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; HARRY L. CHEN, in his official capacity as 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 **ORAL ARGUMENT REQUESTED**

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFFS' COMPLAINT

STATE OF VERMONT

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INTRODUCTION

"States have traditionally acted to protect consumers by regulating foods produced and/or marketed within their borders." *Grocery Mfrs. of Am., Inc. v. Gerace*, 755 F.2d 993, 1003 (2d Cir. 1985). This case involves a challenge to such a regulation: Vermont's Act 120, which requires manufacturers to label genetically engineered ("GE") foods as such, and prohibits manufacturers from describing GE products as "natural." Roughly 80 percent of the processed food sold in the United States is produced with genetic engineering. Despite the proliferation of GE foods, however, long-term studies establishing the safety of GE products are lacking. While some studies suggest that GE foods present few risks, others raise significant concerns. In the face of that scientific uncertainty, one thing is clear: consumers with health, environmental, and religious concerns related to GE foods are left in the dark about whether the food they purchase was in fact produced with genetic engineering.

On May 8, 2014, after hearing testimony from more than one hundred individuals and reviewing the literature on both sides of the issue, the Vermont Legislature enacted Act 120 to address the concerns related to GE foods. One month later, Plaintiffs filed suit. A collection of trade associations representing food producers, Plaintiffs insist that GE foods are harmless, and that Vermont's health, environmental, and religious concerns are insubstantial. But even as they proclaim the harmlessness of GE foods, Plaintiffs are unwilling to actually *tell* consumers that their products are made with genetic engineering. They therefore ask this Court to declare that Act 120 is invalid in its entirety. This Court should dismiss their Complaint.

Plaintiffs first allege that Act 120 violates the First Amendment by compelling them to speak (the GE labeling requirement) and by restricting their speech (the "natural" prohibition). Because the GE labeling requirement compels the disclosure of purely factual speech, however, it is subject to rational-basis review. Act 120's labeling requirement easily satisfies that

standard. It is reasonably related to several legitimate state interests, including the State's interest in promoting informed decision-making on matters of public health and the environment. As to the "natural" prohibition, Plaintiffs lack standing to challenge it. They do not allege that they currently use the term "natural" on GE foods – or even that they *intend* to do so. In any event, because the use of the term "natural" to describe GE foods is inherently misleading – genetically modified food, by definition, is not "natural" – such speech is not entitled to any First Amendment protection in the first place.

Plaintiffs next allege that Act 120's "natural" prohibition is unconstitutionally vague because it bans "words of similar import" to "natural." To prevail on that claim, Plaintiffs must show that the "natural" ban has no identifiable core meaning. Plaintiffs come nowhere close to meeting that demanding standard. And any such challenge is premature and unnecessary given that rulemaking by the Attorney General will explicitly define "words of similar import."

Plaintiffs also allege that Act 120 violates the dormant Commerce Clause. Act 120 is not a "clearly discriminatory" statute, however, as it applies equally to in-state food manufacturers and out-of-state food manufacturers. Nor does Act 120 impose burdens on interstate commerce that are clearly excessive in relation to the Act's putative local benefits. The Second Circuit has squarely held that the only burden alleged by Plaintiffs – the cost of reconfiguring product labels and distribution channels for the Vermont market – is not even cognizable under the Commerce Clause. And courts have repeatedly made clear that the asserted benefits advanced by Act 120 – enabling consumers to make informed choices about potential health risks, environmental effects, and religious implications of food products – easily outweigh any alleged burdens on interstate commerce.

Next, Act 120 is neither expressly nor impliedly preempted by any of the four federal statutes Plaintiffs invoke: the Federal Food, Drug, and Cosmetic Act, the Nutrition Labeling and Education Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act. Indeed, courts have routinely held that similar labeling requirements – including requirements applied to GE food – are not preempted by federal law.

Finally, several parties do not belong in this case. Plaintiff National Association of Manufacturers lacks standing, as it has alleged no facts showing an injury in fact from any portion of the statute. Additionally, Governor Shumlin, Commissioner Chen, and Commissioner Reardon are not proper defendants here because they are not responsible for enforcing Act 120.

FACTUAL BACKGROUND

On May 8, 2014, Governor Peter Shumlin signed House Bill 112, "An act relating to the labeling of food produced with genetic engineering," into law as Act 120.[1] 2014 Vt. Acts & Resolves No. 120 ("Act 120"). Act 120 requires manufacturers and retailers to label GE foods offered for retail sale in Vermont. Packaged raw food produced entirely or in part from genetic engineering must be labeled by manufacturers as "produced with genetic engineering." Act 120, Sec. 2, § 3043(b)(1). In the case of unpackaged raw food, Act 120 requires retailers to post a "produced with genetic engineering" label on the retail store shelf or bin where the product is displayed for sale. *Id.* Sec. 2, § 3043(b)(2). Processed foods produced entirely or partially with genetic engineering must be labeled as "produced with genetic engineering," "partially produced with genetic engineering," or "may be produced with genetic engineering." *Id.* Sec. 2, §§ 3043(a)-(b). Act 120 also prohibits manufacturers from advertising or labeling any food produced entirely or in part from genetic engineering as "natural," "naturally made," "naturally

[1] The full text of Act 120 is attached as Exhibit A.

grown," "all natural," or any words of similar import that would have a tendency to mislead a consumer. *Id.* Sec. 2, § 3043(c).

Act 120 does not require manufacturers to identify which ingredients were genetically engineered. *Id.* Sec. 2, § 3043(d). Nor does it prohibit manufacturers from including additional information or disclaimers on their packaging about the difference (or lack thereof) between GE crops and their traditional counterparts. Finally, Act 120 exempts certain categories of food from its labeling requirements, including food "derived entirely from an animal which has not itself been produced with genetic engineering"; processing aids and enzymes produced with genetic engineering; alcoholic beverages; processed foods not packaged for retail and intended for immediate consumption; food served in restaurants; food containing only minimal amounts of GE material; and certain foods not "knowingly or intentionally" produced with genetic engineering. *Id.* Sec. 2, § 3044 (listing exemptions).[2]

Act 120 has four stated purposes, each grounded in express legislative findings and codified at § 3041(1)-(4).[3] *First*, Act 120 was designed to enable persons to "make informed decisions regarding the potential health effects of the food they purchase and consume," and, if

[2] The full scope of these exemptions will be clarified through rulemaking by the Attorney General, as contemplated by Act 120. *See* Act 120, Sec. 3.

[3] All documents cited herein are located in the legislative bill file of H.112 (2014), signed into law as Act 120. The referenced documents from the file, attached as Exhibit B, were provided to committees in the House and Senate. *See* Ex. B at 14, 22, 24. "In ruling on a 12(b)(6) motion to dismiss, the Court may . . . take judicial notice of public documents, such as legislative histories." *Wang v. Pataki*, 396 F. Supp. 2d 446, 453 n.1 (S.D.N.Y. 2005) (finding on motion to dismiss First Amendment challenge that materials in legislative history confirmed State's legitimate interest); *see Nat'l Ass'n of Pharm. Mfrs. v. FDA*, 637 F.2d 877, 828-88 (2d Cir. 1981) (discussing legislative history at length in affirming Rule 12(b)(6) dismissal); *Anheuser-Busch, Inc. v. Schmoke*, 63 F.3d 1305, 1311-12 (4th Cir. 1995) (finding that court could consider studies presented to City Council on motion to dismiss constitutional challenge to local ordinance), *vacated on other grounds*, 517 U.S. 1206 (1996), *readopted*,101 F.3d 325, 327 (4th Cir. 1996).

they choose, to "avoid potential health risks of food produced from genetic engineering." Act 120, Sec. 2, § 3041(1). Based on voluminous materials and testimony, the Legislature found that there are "conflicting studies assessing the health consequences of food produced from genetic engineering," and that genetic engineering of plants and animals may cause unintended consequences. *Id.* Sec. 1(4)(A)-(B).[4] Moreover, the Legislature found, the FDA relies entirely on safety studies submitted by manufacturers (*id.* Sec. 1(2)(B)-(C)), while independent scientists may be limited in their ability to assess GE foods because of industry or patent restrictions on research (*id.* Sec. 1(2)(F)). The Legislature also found that no long-term or epidemiologic studies have been conducted in the United States examining the safety of human consumption of GE foods. *Id.* Sec. 1(2)(E).

Second, Act 120 was designed to "[i]nform the purchasing decisions of consumers who are concerned about the potential environmental effects of food from genetic engineering." Act 120, Sec. 2, § 3041(2).[5] The Legislature found that the use of GE crops contributes to genetic homogeneity, loss of biodiversity, and increased vulnerability of crops to pests, diseases, and variable climate conditions. *Id.* Sec. 1(4)(C). It also found that pollen drift from GE crops threatens to contaminate organic crops and impairs the marketability of those crops. *Id.* Sec. 1(4)(D). In addition, the Legislature found that GE crops can adversely affect native plants through the transfer of unnatural DNA, thereby displacing natural wildlife. *Id.* Sec. 1(4)(E). The Legislature concluded that a labeling requirement will allow Vermonters who are concerned

[4] The bill file contains numerous published studies revealing negative health effects of GE foods. Ex. B at 25-29, H.112 Bill File (2014) (listing studies presented to Vermont Legislature that address the health and safety risks of GE foods).

[5] The bill file also contains numerous published studies addressing the environmental risks of GE crops. Ex. B at 30, H.112 Bill File (2014) (listing environmental studies in bill file).

about the environmental impact of GE foods to adjust their purchasing decisions accordingly. *Id.* Sec. 2, § 3041(2).

Third, Act 120 is intended to "[r]educe and prevent consumer confusion." *Id.* Sec. 2, § 3041(3). The Legislature found, based on polling results, that many consumers are misinformed about whether they are purchasing GE foods, and that labeling GE food will lessen such confusion. *Id.* Sec. 1(5)(B).[6] In addition, the Legislature found that labeling GE foods "natural" is "inherently misleading" because it "conflicts with the general perception that 'natural' foods are not genetically engineered." *Id.* Sec. 1(5)(C).

Finally, Act 120 "[p]rovide[s] consumers with data from which they may make informed decisions for religious reasons." *Id.* Sec. 2, § 3041(4). The Legislature found that many individuals hold religious objections to genetic tampering with natural life forms.[7] *Id.* Sec. 1(5)(D). By requiring GE labeling, the Legislature concluded that it could accommodate the concerns of individuals seeking to maintain the dietary restrictions associated with various religious beliefs. *Id.* Sec. 1(5)(E); *id.* Sec. 2, § 3041(4).

Persons who fail to comply with the labeling requirements of Act 120 face a civil penalty of not more than $1,000 per day, per unique product. Act 120, Sec. 2, § 3048(a). Retailers are not liable for a manufacturer's failure to label processed foods. *Id.* Sec. 2, § 3045(a). Retailers are liable, however, for failure to display the required labeling for unpackaged produce, unless the retailer secures a sworn statement from the seller that the food "has not been knowingly or

[6] *See* Ex. B at 31, H.112 Bill File (2014) (bill file includes New York Times poll from July 2013). The referenced poll, available at http://www.nytimes.com/2013/07/28/science/strong-support-for-labeling-modified-foods.html?_r=0 (last visited Aug. 7, 2014) reveals that fewer than half of those polled knew that a large amount of processed foods at grocery stores are genetically engineered and reports that 93% of those surveyed support GE labeling.

[7] The bill file contains materials addressing various religious concerns raised by GE foods. *See* Ex. B at 32, H.112 Bill File (2014) (listing materials given to Legislature).

intentionally produced with genetic engineering and has been segregated from and has not knowingly or intentionally commingled with food that may have been produced with genetic engineering." *Id.* Sec. 2, § 3044(2). Act 120 takes effect on July 1, 2016, but effective immediately, the Vermont Attorney General may promulgate implementing regulations. *Id.* Sec. 7. The Attorney General has begun draft rulemaking to clarify how Act 120 will be implemented.

