15-1504-cv

In the United States Court of Appeals for the Second Circuit

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

Plaintiffs-Appellants,

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; JAMES B. REARDON, in his official capacity as Commissioner of the Vermont Department of Finance and Management; and HARRY L. CHEN, in his official capacity as Commissioner of the Vermont Department of Health,

Defendants-Appellees.

ON APPEAL FROM THE
UNITED STATES DISTRICT COURT FOR THE DISTRICT OF VERMONT

BRIEF FOR DEFENDANTS-APPELLEES

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TABLE OF CONTENTS

Page

TABLE OF CONTENTS – Cont'd

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES – Cont'd

Page(s)

TABLE OF AUTHORITIES – Cont'd

Page(s)

TABLE OF AUTHORITIES – Cont'd

Page(s)

TABLE OF AUTHORITIES – Cont'd

Page(s)

TABLE OF AUTHORITIES – Cont'd

Page(s)

Statutes and Rules

TABLE OF AUTHORITIES – Cont'd

Page(s)

TABLE OF AUTHORITIES – Cont'd

Page(s)

Other Authorities

TABLE OF AUTHORITIES – Cont'd

Page(s)

INTRODUCTION

Over the course of two years, the Vermont Legislature held 50 days of hearings, received testimony from more than 100 witnesses, and reviewed dozens of scientific articles about genetically engineered (GE) plants. Based on that evidence, it found that GE foods "pose risks to health, safety, agriculture, and the environment," Act 120, Sec. 1(4), and enacted Act 120 to let Vermont consumers make informed choices about whether, and to what extent, they wish to purchase GE products. Although Appellants (collectively, GMA) repeatedly proclaim that GE foods are "safe" for human consumption, Br. 2 (a disputed proposition in its own right), they barely even mention, let alone dispute, the many other concerns that Vermont identified in Act 120. In light of these risks – to humans, to plant and insect life, and to the environment as a whole – Act 120 requires GE producers to do two things: make a truthful, factual disclosure on their labels about the use of GE technology; and refrain from using the word "natural" to characterize a production process that is anything but.

The First Amendment does not forbid these two entirely rational requirements. GMA's contrary view mischaracterizes the Vermont statute, the abundant legislative record, the findings and purposes of Act 120, and the district court's carefully reasoned decision. It denigrates Vermont's well-supported concerns as a sop to idle curiosity, worthy of no greater intellectual respect than

alchemy or the Flat Earth Society. And GMA advances these positions in seeking to enjoin state action that will not occur for another year.

This Court should deny GMA's request.

STATEMENT OF THE CASE

I. BACKGROUND

A. Genetically Engineered Crops

Genetic engineering typically uses recombinant DNA technology to transfer a gene with a desired trait from one organism into the genome of a different (and often distantly related) organism. Two types of GE crops are most prevalent in the United States. "Bt" crops are engineered to contain a gene from a bacterium, known as *B. thuringiensis* (Bt), that produces proteins toxic to certain insects, so that the GE plant produces the toxin directly. And "Roundup Ready®" crops have been engineered to confer tolerance to the herbicide glyphosate, which is toxic to certain weeds (and, as the World Health Organization recently declared, carcinogenic in humans). *See* Antoniou Decl. ¶¶ 13-23 (Dist. Ct. Dkt. 63-14).

Approximately 85% of all soy and corn in the United States today is engineered to be resistant to glyphosate, and 75% of all corn in the United States is engineered to produce the Bt toxin. Benbrook Decl. ¶¶ 25, 31 (Dist. Ct. Dkt. 63-16). These crops "enter the food supply just as other crops do," Br. 7 – meaning

that GE crops such as Bt-producing sweet corn can either be eaten raw by consumers, or processed into ingredients used in multi-ingredient food products.

But beyond touting GE crops as "resistant to drought, or [as] more productive food sources," *id.*, GMA never identifies *any* of the GE crops that are actually in use today. It does not utter the words "Bt" or "glyphosate." As discussed below, however, the Vermont Legislature enacted Act 120 not only in response to studies showing the risks of GE crops generally, but also in response to studies showing that Bt-producing and glyphosate-resistant crops *in particular* present risks to human health and the environment.

B. Vermont Act 120

Enacted in 2014, Act 120 has two components. First, it 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 sold. *Id.* Sec. 2, § 3043(b)(2). And processed GE foods 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).[1]

Second, Act 120 prohibits manufacturers from advertising or labeling any food produced from genetic engineering as "natural," "naturally made," "naturally grown," "all natural," or any words of similar import that would have a tendency to mislead a consumer. *Id.* Sec. 2, § 3043(c). As Consumer Protection (CP) Rule 121 states, that prohibition applies only to advertising at retail premises in Vermont. JA166.[2]

The Legislature was mindful of federal law when drafting Act 120. Thus, because the Food and Drug Administration (FDA) regulates certain aspects of food labeling, Act 120 does not require the listing of any GE ingredient, or prescribe "the placement of the term 'genetically engineered' immediately preceding any common name or primary product descriptor of a food." Act 120, Sec. 2, § 3043(d). Nor does it prohibit manufacturers from disclosing additional

[1] In April 2015, the Attorney General formally adopted Consumer Protection Rule 121 implementing Act 120. CP Rule 121 provides that a manufacturer can state that a product "may be" produced with genetic engineering "only when the food's manufacturer does not know, after reasonable inquiry, whether the food is, or contains a component that is, produced with genetic engineering." JA166.

[2] CP Rule 121 also states that "[n]atural or any words of similar import" means "the words nature, natural, or naturally." JA164.

information on a product's packaging, including that the FDA does not consider GE foods to be materially different from traditional foods. JA166.

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"; 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. As discussed below, those exemptions are consistent with (and in some cases required by) federal food-labeling laws.

Act 120 takes effect on July 1, 2016. Act 120, Sec. 7(b).

C. The Legislature Made Detailed Findings After Considering Extensive Evidence On The Risks And Benefits Of GE Foods

Act 120 contains five pages of legislative findings supporting the conclusion that GE labeling "serve[s] the interests of the State . . . to prevent inadvertent consumer deception, prevent potential risks to human health, protect religious practices, and protect the environment." Act 120, Sec. 1(6); *see* JA144-148 ("Findings"). The Legislature considered a wealth of evidence, including studies published in peer-reviewed scientific journals and testimony from food-science and health professionals, showing that GE crops present risks to human health and the environment. *See* Ex. K (Dist. Ct. Dkt. 63-13) (testimony); Ex. J (Dist. Ct. Dkts. 63-10, 63-11, 63-12) (studies).

Act 120 has four stated purposes, each grounded in legislative findings and codified at section 3041(1)-(4). *See* JA149 ("Purpose").

1. First, the Legislature found that "[t]here are conflicting studies assessing the health consequences of food produced from genetic engineering" and that the "genetic engineering of plants and animals may cause unintended consequences." Act 120, Sec. 1(4)(A-B). Accordingly, the Legislature enacted Act 120 so that consumers could, if they choose, "avoid potential health risks of food produced from genetic engineering." *Id.* Sec. 2, § 3041(1).

In reaching those conclusions, the Legislature examined dozens of journal articles showing that GE crops present health risks. Included were studies showing immune disturbances in mice fed Bt corn, Ex. J at 252-259; acute liver aging in mice fed GE glyphosate-resistant soy, Ex. J at 328-338; toxic effects in multiple organ systems in rats fed GE potatoes, Ex. J at 235-236; histopathological changes in the liver and kidney in rats fed Bt corn, Ex. J at 314-320; and abnormalities in small intestines in mice fed a diet of Bt potatoes (or non-GE potatoes supplemented with Bt toxin), Ex. J at 237-251. The Legislature also considered several detailed reviews of the scientific literature regarding the toxicity of GE foods, Ex. J at 194-206 and 207-218, and a 100-plus page examination of the available evidence regarding hazards of GE technology, including its impact on human health, Ex. J at 18-140.

The Legislature recognized that the scientific literature lacked "long-term or epidemiologic studies in the United States that examine the safety of human consumption of genetically engineered foods," and that "the FDA does not independently test the safety of genetically engineered foods." Act 120, Sec. 1(2)(E), (B). It heard, for example, from Michael Hansen, Ph.D., Senior Staff Scientist with Consumers Union (the publisher of *Consumer Reports*), who testified about the lack of premarket safety testing, the inadequacy of existing FDA regulations, and the uncertainty regarding the safety of GE foods. *See* Ex. K at 1-50. Dr. Hansen highlighted recent studies showing unintended effects of genetic engineering, such as pesticides entering the human body. Ex. J at 763-765. The Legislature reviewed an article by Michael Antoniou, Ph.D., a molecular geneticist at King's College London, detailing the lack of long-term studies demonstrating that GE foods are safe. Ex. J at 18-140. And it reviewed a paper by Dave Schubert, Ph.D., head of the Cellular Neurobiological Laboratory at the Salk Institute, explaining that "the FDA has not formally approved a single GE crop as safe for human consumption." Ex. J at 260-283. Rather, after a voluntary consultation process, the FDA "merely issues a short note summarizing the review process and a letter that conveys the *crop developer's* assurances that the GE crop is substantially equivalent to its conventional counterpart." *Id.* at 265 (emphasis added).

2. Second, the Legislature found that GE plants present risks to the environment. Specifically, it found that GE plants "contribute to genetic homogeneity, loss of biodiversity, and increased vulnerability of crops to pests, diseases, and variable climate conditions," and that "cross-contamination by genetically engineered crops may contaminate organic crops and, consequently, affect marketability of those crops." Act 120, Sec. 1(4)(A-E). The Legislature therefore enacted Act 120 to "[i]nform the purchasing decisions of consumers who are concerned about the potential environmental effects of food produced from genetic engineering." *Id.* Sec. 2, § 3041(2).

Significantly, GMA does not even attempt to dispute the State's environmental findings. Nor can it, given the wealth of material considered by the Legislature, which included studies showing that GE production has increased the use of glyphosate by more than 500 million pounds, resulting in the emergence of glyphosate-resistant weeds, Ex. J at 633-645; that there has been an extensive escape of GE canola into wild populations, Ex. J at 669-672; that Bt corn has damaged soil organisms, Ex. J at 646-653; and that a reduction in milkweed populations correlated with GE crops has dramatically suppressed the monarch butterfly population, Ex. J at 753-762.

