15-1504-cv

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 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 the Commissioner of the Vermont Department of Health,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Vermont Case No. 1:14-cv-117-cr (Hon. Christina Reiss)

BRIEF OF *AMICI CURIAE* CONSUMERS UNION OF UNITED STATES, INC., VERMONT BUSINESSES FOR SOCIAL RESPONSIBILITY, and BEN & JERRY'S HOMEMADE, INC.

(*counsel listed on inside cover*)

August 31, 2015

MARIANNE L. ENGELMAN LADO
BENJAMIN JULIAN COLE
EARTHJUSTICE
48 Wall Street
19th Floor
New York, NY 10005
(212) 845-7376
mengelmanlado@earthjustice.org
bcole@earthjustice.org

Counsel for Amici Curiae

CORPORATE DISCLOSURE STATEMENT

Consumers Union of United States, Inc., dba "Consumer Reports," ("Consumer Reports" or "CR") and Vermont Businesses for Social Responsibility ("VBSR") are nonprofit corporations organized under § 501(c)(3) of the Internal Revenue Code. They have no parent corporations and issue no stock.

Ben & Jerry's Homemade, Inc. ("Ben & Jerry's") is a wholly-owned autonomous subsidiary of Unilever, which is a publicly traded company.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Other Authorities

INTERESTS OF AMICI CURIAE[1]

Consumers Union of United States, Inc., dba "Consumer Reports," ("Consumer Reports" or "CR") is a nonprofit membership organization founded in 1936 and the world's largest independent reporter and tester of consumer products.[2] CR supports the rights of consumers across a broad array of products and services, including prepared or packaged foods. A primary function of the organization is to advocate for consumer protection laws at the state and federal level and to hold corporations accountable both for the quality of their goods and services and for the way in which they are marketed.

By virtue of its longstanding record of accomplishment in consumer protection, its reputation and nationwide presence, its decade-long record of engaging with consumers on labeling and food safety issues, and its highly regarded national consumer survey operations, Consumer Reports has a unique understanding of the issues and concerns that matter most to Americans' everyday purchasing decisions. Consumer Reports believes that informed decisionmaking is

---

[1] No party or party's counsel authored this brief in whole or in part, and no party, party's counsel, or any other person, other than Amici or their counsel, contributed money intended to fund the preparation or filing of this brief. On June 15, 2015, parties' counsel jointly filed a letter with the Court stipulating to the submission of amicus briefs without the need for individualized consent.

[2] Consumers Union is the public policy and advocacy arm of CR. Over 8 million people subscribe to Consumer Reports' magazine, website, and other publications.

critical to the success of the marketplace. Accordingly, Consumer Reports fully supports Act 120 and has persistently advocated for mandatory labeling of genetically engineered ("GE") ingredients in food products for more than two decades.[3] Consumer Reports' position on GE labeling was most recently supported by the results of CR's 2014 nationwide poll, in which 92% of consumers agreed that all GE food sold on the market should be labeled accordingly. *See* Consumer Reports National Research Center, *Consumer Support for Standardization and Labeling of Genetically Engineered Food: 2014 Nationally-Representative Phone Survey* 2-3 (2014), https://goo.gl/pk3kF2.

Vermont Businesses for Social Responsibility ("VBSR") is a nonprofit, statewide business trade organization with a mission to advance business ethics that value multiple bottom lines – economic, social, and environmental. VBSR strives to help its members set high standards for protecting Vermont's natural, human, and economic environments while remaining profitable. VBSR advances its mission by providing concrete resources and information to help improve

[3] Michael Hansen, Senior Staff Scientist at Consumers Union, testified before the Vermont Senate Judiciary Committee to support passage of Act 120. *See* Testimony on H.112, a Bill to Require the Labeling of Genetically Engineered Food Before the Senate Judiciary Committee (Mar. 19, 2014), http://goo.gl/CfaO3H.

business practices and promoting socially responsible ideals before state legislators and regulators.

VBSR's diverse business membership, representing all sectors and geographic regions of Vermont, collectively employs more than 12% of the state workforce and generates more than $4 billion of revenue annually. Many members are in the food business, including farm-to-plate as well as large companies that distribute and sell products out of state. VBSR prides itself on the resiliency and sustainability demonstrated by its members, 60% of which have been in business more than 10 years. A 2012 survey of VBSR members found that 80% were in favor of a state law requiring GE food labeling.

Ben & Jerry's Homemade, Inc., ("Ben & Jerry's") produces a wide variety of premium ice creams, yogurts, and sorbets using high-quality ingredients. Its products are distributed across the United States and in 35 countries throughout the world, in supermarkets, grocery stores, convenience stores, franchisee "Scoop Shops," restaurants, and other venues. A Vermont business since 1978, Ben & Jerry's structures its operations around a three-part mission, emphasizing product quality, economic reward, and a commitment to the community.

Ben & Jerry's is proud of the ingredients used in its products, and has long been an advocate for transparency in supply chains. In 2015, the company completed its transition to sourcing exclusively non-GE ingredients. While this

transition is consistent with the company's values, it is also clear that consumers increasingly want to have more information about the food they purchase. Ben & Jerry's believes that this is not a short term consumer trend, but part of a larger movement toward transparency in the food system.