On June 12, 2014, Plaintiffs filed this action, alleging that Act 120 is infirm on various constitutional grounds. Doc. 1 (Complaint). First, Plaintiffs allege that the GE disclosure requirement and the ban on the use of "natural" in GE advertising violate the First Amendment (Counts I and II). Second, they allege that Act 120's ban on the use of "words of similar import" to "natural" is unconstitutionally vague (Count III). Third, they allege that Act 120 violates the Commerce Clause (Count IV). Finally, Plaintiffs allege that Act 120 is preempted, either expressly or impliedly, by certain federal food-labeling statutes (Count V).

We address Plaintiffs' particular allegations in the arguments below. But two observations are warranted at the outset. *First*, Plaintiffs focus exclusively on the public-health purposes of Act 120. In so doing, Plaintiffs make no mention of Vermont's stated concerns regarding the environmental effects of GE crops, or of the State's interest in accommodating Vermonters' religious practices. Nor do Plaintiffs dispute the Legislature's finding – based on compelling polling data – that there is widespread consumer confusion about the prevalence of genetic engineering in the production of food purchased and consumed on a daily basis.

Second, the constitutional challenges asserted in this case are facial in nature. Plaintiffs do not contend that Act 120 is unconstitutional as applied to them or to their members. Consistent with a facial challenge, Plaintiffs seek drastic and far-reaching relief from this Court:

a declaration "that the Act in its entirety is invalid and unenforceable," and an injunction barring enforcement of "any aspect of the Act." Compl. at 22.

ARGUMENT

The Complaint should be dismissed under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). To survive dismissal, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The Court must take factual allegations as true, but it need not credit "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "[C]ourts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

Plaintiffs can prevail on their *facial* challenge to Act 120 only by "'establish[ing] that no set of circumstances exists under which the Act would be valid,' *i.e.*, that the law is unconstitutional in all of its applications." *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 449 (2008) (quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987)). A facial statutory challenge "that is deficient as a matter of law may be dismissed" for failure to state a claim under Rule 12(b)(6). *Clift v. City of Burlington, Vt.*, 925 F. Supp. 2d 614, 633 (D. Vt. 2013) (citing *Kittay v. Giuliani*, 252 F.3d 645, 646-47 (2d Cir. 2001)).

I. PLAINTIFFS FAIL TO STATE A CLAIM THAT THE GE DISCLOSURE REQUIREMENT VIOLATES THE FIRST AMENDMENT

Plaintiffs challenge Act 120's GE disclosure requirement on First Amendment grounds. Compl. ¶¶ 41-56. Because the Act compels disclosure of purely factual, commercial information (whether a food product was or may have been produced with genetic engineering), it is subject

to rational-basis review under *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985). Under that standard, the Complaint fails to state a claim for relief.

A. The GE disclosure requirement is subject to rational-basis review.

Commercial speech is generally afforded less protection under the First Amendment than other forms of speech. *Zauderer*, 471 U.S. at 637. And as the Supreme Court recognized in *Zauderer*, even within the less-protected universe of commercial speech, there are "material differences between *disclosure* requirements and outright *prohibitions* on speech." *Id.* at 650 (emphasis added). In particular, *Zauderer* holds that compelled disclosure of purely factual information need only be "reasonably related to the State's interest in preventing deception of consumers." *Id.* at 651.

That is the controlling First Amendment standard in this case, as the Second Circuit has held in a closely related setting. In *National Electrical Manufacturers Association v. Sorrell* ("*NEMA*"), 272 F.3d 104 (2d Cir. 2001), the court rejected a constitutional challenge to a Vermont statute requiring labeling of certain mercury-containing products. Applying only rational-basis scrutiny, the Second Circuit explained:

> Commercial disclosure requirements are treated differently from restrictions on commercial speech because mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests. Such disclosure furthers, rather than hinders, the First Amendment goal of the discovery of truth and contributes to the efficiency of the "marketplace of ideas." . . . In such a case, then, less exacting scrutiny is required than where truthful, nonmisleading commercial speech is restricted.

Id. at 113-14.

Significantly, the Second Circuit applies rational-basis review even where a compelled disclosure requirement is designed, not to prevent consumer deception, but instead for the

broader purpose of "increasing consumer awareness" in the interest of "protecting human health and the environment." *Id.* at 115. The Court reiterated that principle only five years ago in *New York State Restaurant Association v. New York City Board of Health* ("*NYSRA*"), 556 F.3d 114, 118 (2d Cir. 2009), upholding under *Zauderer* a statute requiring that New York City restaurants post calorie content on menus. The court emphasized that commercial disclosure requirements "are subject to more lenient review" than regulations restricting speech – whether they address consumer confusion or another state interest – and upheld New York City's regulation as reasonably related to its goal of "promot[ing] informed consumer decision-making so as to reduce obesity." *Id.* at 132, 134; *see also Safelite Grp., Inc. v. Jepsen*, 988 F. Supp. 2d 199 (D. Conn. 2013) (upholding under *Zauderer* a state law requiring insurance companies to provide policyholders with information about non-affiliate repair shops).

And, just last week, the D.C. Circuit, sitting en banc, reaffirmed that the *Zauderer* standard applies to commercial disclosure requirements – in that case, a country-of-origin meat-labeling regulation. Applying the *Zauderer* standard, the court upheld the labeling requirement on the ground that it would "enabl[e] customers to make informed choices based on characteristics of the products they wished to purchase." *Am. Meat Inst. v. U.S. Dep't of Agric.*, No. 13-5281, 2014 WL 3732697, at *5 (D.C. Cir. July 29, 2014) (en banc). In so holding, the court rejected the plaintiff's attempt to cabin *Zauderer* to disclosures intended to remedy consumer deception – and relied on the Second Circuit's decisions in *NEMA* and *NYSRA* for the proposition that a speaker's interest in withholding factual information is "minimal." *Id.* at 7-8.

Like the labeling statutes in *NEMA*, *NYSRA*, and *American Meat Institute*, the GE labeling requirement in Act 120 is subject to rational-basis review under *Zauderer*. Act 120 requires manufacturers of GE food products to make one of three purely factual disclosures:

"produced with genetic engineering," "partially produced with genetic engineering," or "may be produced with genetic engineering." Act 120, Sec. 2, § 3043(b). It requires those disclosures so that Vermonters will not be confused about whether their foods contain GE ingredients, and so they will have sufficient information to avoid the potential health risks, environmental effects, and religious implications associated with the production and consumption of GE foods. Those goals are consistent "with the policies underlying the First Amendment protection of commercial speech . . . and the reasons supporting the distinction between compelled and restricted commercial speech." *NEMA*, 272 F.3d at 115.

Nevertheless, Plaintiffs allege that the GE disclosure requirement warrants more exacting First Amendment scrutiny. They first allege that the labeling requirement should be subject to strict scrutiny, because it somehow "imposes a burden on protected speech based upon its content, and the identity and viewpoint of the speaker." Compl. ¶ 45. Plaintiffs rely on *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011), in which the Supreme Court applied heightened scrutiny to a Vermont law that prohibited pharmaceutical manufacturers from using prescriber-identifying information for marketing purposes. *Id.* at 2664. But *IMS Health* is inapposite – it addressed *restrictions* on speech; Act 120's GE labeling requirement, in contrast, requires the *disclosure* of factual speech. And, as noted, the courts have long applied minimal scrutiny to factual disclosure requirements. Plaintiffs here, like the appellant in *Zauderer,* thus "overlook[] material differences between disclosure requirements and outright prohibitions on speech." *Zauderer*, 471 U.S. at 650.

Nor does Act 120 constitute a viewpoint-based regulation of speech. Act 120 requires the disclosure of a *fact* – that GE foods are or may be "produced with genetic engineering." Act 120 does not require manufacturers to state a particular *viewpoint*, such as whether GE foods are

good or bad. To the contrary, as discussed further below, nothing in Act 120 prohibits manufacturers from expressing their own views about genetic engineering or stating that the FDA does not consider GE foods to be materially different from natural food. Thus, unlike speech regulations that discriminate based on viewpoint, "the specific motivating ideology" of the speaker was plainly not the rationale for Act 120's disclosure requirement. *Rosenberger v. Rector & Visitors of Univ. of Va.*, 515 U.S. 819, 829 (1995).

Backing off their claim for strict scrutiny, Plaintiffs next invoke the "intermediate" scrutiny test articulated in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980), allegedly because Act 120 "compels disclosures that are controversial." Compl. ¶¶ 51-52. Plaintiffs appear to suggest that the GE disclosure requirement is controversial, not factual, simply because they'd rather not make the required disclosure. But that is true of almost *any* compelled disclosure – it is almost never something that the commercial party wishes to do voluntarily. Plainly, such disagreements do not make a purely factual disclosure "controversial." *See Jepsen*, 988 F. Supp. 2d at 207 ("[T]he fact that [plaintiff] would prefer not to make the required disclosure is insufficient to make it 'controversial.'" (citing *NYSRA*, 556 F.3d at 133-34)). A compelled commercial disclosure is "controversial" only if the *disclosure itself* is opinion-based.[8] But a disclosure that food was produced with genetic engineering – which is all Act 120 requires – is a true and objective fact.

Plaintiffs next suggest that disclosing the presence of GE material in food will effectively

[8] *Compare Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) ("sexually explicit" label was "controversial" because "State's definition of this term is far more opinion-based than the question of whether a particular chemical is within any given product") *with Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 560-61 (6th Cir. 2012) (reviewing First Amendment challenge to mandated, factual warning about health risks of tobacco under *Zauderer*) (distinguishing *Blagojevich*) *and Am. Meat Inst.*, 2014 WL 3732697, at *8 (rejecting argument that country-of-origin meat labels are controversial).

convey a negative message to consumers about the use of genetic engineering in food. Compl. ¶ 43. That argument again proves too much: it is hard to imagine any compelled disclosure that does not meet Plaintiffs' test for "controversy." In any event, as noted, Act 120 does not require manufacturers to express any opinion in the ongoing debate surrounding GE foods. It requires only that they label GE foods – factually, and truthfully – so that consumers can make their own judgments about the health, environmental, and religious implications of consuming GE foods. Indeed, Act 120 does nothing to prohibit manufacturers from including *more* information on their products than is required by the mandated disclosure. If a manufacturer believes that the mere disclosure of genetic engineering will convey a message about GE foods with which it disagrees, it is free to add onto its label its own views about the significance of genetic engineering, or state that the FDA does not consider GE foods to be materially different from other foods. *See, e.g.*, *Jepsen*, 988 F. Supp. 2d at 207 (rejecting argument that disclosure of competitor's name would "be misleadingly seen by claimants as an endorsement of its competitors" because law did not require plaintiff "to express any opinion at all regarding these names nor to take a position in any ongoing debate" and gave plaintiff "latitude to expressly inform consumers that it does not recommend the non-affiliated repair shop").[9]

Nor is Plaintiffs' reference to the Second Circuit's decision in *International Dairy Foods Association v. Amestoy* ("*IDFA*"), 92 F.3d 67 (2d Cir. 1996), pertinent. In that case, the court applied *Central Hudson* to strike down a law requiring manufacturers to label certain milk

[9] *Cf. Conn. Bar Ass'n v. United States*, 620 F.3d 81, 98 (2d Cir. 2010) (rejecting argument that compelled disclosure was misleading where it did not "preclude[] an attorney from providing . . . *more* information than is contained in the mandated disclosures to ensure accurately informed choice"); *Envtl. Def. Ctr. Inc. v. EPA*, 344 F.3d 832, 849-51 (9th Cir. 2003) (rejecting argument that compelled disclosure required dissemination of an ideological message where it did not prohibit speaker from "stating its own views" about the subject matter of the disclosure).

products. But *IDFA* is sharply distinguishable, as explained further below, not least because the court never considered whether *Zauderer* governed. And in *NEMA* and *NYSRA* – both decided after *IDFA* – the Second Circuit made abundantly clear that "*Zauderer*, not *Central Hudson* . . . describes the relationship between means and ends demanded by the First Amendment in compelled commercial disclosure cases." *NEMA*, 272 F.3d at 115; *see NYSRA*, 556 F.3d at 132.