The Legislature also considered several review articles examining the contamination of traditional seeds with GE gene sequences, Ex. J at 673-752, the

development of new GE herbicide-resistant varieties that resist even more hazardous herbicides, Ex. J at 662-668, and the environmental risks posed by herbicide-tolerant crops, including harms to other plant communities and to biodiversity, Ex. J at 18-140. *See also* Benbrook Decl. ¶¶ 38-67; Antoniou Decl. ¶¶ 65-79.

The Vermont Legislature is not alone in recognizing these environmental risks. The Supreme Court, too, has recognized the environmental and economic impact of gene flow from GE to traditional crops. *Monsanto Co. v. Geerston Seed Farms*, 130 S. Ct. 2743, 2756 (2010). Indeed, contamination of traditional crops by GE crops has jeopardized many U.S. crop exports – causing hundreds of millions of dollars in losses.[3] And the World Health Organization (WHO) recently confirmed that glyphosate, which has proliferated along with the increase of GE crops, causes cancer in laboratory animals, causes DNA and chromosomal damage in human cells, and may cause cancer in humans. Dist. Ct. Dkt. 91 Ex. A (IARC

[3] *See*, *e.g.*, Jesse Newman, *China's Hard Line on Biotech Burns U.S. Hay*, Wall St. J. (Dec. 15, 2014), http://goo.gl/2CppSD; Nicholas Bergin, *Farmers Sue Seed Company Over China Rejection of U.S. Corn*, Lincoln Journal Star (Oct. 6, 2014), http://goo.gl/Ge6dbF; Benbrook Decl. ¶¶ 51-59.

Monographs Volume 112: Evaluation of five organophosphate insecticides and herbicides, at 1 (Mar. 20, 2015), http://goo.gl/xWUzVS).[4]

These risks are not likely to abate. GE glyphosate-resistant crops and associated glyphosate usage have led to the evolution of glyphosate-resistant "superweeds." In response, the Legislature learned, biotechnology companies are developing new herbicide-tolerant varieties engineered to withstand applications of higher-risk herbicides including 2,4-D (a component of Agent Orange), which has been linked to birth defects and cancer in humans. *See* Ex. J at 633-645 and 662-668; Andrew Pollack, *Altered to Withstand Herbicide, Corn and Soybeans Gain Approval*, N.Y. Times (Sept. 17, 2014), http://goo.gl/uqHvzc. The evolutionary arms race between GE crops and pests presents real risks to the environment and to human health.

3. Third, the Legislature found that "labeling food as produced from genetic engineering will reduce consumer confusion" and that the use of the term "natural" on GE food "is inherently misleading, [and] poses a risk of confusing or deceiving consumers." Act 120, Sec. 1(5)(B-C).

[4] As noted recently in the New England Journal of Medicine, GE "crops are now the agricultural products most heavily treated with herbicides and . . . two of these herbicides may pose risks of cancer." Philip Landrigan & Charles Benbrook, *GMOs, Herbicides, and Public Health*, 373 New Eng. J. Med. 693-95 (2015), http://goo.gl/vng4TP.

The Legislature reviewed two national surveys showing that Americans are generally unaware that many products sold in supermarkets today have been genetically engineered. *See* Ex. J at 796-797, Allison Kopicki, *Strong Support for Labeling Modified Foods*, N.Y. Times (July 27, 2013) (fewer than half those polled knew that many foods sold at supermarkets had been genetically engineered); Ex. J at 799-803, Thomson Reuters, *National Survey of Healthcare Consumers: Genetically Engineered Food* (Oct. 2010) (only around half of those earning less than $25,000 per year knew that food in stores had been genetically engineered). The Legislature also considered studies showing that 61% of consumers believe "natural" connotes the absence of GE methods, Ex. J at 804-805, and that the word "natural" on food products matters to consumers because they desire "less processed" foods with "clean ingredient lists" and "fresh, real foods," Ex. J at 806-826 – characteristics decidedly not associated with GE foods. Other recent surveys confirm the Legislature's conclusion that consumers are, in fact, misled by "natural" advertising on GE foods. Kolodinsky Decl. ¶¶ 8-27 (Dist. Ct. Dkt. 63-20).

4. Finally, the Legislature found that "[p]ersons with certain religious beliefs object to producing foods using genetic engineering because of objections to tampering with the genetic makeup of life forms." Act 120, Sec. 1(5)(D). The Legislature heard testimony from Rabbi Elihu Gevirtz, who explained that food

labeling is important to the Jewish community in light of dietary restrictions, Ex. K at 231-234, and reviewed an article on religious objections to GE food, Ex. J at 776-783. The Legislature concluded that Act 120 would "[p]rovide consumers with data from which they may make informed decisions for religious reasons." Act 120, Sec. 2, § 3041(4).

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GMA barely mentions this extensive legislative record, except to dismiss it as a "lengthy compilation of documents." Br. 49. But those "documents" – generally peer-reviewed journal articles and other scientific studies – are exactly what the Legislature should consider when debating legislation. Nor does GMA acknowledge that the Legislature held more than 50 days of hearings on Act 120, receiving hundreds of hours of testimony from more than 100 witnesses – scientists, attorneys, regulators, and lobbyists – on *both* sides of the issue. *See* Dist. Ct. Dkt. 24-3, at 6-23 (listing witnesses).

The Legislature concluded based on that record that there was good reason to require GE labeling. And while GMA challenges the State's findings (and its decision to require labels) as "contrary to the conclusion of *every* professionally recognized scientific and medical organization," Br. 23 (emphasis added), GMA simply ignores the evidence with which it disagrees:

- The American Public Health Organization has stated that "any food product containing genetically modified organisms [should] be so labeled" in light of "concerns related to human exposure to and consumption of these [GE] plant proteins" (quoted in Antoniou Decl. ¶ 35);
- The British Medical Association has stated that "[t]here is a lack of evidence-based research with regard to medium and long-term effects [of GE foods] on health and the environment," *id.*;
- The California Medical Association has stated that "genetic engineering can introduce new proteins into food crops not just from known sources of common allergens . . . but from plants of all kinds, animals, bacteria and viruses, whose allergenicity is largely unknown," *id.*;
- The Public Health Association of Australia has stated that, because "it is not certain whether there are serious risks to the environment or to human health involved in producing or consuming GM foods or their products," it supports a ban on GE crops altogether, *id.*

Indeed, more than 60 countries around the world, including Great Britain, Germany, Australia, China, Japan, Russia, and Brazil, require labels. *Id.* ¶ 24.[5] Maine and Connecticut have passed GE labeling laws (albeit laws that will not go into effect until certain conditions are triggered).[6] Vermont is scarcely alone in deciding that a mandatory labeling regime is justified.

[5] Scotland is poised to ban growing GE crops altogether. Severin Carrell, *Scotland to Issues Formal Ban on Genetically Modified Crops*, The Guardian (Aug. 9, 2015), http://goo.gl/WLNtY5.

[6] *See* 22 Me. Rev. Stat. §§ 2591-2596 (2013); Conn. Pub. Act No. 13-183 (2013).

II. PROCEDURAL HISTORY

GMA filed suit on June 12, 2014. It alleged that Act 120 was preempted by federal law; was unconstitutionally vague; violated the Commerce Clause; and ran afoul of the First Amendment. The State moved to dismiss, and GMA responded with an amended complaint and a motion for preliminary injunction – almost two years before Act 120 was slated to go into effect on July 1, 2016.[7] In an 84-page opinion, the district court dismissed several of GMA's claims, and denied GMA's motion for a preliminary injunction.

GMA appeals only with respect to its First Amendment claims, so we discuss only those portions of the district court's opinion. The court first rejected GMA's contention that strict scrutiny applied to the GE disclosure requirement. JA70. GMA had argued that Act 120 compels *political* speech, not commercial speech – a position it has now abandoned.

The district court next held that, under this Court's precedents, the rational-basis test under *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985), not the intermediate-scrutiny test set forth in *Central*

[7] In opposition, the State submitted declarations from two scientists who addressed the health and environmental risks of GE foods: Michael Antoniou, Ph.D., a Reader in Molecular Genetics in the Department of Medical and Molecular Genetics at King's College London; and Charles Benbrook, Ph.D., a research professor at Washington State University's Center for Sustaining Agriculture and Natural Resources. Dist. Ct. Dkts. 63-14, 63-16.

Hudson Gas & Electric Corp. v. Public Service Commission of New York, 447 U.S. 557 (1980), "dictates the appropriate level of First Amendment scrutiny to be applied to Act 120's GE disclosure requirement." JA79. The district court rejected GMA's contention that Act 120 compels "controversial" speech outside the ambit of *Zauderer*. The court explained that a compelled factual disclosure does not become "controversial" merely because it deals with a *topic* that is subject to political debate. Rather, the court explained, "the compelled information must, itself, be 'controversial.'" JA74. And here, Act 120 requires only a statement of uncontroversial (and indisputable) fact: that a product was produced with genetic engineering. JA76.

The district court also rejected GMA's contention that intermediate scrutiny applies (and that Act 120 fails such scrutiny) because the Legislature has sought only to appease consumer curiosity, as in *International Dairy Foods Ass'n v. Amestoy (IDFA)*, 92 F.3d 67 (2d Cir. 1996). The court noted that "Act 120's 'Findings' and 'Purpose' extend beyond the mere appeasement of consumer curiosity," and that the extensive legislative record "includes studies about the safety of consuming GE plant-based foods, as well as studies about the environmental impacts of GE and GE crops." JA78. The "safety of food products" and "protection of the environment," said the district court, are "quintessential governmental interests." JA82-83.

The district court then held that, "[b]ecause the State has established that Act 120's GE disclosure requirement is reasonably related to the State's substantial interests, under *Zauderer*, Act 120's GE disclosure requirement is constitutional." JA84. The court had "little difficulty in characterizing" the State's interest in human health and the environment as "'substantial.'"[8] JA82. The court further held that Act 120's labeling requirement bears a reasonable relationship to its goals because "'encouraging . . . changes in consumer behavior' through compelled disclosure is 'rationally related' to a disclosure requirement even if the disclosure is not the *best means* of furthering that goal." JA83 (quoting *Nat'l Elec. Mfrs. Assoc. v. Sorrell* (*NEMA*), 272 F.3d 104, 115 (2d Cir. 2001)).