As a large multinational food company doing business in many countries with mandatory GE labeling laws, it is Ben & Jerry's experience that minor changes to labels do not impact the price of products. As Jerry Greenfield, the company's co-founder and present employee, stated in his declaration to the lower court,[4] Ben & Jerry's regularly changes its product packaging, in any number of ways, for any number of reasons. On average, Ben & Jerry's makes label changes to 20% to 30% of all of its products every year. Even with the 3 full-line redesigns it has performed in the last 7 years, label changes have never caused Ben & Jerry's to increase prices. Any minor label changes required by Act 120 for GE food packaging would be consistent with the label changes Ben & Jerry's regularly makes as an ordinary part of doing business.

[4] Greenfield offered his statement to the court below in his individual capacity, as an expert in marketing and packaging, whose personal knowledge covers the processes involved in making changes to processed-food packages. *See* Greenfield Decl. (Dist. Ct. Dkt. 63-7).

ARGUMENT

As the Supreme Court has held, "a preliminary injunction is an extraordinary and drastic remedy" and "should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997); *see also Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). Plaintiffs-Appellants Grocery Manufacturers of America et al. ("GMA") failed to meet this burden below, and their appeal should be denied.

Amici Curiae, Consumer Reports, VBSR, and Ben & Jerry's ("Amici"), make two points in support of Defendants-Appellees William H. Sorrell et al. ("Vermont" or "the State"). First, Act 120's GE disclosure requirement for processed food products containing genetically engineered ("GE") ingredients, *see* 9 V.S.A. § 3043(a)-(b) ("disclosure requirement" or "labeling mandate"), serves legitimate and substantial state interests – including advancing public health and food safety, informing consumers about potential environmental effects, avoiding consumer confusion and deception, and protecting religious practices, *see* 9 V.S.A. § 3041; *see also* Brief for Defendants-Appellees 6-12 ("State Br."). Vermont's GE disclosure requirement is consistent with international norms and food labeling policies and practices across the country that serve these very purposes. Second, Act 120's labeling mandate does not impose significant – let alone irreparable – harm on affected companies. Because at least one of the available compliance

methods, nationwide relabeling, is a routine, low-cost process, there is no risk of serious harm occurring before a final ruling on the merits.[5]

For these reasons, Amici urge this Court to affirm the District Court's denial of preliminary injunctive relief.

I. ACT 120 IS CONSISTENT WITH INTERNATIONAL NORMS AND FOOD LABELING POLICIES AND PRACTICES ACROSS THE UNITED STATES.

GMA summarily dismisses the interests served by Act 120, ignoring the fact that Vermont's GE labeling mandate is consistent with both international norms and disclosure requirements long recognized as fundamental to consumer protection, an equitable and efficient marketplace, and other legitimate and substantial state interests. Indeed, food labeling is a traditional and important part of how businesses provide consumers with health, safety, and other relevant information.

[5] GMA also challenges Act 120's restriction on the use of the term "natural." *See* Brief For Plaintiffs-Appellants 3-4 ("GMA Br."). Amici focus on the disclosure requirement and refer to briefs submitted by the State and other amici supporting Vermont on issues related to the use of the term "natural."

A. GE Food Labeling is Now the Norm Internationally.

GE labeling is required by governments across the globe. Far from being unusual, more than 60 countries now require GE labeling and the Codex Alimentarius Commission, the international body governing food standards, has adopted language clarifying that governments may require labels to inform consumers that what they are eating contains GE ingredients without fear of trade sanctions.

The first GE labeling requirements were enacted by the European Union ("EU") – a market for American food companies[6] – nearly two decades ago, in 1997. Valery Federici, *Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Laws*, 35 Brook. J. Int'l L. 515, 527-28 (2010). By 2013, the 28 EU-member nations had been joined by more than additional countries, from Saudia Arabia to New Zealand. *See Genetically Engineered Food Labeling Laws*, Ctr. for Food Safety, http://goo.gl/oJ61Uq (last visited Aug. 31, 2015) (interactive map of countries with GE labeling laws). Some mandatory-labeling countries, such as South Africa and Argentina, rank among the

---

[6] *See* Foreign Agric. Servs., U.S. Dep't of Agric., U.S. Processed Food Exports: Category Growth & Outlook (2014), http://goo.gl/4HXt0e (showing EU as among top export markets for U.S. processed foods); *see also* Directorate Gen. for Health & Consumers, European Comm'n, *Evaluation of the EU Legislative Framework in the Field of GM Food and Feed* 114 (2010), http://goo.gl/Dvbyv1 (discussing responses by U.S. food companies to EU labeling requirements).

world's top producers of GE crops, while others, such as Japan, are among the largest GE importers. *See* Law Library of Congress, *Restrictions on Genetically Modified Organisms* 1, 114, 175 (2014), http://goo.gl/9mwx0x.

The EU requires GE labeling in order to increase awareness of food sourcing and promote informed consumer choice. *See* Commission Regulation 1829/2003, 2003 O.J. (L 268) 1 (EC); Commission Regulation 1830/2003, 2003 O.J. (L 268) 24 (EC). Specifically, EU rules require that "for pre-packaged products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' … appear on [the] label." Regulation 1830/2003 art. (4)(B). Like Act 120, the EU excludes packaged foods containing "GMOs in a proportion no higher than [0.9]%" from mandatory labeling. *Id*. art. (7)(2); *see also id.* art. (3)(1).