B. The disclosure requirement is entirely rational and therefore constitutional under *Zauderer*.

Compelled commercial disclosures are constitutional under *Zauderer* so long as they are "reasonably related" to a legitimate state interest. *NYSRA*, 556 F.3d at 136; *Zauderer*, 471 U.S. at 651. The GE disclosure requirement easily meets that standard.

To begin with, a State "'has no obligation to produce evidence, or empirical data to sustain . . . rationality.'" *NYSRA*, 556 F.3d at 134 n.23 (quoting *Lewis v. Thompson*, 252 F.3d 567, 582 (2d Cir. 2001)); *see also Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 250 (2010) (citing *Zauderer*, 471 U.S. at 652-53). "'Any reasonably conceivable set of facts will suffice to satisfy rational-basis scrutiny. The burden falls on the party attacking the statute as unconstitutional to negative every conceivable basis which might support it.'" *Jepsen*, 988 F. Supp. 2d at 211 (quoting *Thompson*, 252 F.3d at 582); *see also Gen. Media Commc'ns, Inc. v. Cohen*, 131 F.3d 273, 286 (2d Cir. 1997) ("Rational basis review does not pass judgment upon the wisdom, fairness, or logic of legislative decisions; it turns on whether there are 'plausible' reasons for Congress's choices.").

Four separate state interests justify Act 120, each one of which is independently sufficient: public health and food safety, environmental protection,[10] prevention of consumer

[10] Courts, including the Supreme Court, have recognized in recent years that gene flow from GE crops to non-GE crops does occur, and that such gene flow may have environmental impacts

confusion, and accommodation of religious practices. Act 120, Sec. 2, § 3041. *See generally Zauderer*, 471 U.S. at 651 (recognizing state's interest in preventing consumer confusion); *NYSRA*, 556 F.3d at 134 (recognizing state's interest in promoting informed decision-making on matters of public health); *Ass'n of Nat'l Advertisers, Inc. v. Lungren*, 44 F.3d 726, 735 (9th Cir. 1994) (recognizing state's interest in providing "ecologically-oriented consumers" with information to allow them to purchase environmentally sound products); *cf. Mayweathers v. Newland*, 314 F.3d 1062, 1069 (9th Cir. 2002) (upholding federal law that had legislative purpose of accommodating free exercise of religion). Moreover, although rational-basis review requires nothing more, the Vermont Legislature also made findings that amply support the reasonableness of the statute. *See generally* Factual Background, *supra.*

Plaintiffs proclaim that Act 120 does not serve state interests at all, but only "consumer desire" and "consumer interest." Compl. ¶¶ 30, 47 (citing *IDFA*). But consumer interests *are* state interests; if they weren't, it would be difficult to explain the prevalence of consumer-protection laws across the country. Indeed, the en banc D.C Circuit upheld the country-of-origin meat-labeling regulation on the ground that it was enacted "to empower consumers to take possible country-specific differences in safety practices into account" when purchasing meat

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and cause economic harm to organic and conventional farmers. *See Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153-56 (2010) (discussing environmental and economic harms caused by gene flow from GE to conventional alfalfa); *Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, 718 F.3d 1350, 1357 (Fed. Cir. 2013) (noting that "Monsanto acknowledges that conventional crops could be exposed to 'cross-pollination from nearby fields'" and that the district court deemed contamination of conventional crops "likely inevitable"); *In re Genetically Modified Rice Litig.*, 666 F. Supp. 2d 1004, 1014 (E.D. Mo. 2009) ("In August of 2006 the United States Department of Agriculture announced that trace amounts of LLRICE 601, a genetically modified rice strain, had been detected in the U.S. long-grain rice supply"), *adhered to on reconsideration*, 2011 WL 5024548 (E.D. Mo. Oct. 21, 2011). Environmental protection alone is a sufficient state interest to support the Legislature's decision to enact Act 120 – yet Plaintiffs entirely ignore the environmental impacts of GE crops.

products. *Am. Meat Inst.*, 2014 WL 3732697, at *6. The court went on to explain that "[t]he self-evident tendency of a disclosure mandate to assure that recipients get the mandated information may in part explain why, where that is the goal, many such mandates have persisted for decades without anyone questioning their constitutionality." *Id.* at *7.

In any event, Act 120's text and history confirm that it was enacted to address *the State's* specific concerns about GE foods – concerns based on scientific material presented during the legislative process. *See* Factual Background, *supra*. In that regard, the present case bears no resemblance to *IDFA*, where the court held that Vermont never even suggested that "health or safety concerns prompted the passage of the [law]," but instead defended the law only by reference to "consumer curiosity." *IDFA*, 92 F.3d at 73 & n.1; *see NYSRA*, 556 F. 3d at 134 ("[O]ur decision in [*IDFA*] 'was expressly limited to cases in which a state disclosure requirement is supported by no interest other than the gratification of 'consumer curiosity.'") (quoting *NEMA*, 272 F.3d at 115 n.6). To the contrary, the passage of Act 120 was expressly prompted by health and safety concerns – not to mention the goals of environmental protection, prevention of consumer deception, and religious accommodation. Thus, this case is controlled by *NEMA* and *NYSRA*, in which the Second Circuit upheld commercial disclosure requirements that were reasonably related to the government's interest in promoting informed consumer choice regarding issues of health and environmental protection.

II. PLAINTIFFS LACK STANDING TO CHALLENGE ACT 120'S RESTRICTION ON THE USE OF THE TERM "NATURAL," AND, IN ANY EVENT, FAIL TO STATE A CLAIM THAT THE "NATURAL" PROHIBITION VIOLATES THE FIRST AMENDMENT

Plaintiffs' First Amendment challenge to Act 120's ban on the use of the term "natural" fails as well. As an initial matter, Plaintiffs lack standing to assert it. Article III requires a plaintiff, "at an irreducible minimum, . . . to show that he personally has suffered some actual or

threatened injury as a result of the putatively illegal conduct of the defendant." *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 472 (1982). Associations must allege that at least one member suffers injury "'of the sort that would make out a justiciable case had the members themselves brought suit.'" *Disability Advocs., Inc. v. N.Y. Coal. for Quality Assisted Living, Inc.*, 675 F.3d 149, 156-57 (2d Cir. 2012) (quoting *Warth v. Seldin*, 422 U.S. 490, 511 (1975)). Because Plaintiffs bring a pre-enforcement facial challenge, they must allege that their members have "an intention to engage in a course of conduct" that Act 120 proscribes. *Vt. Right to Life Comm., Inc. v. Sorrell*, 221 F.3d 376, 382 (2d Cir. 2000) (quoting *Babbitt v. United Farm Workers Nat'l Union*, 422 U.S. 289, 298 (1973)).

The Complaint conspicuously flunks that test. Nowhere do Plaintiffs allege that their members currently advertise or label GE products as "natural" or plan to do so.[11] Because Plaintiffs do not allege that they intend to engage in conduct proscribed by section 3403(c)'s ban on "natural" advertising, they lack standing to challenge that portion of Act 120. *See Carrico v. City & Cnty. of S. F.*, 656 F.3d 1002, 1007 (9th Cir. 2011) (ordering dismissal due to lack of standing where there was "no allegation on which to base an inference that any of [plaintiffs'] members intend to engage in conduct even arguably proscribed by" the ordinance); *Glenn v. Holder*, 738 F. Supp. 2d 718, 731 (E.D. Mich. 2010) (dismissing complaint for lack of standing where plaintiffs "[did] not allege that they have violated the [law] in the past, nor that they intend to violate it in the future"), *aff'd*, 690 F.3d 417 (6th Cir. 2012).

[11] Indeed, as explained in detail below, it is inherently misleading to label GE products as "natural," and in fact numerous consumers have brought false-advertising claims when they learned that purportedly "natural" food products they consumed were produced with GE crops. *See, e.g., In re Frito-Lay N. Am., Inc. All Natural Litig.*, No. 12-md-2413, 2013 WL 4647512 (E.D.N.Y. Aug. 29, 2013); *Randolph v. J.M. Smucker Co.*, No. 13-80581, 2014 WL 1018007 (S.D. Fla. Mar. 14, 2014). This Court thus cannot assume that Plaintiffs make or intend to make such misleading claims on their products.

And even if they had standing to assert it, Plaintiffs' First Amendment challenge fails on the merits because misleading commercial speech is not entitled to the protection of the First Amendment. *Central Hudson*, 447 U.S. at 563; *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 623-24 (1995). The scope of permissible state regulation depends on whether the commercial speech is "actually or inherently misleading" or "potentially misleading." *Peel v. Att'y Registration & Disciplinary Comm'n of Ill.*, 496 U.S. 91, 111 (1990) (Marshall, J., concurring). Commercial speech that is "inherently misleading" falls outside the protection of the First Amendment and may be banned outright. *Id.* Whether speech is "inherently misleading" – meaning whether it "inevitably will be misleading to consumers" – is a question of law that this Court can resolve at the motion to dismiss stage. *1-800-411-Pain Referral Serv., LLC v. Otto*, 744 F.3d 1045, 1056 (8th Cir. 2014) (citing *Peel*, 496 U.S. at 108).

When used to describe foods produced from genetic engineering, as that term is defined by Act 120, the words "natural," "naturally made," "naturally grown," and "all natural" are inherently misleading. Black's Law Dictionary defines "natural" as "in accord with the regular course of things in the universe and without accidental or purposeful interference"; as "brought about by nature as opposed to artificial means"; and as "untouched by civilization." *Id.* at 1054 (rev. 8th ed. 2004); *see also* Merriam-Webster's Online Dictionary, www.merriam-webster.com/dictionary/natural (defining "natural" as "existing in nature and not made or caused by people"; "coming from nature"; and "not containing anything artificial"). In contrast, Act 120 defines "genetic engineering" as "a process by which food is produced from an organism or organisms in which the genetic material has been changed" by techniques including the direct injection of genes into cells, the fusion of cells, and the hybridization of genes that does not occur in nature. Act 120, Sec. 2, §§ 3042(4)-(5); *id.* Sec. 1(5)(C). Those techniques are, by definition, not

"brought about by" or "existing in" nature, but instead are "manmade" and brought about by "purposeful interference" and "artificial means." Indeed, both the World Health Organization and food manufacturer Monsanto Company, a member of Plaintiff GMA, define genetically modified organisms as those that have been *altered* from their "natural" state.[12] Referring to these foods as "natural" inevitably will be misleading to consumers. The State thus may freely regulate this commercial speech without offending the First Amendment.

III. PLAINTIFFS FAIL TO STATE A VAGUENESS CLAIM, AND ANY SUCH CLAIM IS PREMATURE AT THIS TIME

Plaintiffs allege that the ban on using "words of similar import" to "natural" is unconstitutionally vague. Compl. ¶¶ 66-67. Again, their claim is facial – there are no claims about *particular* labels or advertisements. Instead, Plaintiffs "challenge the application of the law more broadly." *Vt. Right to Life Comm., Inc. v. Sorrell*, No. 12-2904, 2014 WL 2958565, at *6 (2d Cir. July 2, 2014) (treating as a facial claim a vagueness challenge that was "not limited to plaintiff's particular case"). The challenge is meritless and premature.