Finally, the district court held that GMA was likely to succeed on its challenge to Act 120's ban on "natural" advertising on GE foods, JA75, but determined that GMA had failed to show imminent irreparable harm. The court discerned "no evidence that Plaintiffs' members' use of the 'natural' terminology . . . will be chilled prior to trial." JA101. The district court therefore denied GMA's motion for a preliminary injunction.

[8] The district court doubted that *Zauderer* actually requires a "substantial" state interest, but held that Act 120 easily satisfies any such requirement. JA81-82.

SUMMARY OF ARGUMENT

The district court did not abuse its discretion in denying a preliminary injunction. GMA cannot show that it is likely to prevail on its First Amendment claims, and, in any event, cannot show that it will suffer imminent irreparable harm from a statute that does not go into effect for a year.

I. "[D]isclosure requirements about a company's own products or services" are subject to rational-basis review under *Zauderer*. *Safelite Group, Inc. v. Jepsen*, 764 F.3d 258, 264 (2d Cir. 2014). Act 120's disclosure requirement – a label making the accurate, factual statement "produced with genetic engineering" – is just such a requirement. *Zauderer* applies.

It may be, as GMA maintains, that genetic engineering is "hotly debated in many circles." Br. 26. But the mere fact that a *topic* is "hotly debated" does not transform a purely factual disclosure *related* to that topic into a "controversial" statement outside *Zauderer's* purview. Rather, the compelled speech must *itself* be controversial. There is nothing remotely controversial about the purely factual statement "produced with genetic engineering." GMA's contrary argument would improperly subject any number of disclosure requirements related to controversial issues to "searching scrutiny by unelected courts." *NEMA*, 272 F.3d at 116.

Act 120 easily satisfies rational-basis review. GMA contends that Act 120 was enacted solely to placate consumer curiosity. Not so. The Legislature

reviewed a wealth of scientific evidence showing that GE foods present risks to health and the environment and expressly stated that it enacted Act 120 to address those risks. There can be no doubt that those are substantial state interests. And based on the evidence before it, the Legislature reasonably concluded that labeling such foods is necessary to enable consumers to make informed purchasing decisions that could account for those risks.

GMA's contention that there is *zero* evidence that GE foods present any risk to human health ignores the legislative record, and improperly second-guesses the Legislature's empirical judgment. It also overlooks the fact that the Legislature also enacted Act 120 to protect against environmental risks – risks that GMA does not even dispute. Indeed, because the Legislature's interests are so substantial, and because Act 120 directly advances those interests, Act 120 would survive even intermediate scrutiny, should this Court decide that it applies (though it should not).

II. Act 120's regulation of "natural" does not run afoul of the First Amendment. "[T]here can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public." *Central Hudson*, 447 U.S. at 563. Here, the Legislature considered studies showing that consumers believe that "natural" labels connote the *absence* of GE food. On that record, the State was well within its constitutional rights to forbid such misleading labeling.

III. In any event, GMA cannot show irreparable harm. GMA will suffer no alleged First Amendment harms until *after* Act 120's July 2016 effective date. Until then, its members will incur only ordinary compliance costs that do not constitute irreparable harm. And as to "natural" labels, the district court correctly found that GMA offered "no evidence" that its members' use of such labels "will be chilled prior to trial." JA101.

ARGUMENT

I. THE GE DISCLOSURE REQUIREMENT DOES NOT VIOLATE THE FIRST AMENDMENT.

A. Rational-Basis Review Applies.

This Court's inquiry into the applicable standard of review can begin and end with *Safelite*, which reaffirmed the well-established principle that "disclosure requirements about a company's own products or services" are subject to rational-basis review under *Zauderer*. 764 F.3d at 264; *see NEMA*, 272 F.3d at 116 (applying *Zauderer* to product-labeling requirement); *Nat'l Ass'n of Mfrs. v. SEC* (*NAM*), No. 13-5252, 2015 U.S. App. LEXIS 14455, at *8 (D.C. Cir. Aug. 18, 2015) (confirming that *Zauderer* applies to "advertising or product labeling at the point of sale"). That is precisely what is at issue here: Act 120 instructs food manufacturers to disclose an undisputed fact about food products they choose to sell to Vermont consumers. It is a commercial disclosure requirement, plain and simple.

Zauderer recognized that such disclosure requirements – which promote the exchange of information and do not chill protected speech – stand in stark contrast to efforts by the government to "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion." 471 U.S. at 651 (citing *W. Va. State Bd. of Ed. v. Barnette*, 319 U.S. 624 (1943) (law requiring recitation of pledge of allegiance); *Wooley v. Maynard*, 430 U.S. 705 (1977) (law requiring "Live Free or Die" on license plate)). The *Zauderer* Court explained that a commercial speaker's "constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." *Id.* at 651. It therefore held that a requirement to disclose "purely factual and uncontroversial information" warranted minimal scrutiny under the First Amendment. *Id.*

GMA nevertheless insists that this Court should disregard *Zauderer* and *Safelite* (not to mention other Second Circuit cases) and subject the disclosure requirement to more exacting scrutiny under *Central Hudson.* It should not.

1. The public debate surrounding genetic engineering does not trigger intermediate scrutiny under *Central Hudson*.

To qualify as "factual and uncontroversial information" within the meaning of *Zauderer*, a statement (a) must be one of fact, rather than opinion, belief, or ideology (such as a pledge of allegiance), (b) must not be highly disputed, and (c) must relate to the commercial speaker's own product or service. Thus, for example, a label stating "produced with genetic engineering, which contaminates

organic crops" would be factual, but not necessarily uncontroversial. But the label here – "produced with genetic engineering" – is factual *and* uncontroversial. GMA does not contend that the labeled products are not, in fact, produced with genetic engineering.

GMA's primary argument on appeal is that Act 120 compels "controversial" speech because the very *topic* of genetic engineering is "hotly debated in many circles." Br. 26.[9] But GMA conflates controversial *speech* with controversial *subject matter*. The fact that genetic engineering, broadly speaking, may be a hotly debated topic does not transform an informational food label into "a politically motivated warning." Br. 30. Rather, as the district court held, "before compelled commercial information is deemed 'controversial,' the compelled information must, *itself*, be controversial." JA74 (emphasis added).[10]

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[9] Although GMA has abandoned its claim that Act 120 compels political speech subject to strict scrutiny, it continues to characterize Act 120 as mandating "political" discussion. Br. 22, 31. The district court correctly held that Act 120 compels commercial – not political – speech. JA73. Citing *Reed v. Town of Gilbert, Ariz.*, 135 S. Ct. 2218 (2015), the Chamber of Commerce suggests (Dkt. 62 at 27-28) that Act 120 constitutes content-based regulation subject to strict scrutiny. GMA makes no such argument. And for good reason: *Reed* is not a commercial-speech case, and (contrary to the Chamber's suggestion) says nothing whatsoever about *compelled* commercial disclosures.

[10] GMA suggests that the district court agreed that GMA's "characterization of the GE disclosure requirement as mandating a 'controversial' disclosure appears unassailable." Br. 19. But what the district court *actually* – and correctly – found was that, although GMA's contentions appeared unassailable "*[a]t first blush*,"

This Court has never applied *Central Hudson* to a commercial disclosure law merely because it addressed a publicly debated topic. Indeed, it squarely rejected GMA's theory of "controversial" disclosures in *New York State Restaurant Ass'n v. New York City Board of Health* (*NYSRA*), 556 F.3d 114 (2d Cir. 2009). There, restaurants opposed a New York City ordinance requiring them to post calories on menu boards, arguing that there is robust controversy about whether calories relate to overall nutrition. Appellant's Brief, *NYSRA*, 2008 WL 6513103, at *48. The restaurants argued that "substantive disagreement" about whether calories should factor into consumers' food purchasing decisions removed the regulation from *Zauderer's* purview. *Id.* at *48-49. This Court disagreed, upholding the labeling requirement under *Zauderer*. *NYSRA*, 556 F.3d at 134.

This Court likewise declined in *National Electrical Manufacturers Ass'n v. Sorrell* (*NEMA*), 272 F.3d 104 (2d Cir. 2001), to give heightened scrutiny to a Vermont statute requiring manufacturers to add labels stating whether their lamps contained mercury (and instructing consumers how they should dispose of such lamps). The Court explained that such a disclosure of "accurate, factual

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courts "have not affixed the 'controversial' label lightly, and the fact that Plaintiffs would prefer not to make the required disclosure is insufficient to render it 'controversial.'" JA73-74 (emphasis added); *see Zauderer*, 471 U.S. at 650 (disclosure is not controversial simply because it requires speakers "to provide somewhat more information than they might otherwise be inclined to present").

commercial information" presents little risk of "suppressing dissent" or hindering "self-governance," and emphasized that the plaintiffs did not challenge the labels as "inaccurate," *id.* at 114 & n.4, further confirming that the relevant question is whether the speech *itself* is factual and uncontroversial.[11] Explaining that "*Zauderer*, not *Central Hudson* . . . , describes the relationship between means and ends demanded by the First Amendment in compelled commercial disclosure cases," the Court held that the law was rationally related to the State's goals. *Id.* at 115.

And the en banc D.C. Circuit recently reached the same conclusion about "country of origin" labels in *American Meat Institute v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc). The law at issue there requires meat-product labels to state the location of each production step, such as "Born in Canada," or "Raised in the United States." *See id.* at 21. Because manufacturers are not required to use the word "slaughter" on their labels (which would arguably add a controversial connotation), and because they did "not disagree with the truth of the facts required to be disclosed," the court deemed the content of the message uncontroversial and applied *Zauderer*. *Id.* at 27. In other words, although the *subject matter* of (and

[11] The Court stated that requiring actors to "espouse particular opinions" would likely "raise issues" not presented by a requirement to disclose "factual commercial information." *NEMA*, 272 F.3d at 114 n.5.

need for) country-of-origin labels is quite controversial indeed – to the point where "some expect" it to result in a "trade war" among otherwise friendly nations[12] – the statements on the labels themselves are not.[13]

So too here. Like the labels at issue in *NEMA*, *NYSRA*, and *American Meat*, the labels required by Act 120 disclose only factual and accurate information. Yet GMA seeks to have this Court treat Act 120 as though it compels manufacturers to brand their products "Infected with GE bacteria," or "Produced with genetic engineering, which presents significant and unknown health risks."