Not only are GE disclosure requirements now widespread, they have been sanctioned by the Codex Alimentarius Commission ("CAC"), the international body authorized by two United Nations agencies, the Food and Agriculture Organization ("FAO") and the World Health Organization ("WHO"), to promulgate standards that "protect[] the health of . . . consumers and ensur[e] fair practices in the food trade." Statutes of the CAC art. 1 (1966), *in* CAC, Procedural Manual 4 (12th ed. 2001), http://goo.gl/G4TEwb. The Codex Commission currently has 185 member nations, including the United States. *See List of Codex Members*, Codex Alimentarius (July 27, 2015), http://goo.gl/tFgwWF. Although

Codex standards are not legally binding, they confer protected status in international trade disputes. *See* Secretariat of the CAC, *Understanding the Codex Alimentarius* 31 (2006), http://goo.gl/Dwxdk0 ("*Understanding Codex*"); Don Buckingham, *The Labeling of GM Foods – the Link Between the Codex and the WTO*, 3 AgBioForum 209, 210-211 (2000), http://goo.gl/ZZAQQ4.

In 2011, the CAC adopted its *Proposed Draft Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology* ("*Draft Compilation*"), reflecting international acceptance of the "[d]ifferent approaches regarding labelling of foods derived from modern biotechnology [that] are used" by national governments. *See id.* § 2, *in* Rep. of the CAC, 34th Sess., July 4-9, 2011, Doc. REP 11/FL, at 43 (2011), http://goo.gl/R8yqrn. The 2011 document built on a series of previous principles and guidance documents adopted by the Codex Commission, including *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, CAC/GL 44-2003 (2003), http://goo.gl/lc4rMa ("*Principles*"), which defined "modern biotechnology" and contrasted foods derived from modern biotechnology with their conventional counterparts.[7] *See Draft Compilation* § 3.7, *in* Rep. of the CAC, *supra*, at 43. The CAC specifically

[7] "Modern Biotechnology" is the Codex term equivalent to "genetic engineering," as defined in Act 120. *See Principles* ¶ 8 (defining "modern biotechnology" by reference to same cell fusion and in vitro nucleic acid techniques featured in 9 V.S.A. § 3042(4)).

endorsed language in the *Principles* stating, "Risk management measures may include, as appropriate, food labeling conditions for marketing approvals and post-market monitoring." *Principles* ¶ 19. Since Codex standards are "used as the benchmark in international trade disputes," the CAC's approval of the *Principles* established that GE labeling will have protected status in any trade dispute before the World Trade Organization. *See Understanding Codex*, *supra*, at 31.

Consistent with the adoption of international GE disclosure standards, the International Assessment of Agricultural Knowledge, Science and Technology for Development ("IAAKSTD") released a report in 2009 synthesizing the work of hundreds of experts across the globe on GE food crops. IAAKSTD, Agriculture at a Crossroads: Synthesis Report (2009), http://goo.gl/j10Wrh. The Synthesis Report discussed "lingering doubts about the adequacy of efficacy and safety testing, or regulatory frameworks for testing," as well as the impacts of GE crops on farmers. *Id.* at 40. It also raised questions about the health and environmental impacts of GE crops, calling for the collection of long-term data to identify impacts on human health and the environment and "timely counter-measures." *Id.* at 45.

Although the U.S. government thus far has failed to join the broader community of nations with GE disclosure requirements, the issue has appeared on ballots and been introduced in legislatures across the country. In addition to

Vermont, three other states – Connecticut, Maine, and Alaska – have passed laws requiring labeling of GE food. *See* 22 Me. Rev. Stat. § 2593 (2014); Conn. Gen. Stat. § 21a-92c (2013); Alaska Stat. § 17.20.040 (2005).[8] Proposals to enact labeling laws similar to Act 120 are being considered in an additional 19 states. *See State Labeling Legislation Map*, Ctr. for Food Safety, http://goo.gl/jb41fL (last visited Aug. 31, 2015) (map showing states with pending legislation in green).

B. Food Labeling is a Traditional and Important Part of How Businesses Inform Consumers in the U.S. and Serve Legitimate and Substantial Interests.

Act 120's stated purposes are fourfold: protect public health and food safety, inform purchasing decisions of consumers who are concerned about the environmental consequences of GE crop production methods, prevent consumer deception or confusion, and protect religious practices. 9 V.S.A. § 3041.[9] As the district court found, "Act 120's 'Findings' and 'Purpose' extend beyond the mere appeasement of consumer curiosity." JA78. Indeed, Act 120's fusion of several distinct policy objectives into a single, straightforward disclosure requirement is

[8] The Maine and Connecticut provisions go into effect if other states pass similar laws. Alaska requires that GE fish be labeled.

[9] Amici incorporate by reference Vermont's Statement of the Case. *See* State Br. 2-13.

typical of standard food labeling policies and practices, which provide consumers with factual information and ensure that markets operate safely and efficiently.

Over time, food labels have served multiple goals, providing consumers with point-of-purchase information, increasing consumer confidence in the food supply, and promoting public engagement on agricultural and food safety issues. *See* Julie A. Caswell & Daniel I. Padberg, *Toward a More Comprehensive Theory of Food Labels*, 74 Am. J. Agric. Econ. 460, 463 (1992). As one proponent of GE foods commented, "people should be able to control what they eat." Federici, *supra*, 35 Brook. J. Int'l L. at 531. Transparency is a prerequisite for consumers to make informed decisions, and the rationale for GE labeling is all the more compelling because the presence of GE ingredients in food cannot be detected or evaluated by the consumer absent information by the manufacturer or supplier.