The Due Process Clause is not an invitation to hold state legislatures to exacting drafting standards. All due process requires is "that laws be crafted with sufficient clarity to give the person of ordinary intelligence a reasonable opportunity to know what is prohibited and to provide explicit standards for those who apply them." *VIP of Berlin, LLC v. Town of Berlin*, 593 F.3d 179, 186 (2d Cir. 2010) (internal quotation marks omitted). Moreover, because Act 120 is a

[12] *See* Ex. B at 35, 41, H.112 Bill File (2014) (including Monsanto Definition of GMO, http://www.monsanto.com/newsviews/Pages/glossary.aspx#g (last visited Aug. 7, 2014), which defines GMOs as "[p]lants or animals that have had their genetic makeup altered to exhibit traits that *are not naturally theirs*," (emphasis added) and World Health Organization, 20 Questions on Genetically Modified (GM) Foods (2012), http://www.who.int/foodsafety/publications/biotech/en/20questions_en.pdf (last visited Aug. 7, 2014), which states: "Genetically modified organisms (GMOs) can be defined as organisms in which the genetic material (DNA) has been *altered in a way that does not occur naturally*." (emphasis added)).

civil, not criminal, statute – and in particular because it is an economic regulation – it may be "deemed unconstitutionally vague only if it commands compliance in terms 'so vague and indefinite as really to be no rule or standard at all.'" *Advance Pharm., Inc. v. United State*s, 391 F.3d 377, 396 (2d Cir. 2004) (quoting *Boutilier v. INS*, 387 U.S. 118, 123 (1967)); *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982). Finally, as the Second Circuit reaffirmed just last month, because Plaintiffs are bringing a facial challenge to the statute, they may "succeed only when the challenged law can *never* be validly applied." *Vt. Right to Life*, 2014 WL 2958565, at *7 (emphasis added). "[I]f a statute has a core meaning that can be reasonably understood, then it may validly be applied to conduct within the core meaning, and the possibility of such a valid application necessarily means that the statute is not vague on its face." *Brache v. Westchester Cnty.*, 658 F.2d 47, 51 (2d Cir. 1981).

To be sure, vagueness challenges are evaluated "more stringently where the rights of free speech or free association are implicated." *Vt. Right to Life*, 2014 WL 2958565, at *7. As explained above, however, Act 120's ban on "natural" advertising regulates misleading speech, which falls outside the protection of the First Amendment. Moreover, the specific portion of section 3403(c) that Plaintiffs challenge as vague prohibits "words of similar import that would have a tendency to mislead a consumer" – which is, by definition, misleading speech.[13] Even under a more exacting due process standard, however, "'perfect clarity and precise guidance have never been required even of regulations that restrict expressive activity.'" *Vt. Right to Life*, 2014 WL 2958565, at *7 (quoting *Holder v. Humanitarian Law Project*, 561 U.S. 1, 19 (2010)).

[13] *See Vill. of Hoffman Estates*, 455 U.S. 489, 496-99 (analyzing vagueness claim under standard applicable to commercial and economic regulations after rejecting First Amendment challenge); *Magee v. City of S. Padre Island*, 463 Fed. App'x 377, 381 (5th Cir. 2012) (rejecting vagueness challenge to ordinance that could be enforced "only against commercial activity and in a manner that will not offend the First Amendment").

Indeed, the Supreme Court has made clear that "flexibility and reasonable breadth" in the language of a statute does not render it unconstitutional, so long as it is "clear what the ordinance as a whole prohibits." *Grayned v. City of Rockford*, 408 U.S. 104, 110 (1972).

The Complaint fails to allege sufficient facts to meet that standard. In truth, the Complaint alleges no pertinent facts at all. The Complaint asserts, conclusorily, that Act 120 "does not give food manufacturers reasonable notice," and "opens the door to arbitrary enforcement." Compl. ¶¶ 66-67. But such "[t]hreadbare recitations" cannot withstand a motion to dismiss. *Iqbal*, 556 U.S. at 679; *see also Commack Self-Serv. Kosher Meats, Inc. v. Hooker*, 800 F. Supp. 2d 405, 417 (E.D.N.Y. 2011) (dismissing facial vagueness claim), *aff'd*, 680 F.3d 194 (2d Cir. 2012).

Moreover, Plaintiffs' allegations, conclusory as they are, cannot be reconciled with the straightforward text of the statute, construed as a whole. The phrase "words of similar input" follows a list of examples that all contain the word "natural" or "naturally." This makes "clear what the [statute] as a whole prohibits" (*Grayned*, 408 U.S. at 110): advertisements and labels that contain variations on the word "natural" that suggest to consumers that a GE product was naturally made. Because Act 120 can be validly applied to advertising within that "core meaning," Plaintiffs fail to state a facial vagueness claim. *Brache*, 658 F.2d at 51.

Plaintiffs' vagueness claim is also premature, as it asks this Court to engage in constitutional adjudication before the Attorney General has a chance to clarify the statute through rulemaking. Consistent with his authority under Act 120 (*see* Sec. 3), the Attorney General is developing rules for the Act's implementation.[14] Those rules will spell out the

[14] Plaintiffs' assertion (at ¶ 68) that such rulemaking is impermissible – offered without explanation – has no basis in the text of the statute. To the contrary, defining an undefined term

meaning of "words of similar import" and guide Act 120's application to Plaintiffs' advertising. *See Vill. of Hoffman Estates*, 455 U.S. at 498 ("administrative regulation will often suffice to clarify a standard with an otherwise uncertain scope."); *Gun Owners' Action League, Inc. v. Swift*, 284 F.3d 198, 208-09 (1st Cir. 2002) (finding vagueness claim unripe where plaintiffs "had not given the relevant rulemaking authority a chance to clarify the statute").[15] The Second Circuit has directed that, under prudential ripeness principles, if a case would be "better decided later," it should be – in particular where the "the potentially unripe question presented for review is a constitutional question." *Connecticut v. Duncan*, 612 F.3d 107, 113-14 (2d Cir. 2010) (quotations omitted). And only "unavoidable" constitutional questions should be adjudicated. *Id.* at 113 n.3 (quotations omitted). Here, adjudication of Plaintiffs' vagueness challenge is eminently avoidable; the phrase "words of similar import" will explicitly be defined by rulemaking long before any enforcement action could occur, and any vagueness challenge, even if warranted, should await that rulemaking.

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

Plaintiffs next allege that Act 120 violates the dormant Commerce Clause. Compl. ¶¶ 70-79. Because Act 120 does not discriminate between in-state and out-of-state commerce, however, Plaintiffs must show that the Act's burdens on interstate commerce are clearly excessive in relation to its putative local benefits. Second Circuit case law forecloses that claim.

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is precisely the type of rulemaking that Act 120 contemplates, and falls well within the broad authority granted to the Attorney General to promulgate rules for the enforcement of Act 120.

[15] *Cf. Marchi v. Bd. of Coop. Educ. Servs. of Albany*, 173 F.3d 469, 478 (2d Cir. 1999) (declining to entertain "open-ended and indefinite challenge" that would "force[the court] to guess" how directive would be applied); *Richmond Boro Gun Club, Inc. v. City of N.Y.*, 97 F.3d 681, 686 (2d Cir. 1986) (vagueness challenge premature where city could limit enforcement).

The dormant Commerce Clause "prohibits economic protectionism – that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *Wyoming v. Oklahoma*, 502 U.S. 437, 454 (1992). "The limitation imposed by the Commerce Clause on state regulatory power is by no means absolute," however, "and the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." *Maine v. Taylor*, 477 U.S. 131, 138 (1986).

A statute may violate the dormant Commerce Clause in two ways. First, it may "clearly discriminate" against interstate commerce, in which case it will be upheld only if the State can show that it is "'demonstrably justified by a valid factor unrelated to economic protectionism.'" *Automated Salvage Transp., Inc., v. Wheelabrator Envtl. Sys., Inc.*, 155 F.3d 59, 74 (2d Cir. 1998) (quoting *Wyoming*, 502 U.S. at 454). Second, a nondiscriminatory statute may have "incidental" effects on interstate commerce, in which case it will be upheld unless the challenger shows, under the so-called *Pike* balancing test, that "the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Id.* (quoting *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)).[16] Plaintiffs fail to state a claim under either test.

A. Act 120 does not "clearly discriminate" against interstate commerce.

"A clearly discriminatory law may operate in three ways: (1) by discriminating against interstate commerce on its face; (2) by harboring a discriminatory purpose; or (3) by discriminating in its effect." *Town of Southold v. Town of East Hampton*, 477 F.3d 38, 48 (2d Cir. 2007) (citations omitted).

[16] The Second Circuit sometimes analyzes "the extraterritorial effects of state regulations as a form of excessive burden under the *Pike* balancing test," and other times "as a basis for per se invalidity" – *i.e.*, as a separate step in the dormant Commerce Clause inquiry. *SPGGC, LLC v. Blumenthal*, 505 F.3d 183, 193 (2d Cir. 2007). We address extraterritoriality (and the question of interstate regulatory conflicts) below in the context of the *Pike* analysis.

Plaintiffs do not allege that Act 120 is facially discriminatory. Nor can they: Act 120, by its own terms, "applies equally to both in-state and out-of-state" food manufacturers. *Id.* at 48. Plaintiffs also do not allege that Act 120 was enacted with the purpose of discriminating against interstate commerce. And again, any such argument is foreclosed by the text of the statute, which states that its "Purpose" is to enable consumers to make informed decisions about the potential health, environmental, and religious consequences of the food they purchase. Act 120, Sec. 2, § 3041; *see, e.g.*, *Minnesota v. Clover Leaf Creamery Co*., 449 U.S. 456, 463 n.7 & 471 n.15 (1981) (assuming for purposes of a dormant Commerce Clause challenge that a statute's articulated purpose is its actual purpose).

It is not entirely clear whether Plaintiffs claim that Act 120 has the effect of discriminating against interstate commerce. What is clear, however, is that they allege no facts that could plausibly support such a claim – and that any such claim fails as a matter of law. In the context of the dormant Commerce Clause, "discrimination" means "differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter." *Automated*, 155 F.3d at 74. Plaintiffs allege that "Vermont's restaurant and dairy industries, as well as its organic industry, are all exempted from the Act's requirements." Compl. ¶73. "Consequently," they allege, "the cost of implementing the regulation falls largely, if not entirely, on out-of-state companies." *Id.*

"[L]aws that draw distinctions between entities that are not competitors," however, "do not 'discriminate' for purposes of the dormant Commerce clause." *Town of Southold*, 477 F.3d at 49. Thus, "in order to show a discriminatory effect on interstate commerce, the Plaintiffs must demonstrate that the Statute confers on their in-state counterparts a competitive advantage." *Brown & Williamson Tobacco Corp. v. Pataki*, 320 F.3d 200, 216 (2d Cir. 2003). Act 120 may,

as Plaintiffs allege, distinguish between some dairy producers and some non-dairy producers.[17] But Act 120 does not distinguish between in-state dairy producers and their relevant counterparts: *out-of-state dairy producers*. *All* dairy producers – in-state and out-of-state – are equally subject to (or exempted from) Act 120's requirements. *See Gerace*, 755 F.2d at 1003 ("[T]o the extent that [the statute] indirectly advantage[s] the dairy industry, that effect is not necessarily limited to in-state dairy producers."). The same goes for Vermont's restaurant and organic industries, which are likewise subject to the same rules as their out-of-state counterparts.