If this Court were to accept GMA's sweeping theory, it is hard to imagine *any* food labeling law that would escape exacting First Amendment scrutiny. FDA regulations mandating the disclosure of sugar content would certainly be subject to heightened scrutiny in light of increasing debate – dubbed the "sugar controversy" – about the health effects of sugar consumption. Fernando Vio & Ricardo Uauy, *Case Study #9-5, The Sugar Controversy* (2007), http://goo.gl/cn0rfu. So, too, would the FDA's requirement that irradiated food be labeled as "treated with

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[12] *NAM*, 2015 U.S. App. LEXIS 14455, at *4 n.6; *see also id.* at *28 (noting "controversy" regarding country-of-origin labeling).

[13] *See id.* at *89 (Srinivasan, J., dissenting) ("While it might be said that the Conflict Minerals Rule's disclosure requirement touches on a 'controversial' topic, that alone cannot render the disclosure 'controversial' in the sense meant by *Zauderer*. Otherwise, our decision in *AMI* presumably would have turned out differently.").

radiation" – even though the agency found "the process to be safe" after evaluating it for more than thirty years. FDA, *Food Irradiation, What You Need To Know*, http://goo.gl/uSccfD. And industry groups could elevate the standard of review simply by challenging the merits of a disclosure law by, for instance, hiring scientists to suggest that lack of exercise, rather than diet, causes obesity. *See*, *e.g.*, Anahad O'Connor, *Coca-Cola Funds Scientists Who Shift Blame for Obesity Away From Bad Diets*, N.Y. Times (Aug. 10, 2015), http://goo.gl/DSbWlz.

Nor would GMA's argument stop at food labels. In *NEMA*, this Court warned against the "potentially wide-ranging implications" of GMA's First Amendment theory, highlighting that

> [i]nnumerable federal and state regulatory programs require the disclosure of product and other commercial information. *See*, *e.g.*, 2 U.S.C. § 434 (reporting of federal election campaign contributions); 15 U.S.C. § 78l (securities disclosures); 15 U.S.C. § 1333 (tobacco labeling); 21 U.S.C. § 343(q)(1) (nutritional labeling); 33 U.S.C. § 1318 (reporting of pollutant concentrations in discharges to water); 42 U.S.C. § 11023 (reporting of releases of toxic substances); 21 C.F.R. § 202.1 (disclosures in prescription drug advertisements); 29 C.F.R. § 1910.1200 (posting notification of workplace hazards); Cal. Health & Safety Code § 25249.6 ("Proposition 65"; warning of potential exposure to certain hazardous substances); N.Y. Envtl. Conserv. Law § 33-0707 (disclosure of pesticide formulas).

272 F.3d at 116. Each of these topics – from pharmaceuticals to pesticides – is a matter of public debate, just as "controversial" to some as genetic engineering. GMA's approach to the First Amendment would inevitably "expose these long-

established programs to searching scrutiny by unelected courts." *Id.* As this Court cautioned, "[s]uch a result is neither wise nor constitutionally required." *Id.*[14]

Courts have therefore applied heightened scrutiny to commercial disclosure laws only when they require the disclosure of something *more* than accurate factual information about a company's own product or services, such as an opinion or highly disputed fact.[15] In *Entertainment Software Ass'n v. Blagojevich*, for example, the court applied intermediate scrutiny to a law requiring "18" stickers on video games that met the State's definition of "sexually explicit," because the term was "far more opinion-based than the question of whether a particular chemical is within any given product." 469 F.3d 641, 652 (7th Cir. 2006).

National Ass'n of Manufacturers v. SEC illustrates the same point. There, the D.C. Circuit addressed a disclosure requiring companies to report to the SEC that minerals used in their products were "not found to be DRC conflict free"

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[14] *Zauderer* itself would be wrongly decided under GMA's understanding of "controversial," as contingency fees have generated significant controversy. *See Mitzel v. Westinghouse Elec. Corp.*, 72 F.3d 414, 420 n.2 (3d Cir. 1995) ("We have no desire to enter into the debate about contingency fees currently underway in legal circles.").

[15] GMA cites *Riley v. National Federation of the Blind of North Carolina, Inc.*, 487 U.S. 781 (1988), and *Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston*, 515 U.S. 557 (1995), to argue that laws compelling factual statements may warrant heightened review. Br. 27-28. But those were not commercial speech cases. *See Riley*, 487 U.S. at 796 (charitable solicitations are not commercial speech); *Hurley*, 515 U.S. at 573 (parades involve core protected expression).

(thereby indicating that they likely were mined in the war-torn Democratic Republic of Congo). In one of three alternative holdings – none of which applies to Act 120[16] – the panel stated (over a dissent by Judge Srinivasan) that the Conflict Minerals disclosure was not factual and uncontroversial because "[p]roducts and minerals do not fight conflicts." *NAM*, 2015 U.S. App. LEXIS 14455, at *31. Rather, the disclosure was "a metaphor that conveys moral responsibility for the Congo war." *Id*. Put another way, the Conflict Minerals disclosure attributed "moral responsibility" for the DRC war to the companies.

And in *R.J. Reynolds Tobacco Co. v. Food & Drug Administration*, the D.C. Circuit held that graphic warnings on cigarette packages did not constitute the type of factual and uncontroversial disclosures contemplated by *Zauderer*. 696 F.3d 1205 (D.C. Cir. 2012). Rather, an image of a man smoking through a tracheotemy hole "might be misinterpted as suggesting that such a procedure is a common consequence of smoking." *Id.* at 1216. That and other "inflammatory images," the court explained, were primarily intended to "shock the viewer," making them "a much different animal" than accurate factual disclosures. *Id.*[17]

[16] The Court first held in *NAM* that *Zauderer* was inapplicable because – unlike Act 120 – the disclosures there were not "advertising or point of sale disclosures." 2015 U.S. App. LEXIS 14455, at *10.

[17] In *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012), the Sixth Circuit stated that "whether a disclosure is scrutinized

GMA compares Act 120 to the ordinance at issue in the Ninth Circuit's unpublished decision in *CTIA-The Wireless Ass'n v. City & County of San Francisco* (*CTIA*), 494 F. App'x 752 (9th Cir. 2012), which required cell phone retailers to post a "fact sheet" warning consumers about radiofrequency energy emissions from cell phones and to recommend ways of avoiding such emissions. But GMA concedes that, unlike here, San Francisco's ordinance required retailers to disclose "more than just facts" about their own products. Br. 30. It required retailers to spread the City's recommendations about what consumers *should do* to avoid radiofrequency exposure, and included large silhouettes of individuals with radiofrequencies beaming into their head and hips – which, the district court observed, were not facts at all, but rather "images subject to interpretation," *CTIA*, 827 F. Supp. 2d 1054, 1063 (N.D. Cal. 2011).

GMA also relies on dictum in a footnote in *Evergreen Ass'n, Inc. v. City of New York*, where this Court addressed First Amendment challenges to an ordinance that required pro-life centers that offered free pregnancy-related services to disclose, among other things, that they did not offer abortions. 801 F. Supp. 2d 197, 202 (S.D.N.Y. 2011), *aff'd in part, vacated in part*, 740 F.3d 233 (2d Cir.

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under *Zauderer* turns on whether the disclosure conveys factual information or an opinion, not on whether the disclosure emotionally affects its audience or incites controversy." *Id.* at 569.

2014). But *Evergreen* was a *political-speech* case. The ordinance operated in a political setting – forcing pro-life advocates to speak about services they fundamentally oppose. Act 120, in contrast, operates in a commercial setting – requiring sellers of food to disclose an uncontroverted fact about a product they offer to consumers. And even if the speech at issue in *Evergreen* could somehow be considered commercial speech, the abortion disclosure requirement – like the regulation at issue in *Safelite* – extended beyond the clinics' *own* products or services, making *Zauderer* inapplicable. *Safelite*, 764 F.3d at 264. Act 120 could be analogized to *Evergreen* only if it required retailers who fundamentally opposed GE products to affix a sign to their store fronts: "No GE foods sold here: Go next door."

Act 120 is decidedly unlike these regulations. It requires manufacturers to disclose just the facts – "produced with genetic engineering" – and nothing more. It requires no inflammatory images (*R.J. Reynolds*), recommendations (*CTIA*), opinions (*Blagojevich*), moral metaphors (*NAM*), or referrals to grocery stores specializing in GE-free foods (*Evergreen*). It allows consumers to decide for themselves whether and how to incorporate the disclosed fact into their purchasing decisions. And, setting aside any controversy over the *need* for such labels (a debate best left to the legislative process), the accuracy of these four words is not disputed.

GMA contends that a factual label may nonetheless convey an "implicit controversial message," Br. 28, and that Act 120 does so by "attach[ing] relevance to information that is scientifically irrelevant," Br. 30.[18] To begin, it is doubtful that a GE label in fact conveys some hidden and controversial message; certainly the FDA does not appear to think so, having stated that GE food labels are *not* misleading. *See* FDA, *Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering* (2001), http://goo.gl/XObz6M. In any event, GMA's claim of "scientific irrelevance" is legally misplaced: The question whether GE foods present actual risks is relevant to whether Act 120 is *rationally related to the State's interest* – not to the threshold question, which is *whether Zauderer applies in the first place*.

This Court should reject GMA's pleas to ratchet up the level of scrutiny by reference to the public debate about genetic engineering. "[D]espite the partisan debate which gave rise to [Act 120's] enactment, the 'nature of the speech taken as a whole' remains a factual disclosure regarding a food product's ingredients made in conjunction with the purchase and sale of food." JA73 (quoting *Riley*, 487 U.S. at 796).

[18] Some of GMA's own members evidently regard the absence of GE ingredients as highly "relevant" to the public, since they prominently advertise that fact. Dist. Ct. Dkt. 63, at 44; *Cheerios Cereal*, http://goo.gl/KRR0Gr.

2. *Zauderer* is not limited to regulations that prevent deception.