More generally, product labeling – for both food and other goods – is a common feature of consumer markets. Groceries, toys, clothes, electronics, and countless other goods are offered for sale in packages bearing labels with required information, only some of which pertain to health and safety risks. Examples of labeling requirements without express health and safety justifications include laws addressing country-of-origin labeling ("COOL"), ingredient labeling, recycling labeling, and food expiration dating, as well as disclosure of whether food is

frozen, homogenized or from concentrate. These requirements all ensure disclosure of vital information to consumers.[10]

The U.S. Department of Agriculture ("USDA") administers federal law requiring COOL for several foods, such as meat, fish, and produce. *Country of Origin Labeling (COOL)*, USDA, http://goo.gl/GVEwPG (last visited Aug. 31, 2015). Like GE labeling, COOL facilitates consumer choice related to the process by which a product, or any of its components, was made and the environmental or other consequences of that process – for example, whether the purchase will support the local economy or, on the other hand, production practices abroad to which a consumer might object.[11] In 2013, the U.S. Court of Appeals for the D.C. Circuit upheld COOL against a challenge brought by trade associations under the First Amendment. *See Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014). The D.C. Circuit recognized the legitimacy of the government interest in "enabling customers to make informed choices based on the characteristics of the products they wished to purchase." *Id.* at 24.

---

[10] GMA's arguments echo a long history of efforts to resist labeling requirements. *See, e.g.*, Jerry Perez, *The Product Labeling Controversy*, 36 Food Drug Cosm. L.J. 381, 385-88 (1981) (summarizing arguments against labeling laws).

[11] *See Place-of-Origin Labeling*, Inst. for Local Self-Reliance (2008), http://goo.gl/vuLnNo (listing "support[ing] domestic farmers," "minimiz[ing] the 'food miles' . . . groceries travel," and reducing pesticide use as reasons "consumers want [COOL]").

The FDA also requires ingredient labeling pursuant to a host of federal statutes. *See* FDA, *Guidance for Industry: A Food Labeling Guide*, 2008 WL 2155725 (2008). As with COOL, ingredient lists do not confer health or safety information *per se*, but rather enable consumers to make choices consistent with their values. *See also, e.g.*, Conn. Gen. Stat. §§ 21a-102 (2013); Mass. Gen. Laws Ch. 94 §§ 105, 187 (2004); N.J. Rev. Stat. § 24:5-16 (1940); N.Y. Agric. & Mkts. § 201 (2004); R.I. Gen. Laws § 21-31-11 (1956) (state counterparts).

State container deposit laws (or "bottle bills") require refundable deposits on certain types of beverage containers, as well as labels indicating the existence and amount of the deposit. *See, e.g.*, Cal. Pub. Res. Code § 14561 (2008) (requiring "CRV" or "CA Cash Refund" to appear on all aluminum, glass, or plastic beverage containers sold in California). Connecticut, Hawaii, Iowa, Maine, Massachusetts, Michigan, New York, Oregon, and Vermont all have similar laws. *See Bottle Bill Resource Guide*, Consumer Recyc. Inst. (Mar. 4, 2015), http://goo.gl/PMMK4m.

Finally, a patchwork of state laws regulates food expiration dating, including "sell-by," "best-by," and "use-by" dates, while infant formula is subject to a federal use-by date labeling requirement. *See Food Product Dating*, USDA (Mar.

24, 2015), http://goo.gl/WXZkQg.[12] Notably, states also require product labels for non-food products that are intended to inform the consumer. *See, e.g.*, N.Y. Gen. Bus. Law § 399-aaa (requiring clothes made with "real fur" or "faux fur" to be labeled accordingly); 15 U.S.C. § 70b(b)(2) (requiring labels of products made with textile fibers to indicate "percentage by weight of each fiber present").

As Act 120's statement of purpose indicates, there are several legitimate and substantial reasons for GE labeling. Transparency promotes more informed choices and a stronger marketplace. Environmental and related health concerns are also significant, including the impact of GE crops on biodiversity and increases in the use of pesticides on crops that have been genetically engineered to withstand the direct application of those pesticides. *See* Charles Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Thirteen Years* (2009), https://goo.gl/e5pMfz (reporting "steep rise" in use of herbicides applied to GE crops and resultant growth of herbicide-resistant weeds). The majority of corn, soybeans, and other GE crops grown in the United States are genetically engineered to be resistant to glyphosate, which the WHO's International Agency for the Research on Cancer ("IARC") lists as "probably

[12] For other examples of non-safety-related food labeling requirements, see, *e.g.*, 21 C.F.R. § 131.110 (federal rule requiring labeling for frozen orange juice from concentrate); *id.* § 146.146 (homogenized milk); *id.* § 179.26 (irradiated food).

carcinogenic to humans." IARC, Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 112: Glyphosate (2015), http://goo.gl/K3tHC4. In 2014, the Dow Chemical Company introduced Enlist™ corn and soybeans, which are engineered to be resistant to glyphosate and the herbicide 2,4-Dichlorophenoxyacetic acid ("2,4-D"). *See Enlist™ Traits*, Dow Chem. Co., http://goo.gl/qAccx4 (last visited Aug. 31, 2015). According to the U.S. Environmental Protection Agency, "[e]xposure to 2,4-D has been reported to result in blood, liver, and kidney toxicity." U.S. EPA, 2,4-Dichlorophenoxyacetic Acid (2,4-D) Chemical Summary 1 (Mar. 30, 2007), http://goo.gl/MY67OF. Even ultra-low, chronic exposure to these chemicals can impair health. *See, e.g.*, Robin Mesnage et al., *Trancriptome Profile Analysis Reflects Rat Liver and Kidney Damage Following Chronic Ultra-Low Dose Roundup Exposure*, 14 Envtl. Health 70 (2015), http://goo.gl/JW3lSL. Contrary to GMA's attempts to minimize the state's interest, GMA Br. at 49, these concerns clearly constitute a sufficient basis for Act 120's GE disclosure requirement.