More broadly, courts have rejected Commerce Clause challenges to state labeling requirements analogous to those imposed by Act 120. In *American Beverage Association v. Snyder*, 735 F.3d 362, 367 (6th Cir. 2013), for example, the court addressed a Michigan law that required canned and bottled beverages sold within the state to contain a mark that is "unique to the state" – and which could be used only in the state. The challengers argued (much like Plaintiffs here allege) that the law was discriminatory in effect because it "require[d] the creation and maintenance of special state-exclusive production and distribution operations." *Id.* at 372. The court rejected that argument on the ground that the labeling "provision requires all those

[17] Plaintiffs' reference (at ¶ 73) to a "dairy" exemption is misleading. Act 120 does not contain a "dairy" exemption; it contains an exemption for *all* "[f]ood consisting entirely of or derived entirely from an animal which has not itself been produced with genetic engineering, regardless of whether the animal has been fed or injected with any food, drug, or other substance produced with genetic engineering." Act 120, Sec. 2, § 3044(1). It is true that the exemption covers some dairy products. But it doesn't *only* cover dairy products: eggs, steak, chicken, and other animal products are similarly excluded from the Act's requirements. Nor does the exemption cover *all* dairy products: products containing additives produced with genetic engineering (*e.g.*, ice cream made with GE sugar or corn syrup) would fall outside the scope of the exemption. Far from a protectionist measure, the animal exemption reflects the Legislature's sensible judgment that steak from a cow that was fed GE corn is not itself "produced" with genetic engineering. As discussed further below, moreover, the Legislature likely added the animal exemption to stay within reserved state authority under the Federal Meat Inspection Act and Poultry Products Inspection Act.

who sell certain amounts of beverages in Michigan to use the same unique-to-Michigan mark, without any reference to in-state or out-of-state origins." *Id.* at 373.[18]

And in *International Dairy Foods Association v. Boggs*, 622 F.3d 628 (6th Cir. 2010), the court likewise rejected a Commerce Clause challenge to an Ohio regulation that prohibited dairy manufacturers from making claims about the absence of artificial hormones in their milk (and required them to issue a disclaimer when making such claims about their production processes). The court explained that the rule regulated evenhandedly because it "burdens Ohio dairy farmers and processors who do not use [hormones] in their production of milk products to the same extent as it burdens out-of-state farmers and processors not using [hormones]." *Id.* at 649; *see also NEMA*, 272 F.3d at 110-12 (upholding a Vermont law requiring manufacturers to label mercury-containing lamps, even though the challengers argued that the statute would compel them to conform all their labels to Vermont's requirements).

"[B]ecause consumer protection is a field traditionally subject to state regulation," courts are "particularly hesitant to interfere with the [state's consumer protection] efforts under the guise of the Commerce Clause." *SPGGC, LLC v. Blumenthal*, 505 F.3d 183, 194 (2d Cir. 2007). Act 120 represents such an effort, and like the statutes at issue in *Snyder*, *Boggs*, and *NEMA*, it treats in-state food manufacturers the same as out-of-state food manufacturers.[19] Plaintiffs therefore fail to state a claim that Act 120 is clearly discriminatory.[20]

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[18] The Sixth Circuit went on to hold that Michigan's unique-mark requirement impermissibly operated extraterritorially because it "not only requires beverage companies to package a product unique to Michigan but also allows Michigan to dictate where the product can be sold." *Snyder*, 735 F.3d. at 376. Act 120 does not do either of those things. *See id.* at 382 (Rice, J, concurring) ("In contrast to [*NEMA*], where manufacturers had the option of using the [Vermont]-compliant label nationwide, manufacturers have no such option under Michigan's law.").

[19] Plaintiffs' dormant Commerce Clause argument also completely ignores section Sec. 2, § 3043(b)(2) of Act 120, which, far from protectionist, imposes requirements only on Vermont

B. The alleged burdens of Act 120 are not clearly excessive in relation to its putative local benefits.

Under the *Pike* balancing test, a nondiscriminatory state law with incidental effects on interstate commerce will violate the dormant Commerce Clause only if the law places a burden on interstate commerce that is "clearly excessive in relation to the putative local benefits." *Pike*, 397 U.S. at 142. "[T]he minimum showing required to succeed in a Commerce Clause challenge to a state regulation is that it have a disparate impact on interstate commerce." *Automated*, 155 F.3d at 75. Thus, "[u]nder *Pike*, if no such unequal burden be shown, a reviewing court need not proceed further." *NEMA*, 272 F.3d at 109.

This Court need not proceed further here, because the Second Circuit has expressly held that the only burden alleged by Plaintiffs is no burden at all for purposes of the *Pike* balancing test. In *NEMA*, the plaintiffs (an association of manufacturers) argued that Vermont's mercury-labeling law disproportionately burdened interstate commerce because, "if its members continue selling in Vermont, they would also be forced as a practical matter to label lamps sold in every other state." *NEMA*, 272 F.3d at 110. The district court agreed, holding that the Vermont

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retailers and thus comes nowhere near the type of discrimination against out-of-state interests that would violate the dormant Commerce Clause.

[20] Plaintiffs make the blanket assertion that there "are no *major* food manufacturers based in Vermont." Compl. ¶ 73 (emphasis added). There are many food manufacturers in Vermont that would disagree. But even if Plaintiffs were right, so what? Act 120 applies to both "major" and "minor" food manufacturers. Plaintiffs do not allege that *no* in-state manufacturers would incur any of the burdens Act 120 supposedly imposes on out-of-state manufacturers. Indeed, it is likely more burdensome for a minor food manufacturer on a tight budget to change its label than for a major manufacturer to do so. Plaintiffs likewise do not allege that *all* out-of-state manufacturers would incur those burdens. To the contrary, Plaintiffs acknowledge that organic-food producers – many of which are outside Vermont – would *not* have to label their products or refrain from using the term "natural." Compl. ¶¶ 40, 73, 78; *see Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 127 (1978) ("[I]nterstate 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.").

labeling law burdened interstate commerce because it "'would require manufacturers either to stop selling in Vermont, [or] to change [their] distribution system to isolate bulbs going to Vermont.'" *Id.* at 110 n.2 (quoting 72 F. Supp. 2d 449, 453-54 (D. Vt. 1999)).

The Second Circuit rejected that argument. "[L]amp manufacturers," the court explained, could simply "arrange their production and distribution processes to produce labeled lamps solely for the Vermont market and then pass much of the increased costs along to Vermont consumers in the form of higher prices." *Id.* at 110. The Second Circuit therefore held that the mercury-labeling statute did not "disproportionately burden interstate commerce" – and declined even to address the putative local benefits of the statute. *Id.*

Plaintiffs here allege precisely the same burdens alleged by the plaintiffs (and rejected by the Second Circuit) in *NEMA*. As in *NEMA*, Plaintiffs allege that, "[i]n order to comply with the Act, they would need to establish Vermont-specific distribution channels that do not currently exist" and would be "commercially [un]reasonable." Compl. ¶ 74. As in *NEMA*, Plaintiffs further allege that manufacturers that cannot establish Vermont-specific distribution channels "would have to revise their labeling on a regional or even nationwide basis." *Id.* As in *NEMA*, then, Plaintiffs fail to state a claim that Act 120 "disproportionately burden[s] interstate commerce." *NEMA*, 272 F.3d at 110.[21]

A statute can also impermissibly burden interstate commerce if it "regulates commercial activity that takes place wholly beyond the state's borders" or "imposes a regulatory requirement

[21] In *NEMA*, the Second Circuit analyzed the plaintiffs' argument in the context of addressing the question whether the Vermont statute impermissibly regulated extraterritorial commerce. But the court explained that extraterritorial control of commerce constitutes a type of disproportionate burden under *Pike*. *NEMA*, 272 F.3d at 110. Accordingly, the Second Circuit's holding that Vermont's mercury-labeling statute did *not* constitute a disproportionate burden on interstate commerce compels the same conclusion with respect to Act 120.

inconsistent with those of other states." *Town of Southold*, 477 F.3d at 50. Act 120 does not impose either of those burdens. Although Plaintiffs allege (at ¶ 77) that the Act "has the effect of regulating products, conduct, and commerce occurring outside Vermont's borders," the Second Circuit rejected that exact argument with respect to Vermont's mercury-labeling statute in *NEMA*: because food "manufacturers are not required to adhere to the Vermont rule in other states," Act 120 does not impermissibly regulate extraterritorial commerce. *NEMA*, 272 F.3d at 111; *see also Boggs*, 622 F.3d at 647.

Nor does Act 120 impose regulatory requirements inconsistent with those of other states. "It is not enough to point to a risk of conflicting regulatory regimes in multiple states; there must be an *actual conflict* between the challenged regulation and those in place in other states." *NEMA*, 272 F.3d at 112 (emphasis added); *accord SPGGC*, 505 F.3d at 196. Plaintiffs do not allege that Act 120's requirements actually conflict with those in place in other states – nor can they, since no other state has a GE labeling law in effect. Act 120, moreover, 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).[22]

[22] Plaintiffs also allege that manufacturers "cannot achieve compliance with the advertising restrictions in the Act without changing their nationwide and regional advertising." Compl. ¶ 75. But Plaintiffs never allege that any actual *costs* would be associated with any such change in advertising. Nor do plaintiffs allege that any such costs would fall disproportionately on out-of-state manufacturers. After all, in-state advertisers, too, would have to refrain from using the term "natural" to describe GE foods in their advertising. In any event, *NEMA* squarely forecloses Plaintiffs' advertising-based challenge: if, as the Second Circuit held in *NEMA*, Vermont-specific labeling requirements present no disproportionate burden on interstate commerce, then refraining from using the term "natural" in Vermont advertising likewise presents no such burden. As discussed further below, moreover, state false-advertising laws already prohibit manufacturers from using misleading terms such as "natural" to describe GE foods. Act 120's requirements do not impose any additional burden on in-state advertising.

Because Act 120 does not incidentally burden interstate commerce, this Court need not proceed to the second step of the *Pike* balancing test. But even if this Court determines that Plaintiffs have alleged cognizable burdens on interstate commerce, those alleged burdens are not excessive in relation to Act 120's putative benefits. "States have traditionally acted to protect consumers by regulating foods produced and/or marketed within their borders." *Gerace*, 755 F.2d at 1003. States also "ha[ve] a legitimate interest in guarding against imperfectly understood environmental risks." *Taylor*, 477 U.S. at 148. As noted above, Act 120 was enacted to enable consumers to make informed decisions regarding the potential health, environmental, and religious implications of the food they purchase, and to reduce consumer confusion – all unquestionably legitimate local interests. *See* Act 120, Sec. 2, § 3041.

Plaintiffs, however, allege that Act 120 doesn't *actually* advance those legitimate local interests, for two reasons. First, they allege that the putative benefit to Vermont consumers "is effectively zero," because "they can already avoid GE foods if they wish by buying certified organic or other voluntarily labeled products." Compl. ¶ 78. Not only is that inaccurate, but it misses the point entirely. The Legislature determined that consumers are unaware of the extent to which the food they purchase is produced with genetic engineering. *See* Act 120, Sec. 1(5)(B). Act 120 was enacted to abate that confusion and allow consumers to know whether any *particular* food product was produced with genetic engineering – not just products that manufacturers *choose* to label as organic or produced with genetic engineering. And the fact that consumers can choose to purchase organic products does nothing to further the Legislature's legitimate goal of eliminating the misleading use of the term "natural" on GE food. *See id.* Sec. 1(5)(C).

Second, Plaintiffs allege (though not in the context of their Commerce Clause claim) that scientific studies identifying health risks associated with GE foods are "unreliable, irrelevant, or both." Compl. ¶ 28. But Plaintiffs utterly disregard the fact that Act 120 was also enacted to inform consumers about which foods have potential environmental impacts – and never allege that those impacts are illusory. In any event, the courts have made clear that a "putative" local benefit is just that; scientific certainty is not required. Indeed, in *Maine v. Taylo*r, the Supreme Court held that states have a legitimate interest in guarding against "imperfectly understood" risks – "despite the possibility that they may ultimately prove to be negligible." 477 U.S. at 148. Thus, "[i]t matters not whether these benefits actually come into being at the end of the day." *Pharm. Care. Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 313 (1st Cir. 2005); *see also Gerace*, 755 F.3d at 1004 (the existence of a "controversy" was sufficient to show that the State's concerns were not unreasonable).

As noted above, Act 120's bill file contains numerous studies addressing the safety and environmental risks of GE foods. Based on those studies – and on testimony from more than one hundred witnesses on all sides of the issue – the Legislature determined that Act 120 would enable consumers to make informed health and safety decisions. "The disputed provisions here are the result of legislative choices." *Gerace*, 755 F.2d at 1005. Plaintiffs may *disagree* with those legislative choices, or believe that the Legislature should have weighted some studies more than others. But the dormant Commerce Clause is not an invitation "to second-guess the empirical judgments of lawmakers." *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 93 (1978); *see Brown & Williamson*, 320 F.3d at 209. Because the alleged burdens of Act 120 are not "clearly excessive in relation to [its] putative local benefits," *Pike*, 397 U.S. at 142, this Court should dismiss Plaintiffs' Commerce Clause challenge in its entirety.