GMA acknowledges that this Court has applied *Zauderer* beyond disclosures aimed at preventing consumer deception. Br. 35. *See NYSRA*, 556 F.3d at 133 ("[W]e held [in *NEMA*] that *Zauderer's* holding was broad enough to encompass nonmisleading disclosure requirements."); *NEMA*, 272 F.3d at 115 (applying *Zauderer* to mercury-labeling law even though it was "not intended to prevent consumer confusion or deception"). And, as the district court recognized, this Court has applied *Zauderer* to disclosures – like Act 120 – intended "'to better inform consumers about the products they purchase.'" JA80 (quoting *NEMA*, 272 F.3d at 115).

GMA insists, however, that *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229 (2010), has overtaken this Court's precedent. Br. 35. Not so. Although the Supreme Court confirmed that *Zauderer* applies to disclosures that combat misleading advertisements, it did not *limit Zauderer* to that context. *Milavetz*, 559 U.S. at 249; *Am. Meat Inst.*, 760 F.3d at 22 (noting that *Milavetz* "focused on remedying misleading advertisements," but holding that *Zauderer* "sweeps far more broadly than the interest in remedying deception"). This Court's *Zauderer* precedents remain controlling.

3. In any event, the GE disclosure prevents deception.

Even under the most limited view of *Zauderer* – as applying only to matters of "consumer deception" – Act 120 passes muster. *Zauderer* applies whenever commercial speech occurs in an area where "frequent ignorance and confusion on [a] subject *could* otherwise subject [consumers] to easy deception." *Conn. Bar Ass'n v. United States*, 620 F.3d 81, 96 (2d Cir. 2010) (emphasis added). That is precisely the case here: The Legislature found that "many consumers are under an incorrect assumption about whether the food they purchase is produced from genetic engineering," and that labels "will reduce consumer confusion or deception regarding the food they purchase." Act 120, Sec. 1(5)(B).

B. Under *Zauderer's* Rational-Basis Standard, The GE Disclosure Requirement Is Plainly Constitutional.

Compelled commercial disclosures are constitutional under *Zauderer* so long as they are "reasonably related to a legitimate state interest." *Conn. Bar. Ass'n*, 620 F.3d at 104; *Safelite*, 764 F.3d at 262. Act 120 easily satisfies that standard.

1. The State's interests are legitimate and substantial.

GMA first tries to raise the bar: It asserts that this Court has imported a "substantial" state interest requirement into *Zauderer's* rational-basis test. Br. 46-47. As the district court recognized, however, "*Zauderer*, itself, does not impose this requirement." JA81. Although this Court used the term "substantial" in

passing to describe the interests at stake in *NEMA* and *NYSRA*, its holding in those cases – that a substantial interest satisfies rational-basis review, which requires only a "legitimate" state interest – does not change the standard. *Conn. Bar Ass'n*, 620 F.3d at 104 (*Zauderer* requires "legitimate state interest"); *NEMA*, 272 F.3d at 115 (citing "legitimate" public goal).[19]

In any event, the State's interests here are unquestionably substantial. As the district court correctly explained, "[t]he safety of food products, the protection of the environment, and the accommodation of religious beliefs and practices are all quintessential governmental interests," as is the State's interest in preventing consumer confusion. JA82-83. In *NEMA*, this Court stated that "Vermont's interest in protecting human health and the environment from mercury poisoning is a legitimate and significant public goal." *See NEMA*, 272 F.3d at 115. Even GMA cannot dispute that these are substantial public interests.[20]

So GMA tries Plan B. It insists that Vermont's *real* interest here is mere "consumer curiosity," which, it argues, is insufficient under *IDFA*, 92 F.3d 67. But

[19] At least two other Courts of Appeals have likewise concluded that *Zauderer's* test is "akin to the general rational-basis test." *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 316 (1st Cir. 2005); *King v. Governor of New Jersey*, 767 F.3d 216, 236 (3d Cir. 2014).

[20] GMA contends that GE foods do not actually present any health risks (ignoring the Legislature's environmental concerns). But that argument, frail as it is, bears only on the fit between the means (Act 120) and the ends, not the validity of the ends.

this case is hardly a reprise of *IDFA*. As the district court recognized, this Court has limited the reach of *IDFA* to cases where a state can defend its law "by *no interest* other than the gratification of 'consumer curiosity.'" JA77-78 (quoting *NSYRA*, 556 F.3d at 134) (emphasis added). Here, in contrast, the Legislature made clear that GE labeling is necessary to "*serve the interests of the State*," including "to prevent inadvertent consumer deception, prevent potential risks to human health, protect religious practices, and protect the environment." Act 120, Sec. 1(6) (emphasis added).

To be sure, the State believes that Act 120 will serve those substantial interests by enabling consumers to make informed decisions about GE products. GMA protests that, *because* Act 120 facilitates consumer choice, its sole purpose is to satisfy idle consumer curiosity. But every labeling law operates, in part, by informing consumers; that's how labels work. The question under *IDFA* is whether there is any reason to give consumers information *other than* to sate their curiosity. Here, the State articulated several reasons: GE foods present risks to human health and the environment and implicate consumers' religious beliefs, and labels are necessary to prevent confusion and enable informed decision-making. *See NYSRA*, 556 F.3d at 133 (explaining that, while the goal of the statute in *NEMA* was to reduce the amount of mercury released in the environment, "it is

inextricably intertwined with the goal of increasing consumer awareness of the presence of mercury in a variety of products").

Promoting informed consumer choice on a matter deemed worthy by the State of consumer consideration cannot be denigrated as a mere sop to curiosity.[21] The D.C. Circuit rejected that very argument in *American Meat*, explaining that, as here, because there were *reasons* to require country-of-origin meat labels – including to "empower consumers to take *possible* country-specific difference in safety practices into account" – the regulation served an interest that rose above "idle curiosity." 760 F.3d at 23-25 (emphasis added). Moreover, whereas this Court found that the record in *IDFA* "contain[ed] no scientific evidence" about the impacts of rBST, *IDFA*, 92 F.3d at 73, the record here contains voluminous scientific evidence supporting the State's findings.

2. Act 120 is rationally related to the State's interests.

GMA next contends that Act 120 is not rationally related to the State's interests because it is based on junk science. This triumphalist rhetoric simply ignores the legislative record. The Legislature reviewed ample evidence on both

[21] GMA's statement, Br. 40, that Vermont "never goes so far as to affirmatively adopt any of the rationales listed in the Act" is baffling. The Legislature expressly stated that Act 120 was necessary to "prevent potential risks to human health," to "protect the environment," and "to prevent inadvertent consumer deception." Act 120, Sec. 1(6).

sides of the issue, concluding that there is a reasonable basis for competing views. The Legislature voted to address the identified health and environmental concerns by enabling Vermont consumers to make their own, informed purchasing choices. And it elected to do so by requiring food labels. That was an eminently reasonable decision – and easily satisfies *Zauderer's* rational-basis test.

GMA disparages the robust legislative record as a "lengthy compilation of documents," insufficient to justify a labeling requirement. Br. 48-49. But *Zauderer* "does not demand 'evidence or empirical data' to demonstrate the rationality of mandated disclosures in the commercial context." *Conn. Bar Ass'n*, 620 F.3d at 97-98 (quoting *NYSRA*, 556 F.3d at 134 n.23). "[A]s the Court recognized in *Zauderer*, such evidentiary parsing is hardly necessary when the government uses a disclosure mandate to achieve a goal of informing consumers about a particular product trait, assuming of course that the reason for informing consumers qualifies as an adequate interest" (as it does here). *Am. Meat*, 760 F.3d at 26.[22]

[22] GMA insists (citing *Edenfield v. Fane*) that the State must produce "scientific evidence" to prove rationality. Br. 47. But *Edenfield* was an intermediate-scrutiny case, and this Court requires no such proof under *Zauderer*. In any event, unlike in *Edenfield*, where "no studies" or even "anecdotal evidence" supported the restriction on speech, 507 U.S. 761, 771 (1993), the Vermont Legislature relied on a vast array of scientific material and testimony.

The district court correctly declined to sit as a "super science expert" to "decide whether GE ingredients are safe," Dist. Ct. Dkt. 87, at 13-14, and instead found it sufficient that the Legislature's findings were "ground[ed] in an extensive legislative record," which "includes studies about the safety of consuming GE plant-based foods, as well as studies about the environmental impacts of GE and GE crops." JA78-79. Recognizing that "'a legislature is an institution better equipped to amass and evaluate the vast amounts of data bearing on such an issue," the district court "view[ed] these legislative findings with deference.'" JA82 (quoting *Walters v. Nat'l Ass'n of Radiation Survivors*, 473 U.S. 305, 330 n.12 (1985)).

GMA, by contrast, urges this Court to perform a more exacting review, asking it to find that *every study* considered by the Legislature was "outdated, retracted, or debunked." Br. 48. *Zauderer* does not sanction that approach. In "reviewing the constitutionality of a statute, courts must accord substantial deference to the predictive judgments of [the Legislature]," and its evaluation of the evidence. *Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 195 (1997).

But even if it *were* this Court's role to second-guess the Legislature, GMA is flat wrong when it declares that *no* evidence supports Act 120. The Legislature's detailed findings were based on its careful consideration of dozens of studies and articles, and weeks of testimony, showing that GE foods present health risks. The

declarations filed in the district court confirm the State's findings that GE foods are different from traditional foods, that GE plants present risks to human health, that federal oversight is inadequate to ensure the safety of GE foods, and that there have been few long-term or epidemiological studies confirming the safety of GE foods. Benbrook Decl. ¶¶ 15-23; Antoniou Decl. ¶¶ 13-64.

Moreover, GMA focuses, myopically, only on the State's *health-related* interests. Yet Act 120 also addresses the environmental impacts of GE technology and crops. The Legislature considered studies showing that the increased use of GE crops has led to a dramatic increase in herbicide use; the emergence and spread of herbicide-resistant weeds; gene flow from GE crops to non-GE crops, contaminating conventional or organic crops (often with devastating effects on commerce and international trade); alterations in soil microbial communities; and reductions in biodiversity. *See supra* pp. 7-10; Benbrook Decl. ¶¶ 24-67; Antoniou Decl. ¶¶ 65-79. The State properly seeks to enable consumers to make purchasing decisions based on a product's environmental impacts.

