2.24% of the average per-SKU annual sales in Vermont); Greenfield Decl. ¶ 11 (entire cost of changing labels would be \$500 per-SKU, which would “not affect the cost a consumer would pay for our product at retail”); Miller Decl. ¶ 11 (estimating one-time cost of relabeling to comply with Act 120 at \$500-\$1950 per-SKU); Glidden Decl. ¶ 10 (estimating costs at \$300-\$400 per label change). And whatever the costs, Vermonters have already decided that Act 120 is worth it: More than 90% of the public supports this law, which was duly enacted by their Legislature.⁶⁴ Plaintiffs’ assertion (P.I. Mem. 60) that “Act 120’s main benefit to the State is its symbolic value,” moreover, simply begs the question: It *assumes* that Act 120 is symbolic because, according to Plaintiffs, GE labeling is irrational. As discussed above, however, the Legislature plainly disagrees – and has good reason for doing so. The mere fact that Plaintiffs quarrel with the Legislature’s empirical judgment does not make a law that it enacted “symbolic.”

VII. DEFENDANTS SHUMLIN, REARDON, AND DOLAN ARE NOT PROPER *EX PARTE* YOUNG DEFENDANTS.

Despite its new allegations, the Amended Complaint fails to supply the necessary direct connection between the enforcement of Act 120 and Governor Shumlin, Commissioner Reardon or Acting Commissioner Dolan. *See, e.g., Brisco v. Rice*, No. 11-578, 2012 WL 253874, at *4 (E.D.N.Y. Jan. 27, 2012) (“The individual sued must have a direct connection to, or responsibility for, the alleged illegal action.”). Plaintiffs now suggest that Governor Shumlin’s power to appoint the finance and health commissioners, as well as members of the interagency committee on administrative rules, is an adequate enforcement connection. *See* Am. Compl.

⁶⁴ Plaintiffs also assert that the State has no interest in the enforcement of an unconstitutional law (P.I. Mem. 60). But Act 120 *is* constitutional. And at any rate, no enforcement of Act 120 can occur until after July 1, 2016 – well beyond the likely duration of any preliminary injunction.

¶ 14. It is not. Courts in this and other circuits have rejected the argument that “a sufficient connection exists under *Ex parte Young* where the only nexus alleged between the state official and the challenged action is the power to appoint.” *Kuck v. Danaher*, 822 F. Supp. 2d 109, 142-43 (D. Conn. 2011) (collecting cases). Further, the role played by the finance and health commissioners and the administrative rules committee with respect to Act 120 is limited to advising and consulting with the Attorney General on matters of public comment, administration and budgeting, and not on enforcement actions.⁶⁵ Thus, Governor Shumlin’s authority to appoint those officials has no connection to enforcement.

Plaintiffs also suggest that Governor Shumlin’s power to approve certain donations to Act 120’s special fund, and Commissioner Reardon’s management of that fund, constitute a sufficient enforcement connection. But determining the funds available to implement an act or practice does not constitute a “connection with the *enforcement* of the act.” *See Conn. Ass’n of Health Care Facilities, Inc. v. Rell*, No. 10-136, 2010 WL 2232693, at *5 (D. Conn. June 3, 2010) (dismissing claims against governor because her introduction of original budget bill had no connection to enforcement of resulting rate freeze), *aff’d*, 395 F. App’x 741 (2d Cir. 2010); *see also Hendricks v. Kasich*, No. 12-729, 2013 WL 2243873, at *9 (S.D. Ohio May 21, 2013) (holding that, absent any allegation that governor had “responsibility for the enforcement of any law relating to the provision of medical care for Ohio prison inmates,” governor was improper *Ex parte Young* defendant despite role in budget cuts affecting prison health care).

⁶⁵ Plaintiffs fare no better with their allegation regarding Acting Commissioner Dolan’s role to consult with Attorney General Sorrell about a procedure for qualifying independent organizations to verify a product’s non-GE status. Am. Comp. ¶ 15. As explained in the State’s opening brief (at 46-47), such consultation remains too far removed from the Attorney General’s enforcement activities to constitute a “direct connection.”

Plaintiffs have twice failed to sufficiently allege the requisite connection between enforcement of Act 120 and Governor Shumlin, Commissioner Reardon and Acting Commissioner Dolan. The Court should dismiss Plaintiffs' claims against those Defendants.

CONCLUSION

For the reasons stated above and in the State's Motion to Dismiss, the Court should dismiss the Amended Complaint with prejudice. The Court should also deny Plaintiffs' Motion for a Preliminary Injunction.

DATED at Montpelier, Vermont this 14th day of November, 2014

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CERTIFICATE OF SERVICE

I, Megan J. Shafritz, Esq., attorney for Defendants, hereby certify that on November 14, 2014, I electronically filed Defendants' Reply Brief in Support of their Motion to Dismiss and Opposition to Plaintiffs' Motion for a Preliminary Injunction with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all registered participants.

DATED at Montpelier, Vermont this 14th day of November, 2014.

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