II. GMA FAILED TO MEET THE STANDARD FOR IRREPARABLE HARM.

On appeal from a denial of a motion for preliminary injunction, this Court reviews for abuse of discretion. *See Moore v. Consol. Edison Co. of N.Y.*, 409 F.3d 506, 511 (2d Cir. 2005). Denial will not be reversed unless the district court

"appl[ied] an incorrect legal standard or rel[ied] on a clearly erroneous finding of fact." *Jolly v. Coughlin*, 76 F.3d 468, 473 (2d Cir. 1996). Significantly, "[t]he preliminary injunction's legality must be adjudged on the evidence presented to the district court, not in light of any possible subsequent developments." *Hyde v. KLS Prof'l Advisors Grp., LLC*, 500 F. App'x 24, 26 n.** (2d Cir. 2012) (citing *Diversified Mortg. Investors v. U.S. Life Ins. Co.*, 544 F.2d 571, 576-77 (2d Cir. 1976)).

GMA had to prove that preliminary relief would be both necessary and sufficient to avoid irreparable harm. *See Faiveley Transp. Malmo AB v. Wabtec Corp.*, 559 F.3d 110, 118 (2d Cir. 2009) (describing irreparable harm as "the single most important prerequisite for the issuance of a preliminary injunction"). Not all injuries meet this high threshold, only those which are "imminent, not remote or speculative," *Reuters Ltd. v. United Press Int'l, Inc.*, 903 F.2d 904, 907 (2d Cir. 1990), and alleged economic impacts must be exceptional in amount or degree, as well as irreparable, *see Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005) (holding "ordinary compliance costs" insufficient to warrant preliminary injunction). GMA failed to demonstrate irreparable harm in the absence of an injunction. Indeed, Act 120 does not pose any imminent consequences, as it does not take effect for nearly an entire year, and will not be enforced for an additional 6 months. By then, manufacturers of affected products,

which are more than technically and economically capable of implementing labeling changes, will have had ample time to comply.

Act 120's disclosure mandate merely requires processed food manufacturers choosing to do business in Vermont to let consumers in the State know which products contain GE ingredients. In practice, this amounts to little more than incorporating 4-6 words into the label template files for products that are – or "May Be" – "Produced with Genetic Engineering," 9 V.S.A. § 3043(a). This straightforward labeling change, which "represents a minimal, one-time, incremental cost" to manufacturers of less than $2,000 per stock keeping unit ("SKU"),[13] Dyke Decl. ¶ 20 (Dist. Ct. Dkt. 63-6), is just the sort of ordinary compliance cost this Court declines to equate with irreparable harm. *Freedom Holdings*, 408 F.3d at 115.

A. Act 120 Only Requires One-Time Relabeling.

In order to prove that the imminent consequences of Act 120's disclosure requirement constitute irreparable harm, the burden was on GMA to describe those consequences and explain how Act 120 will cause them. *See Time Warner Cable of N.Y. City v. Bloomberg L.P.*, 118 F.3d 917, 924 (2d Cir. 1997). Yet GMA failed to identify which "adverse factual consequences" manufacturers are likely to

[13] "SKU" refers to a particular packaging configuration of a particular product.

suffer, or how these are the necessary results of Act 120. *See id.* While manufacturers can choose how they will comply with Act 120, *see* Dyke Decl. ¶¶ 5-6; Blasgen Decl. ¶ 20 (Dist. Ct. Dkt. 33-3), they cannot base their theory of irreparable harm on scenarios that are "speculative," only those that are actual and imminent. *See Reuters*, 903 F.2d at 907. Furthermore, GMA "must show that, on the facts of the[] case, the failure to issue an injunction" – and not merely the independent business judgment of GMA's members – "would actually cause irreparable harm." *Salinger v. Colting*, 607 F.3d 68, 82 (2d Cir. 2010). *See also* Dyke Decl. ¶ 6 ("Act 120 only compels manufacturers to incur incremental costs equal to the difference between the least costly feasible compliance option and the costs of status quo operations in the absence of Act 120.").

Compliance with Act 120 can be achieved in essentially four ways – reformulation; exiting the Vermont market; or relabeling, national or state-specific, *see* Dempsey Decl. ¶ 9 (Dist. Ct. Dkt. 33-4); *see also* Dyke Decl. ¶ 5; Blasgen Decl. ¶ 24. As these are distinct options, a manufacturer is free to choose whichever best suits its individual business needs – and to avoid the compliance methods it views as unduly costly or harmful. As the method of compliance that

will generally be the least costly, nationwide labeling is the most instructive for this Court to consider.[14]

1. Product reformulation

Reformulation refers to two processes: (1) substitution of one ingredient that is often made from GE crops for another that is not; or (2) re-sourcing of an ingredient from a grower of GE crops to a non-GE grower. The goal in either case is to eliminate the presence of GE ingredients from an otherwise affected product.