GMA effectively concedes that there are environmental risks here. In the only sentence in its brief even alluding to the State's environmental purposes, GMA asserts that the State "can point to no environmental harms from GE crops, *other than* distinct alleged harms from pesticides or farming techniques that it has not attempted to directly regulate." Br. 49-50 (emphasis added). But that anemic

claim ignores, first and foremost, most of the evidence the State considered, including evidence of *direct risks* to the environment posed by GE plants. It also ignores that the most widely used GE crops are genetically engineered *precisely* so they can withstand increased exposure to herbicides known to cause cancer (and to produce insecticides in their own cells). *See supra* p. 2. Whether the State could have chosen to regulate pesticides more "directly" is irrelevant; a labeling law does not fail rational-basis review merely because it would not make "the greatest possible contribution" to the State's environmental interest. *NEMA*, 272 F.3d at 115-16 ("a state may choose to tackle a subsidiary cause of a problem rather than its primary cause"); *see also Am. Meat Inst.*, 760 F.3d at 25 ("Simply because the agency believes it has other, superior means to protect [its interest] doesn't delegitimize a congressional decision to empower consumers.").

Finally, GMA emphasizes that the "federal government" has concluded that GE foods are safe and that the FDA does not require labeling – as though those facts bear on the constitutionality of Act 120. Br. 9. They do not. To begin with, "[h]ealth 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); *Grocery Mfrs. of Am., Inc. v. Gerace*, 755 F.2d 993, 1003 (2d Cir. 1985) ("States have traditionally acted

to protect consumers by regulating foods produced and/or marketed within their borders.").

Indeed, it is standard practice for states – "laboratories for devising solutions to difficult legal problems," *Oregon v. Ice*, 555 U.S. 160, 171 (2009) – to fill gaps in federal regulations on matters of health and safety. For example, the same New York City calorie-content disclosure law upheld by this Court in *NYSRA* preceded federal menu labeling requirements. *Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments*, 79 Fed. Reg. 71156-01 (Dec. 1, 2014). And only after several states had enacted laws restricting the use of BPA in children's food containers did the FDA amend its regulations. FDA, *Bisphenol A (BPA): Use in Food Contact Application*, http://goo.gl/zCpPgW. GMA seeks to upend core principles of our federalist system by suggesting that Vermont *cannot* rationally act where the FDA has chosen not to.

C. The Disclosure Requirement Also Satisfies *Central Hudson's* Intermediate Scrutiny Test.

If the Court nevertheless determines that *Zauderer* does not apply, Act 120 readily satisfies intermediate-scrutiny under *Central Hudson.*

For the reasons set forth above, the State's interests are plainly substantial. GMA cannot legitimately dispute that promoting human health, protecting the environment, and remedying consumer confusion are substantial state interests.

Both this Court, *NEMA*, 272 F.3d at 115, and the D.C. Circuit, *Am. Meat*, 760 F.3d at 24, have confirmed that states have a substantial interest in promoting informed consumer choice on matters related to health and the environment.

GMA intimates that Act 120 does not "directly advance" its articulated purposes because the State did not go *far enough*. It says the State cannot regulate only "potential" risks and should have taken a more definitive stance on the harms caused by genetic engineering. Br. 42. And it criticizes the State both for exempting certain foods and for permitting manufacturers to use the less definitive formulation "may be produced with genetic engineering" labels. *Id.* at 43. But GMA disregards the fundamental principle that courts do not "require that the Government make progress on every front before it can make progress on any front." *United States v. Edge Broad. Co.*, 509 U.S. 418, 434 (1993).

GMA and its allies also assert that GE risks to human health have not been proved with absolute certainty.[23] The American Chemical Council goes so far as to suggest as *amicus curiae* that an ingredient must be a *known carcinogen* before a State can require a label. Only a "*life-impairing injury*," say the Chemists, can justify a food label. Dkt. 84 at 12-15 (emphasis added).

[23] As noted, GMA does not dispute the environmental impacts of GE crops.

Surely "certain death" cannot be the standard against which courts measure a state's police powers when it comes to commercial disclosures. As the American Cancer Society has stated with respect to genetic engineering, "the *absence* of evidence of harmful effects is not equivalent to evidence of safety." Antoniou Decl. ¶ 35. States have a substantial interest in guarding against "imperfectly understood" risks – "despite the possibility that they may ultimately prove to be negligible." *Maine v. Taylor*, 477 U.S. 131, 148 (1986); *see Gerace*, 755 F.2d at 1004; *see* Mark Spitznagel & Nassim Taleb, *Another 'Too Big to Fail' System in G.M.O.s*, N.Y. Times (July 13, 2015), http://goo.gl/MCeTsF. And Vermont is by no means the first state to do so; California, as a precautionary measure, has for years required warning labels on products that contain levels of toxic chemicals *far below* those shown "not to pose any harm to humans." California Office of Environmental Health Hazard Assessment, *Proposition 65 in Plain Language!*, http://goo.gl/tiiAM8.

Nor do Act 120's exemptions render it fatally under-inclusive. A regulation does not run afoul of *Central Hudson* simply because it contains exemptions (as most laws do), but only where it "discriminate[s]" or draws "arbitrary" distinctions. *Clear Channel Outdoor, Inc. v. City of N.Y.*, 594 F.3d 94, 105-06 (2d Cir. 2012). Act 120's exemptions are anything but arbitrary: They reflect the State's consideration of the current regulatory landscape, as well as certain

practical limits on labeling. GMA, for example, takes issue, Br. 43, with the restaurant exemption. Act 120, Sec. 2, § 3044(7). But if that exemption were to cause Act 120 to falter, so too would it invalidate the Nutrition Labeling and Education Act, which (recognizing among other things the impracticability of requiring labels in restaurants) exempts certain restaurants from its labeling regime, 21 C.F.R. § 101.9(j)(2)).[24] GMA also criticizes the animal-product exemptions, Act 120, Sec. 2, § 3044(1), which indisputably reflect Vermont's attempts to harmonize its law with federal regulations and avoid the very preemption challenges GMA raised below.[25] *See* 21 U.S.C § 467(e); *id.* § 678.

GMA refuses to acknowledge any of this. In any event, well-reasoned exemptions aside, Act 120 directly advances the State's interests by requiring labeling, as GMA alleges, on "[t]he vast majority of foods sold in grocery stores in the United States today." Dist. Ct. Dkt. 103, at ¶ 23. Here, as in *Clear Channel*, the Legislature has "a 'sufficient basis' to believe that the impact of [Act 120]" – providing more information to consumers where practicable – "will substantially

[24] The State's "knowingly or intentionally" exemptions, Act 120, Sec. 2, §§ 3044(2), (6), take into account the reality of gene flow and seek to avoid penalizing traditional farmers (and the manufacturers they supply) whose crops were, unbeknownst to them, contaminated by GE crops. Act 120, Sec. 1(4)(D-E)

[25] The exemptions for processing aids, alcohol, and medical food, Act 120, Sec. 2, §§ 3044(3)-(4), are likewise designed to ensure that Act 120 complements federal regulations. *See* Ex. K at 193-94.

advance its proffered interests." 594 F.3d at 109. Even if Act 120 does not perfectly advance those interests, *Central Hudson* requires no more.

GMA also takes issue with the provision of Act 120 that permits certain manufacturers to use "may be produced" labels. Br. 43. But GMA does not defend its assertion that such labels are "vague" and "opaque" and would do "little" to inform Vermont consumers. *Id.* Just as a label stating "may be produced" with peanuts can inform the purchasing decisions of consumers with allergies, so too can "may be produced" labels allow consumers that are so inclined to avoid GE foods.

Finally, GMA insists that Act 120 fails *Central Hudson's* fit requirement because GMA would have preferred a different regulation (or none at all). Br. 45. But *Central Hudson* is not an invitation to second-guess the Legislature's judgment. States are entitled to "leeway in a field (commercial speech) traditionally subject to governmental regulation." *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 481 (1989). Thus, satisfaction of *Central Hudson's* "fit" requirement turns on whether the scope of the regulation "is in proportion to the interest served" – not whether the State reached the "single best disposition." *Id.* at 480. Within the range of reasonable alternatives, courts "leave it to governmental decisionmakers to judge what manner of regulation may best be employed." *Id.* at 481.

To be sure, some may view the alternatives proposed by GMA – voluntary labeling, advertising campaigns, or publication of ingredient lists – as reasonable.[26] But so is requiring a four-word, factual product label. Where "the government acts only through a reasonably crafted mandate" that, as here, does not burden or chill commercial speech more than is necessary, "the means-end fit is self-evidently satisfied." *Am. Meat*, 760 F.3d at 26. That is doubtless why "many such mandates have persisted for decades without anyone questioning their constitutionality." *Id.*

II. THE "NATURAL" RESTRICTION IN ACT 120 DOES NOT VIOLATE THE FIRST AMENDMENT

GMA not only wants to withhold truthful information about its members' GE products – it also wants to double down by calling those products "natural." Act 120 forbids such labeling, but the district court, applying *Central Hudson*, held that the "natural" restriction is likely unconstitutional. JA94. The court went on to hold, however, that an injunction was unwarranted because GMA had not proven irreparable harm. *See infra* p. 52. That result was correct for the independent reason that the "natural" restriction is entirely constitutional. *Freedom Holdings*,

[26] The Legislature had reason to reject those alternatives. It heard testimony, for example, that voluntary labeling would "leave most of the grocery store in the dark for consumers." Ex. K at 181. And an informational campaign would not inform consumers whether *particular* foods contain GE materials – only manufacturers can provide that information. *See Evergreen*, 740 F.3d at 250 (advertising campaign was a viable alternative where – unlike here – the intended message did "not require knowledge of discrete information available only to individual [manufacturers]").

Inc. v. Spitzer, 408 F.3d 112, 114 (2d Cir. 2005) (in reviewing district court's denial of a preliminary injunction, court "may affirm on any ground supported by the record").

A. *Central Hudson* Does Not Apply To The Natural Restriction.

Speech that is "actually or inherently misleading" does not enjoy any First Amendment protection and may be banned outright. *Peel v. Att'y Registration & Disciplinary Comm'n of Ill.*, 496 U.S. 91, 111 (1990) (Marshall, J., concurring); *Central Hudson*, 447 U.S. at 563 (speech that is "more likely to deceive the public than to inform it" may be banned). The district court agreed, *see* JA86, but held that the State had failed to show that "natural" is either inherently or actually misleading.