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

Plaintiffs allege that Act 120 is preempted by federal law. But Plaintiffs fail to state a claim that any of the four statutes they cite preempts Act 120's requirements. That is especially true in light of the well-known presumption against preemption, which applies with particular force here.

"[B]ecause the States are independent sovereigns in our federal system, [the Supreme Court has] long presumed that Congress does not cavalierly pre-empt" state law. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Accordingly, "'[c]onsideration of issues arising under the Supremacy Clause "start[s] with the assumption 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 (1992) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). This presumption against preemption is a "corner-stone[] of . . . pre-emption jurisprudence," *Wyeth v. Levine*, 555 U.S. 555, 565 (2009), and it applies to both express and implied preemption. *See, e.g., Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008); *Wyeth*, 555 U.S. at 565 & n.3.

Significantly for this case, "[t]he presumption against preemption is heightened 'where federal law is said to bar state action in fields of traditional state regulation.'" *NYSRA*, 556 F.3d at 123 (quoting *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)). "Health and safety issues have traditionally fallen within the province of state regulation. This is true of the regulation of food and beverage labeling." *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3d Cir. 2009). Courts therefore "assume that state and local regulation related to [those] matters . . . can normally coexist with federal regulations." *NYSRA*, 556 F.3d at 123 (internal quotation marks omitted). Thus, while the presumption against

preemption applies "[i]n all pre-emption cases," *Medtronic*, 518 U.S. at 485, it applies "with particular force" to Act 120. *Altria*, 555 U.S. at 77.

Preemption comes in two forms: express and implied. Plaintiffs allege that Act 120 is expressly or impliedly preempted by each of four federal statutes: the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 343, *et seq.*; the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 343-1(a), *et seq.*; the Federal Meat Inspection Act ("FMIA"), 21 U.S.C. § 601, *et seq.*; and the Poultry Products Inspection Act ("PPIA"), 21 U.S.C. § 451, *et seq.* This Court should dismiss each of Plaintiffs' preemption claims.[23]

A. The Food, Drug, and Cosmetic Act ("FDCA") does not preempt Act 120.

The FDCA, which prohibits the misbranding of food, "does not contain any express preemption language" pertaining to food labeling (other than the NLEA amendments, discussed separately below). *Gerace*, 755 F.2d at 997. Thus, the only way the FDCA could preempt Act 120 is impliedly. Courts will find implied preemption if the state law "regulates conduct in a field that Congress intended the Federal Government to occupy exclusively," or "actually conflicts with federal law." *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990).

Plaintiffs do not allege field preemption. And for good reason: 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); *see also Lockwood v. Conagra Foods*, 597 F. Supp. 2d 1028, 1033 (N.D. Cal. 2009); *Wright v. General Mills, Inc.*, No. 08-cv-1532, 2009 WL 3247148, at *2-3 (S.D. Cal. Sept. 30, 2009); *Hitt v. Arizona Beverage Co.*, No. 08-cv-809, 2009 WL 449190, at *5 (S.D. Cal. Feb. 4, 2009).

[23] As noted above, Plaintiffs lack standing to challenge Act 120's "natural" restrictions. But, as discussed below, Plaintiffs nevertheless fail to state a claim that Act 120's "natural" prohibition is preempted.

Plaintiffs allege only that Act 120 is "conflict-preempted." Compl. ¶ 85.[24] Conflict preemption occurs (1) when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), or (2) when it is "impossible for a private party to comply with both state and federal requirements," *English*, 496 U.S. at 79. Plaintiffs fail to state a claim under either theory.

Courts have consistently held that state-law restrictions on "natural" labels – including the use of labels on GE foods – do not stand as an obstacle to the FDCA. *Holk* is the leading case. There, a consumer brought state-law claims against a beverage manufacturer for labeling products containing high fructose corn syrup as "all natural." 575 F.3d at 332. The defendants argued that state-law requirements pertaining to the term "natural" were preempted because in 1991 the FDA had issued a "policy statement" outlining its views on the meaning of "natural." *Id.* at 340. Explaining that "the FDA's policy statement regarding the use of the term 'natural' is not entitled to preemptive effect," the court held that labeling requirements pertaining to the term "natural" were neither field- nor conflict-preempted. *Id.* at 340, 342.

The Third Circuit is not alone. In *In re Frito-Lay N. Am., Inc. All Natural Litig.*, No. 12-md-2413, 2013 WL 4647512 (E.D.N.Y. Aug. 29, 2013), for example, the plaintiffs brought state-law claims against a manufacturer for touting its snack foods as "all natural," even though the products allegedly contained "unnatural, genetically-modified organisms." *Id.* at *1. Again, the defendants argued that state-law requirements pertaining to the use of the term "natural" were obstacle-preempted in light of the FDA's consideration of the term. And again, the court

[24] It is unclear whether Plaintiffs allege express or implied preemption under any particular statute because their Complaint alleges that "Act 120 is expressly preempted *or* conflict-preempted by each of the above federal enactments." Compl. ¶ 85 (emphasis added). For the reasons stated, we assume that Plaintiffs allege only implied preemption under the FDCA (and, as discussed below, only express preemption under the NLEA).

declined to "give preemptive effect to the FDA's non-binding guidance on the meaning of the term 'natural.'" *Id.* at *10. The court went on to explain that, "[e]ven if that non-binding guidance would be entitled to preemptive effect," the FDA's policy contains "no actual federal requirements regarding the term 'natural' for the Court to endow with preemptive effect." *Id.*[25]

Those cases foreclose any argument that the FDCA impliedly preempts Act 120's regulation of the term "natural." And the same reasoning shows that nothing in the FDCA preempts Act 120's GE disclosure requirements, either. Plaintiffs allege that, in 1992, the FDA issued "a policy statement" announcing that GE foods present no greater risk than foods produced without genetic engineering. Compl. ¶ 24.[26] They further allege that, in 2001, the FDA issued "draft guidance" in which the agency reaffirmed that view and stated that it did not intend to regulate GE labeling. Compl. ¶ 25.[27] Just like the FDA's policy statements on the use of "natural," however, those policy statements lack preemptive effect.

Nor is it relevant that, in the same non-binding guidance, the FDA *declined* to require labeling on GE foods. "[M]ere deliberate agency inaction – an agency decision *not* to regulate

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[25] *See also Randolph*, 2014 WL 1018007, at *6 (no preemption of state-law challenge to "all natural" labels on Crisco made from genetically engineered plants); *Lockwood*, 597 F. Supp. 2d at 1033-34 (no preemption of state-law challenge to "all natural" label on pasta sauce made with high fructose corn syrup); *Astiana v. Ben & Jerry's Homemade, Inc.*, Nos. 10-4387 & 10-4937, 2011 WL 2111796, at *10 (N.D. Cal. 2011) (no preemption of state-law challenge to "all natural" label on ice cream processed with synthetic potassium carbonate); *Wright*, 2009 WL 3247148, at *3 (no preemption of state-law challenge to "natural" label on granola bars containing high fructose corn syrup); *Hitt*, 2009 WL 449190, at *5 (no preemption of state-law challenge to "natural" labels on beverages containing high fructose corn syrup).

[26] *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992).

[27] *See* 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.

an issue – will not alone preempt state law." *Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 247 (3d Cir. 2008); *see Sprietsma v. Mercury Marine, a Div. of Brunswick Corp.*, 537 U.S. 51, 65 (2002) ("[A] Coast Guard decision not to regulate a particular aspect of boating safety is fully consistent with an intent to preserve state regulatory authority."). Thus, in *Fellner*, the court rejected the defendant's argument that the FDCA preempted state-law warnings about the presence of mercury in tuna fish – even though the FDA had repeatedly opined on the safety of mercury in fish. So too here: the FDA's *non-action* regarding GE food "hardly supports preemption." *Holk*, 575 F.3d at 341.

As to "impossibility" preemption, it plainly is not physically impossible for private parties to comply both with Act 120's labeling requirements and with federal law. To begin, there is no federal law regarding the use of the term "natural" or GE labeling in the first place. As Plaintiffs themselves allege, moreover, the FDA's non-binding guidance *permits* GE labeling. *See* Compl. ¶ 25. According to Plaintiffs' own Complaint, then, a party can label a product as "produced with genetic engineering" without violating federal law (which, after all, is silent on the issue). The same goes for Act 120's requirements pertaining to the term "natural": a "manufacturer could comply, that is, not violate, the FDA's policy as to the use of the term 'natural' and still comply with [Act 120]." *Lockwood*, 597 F. Supp. 2d at 1034.

B. The Nutrition Labeling and Education Act ("NLEA") does not preempt Act 120.

Enacted in 1990 as an amendment to the FDCA, the NLEA imposes certain nutritional labeling requirements on food products (such as the familiar "Nutrition Facts" panel on most food packages). *NYSRA*, 556 F.3d at 1. The NLEA further amended the FDCA by adding several express preemption clauses that prohibit states from enacting food labeling requirements that are "not identical" to requirements imposed by specific provisions of the FDCA. 21 U.S.C. § 343-1(a)(1)-(5).

"Helpfully, the NLEA is clear on preemption, stating that it '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].'" *NYSRA*, 556 F.3d at 123 (quoting Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364 (1990)). Accordingly, "[c]ourts may not find implied preemption based on any provision of NLEA." *Holk*, 575 F.3d at 336. Plaintiffs therefore presumably allege only that that Act 120 is expressly preempted by the NLEA – though they never say which of the NLEA's preemption clauses they have in mind. As shown below, however, none of the NLEA's provisions expressly preempts Act 120.

First, section 343-1(a)(1)'s preemption clause prohibits states from enacting "any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title." 21 U.S.C. § 343-1(a)(1). Section 341, in turn, authorizes the Secretary of Health and Human Services to establish a "reasonable definition and standard of identity" for any food. And section 343(g) provides that when the Secretary has done so for a particular food product, the food will be deemed misbranded unless its label "conforms to such definition" and "bears the name of the food specified."

For example, FDA regulations define "peanut butter" as "the food prepared by grinding one of the shelled and roasted peanut ingredients provided for by paragraph (b) of this section, to which may be added safe and suitable seasoning and stabilizing ingredients provided for by paragraph (c) of this section." 21 C.F.R. § 164.150. The regulations further provide that "the fat content of the finished food shall not exceed 55 percent." *Id.* A producer of peanut butter, then, must label it as "peanut butter" – and that product must conform to the definition of peanut butter promulgated by the agency. *See* 21 C.F.R. § 130.8.

As a threshold matter, although the FDA has promulgated standards of identity for several food products (*see* 21 C.F.R. §§ 131-169), it has not done so for *all* food products. Plaintiffs, however, mount a facial challenge to Act 120, alleging that the Act is preempted in all its applications – even though section 343-1(a)(1), by its express terms, applies only to the subset of foods that have federal standard of identity requirements. *See Guerrero v. Target Corp.*, 889 F. Supp. 2d 1348, 1362 (S.D. Fla. 2012) (holding that Florida's honey-standard law was not preempted by the NLEA because "there is no federal standard of identify for honey"); 58 Fed. Reg. 2462, 2463 (Jan. 6, 1993) (stating that section 343-1(a)(1) applies only where a federal regulation imposes a standard of identity). Plaintiffs have therefore failed to state a claim that section 343-1(a) facially invalidates Act 120. *See Cal. Coastal Comm'n v. Granite Rock Co.*, 480 U.S. 572, 593 (1987) ("To defeat Granite Rock's facial challenge, the Coastal Commission needed merely to identify a possible set of permit conditions not in conflict with federal law.").