Some of GMA's declarants asserted that reformulation is "virtually impossible" for many products. JA31; *see also* Bradley Decl. ¶ 14 ("[R]eformulation . . . is not a viable or realistic option for attempted compliance with Act 120."); Blasgen Decl. ¶ 24; Dempsey Decl. ¶ 20. These declarants likely overstate the practical difficulties associated with switching to non-GE ingredients. Regardless, since Act 120 regulates packaging rather than ingredients, reformulation is not required. Like other compliance options, it is a "product-by-

---

[14] To be sure, manufacturers *might* ignore economic incentives by selecting an unnecessarily expensive compliance option. *See* Dyke Decl. ¶ 6 ("[M]anufacturer[s] could decide to relabel . . . for Vermont sales only when relabeling . . . nationwide would impose lower costs."). But irreparable harm analysis looks only at consequences that are "imminent, not remote or speculative," *see Reuters*, 903 F.2d at 907, and that follow directly from the action sought to be enjoined, *see Linde v. Arab Bank, PLC*, 706 F.3d 92, 118 (2d Cir. 2013).

product decision" based on business judgment, not a statutory obligation. *See* Dyke Decl. ¶ 9.[15]

2. Vermont exit

Manufacturers' second option is to halt all sales to Vermont. The disclosure requirement applies only to products "offered for retail sale in Vermont." 9 V.S.A. § 3043(a)(1). Thus, by exiting Vermont entirely, companies can avoid having to reformulate or relabel.

To some companies, such an exit would be "difficult and perhaps even impossible." *See* Baxter Decl. ¶ 29 (Dist. Ct. Dkt. 33-7). Yet at least one industry declarant "expected . . . some brands to cease distribution to Vermont." Michaud Decl. ¶ 10. Once again, the decision is each manufacturer's own. Many, fearing "a loss of sales revenue" or "decline in . . . goodwill," Blasgen Decl. ¶ 45, will continue to market their products in Vermont. Ultimately, this additional, if potentially unattractive, compliance option will be a business decision and does not increase the likelihood of irreparable harm.

[15] *See* ECONorthwest, GE Foods Labeling Cost Study Findings 4 (Sept. 12, 2014), https://goo.gl/nUwTf5 ("[P]roduct reformulation . . . is not a direct cost of labeling regulation.").

3. Vermont- or Northeast-specific labeling

The final two compliance methods both involve the design and application of new labels bearing Act 120's GE disclosure statement to the packages of covered food products. *See* 9 V.S.A. § 3043(a),(b). These two relabeling options differ as to where relabeled products would be marketed. Under the first option, companies would limit distribution of relabeled products to, for example, Vermont only, or the Northeast only.[16] Companies could thus satisfy the disclosure requirement where applicable by law, while continuing to conceal their use of GE ingredients elsewhere.

GMA's declarants expressed concerns regarding Vermont-specific relabeling, with some going so far as to declare this course of action "impossible." *See* Bradley Decl. ¶¶ 17-19 (Dist. Ct. Dkt. 33-8); *see also* Adams Decl. ¶ 25 (Dist. Ct. Dkt. 33-6) (state-specific labeling "would not be feasible"). Their general theory was that Vermont-specific relabeling would require manufacturers "to restructure their supply and distribution chains," at considerable expense. *See* GMA Br. at 56. As discussed below, there are good reasons to doubt whether such "restructuring" would be necessary, even for manufacturers that prefer to relabel on a less-than-nationwide basis. Despite GMA's claims to the contrary, firms with

[16] For convenience, both Vermont- and Northeast-specific relabeling are referred to collectively hereafter as "Vermont-specific relabeling."

nationwide supply and distribution chains will not need to make "fundamental structural changes." *See* GMA Br. at 55-56. They can reformulate, exit Vermont, or follow the fourth approach: nationwide relabeling.

4. Nationwide relabeling

Act 120 does not apply to retail food offerings outside of Vermont. *See* 9 V.S.A. § 3043(a)(1). At the same time, neither it nor any other state or federal law forbids such disclosures.[17] Manufacturers can simply relabel *all* their affected product lines, and thereby avoid any allegedly impractical "restructuring" to achieve compliance.

Indeed, nationwide relabeling is the one option with which GMA's declarants failed to find any serious "economic or logistical barriers," GMA Br. at 56 (quoting Baxter Decl. ¶ 23). This marked absence of identifiable concerns was evident even in declarations that rejected nationwide relabeling out of hand. *See, e.g.*, Dempsey Decl. ¶ 19 (asserting that "none of [GMA's] members plan" to relabel nationwide, without further explanation); Blasgen Decl. ¶ 44 ("barring . . . adoption of a single national label" from consideration in reaching "opinion on Act

[17] As the district court noted, FDA guidance specifically allows companies to add GE disclosure statements. *See* JA49. Products with Act 120 disclosure statements would also be in compliance with Maine and Connecticut's GE laws, should these take effect. *See* 22 Me. Rev. Stat. § 2593 (2014); Conn. Gen. Stat. § 21a-92c (2013) (prescribing same disclosure statement).

120"). The reason, as discussed below, is simple: the costs of relabeling are minimal and fall well short of the high threshold for a showing of irreparable harm.

Notably, manufacturers seeking to relabel need not do so on a truly nationwide basis in order to avoid creating separate-SKU systems for Vermont-specific relabeling. *See* Blasgen Decl. ¶ 28. As long as affected products sold in Vermont are compliantly relabeled, manufacturers can choose not only *whether* relabeled products are marketed outside Vermont but also *where* such products are marketed. In fact, manufacturers can vary the distribution of compliantly relabeled products to any combination of states or countries – as long as Vermont is among them. As with truly nationwide relabeling, GMA's declarants simply failed to acknowledge this possibility and thus grossly exaggerated both the need for and costs of dual inventory systems. *See* Dempsey Decl. ¶ 18.[18]

B. Relabeling Imposes Trivial Costs, Especially Given Act 120's Lengthy Compliance Period.

Relabeling is likely the most inexpensive method of complying with Act 120's disclosure requirement, especially if implemented nationwide. Accordingly, the guiding inquiry behind the Court's irreparable harm analysis should be whether