With respect to inherent confusion, the court found that the word "natural" lacks a universal definition against which "alleged deception [could] be measured." JA87. In the district court's view, "green houses, fertilizers, pesticides, and even watering, weeding, and pruning of plants" are "non-natural" as well; so it may be equally misleading (or not misleading) to call any other food product "natural," yet Act 120 applies only to GE products.

That reasoning has at least three basic flaws. First, it rests on a factual premise that lacks any record support – that consumers are in fact confused about the use of the term "natural" with respect to anything but GE foods. The only

evidence in the record of consumer confusion caused by "natural" claims relates to the use of the term on GE products. *See* Ex. J. at 804. Second, even if there *were* consumer confusion about non-GE foods, the district court wrongly supposed that the State is disabled from preventing *GE-related* confusion unless it addresses *all* forms of confusion. The First Amendment commercial speech cases impose no such burden. *See, e.g.*, *Edge Broad. Co.*, 509 U.S. at 434 (the Supreme Court does not "require that the Government make progress on every front before it can make progress on any front").

Finally, the district court overlooked ample precedent: Courts routinely address claims of consumer confusion arising from the use of the word "natural" in discrete cases, even though there is no universal definition of "natural." As the court held in *Ham v. Hain Celestial Group, Inc.*, "[t]he question is not whether Ham provides a plausible definition of 'All Natural,' but whether a reasonable consumer would expect to find [sodium acid pyrophosphate] in Waffles that are labeled 'All Natural.'" 70 F. Supp. 3d 1188, 1193 (N.D. Cal. 2014). *See also Segedie v. Hain Celestial Grp., Inc.*, No. 14-CV-5029 (NSR), 2015 WL 2168374, at *11 (S.D.N.Y. May 7, 2015); *Ault v. J.M. Smucker Co.*, No. 13-CV-3409 (PAC), 2014 WL 1998235, at *6 (S.D.N.Y. May 15, 2014) ("it is not unreasonable . . . for a consumer to believe that non-organic foods labeled as 'All Natural' do not possess GMOs").

Nor was the district court correct in rejecting the State's "actual confusion" contention. The court acknowledged that the Legislature had considered surveys showing that "*some* consumers may find the use of 'natural' terminology in conjunction with GE food misleading." JA89; *see also* Kolodinsky Decl. ¶ 26 (highlighting poll "indicating that a majority of Vermont consumers perceive 'natural' labels to mean produced without genetic engineering"). The court discounted these surveys, however, because they are "not the equivalent of actual and unsolicited citizen problems or complaints regarding GE manufacturers' use of 'natural' terminology." JA89.

There is no such litmus test for surveys of consumer confusion. Indeed, consumer surveys of this kind are *precisely* the type of evidence that a Legislature may rely on to assess whether consumers are misled by commercial speech. *See Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 620 (1995) (relying on survey evidence); *Conn. Bar Ass'n*, 620 F.3d at 97 (same); *Bronco Wine Co. v. Jolly*, 29 Cal. Rptr. 3d 462, 476 (Cal. Ct. App. 2005) (relying on survey evidence to conclude that "Napa" brand names were misleading when used on wines made from grapes outside the region).

For these reasons, *Central Hudson* does not apply at all, and the "natural" restriction should be sustained under the First Amendment.

B. In Any Event, The "Natural" Restriction Satisfies *Central Hudson*.

Once it decided to apply *Central Hudson*, the district court found the "natural" restriction wanting for much the same reason that prompted the court to apply *Central Hudson* in the first place – equivalent "confusion" could be imputed to *any* food that results from some form of human intervention. Accordingly, the court said: The State's interest cannot be "substantial" because it is "restricting the use of undefined terms by some, but not all, similarly-situated commercial speakers,"JA91; Act 120 does not "directly and materially" advance the State's interest because "only certain commercial speakers are prohibited from using a potentially misleading term," JA91-92; and any benefits stemming from the "natural" restriction are "remote, contingent, and speculative" because "only some food manufacturers" will be prohibited from using such "undefined terms," JA93-74.

The district court held the State to too high a First Amendment burden. For one thing, legislatures may rationally solve one problem at a time, *Edge Broad. Co.*, 509 U.S. at 434, including under *Central Hudson*. Even if "natural" labels could be confusing in other contexts, Vermont was entitled to address the specific problem it had identified (based on the evidence) – confusion caused by "natural" labels on GE food products. *See, e.g.*, *Bd. of Trustees of State Univ.*, 492 U.S. at 480 ("[W]e have not gone so far as to impose upon [regulators] the burden of

demonstrating that the distinguishment" of "harmless from the harmful" is "100% complete."); *Semler v. Oregon State Bd. of Dental Examiners*, 294 U.S. 608, 610-11 (1935) ("The state was not bound to deal alike with all these classes, or to strike at all evils at the same time or in the same way. It could deal with the different professions according to the needs of the public in relation to each.").

Likewise, Act 120 "directly advances" the interest in stemming consumer confusion about GE products, even if it does not dispel all *other* confusion (assuming there is any) in one fell swoop. *Bad Frog Brewery, Inc. v. New York State Liquor Authority*, 134 F.3d 87 (2d Cir. 1998), cited by the district court, JA92, does not counsel otherwise. There, the Court held that a regulation that barred vulgar images on alcoholic beverages failed to "directly advance" the state's interest in curbing the "exposure of children to vulgar displays" where the state did not regulate the "wide currency of vulgar displays" actually directed at children – unlike alcoholic beverages. 134 F.3d at 99-100. Here, by contrast, the regulation advances the State's interest in reducing consumer confusion about GE products by prohibiting misleading labels on those very products – a targeted "sweep" indeed.[27]

[27] Nor do Act 120's exemptions defeat it, as they are neither discriminatory nor arbitrary, *Clear Channel*, 594 F.3d at 105-06, but rather reflect rational line-drawing in light of the regulatory landscape and practical limitations of food labeling. *See infra* pp. 42-43.

Finally, the benefits of the "natural" restriction are not rendered "ineffective" or "remote" simply because there may (supposedly) be confusion about other products in the grocery aisles. The district court's contrary view again rests on the unwarranted assumption that a state must solve all problems or else solve none. *Central Hudson* imposes no such hurdle. The government may prohibit the phrase "good for your heart" on food with high levels of trans fat – if the evidence shows that the phrase is misleading on such food – without also prohibiting the phrase on salty foods.

Nor is it true that the State is constitutionally required to rely on *the GE disclosure requirement* alone to prevent consumer confusion. JA93. Even when the GE disclosure labels are in place, the Legislature was not required to assume that consumers would "look beyond misleading representations on the front of the box to discover the truth" about the products' contents, *Segedie*, 2015 WL 2168374, at *11. And it was not unreasonable for the Legislature to conclude that pairing two contradictory statements on a label – "natural" but "produced with genetic engineering" – would only compound, not dissipate, consumer confusion.

III. GMA FAILED TO PROVE IRREPARABLE HARM.

"Irreparable harm is the single most important prerequisite for the issuance of a preliminary injunction." *Rodriguez v. DeBuono*, 175 F.3d 227, 233-34 (2d Cir. 1999). Because it is an "extraordinary and drastic remedy," a preliminary

injunction may not issue unless the plaintiff makes a "'*clear showing*'" of irreparable harm. *Sussman v. Crawford*, 488 F.3d 136, 139 (2d Cir. 2007) (quoting *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997)). In particular, the plaintiff must establish "that absent a preliminary injunction [it] will suffer an injury that is neither remote nor speculative, but actual and imminent, and one that cannot be remedied if a court waits until the end of trial to resolve the harm." *Freedom Holdings*, 408 F.3d at 114.

The district court, having sustained the GE labeling requirement under *Zauderer*, declined to address whether the mandate posed irreparable harm. JA99-100.[28] As to the regulation of "natural," the district court found that GMA had failed to make the required showing. JA81-82. In fact, GMA has not established irreparable harm as to *either* element of Act 120.

A. Any Alleged Harm To GMA's First Amendment Rights Will Not Occur Until Act 120 Goes Into Effect – Nearly A Year From Now.

GMA contends that "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." Br. 51. But no curtailment of any speech will occur until *after* Act 120's July 2016

[28] GMA claims, Br. 51, that the district court "recognized" that Plaintiffs would suffer irreparable harm with respect to the GE mandate. Not so: the court made no findings regarding GMA's allegations of harm (which it referred to merely as "Plaintiffs' arguments," JA100), and this Court should not assume that fact-finding role. *See Icicle Seafoods, Inc. v. Worthington*, 475 U.S. 709, 714 (1986).

effective date. The parties fully expect the district court to have issued a merits ruling by then. Thus, even if Act 120 abridged GMA's First Amendment rights (it does not), GMA will not suffer any harm for another year.

The cases cited by GMA confirm the point. In *IDFA*, for example, the challenged law had long been in effect when this Court granted the injunction. *See* 1994 Vt. Acts & Resolves No. 127 (requiring rBST labeling to "take effect 60 days from passage" in 1994 – two years before the 1996 appellate decision). Likewise, in *Safelite*, this Court enjoined a law that "took effect" earlier that year. 764 F.3d at 261. Thus, while there could be a need to "self-censor rather than risk an enforcement action" *after* a law's effective date, Br. 51, that is not the case here. GMA's members need not speak until Act 120 goes into effect, and they cannot fear enforcement of a law not yet in operation. *See generally Ashcroft v. Am. Civil Liberties Union*, 542 U.S. 656, 670 (2004) (explaining the risk of self-censorship "[w]here a prosecution is a likely possibility" for an operational statute).