In any event, section 343-1(a)(1) does not expressly preempt Act 120's "natural" restriction or GE disclosure requirement as applied to any food products, including those with a standard of identity. As the FDA has made clear, "under section [343-1(a)(1)] of the act, a State may not *establish* or continue in effect a standard of identity, quality, or fill for a food that is the subject of a standard of identity." 58 Fed. Reg. at 2463 (emphasis added). But Act 120 does not "establish" or alter "a standard of identity" for any food. Requiring a GE label (or prohibiting a "natural" label) wouldn't allow a product to be identified as "peanut butter" if, contrary to the federal standard of identity, it had a fat content of more than 55 percent or was made with hazelnuts instead of shelled and roasted peanuts. And it wouldn't prohibit a manufacturer of peanut butter produced with genetic engineering from calling its product "peanut butter" if it met

the federal standard of identity.[28] As discussed above, the FDA has not promulgated *any* formal regulations regarding the use of "natural" or the labeling of GE foods – much less federal standards of identity that specifically address GE disclosure requirements. Plaintiffs therefore fail to state a claim that Act 120 is preempted by section 343-1(a)(1).

Second, NLEA sections 343-1(a)(4) and (5) preempt state labeling requirements about nutrition facts, nutrient content, and nutrient health benefits.[29] Act 120's GE disclosure and "natural" requirements squarely fall outside the scope of those provisions. A GE label (or "natural" prohibition) says nothing about nutrition facts, such as the number of calories or grams of fat in a product. A GE label (or "natural" prohibition) says nothing about product's nutrient content, such as whether it contains "100 calories" or is "low fat." And a GE label (or "natural" prohibition) says nothing about the health benefits of any nutrient, such as "fiber reduces cholesterol."

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[28] *See, e.g.*, *Vt. Pure Holdings, Ltd. v. Nestlé Waters N. Am., Inc.*, No. 03-11465, 2006 WL 839486, at *9 (D. Mass. March 28, 2006) (claim against manufacturer of bottled water, which has a federal standard of identity, was not preempted because "[n]o federal standards of identity for bottled water *purity* exist"); *In re Pepsico, Inc., Bottled Water Mktg. & Sales Pracs. Litig.*, 588 F. Supp. 2d 527, 538 & n.10 (S.D.N.Y. 2008) (acknowledging that state law can impose requirements "concerning subject matter that the FDA has not endeavored to regulate" in a standard of identity such as requirements concerning "purified water's ability to clear up the drinker's acne or increase the drinker's intelligence").

[29] Section 343-1(a)(4) prohibits states from establishing "any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title." Section 343(q), in turn, requires "that basic nutrition facts be disclosed for most foods" – *i.e.*, information about serving size, total calories, and the like. *NYSRA*, 556 F.3d at 118. Section 343-1(a)(5) prohibits states from establishing "any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title." And section 343(r) addresses "claims that a food purveyor may choose to add to its product label about the nutrient content (for example, 'low sodium') or health benefits (for example, 'fiber reduces cholesterol') of its product." *NYSRA*, 556 F.3d at 119.

In *Chacanaca v. The Quaker Oats Co.*, 752 F. Supp. 2d 1111 (N.D. Cal. 2010), for example, the court stated that a false-advertising suit based on a manufacturer's representations that its granola bars contained "0 Grams Trans Fat" and were a "good source" of calcium and fiber was preempted. *Id.* at 1121, 1123. But the court went on to hold that the plaintiff's challenge to labels touting products as "wholesome" or "smart choices made easy" was *not* preempted by sections 343-1(a)(4) and (5), because that labeling "does not describe *any particular nutrient*." *Id.* at 1123 (emphasis added); *see also Red v. Kraft Foods, Inc.*, 754 F. Supp. 2d 1137, 1142 (C.D. Cal. 2010). Like the term "wholesome," the labels "natural" and "produced with genetic engineering" do not describe a particular nutrient or suggest that a nutrient is absent or present in a certain amount. Plaintiffs apparently agree: the Complaint alleges that "'[genetic engineering] doesn't affect nutrition.'" Compl. ¶ 26 (quoting Secretary of Agriculture). Sections 343-1(a)(4) and (5) are therefore inapplicable to Act 120.

Finally, the preemption clauses in sections 343-1(a)(2) and (3) prohibit states from establishing "any requirement for the labeling food of the type required by" several other FDCA provisions. Those provisions are all inapposite here. For example, Act 120 does not say anything about when a food product must be labeled as an "imitation" of another food, 21 U.S.C. § 343(c), or disclose that it contains "artificial flavoring, artificial coloring, or chemical preservative[s]," *id.* § 343(k). *See, e.g.*, *Lockwood*, 597 F. Supp. 2d at 1031 (rejecting argument that sections 343-1(a)(2) and (3) preempted state-law action alleging that an "all natural" pasta sauce label was misleading); *Brod v. Sioux Honey Ass'n, Coop.*, 927 F. Supp. 2d 811, 823 (N.D. Cal. 2013) (holding that a state-law requirement to label honey as pollen-free was not preempted

under § 343-1(a)).[30]

In sum, nothing in the statute's text supports Plaintiffs' claim that the NLEA expressly preempts Act 120's GE labeling and "natural" requirements. That is particularly true given that courts have a "duty to accept the reading [of a statute] that disfavors pre-emption," *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005). But if there were any doubt, the NLEA's structure and legislative history erases it. The NLEA states that it "shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food." Pub. L. No. 101-535, § 6(c)(2), 104 Stat. 2353, 2364 (1990). If States can impose labeling requirements "concerning" the safety of food, then surely they can impose requirements related to GE foods. Indeed, the NLEA's legislative history makes clear that state laws pertaining to "religious dietary labeling," "container deposit labeling," and "organic labeling" would "*not* be preempted" by the Act. 136 Cong. Rec. H5836 (July 30, 1990) (statement of Rep. Waxman, NLEA's sponsor) (emphasis added). If Congress did not intend the NLEA to preempt state organic labeling laws, how could it have intended to preempt state GE labeling laws?

Despite their remonstrations that GE foods are harmless, Plaintiffs nevertheless are reluctant to disclose to the public that their products are produced with genetic engineering. But if Plaintiffs want to avoid Act 120's requirements, they must go to Congress, not the courts. Indeed, a bill recently introduced in Congress would amend the FDCA to address bioengineered organisms – and, unlike the current FDCA or NLEA, would expressly prohibit states from

[30] Notably, most of the cases discussed above that address (and reject) implied preemption of "natural" labeling requirements did not address express preemption under the NLEA – and those that have done so made quick dispatch of such arguments. *See, e.g.*, *Lockwood*, 597 F. Supp. 2d at 1031.

imposing any mandatory labeling requirements for food produced with bioengineering. Safe and Accurate Food Labeling Act of 2014, H.R. 4432, 113 Cong. (2014).[31] If that bill is enacted, then Plaintiffs might have a case. But unless and until that happens, nothing in the FDCA or NLEA preempts Act 120's labeling requirements.

C. The Federal Meat Inspection Act ("FMIA") and the Poultry Products Inspection Act ("PPIA") do not preempt Act 120.

The FMIA and PPIA regulate the slaughter, labeling, and sale of meat and poultry processed at federally inspected plants. The statutes contain nearly identical preemption clauses that prohibit states from imposing "[m]arking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter." 21 U.S.C. § 678 (FMIA); *see id.* § 467e (PPIA). Plaintiffs allege that the FMIA and PPIA preempt Act 120's requirements.

Plaintiffs, however, bring a facial challenge to Act 120. They allege that "Act 120 is expressly preempted" by "each of the above federal enactments" – and therefore "should be declared invalid and enjoined *in its entirety*." Compl. ¶¶ 85, 86 (emphasis added). To succeed on such a facial challenge, they must demonstrate that "there is no possible set of conditions" imposed by Act 120 "that would not conflict with federal law." *Cal. Coastal Comm'n*, 480 U.S. at 580. Yet the FMIA and PPIA plainly do not restrict the State's authority to impose regulations on food products that are *not* meat or poultry. And even with respect to meat and poultry products, the FMIA and PPIA preempt state requirements pertaining only to meat or poultry "prepared at any establishment under inspection." 21 U.S.C. § 678; *see id.* § 467e (applying to

[31] The fact that the bill includes such a preemption clause suggests that Congress does not believe that any provision of the FDCA or NLEA already prohibits state labeling requirements.

poultry "prepared at any official establishment").[32] Thus, there is an enormous "set of conditions" in which Act 120's requirements "would not conflict with federal law" – namely, as applied to *all* food products *other than* meat and poultry products prepared at establishments under inspection. Plaintiffs therefore fail to state a claim that that the FMIA and PPIA facially invalidate Act 120.

If Plaintiffs' members believe that they produce food products that are covered by the FMIA and PPIA but fall outside the scope of Act 120's exemptions, then "the proper recourse is for the aggrieved individuals *themselves* to bring suit" as to those particular products. *Rent Stabilization Ass'n v. Dinkins*, 5 F.3d 591, 595 (2d Cir. 1993) (emphasis added). Indeed, Plaintiffs lack associational standing to allege that Act 120 is invalid as to particular products produced by particular members. Because any such as-applied challenge is impossible to resolve "without delving into individual [members'] circumstances" (*id.* at 597) – *e.g.*, whether any meat products they produce are prepared at establishments under inspection – only the aggrieved members themselves have standing to bring such a challenge. *Id.*; *see also N.Y. State Nat'l Org. for Women v. Pataki*, 261 F.3d 156, 171 n.4 (2d Cir. 2001).[33]

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[32] *See* 9 C.F.R. § 301.2 (defining "official establishment" as "[a]ny slaughtering, cutting, boning, meat canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations in this subchapter").

[33] Any as-applied challenge to labeling of specific products would be premature. As noted, the Attorney General is currently developing rules for the implementation of Act 120. Those rules may well alter the applicability of Act 120's requirements to particular products. Indeed, Act 120 expressly authorizes the Attorney General to promulgate rules to ensure that Act 120's labeling requirements are "consistent with the requirements in other jurisdictions" – including any requirements imposed by federal law. Act 120, Sec. 3(2). Thus, while Plaintiffs can allege that Act 120 is invalid in all its applications, a challenge to Act 120 as applied to specific products is not ripe for review. *See Duncan*, 612 F.3d at 112 ("Ripeness is a justiciability doctrine designed to . . . protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." (quoting *Nat'l Park Hospitality Ass'n v. Dep't of the Interior*, 538 U.S. 803, 807-08 (2003))).

Act 120, moreover, contains an *exemption* for meat and poultry products. Section 3044 provides that Act 120's labeling requirements do not apply to "[f]ood consisting entirely of or derived entirely from an animal which has not itself been produced with genetic engineering, regardless of whether the animal has been fed or injected with any food, drug, or other substance produced with genetic engineering." Act 120, Sec. 2, § 3044(1). Thus, a steak derived from a cow that was fed transgenic corn or given antibiotics produced with genetic engineering would not be subject to Act 120's labeling requirements. Indeed, Plaintiffs themselves allege that Act 120 exempts "meat and milk" from its labeling requirements. Compl. ¶ 33.[34] This Court should therefore dismiss Plaintiffs claim that the FMIA and PPIA invalidate Act 120 "in its entirety." Compl. ¶ 86.

VI. PLAINTIFF NATIONAL ASSOCIATION OF MANUFACTURERS LACKS STANDING, AND COMMISSIONER CHEN, COMMISSIONER REARDON, AND GOVERNOR SHUMLIN ARE NOT PROPER DEFENDANTS

Finally, if this Court determines that any of Plaintiffs' claims should proceed, the claims made by and against certain parties should nevertheless be dismissed.

A. The National Association of Manufacturers ("NAM") lacks standing.

Plaintiff NAM lacks standing, as it does not allege that any of its members manufacture food products that contain genetically engineered material. Nor does NAM allege that it has any members that sell any products – let alone GE foods – in Vermont. Accordingly, NAM fails to allege that at least one of its members "suffer[s] immediate or threatened injury as a result of" Vermont's enactment of Act 120. *Disability Advocs.*, 675 F.3d at 156-57.

[34] Act 120's requirements would apply to animals that are themselves produced with genetic engineering (*e.g.*, transgenic beef). But Plaintiffs do not allege that they sell meat or poultry that has been produced with genetic engineering – or that such food even exists.