[18] For example, one GMA declarant doubled the "downtime" costs associated with staggered production runs at packaging plants by assuming manufacturers would guard assiduously against any compliantly relabeled products leaving Vermont. *See* Blasgen Decl. ¶ 26-28. Act 120 requires nothing of the sort.

the costs of relabeling rise to the level of irreparable harm.[19] They would not. As discussed below, Act 120's disclosure requirement entails minimal label changes, which manufacturers are more than capable of performing in the time period allotted. After outlining the steps involved in relabeling and addressing the cost-minimizing effect of Act 120's generous compliance period, Amici discuss the labeling cost model developed by the U.S. Food & Drug Administration ("FDA"). Application of this framework supports the conclusion that Act 120 is a minor labeling change with minimal costs.

1. Overview of the relabeling process

Manufacturers will first determine which of their products are affected by Act 120's discosure requirement. This does not require any analytic testing or other expensive procedures. Presently, only 17 types of food plants are commercially available in GE forms.[20] *See* Dyke Decl. ¶ 11. Thus producers need only identify products containing ingredients derived from any such plants at more than 0.9% by weight. *See* 9 V.S.A. § 3044(5). The producer will ask relevant suppliers whether they grow or process GE crops. If all suppliers state that they do

[19] *See* note 14 & accompanying text, *supra*.

[20] This is the number of GE food crops that have completed FDA's voluntary "biotechnology consultation." *See Biotechnology Consultations on Food from GE Plant Varieties*, FDA, http://goo.gl/tZaQrV (last visited Aug. 24, 2015). All GE food crops on the U.S. market have completed FDA consultation. *See* Dyke Decl. ¶ 11.

not raise GE crops, the manufacturer's products are not affected. If any supplier responds affirmatively, the manufacturer will update its labels to read "Produced with Genetic Engineering." Finally, if the suppliers can neither affirm nor deny growing GE crops, the manufacturer will relabel with the statement, "May Be Produced with Genetic Engineering."

Even if a manufacturer identifies affected product lines, it may or may not incur additional costs, depending on whether voluntary label changes have been scheduled for affected products within the compliance period. If so, the manufacturer can incorporate Act 120 relabeling into the scheduled relabeling. *See* Glidden Decl. ¶ 8 ("If a company could time its re-labeling for [Act 120] with its regular re-labeling for marketing purposes, it would not cost the company *anything* to comply . . . .") (emphasis added). This is often the case, as manufacturers regularly change their product packaging for reasons unrelated to their legal obligations. *See* Dyke Decl. ¶ 8 ("Manufacturers relabel 20-50% of all products in any given year."); Glidden Decl. ¶ 7; Greenfield Decl. ¶ 8.

Even for products not scheduled to undergo a voluntary label change during the compliance period, the remaining steps – designing, ordering and operating new label plates – are not burdensome. *See* Mary K. Muth et al., Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration 3-5 (2012),

http://goo.gl/m32Fbx. Manufacturers can place the 4-6 word disclosure virtually anywhere on the outside of product packaging, "in any color that contrasts with the background of the package" and in any font size equal or greater to that of the words "Serving Size" on the FDA Ingredient Panel. CP § 121.02(b)(iii), JA166. This requires minimal labor, as explained by declarant Rhonda Miller, Senior Sourcing Manager for Clif Bar, a snack and energy foods company with nationwide distribution, whose experience includes "thousands of labeling changes." *See* Miller Decl. ¶ 5 (Dist. Ct. Dkt. 63-8). Ms. Miller stated that "copy change and/or adjustment on the electronic artwork files and proofing . . . would take no more than 30 minutes." *See id.* ¶ 12. Material costs are no more significant. Reed Glidden, co-founder of Beanfields, a family-owned snack foods company, estimated such a single-color printing plate change would impose a one-time cost of just $300-$400 per SKU. *See* Glidden Decl. ¶ 10.

Finally, Act 120 operates to keep recordkeeping and product tracking requirements to a minimum. For example, a common result of nationwide labeling regulations is that excess, preprinted label inventory must be fitted with stickers for the first year, and discarded thereafter. In this case, existing noncompliant labels can simply be redirected for use in other states, making it unnecessary to discard inventory.

2. The role of Act 120's long compliance period

Act 120, in conjunction with the Vermont Attorney General's Consumer Protection Rule 121, alleviates any potential burden still further by affording manufacturers a generous amount of time. Act 120 was passed into law on May 8, 2014, with an effective date of July 1, 2016. On April 20, 2015, the Attorney General finalized Rule 121, which effectively lengthened the compliance period by an additional 6 months, to January 1, 2017. *See* CP § 121.04(d)(i), JA 169 ("manufacturers shall not be liable" for non-relabeled food "offered for retail sale in Vermont before January 1, 2017"). Thus, when the district court denied GMA's preliminary injunction motion on April 27, 2015, manufacturers still had a period of 20 months and 4 days to ensure that any products arriving at Vermont stores would be relabeled.