Until that time, there is simply no State action for this Court to enjoin – and thus no imminent injury that "could be remedied by a preliminary injunction." *Dexter 345, Inc. v. Cuomo*, 663 F.3d 59, 63 (2d Cir. 2011).[29] In truth, GMA is

[29] GMA ignores that Rule 65 limits a court's injunctive power to "specific legal violations." *City of N.Y. v. Mickalis Pawn Shop, LLC*, 645 F.3d 114, 144 (2d Cir. 2011); Fed. R. Civ. P. 65(d)(1)(C) (injunction must "describe in reasonable detail . . . the act or acts restrained or required"). GMA cannot identify any action

seeking an order that is no more valuable than the paper it is written on: a preliminary injunction that would relieve GMA's members from speaking at a time when they are *not* required to speak – and likely would be superseded by a ruling on the merits before it has any operative effect. *See, e.g.*, *Local 553, Transport Workers Union of Am., AFL-CIO v. Eastern Air Lines, Inc.*, 695 F.2d 668, 676 n.6 (2d Cir. 1982) (a preliminary injunction "lasts only until the District Court has had an opportunity to adjudicate the merits of the dispute"). That is the very definition of an advisory opinion. Rather than grant preliminary relief against a law that is not yet in effect, the "better practice would be to seek an expedited trial" below. *Brennan's, Inc. v. Brennan's Rest., LLC*, 360 F.3d 125, 129 (2d Cir. 2004); *see also DeBuono*, 175 F.3d at 235 (preliminary relief unavailable where plaintiffs can "wait[] until the end of trial"). GMA chose not to pursue that route. Dist. Ct. Dkt. 49, at 14-15.

B. Ordinary (And Speculative) Compliance Costs Do Not Constitute Irreparable Harm.

Because GMA will not suffer any alleged First Amendment harms until Act 120 goes into effect, the preliminary relief GMA seeks is really from the costs of *preparing* to comply with Act 120. GMA claims that its members are already "be[ing] forced to speak" because of "the expense, time, and resources" they

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currently being taken or that would be taken by state officials to enforce Act 120 prior to July 1, 2016.

contend are involved in preparing for Act 120. Br. 51. But that is not *speech*. Thus, GMA has failed to show that it "will suffer irreparable harm" to its "legal interest" in the First Amendment sense. *See Garcia v. Google, Inc.*, 786 F.3d 733, 744-45 (9th Cir. 2015) (irreparable harm in copyright case must be "in the copyright sense"); *see also Bronx Household of Faith v. Bd. of Educ. of City of N.Y.*, 331 F.3d 342, 350 (2d Cir. 2003) ("plaintiff must demonstrate that the injunction will prevent the feared deprivation of free speech rights"). Its only alleged costs are compliance costs – not First Amendment costs.

GMA does not dispute that "ordinary compliance costs" are "insufficient to constitute irreparable harm." *Freedom Holdings*, 408 F.3d at 115. Instead, it contends that preparations for complying with Act 120 "go well beyond [such] ordinary compliance costs." Br. 55-56. But GMA offers no legal or factual support for that contention. Quoting its own assertions as if they were factual findings, GMA points to the need for "dual-inventory, production, and distribution systems." Br. 56. Setting aside that the State's declarants presented a very different picture of compliance, JA32-33, GMA is invoking costs that Act 120 doesn't require: Manufacturers may comply with Act 120 by relabeling nation-wide (avoiding any dual systems), adding stickers to products destined for Vermont, or pulling out of the Vermont market altogether. The fact that

manufacturers may *choose*, as a business decision, a more expensive option for compliance does not constitute irreparable harm.[30]

GMA's allegations of compliance costs are also wholly speculative. GMA introduced no evidence that they are actually "chang[ing] their business practices *now*." Br. 55. Rather, GMA's declarants discussed only what they believed compliance *might* entail. GMA cannot obtain preliminary relief based on preparations it might undertake before July 1, 2016. *See Tom Doherty Assocs., Inc. v. Saban Entm't, Inc.*, 60 F.3d 27, 38 (2d Cir. 1995) (harm must not be speculative).

In short, GMA's arguments rely entirely on the ordinary compliance costs associated with adapting to a new law. Changing labels to comply with Act 120 will not upend the businesses of manufacturers any more than changing nutritional information, expiration dates, or placing individualized names on each product does. Simply preparing to make such routine changes does not constitute irreparable harm, *Freedom Holdings*, 408 F.3d at 115, especially when costs are limited by Vermont's tiny market percentage. Dist. Ct. Dkt. 63-22, at ¶ 18 (Vermont makes up only 0.3% of the grocery market); *Cf. Mexichem Specialty*

[30] GMA contends that its members would suffer "reputational harm" if they labeled products differently in Vermont (or pulled out of the Vermont market). That conclusory allegation is far too speculative to support a preliminary injunction. *Kamerling v. Massanari*, 295 F.3d 206, 214 (2d Cir. 2002).

Resins, Inc. v. EPA, 787 F.3d 544, 556 (D.C. Cir. 2015) (no irreparable harm where "the overall economic impact" of a new regulation amounted to only "0.7 percent of PVC manufacturers' revenues").

C. GMA Also Failed To Show That Its Members Would Suffer Any Harm From Act 120's "Natural" Restriction.

This Court should affirm the district court's holding with respect to the "natural" restriction on the grounds stated above, namely that GMA will not actually be speaking (and there is therefore no conduct that even implicates the First Amendment) until July 2016. But GMA also provides no basis to disturb the district court's finding that GMA failed to provide any evidence of its members' *actual* use of the term "natural" on GE food products. *See Pope v. Cty. of Albany*, 687 F.3d 565, 570-71 (2d Cir. 2012) (court reviews "the denial of a preliminary injunction motion deferentially for abuse of discretion").

Rather than point to evidence, GMA argues that it can rely on its Amended Complaint, "necessary implication," and even "judicial notice" to demonstrate that its members will be harmed. Br. 51-53. But GMA's allegations, inferences, and requests for judicial notice are not *evidence* of irreparable harm. To begin with, it is black-letter law that the Amended Complaint is not evidence. *Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 404 (2d Cir. 2011) ("[w]hen a preliminary injunction is sought, . . . a plaintiff cannot rest" on "mere allegations" but must establish "specific facts" by "affidavit or other evidence"). The district court correctly

declined to rely on GMA's allegations of irreparable harm because "for a preliminary injunction [it could] consider only facts presented by affidavit or testimony." *Societe Comptoir De L'Industrie Cotonniere, Etablissements Boussac v. Alexander's Dep't Stores, Inc.*, 190 F. Supp. 594, 601 (S.D.N.Y. 1961), *order aff'd*, 299 F.2d 33 (2d Cir. 1962).

Likewise, the district court did not "overlook," Br. 52, but properly disregarded, GMA's imprecise declarations asserting that thousands of product labels generally will be affected by Act 120. As the court observed, GMA's witnesses failed to identify which of these labels must change as a result of the "natural" ban. JA81-82. To date, GMA has not identified a *single* product that is advertised as "natural" but contains GE ingredients.

In the absence of "direct record evidence that [its] member companies use 'natural' to describe products with GE ingredients," Br. 52, this Court should decline GMA's invitation to "infer" harm. *See Sussman*, 488 F.3d at 139. GMA argues that most of its members' products contain GE ingredients, and that some of its members label their products "natural"; therefore, GMA says, its members necessarily label GE products natural. Br. 52-53. That conclusion does not

follow: A company could sell mostly products with GE ingredients, but use "natural" only on the subset of products that do not contain GE ingredients.[31]

As a last-ditch effort, GMA asks this Court to take judicial notice of allegations in *other* lawsuits that its members label GE foods natural – allegations not presented to the district court. Br. 53.[32] But "'[c]ourts will not take judicial notice of factual propositions that are subject to reasonable dispute, even if they appear as allegations in pleadings, trial testimony, or findings of fact in judgments.'" *Abdullahi v. Pfizer, Inc.*, 77 F. App'x 48, 53 (2d Cir. 2003) (quoting *Weinstein's Fed. Evidence* § 201.13[1][b]).[33] *See United States ex rel. Moore v. Martin*, 273 F.2d 344, 345 (2d Cir. 1959) ("We know of no principle by which we can take judicial notice of unreported legal proceedings . . . not offered in evidence before the district court.").

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[31] GMA member Kashi, for example, recently agreed as part of a settlement to stop labeling GE products as natural. *See Eggnatz v. The Kellogg Co.*, No. 12-cv-21678-JAL, Dkt. 179-1 (S.D. Fla. June 5, 2015).

[32] GMA asks this Court to take judicial notice of allegations that were not even admitted as true. *e.g.*, *Briseno v. ConAgra Foods Inc.*, No. 2:11-cv-5379, Dkt. 145 ¶ 46 (C.D. Cal. Jan. 16, 2013) (refusing to admit that its oil products are made from GMOs).

[33] Even the lone case cited by GMA shows that it cannot meet its burden to prove irreparable harm through judicial notice of factual assertions made in a complaint: "A court may take judicial notice of a document filed in another court *not for the truth of the matters asserted in the other litigation*, but rather to establish the fact of such litigation and related filings." *Global Network Comm'ns, Inc. v. City of N.Y.*, 458 F.3d 150, 157 (2d Cir. 2006) (emphasis added).

IV. GMA HAS NOT SHOWN THAT "HARDSHIP" OR THE "PUBLIC INTEREST" JUSTIFIES ENJOINING ACT 120.

The remaining preliminary injunction factors also weigh in favor of the State. "[G]overnment action taken in furtherance of a regulatory or statutory scheme . . . is presumed to be in the public interest." *Register.com, Inc. v. Verio, Inc.*, 356 F.3d 393, 424 (2d Cir. 2004). GMA, however, views the hardship and public-interest factors as "an afterthought." Br. 59. Consistent with that view, GMA offers nothing but bald speculation. For example, GMA asserts that a preliminary injunction would cost Vermont nothing because Act 120's main benefit is "symbolic value." Br. 60. That contention summarily dismisses the actions of the Legislature and the concerns of Vermont consumers – and most American consumers – who overwhelmingly support Act 120. *See* Ex. J at 796 ("93 percent of respondents" to N.Y. Times poll said "foods containing such ingredients should be identified"). The mere fact that GMA *disagrees* with the Legislature's empirical judgment does not make a law that it enacted "symbolic."

CONCLUSION

For the reasons stated above, this Court should affirm the district court's denial of GMA's motion for a preliminary injunction.

Dated: August 24, 2015

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This brief complies with Fed. R. App. P. 32(a)(7)(B)(i) because it contains 13,971 words, as determined by the word-count function of Microsoft Word 2010, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii); and

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionately spaced typeface using Microsoft Word 2010 in 14-point Times New Roman font.

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CERTIFICATE OF SERVICE

I hereby certify that, on August 24, 2015, I caused a true and correct copy of the foregoing to be filed with the Court by CM/ECF, which will send a notice of electronic filing to all registered users.

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