B. Commissioner Chen, Commissioner Reardon, and Governor Shumlin are not proper defendants under the *Ex parte Young* exception to Eleventh Amendment immunity.

"The Eleventh Amendment precludes [plaintiffs] from bringing suit against the state or state agencies, because it deprives the federal courts of subject matter jurisdiction over any action asserted by an individual against a state regardless of the nature of the relief sought." *Madden v. Vt. Sup. Ct.*, 236 F. App'x 717, at *1 (2d Cir. 2007). *Ex parte Young*, 209 U.S. 123 (1908), provides "'a limited exception to the general principle of sovereign immunity [that] allows a suit for injunctive relief challenging the constitutionality of a state official's actions in enforcing state law under the theory that such a suit is not one against the State, and therefore not barred by the Eleventh Amendment.'" *Walters v. Hofmann*, No. 09-cv-84, 2009 WL 6329145, at *3 (D. Vt. Dec. 29, 2009) (quoting *Ford v. Reynolds*, 316 F.3d 351, 354-55 (2d Cir. 2003)). "Under *Ex parte Young*," however, "the state officer against whom a suit is brought 'must have some connection with the enforcement of the act' that is in continued violation of federal law." *Dairy Mart Convenience Stores, Inc., v. Nickel*, 411 F.3d 367, 372-73 (2d Cir. 2005) (quoting *Ex parte Young*, 209 U.S. at 157); *see Spiteri v. Russo*, No. 12-cv-2780, 2013 WL 4806960, at *17 (E.D.N.Y. Sept. 7, 2013) (official sued must have a "direct connection" to the illegal action); *Papazoni v. Vermont*, No. 12-cv-1, slip op. at 8 (D. Vt. May 9, 2013) (holding that "there is no basis for applying the *Ex Parte Young* exception to Eleventh Amendment immunity" since "there is no allegation that Governor Shumlin is connected to any alleged violation").

Defendants Shumlin, Chen and Reardon lack a sufficiently direct connection to the enforcement of Act 120. Thus, the *Ex parte Young* exception to Eleventh Amendment sovereign immunity does not apply to Plaintiffs' claims for injunctive relief against those defendants, and all claims against them should be dismissed for lack of subject matter jurisdiction. Indeed,

because enjoining Defendants Shumlin, Chen or Reardon with respect to Act 120 would do nothing to prevent full enforcement of the Act by Attorney General Sorrell, Plaintiffs lack standing to sue those defendants.

1. Commissioners Chen and Reardon are improper defendants because the duty to render advice is an insufficient enforcement connection under *Ex parte Young*.

Courts have repeatedly held that a mere duty to render advice or provide information is an insufficient enforcement connection under *Ex parte Young.* In *Southern Pacific Transportation Co. v. Brown*, 651 F.2d 613 (9th Cir. 1980), for example, the Ninth Circuit held that the Oregon Attorney General's general statutory duty to "'consult with, advise and direct'" autonomous local district attorneys did not "establish sufficient connection with enforcement to satisfy *Ex parte Young*." *Id.* at 614, 615; *see Old Carco LLC v. Kroger (In re Old Carco LLC)*, 442 B.R. 196, 214-15 (S.D.N.Y. 2010) (citing *S. Pac. Transp.* with approval). And in *1st Westco Corp. v. School District of Philadelphia*, 6 F.3d 108 (3d Cir. 1993), the Third Circuit similarly held that the Pennsylvania Attorney General's "duty to advise the Secretary [of Education], and the Secretary's subsequent advice to the School District, cannot serve as a predicate for liability" under *Ex parte Young* since "the Secretary's act of advising the School District about the constitutionality of the statute differs significantly from a duty to enforce section 754." *Id.* at 113-14; *see also Peterson v. Martinez*, 707 F.3d 1197, 1207 (10th Cir. 2013) (stating that an official's mere provision of database information to local sheriffs charged with enforcing a concealed weapons statute was not a sufficient enforcement connection to sustain an *Ex parte Young* action against him).

Those cases compel the conclusion that Commissioners Chen and Reardon lack the requisite connection to the enforcement of Act 120 to satisfy *Ex parte Young*. Act 120 directs the Attorney General to consult with Commissioners Chen and Reardon concerning,

respectively, (1) the approval of a procedure for designating independent organizations permitted to verify a food's GE-free status for purposes of labeling exemption, and (2) the availability of excess Attorney General settlement proceeds to finance Act 120's implementation. *See* Compl. ¶¶ 15-16 (alleging that "[t]he Department of Health is required to advise the Attorney General in making certain determinations under the Act" and that "[t]he Act requires the Department of Finance and Management to advise the Attorney General as to the amount of State funding, if any, that may be used to defend the Act in court").

Such administrative and budgeting *consultation* by Commissioners Chen and Reardon is far removed from the Attorney General's assigned *enforcement* activities under Act 120 – *i.e.*, to "conduct civil investigations, enter into assurances of discontinuance, and bring civil actions." Act 120, Sec. 2, § 3048(b). The advisory roles of Commissioners Chen and Reardon under Act 120 therefore lack the requisite direct connection to the enforcement of Act 120, and the *Ex parte Young* exception to Eleventh Amendment immunity does not apply to these defendants.[35]

2. Governor Shumlin is an improper defendant because mere oversight over other state officers is an insufficient enforcement connection under *Ex parte Young*.

A governor's ability to oversee the work of other executive branch officials, including those who are statutorily charged with enforcement of an allegedly unconstitutional state law, is too remote from enforcement activities to permit an *Ex parte Young* claim against that governor.

[35] *See Doe v. Sorsai*, No. 12-cv-65, 2012 WL 2954107, at *13 (S.D. W. Va. June 18, 2012) (holding that, where the decision to revoke teaching licenses rested with the state Superintendent of Education, a staff attorney's provision of "legal consultative services" was an insufficient connection under *Ex parte Young*); *Nabers v. Morgan*, No. 09-cv-70, 2011 WL 359069, at *4-5 (S.D. Miss. Feb. 2, 2011) (holding that, because general counsel for Mississippi State Tax Commission was "merely an advisor" neither empowered to direct the activities of the commission nor exercise any enforcement authority, the general counsel was an improper *Ex parte Young* defendant).

"If a governor's general executive power provided a sufficient connection to a state law to permit jurisdiction over him, any state statute could be challenged simply by naming the governor as a defendant. Where the enforcement of a statute is the responsibility of parties other than the governor (the cabinet in this case), the governor's general executive power is insufficient to confer jurisdiction." *Women's Emergency Network v. Bush*, 323 F.3d 937, 949-50 (11th Cir. 2003) (citation omitted).[36] Likewise, "[a] general duty to enforce state law or to supervise other officials responsible for enforcing the challenged provision is insufficient; otherwise, 'the constitutionality of every act passed by the legislature could be tested by a suit against the governor . . . based upon the theory that [he], as the executive of the State was, in a general sense, charged with the execution of all its laws.'" *Emory v. New York*, No. 11-cv-1774, 2013 WL 1881009, at *1 (E.D.N.Y. May 6, 2013).

Plaintiffs seek "a permanent injunction barring Defendants," including Governor Shumlin, "from enforcing or otherwise implementing any aspect of" Act 120. Compl. at 22. But Act 120 does not even *mention* Governor Shumlin, much less assign him any role in the enforcement or implementation of Act 120. Rather, the Legislature explicitly assigned responsibility for the enforcement of Act 120 to a separately elected state officer – the Attorney General, a position held by Defendant William H. Sorrell (who is sued here in his official

[36] *See also Kobe v. Haley*, No. 11-1146, 2012 WL 3269221, at *4 (D.S.C. Aug. 10, 2012) ("While Defendant Haley as the Governor of South Carolina has the power to appoint and general supervisory authority, neither appointment power nor general supervisory power over persons responsible for enforcing a challenged provision will subject an official to suit."); *Clark K. v. Guinn*, No. 06-cv-1068, 2007 WL 1435428, at *22 (D. Nev. May 14, 2007) (holding that Nevada statute that "outlines the requirement for the Director of the Department of Health and Human Services and states that the director 'serves at the pleasure of the governor'" furnished insufficient connection between the governor and enforcement of child welfare statutes).

capacity).[37] Even Plaintiffs agree that, independent of Defendants Shumlin, Chen and Reardon, "[t]he Attorney General is authorized to enforce the Act through penalties and civil actions, and to make rules that add to or modify the mandatory labels." *Id.* ¶ 13.

Instead, the sole basis alleged by Plaintiffs for suing Governor Shumlin is his alleged supervisory powers over other executive branch officials – Commissioners Chen and Reardon. *See id.* ¶ 14 ("The Governor of Vermont oversees the activities of the Commissioner of the Department of Health and the Commissioner of the Department of Finance and Management."). As discussed above, however, any advice to be given by Commissioners Chen and Reardon is insufficiently connected to the Attorney General's enforcement of Act 120 to make them subject to suit under *Ex parte Young*. Therefore, Governor Shumlin's purported ability to "oversee"[38] the advice of Commissioners Chen and Reardon is likewise far too attenuated from the Attorney General's enforcement of Act 120 to make Governor Shumlin a proper *Ex parte Young* defendant. *Cf. Buckner v. Shumlin*, No. 12-cv-90, 2013 WL 6571814, at *7 (D. Vt. Dec. 13, 2013) (dismissing personal-capacity claim for money damages and stating that "Governor Shumlin cannot be held liable merely because he held a position of authority" in state government).

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[37] *See* Act 120, Sec. 2, § 3048(b) (vesting the Attorney General with "the same authority to make rules, conduct civil investigations, enter into assurances of discontinuance, and bring civil actions" to enforce Act 120 as is granted to the Attorney General under Vermont's Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451-2466); *see also* Vt. Stat. Ann. tit. 3, §§ 151-159 (prescribing duties of Attorney General).

[38] Any advice that Commissioners Chen and Reardon provide to the Attorney General is specifically mandated by Act 120, not by Governor Shumlin's general executive power. *See Vermont v. CNA Ins. Cos.*, 172 Vt. 318, 325-26, 779 A.2d 662, 668-69 (2001) ("The steps taken by the secretary of [the Vermont Agency of Natural Resources] against [the Vermont Department of Corrections] were not taken at the direction of the governor, but instead imposed by a statutory duty.").

C. Plaintiffs lack standing to sue Governor Shumlin, Commissioner Chen and Commissioner Reardon.

The *Ex parte Young* enforcement connection "inquiry overlaps with the causation and redressability analyses in the standing inquiry." *Deida v. City of Milwaukee*, 192 F. Supp. 2d 899, 916-17 (E.D. Wis. 2002) . Accordingly, if a government official has an insufficient connection to the enforcement of a statute to render an *Ex parte Young* claim appropriate, the plaintiff will typically also lack Article III standing to sue that official to enjoin the statute's enforcement. *See HealthNow New York, Inc. v. New York*, 448 F. App'x 79, 81 (2d Cir. 2011) ("[n]othing the Attorney General is doing or could threaten to do under [the challenged statute] is effecting" plaintiff's claimed injury-in-fact); *S. Pac. Transp.*, 651 F.2d at 615 ("The attorney general's power to direct and advise [autonomous local district attorneys] does not make the alleged injury fairly traceable to his action, nor does it establish sufficient connection with enforcement to satisfy *Ex parte Young*.").

As noted above, Defendants Shumlin, Chen, and Reardon are improper defendants in this action because they lack the requisite connection to Act 120's enforcement. Thus, prohibiting Governor Shumlin, Commissioner Chen and Commissioner Reardon "from enforcing or otherwise implementing any aspect of the Act," Compl. at 22, will do nothing to redress or avoid the injuries that Plaintiffs claim will ensue from Attorney General Sorrell's enforcement of Act 120. Plaintiffs therefore lack standing to sue Governor Shumlin, Commissioner Chen and Commissioner Reardon.

CONCLUSION

For the reasons stated above, the Court should dismiss the Complaint with prejudice.

DATED at Montpelier, Vermont this 8th day of August, 2014.

STATE OF VERMONT

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