This is considerably longer than the 15-month period FDA considers necessary "to fully implement" most labeling changes, *see* Muth et al., *supra*, at 4-38, and longer still than the time several declarants below estimated would be required to comply with Act 120. *See* Greenfield Decl. ¶ 9 ("The typical time required from package redesign to store shelf in order to comply with [Act 120] . . . would be 6 months."); Miller Decl. ¶ 15 (estimating total compliance time at 1-6 months). It is even twice as long as the 10 months that Cofi Adams, a manager at a

GMA member company, described as necessary for relabeling "[u]nder normal circumstances." *See* Adams Decl. ¶ 20

Such a long compliance period ensures that manufacturers are able to comply in the ordinary course of business, and that they may do so efficiently. With a longer compliance period, a greater number of Act 120 label changes will coincide with routine voluntary changes. *See* Muth et al., *supra*, at 3-10. Retailers can sell prior inventories, avoiding the need to locate non-compliant products in stores and place disclosure stickers on them. Preprinted label inventory need not be discarded or diverted outside Vermont, nor should manufacturers incur overtime or rush charges. *See id.*

3. The minimal costs of Act 120 relabeling

The total economic effect of performing the steps outlined above in a 20-month period is negligible. To estimate the cost of implementing new labeling requirements, the FDA developed a labeling cost model applicable to "a broad range of . . . consumer products," including packaged processed foods. Muth et al., *supra*, at 1-3. Applying this framework, several economists – one of whom submitted his conclusions in a declaration below – described the potential costs imposed by disclosure mandates similar or identical to Act 120's as minimal. Dyke Decl. ¶ 20; *see also* Joanna M. Shepherd-Bailey, Economic Assessment: Proposed California Right to Know Genetically Engineered Food Act 10 (2012),

http://goo.gl/XZuyhz ("trivial"); William K. Jaeger, *Economic Issues and Oregon Ballot Measure 27: Labeling of Genetically Modified Foods*, Or. St. Univ. Ext. Serv. EM 8817, at 5 (2002), http://goo.gl/K1Vw86 ("not high[]"). Expert declarants holding top-level management positions at food companies repeatedly echoed these conclusions. *See, e.g.*, Miller Decl. ¶ 8 (complying with Act 120 "would require nothing more than a simple artwork change and would not be time intensive"); Glidden Decl. ¶ 12 (describing compliance costs as "low" and "easily . . . absorbed"); Greenfield Decl. ¶ 11 (compliance costs are "nominal" and would not be passed on to consumers).

In quantitative terms, estimates of total per-SKU costs to comply with Act 120 ranged from $500-$1,996, *see* Miller Decl. ¶ 11; Greenfield Decl. ¶ 11, Dyke Decl. ¶ 14. A review of cost studies assessing similar GE disclosure requirements explained that "[t]hese costs occur one-time and will not increase the ongoing production cost." *See* ECONorthwest, *supra* note 15, at 3; *see also* Muth et al., *supra*, at 4-32. Overall, for the reasons stated above, Act 120's disclosure mandate imposes no more than ordinary compliance costs, which this Court holds insufficient to justify a preliminary injunction. *See Freedom Holdings*, 408 F.3d at 115.

C. GMA Failed To Provide an Evidentiary Basis For Its Motion.

Finally, GMA's motion for preliminary relief was fatally flawed because it was, as the district court stated, unaccompanied by undisputed factual allegations or judicial findings of fact on several key points needed to show irreparable harm. *See* JA29 ("[B]ecause Plaintiffs do not seek either an evidentiary hearing or a consolidation with the merits for their preliminary injunction the court cannot rely on contested evidence to resolve any factual disputes."); *see also Hsu By & Through Hsu v. Roslyn Union Free Sch. Dist. No. 3*, 85 F.3d 839, 848 n.1 (2d Cir. 1996) (absent explicit findings of fact by district court, this Court asks "whether injunctive relief is warranted based on the undisputed facts"). Should GMA reply by disputing the legislative findings of fact establishing Act 120's several legitimate purposes or by asserting their own theory of the practical and economic necessities of relabeling,[21] this would only prove the "existence of factual disputes," and thus the need to hold "an evidentiary hearing . . . *before* [their] motion for preliminary injunction" could be granted. *Kern v. Clark*, 331 F.3d 9, 12 (2d Cir. 2003) (emphasis added); *see also* State Br. 52 n.28.

[21] The district court made clear that "competing declarations" were submitted on these points. *See* JA30; *see also* JA32 ("The State's declarants challenge [GMA's] GE manufacturers' contentions regarding the costs of creating new packaging, as well as the timing and feasibility of compliance with Act 120.").

CONCLUSION

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

Respectfully submitted,

MARIANNE L. ENGELMAN LADO
BENJAMIN JULIAN COLE
EARTHJUSTICE
48 Wall Street
19th Floor
New York, NY 10005
(212) 845-7376
mengelmanlado@earthjustice.org
bcole@earthjustice.org

Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I hereby certify that this Brief complies with the type-volume limitation of Fed. R. App. P. 29(d) and 32(a)(7)(B) because the Brief contains 6,909 words, excluding the parts of the Brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

I further certify that 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 the Brief has been has been prepared in Times New Roman 14-point font using Microsoft Word 2010.

DATED: August 31, 2015

/s/ Benjamin Julian Cole

BENJAMIN JULIAN COLE
EARTHJUSTICE
48 Wall Street
19th Floor
New York, NY 10005
(212) 845-7376
bcole@earthjustice.org

CERTIFICATE OF SERVICE

I hereby certify that, on August 31, 2015, I caused a true and correct copy of the foregoing to be filed with the Clerk of the Court for the U.S. Court of Appeals for the Second Circuit by CM/ECF, which will send a notice of electronic filing to all registered users.

DATED: August 31, 2015

/s/ Benjamin Julian Cole

BENJAMIN JULIAN COLE
EARTHJUSTICE
48 Wall Street
19th Floor
New York, NY 10005
(212) 845-7376
bcole@earthjustice.org