15-1504

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 Commissioner of the Vermont Department of Health,

Defendants-Appellees.

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

BRIEF OF AMICI CURIAE VERMONT PUBLIC INTEREST RESEARCH GROUP, CEDAR CIRCLE FARM, NORTHEAST ORGANIC FARMING ASSOCIATION OF VERMONT, AND RURAL VERMONT SUPPORTING DEFENDANTS-APPELLEES AND AFFIRMANCE OF THE DISTRICT COURT

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CORPORATE DISCLOSURE STATEMENT

Amici curiae Vermont Public Interest Research Group, Cedar Circle Farm, Northeast Organic Farming Association of Vermont, and Rural Vermont have no parent corporations, are not owned in whole or in part by any publicly held corporation, and do not issue stock.

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INTERESTS OF AMICI

Amici Vermont Public Interest Research Group (VPIRG), Cedar Circle Farm, Northeast Organic Farming Association of Vermont (NOFA-VT), and Rural Vermont comprise the stalwart coalition of Vermont-based advocacy groups that championed Act 120 up to and through its signing on the steps of the Vermont Statehouse.[1] VPIRG is the State's largest non-profit and consumer advocacy group, dedicated to protecting and promoting the health of Vermont's people, environment, and locally based economy. Cedar Circle Farm is a certified organic farm and education center in East Thetford, Vermont that is committed to securing sustainable food systems for future generations. NOFA-VT is a non-profit association of farmers, gardeners, and consumers working to promote an economically viable and ecologically sound food system in Vermont. Rural Vermont is a statewide grassroots membership organization dedicated to ensuring that small-scale family farmers have a voice in public policy decisions, and to resisting corporate control of the food system.

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[1] No party's counsel authored this brief in whole or in part. No party or party's counsel contributed money that was intended to fund preparing or submitting the brief. No person, other than amici curiae or their counsel, contributed money that was intended to fund preparing or submitting this brief.

Amici's source of authority to file this brief is Fed. R. App. P. 29(a). The parties have consented to the filing of this and other amicus briefs. Letter from Catherine E. Stetson and Megan J. Shafritz to Catherine O'Hagan Wolfe (June 15, 2015) (Dkt. No. 43).

Like Vermont's legislature, these groups understand the need for labeling of genetically engineered foods. Amici urge this Court to uphold the District Court's decision denying Plaintiffs-Appellants' motion for a preliminary injunction.

INTRODUCTION

The State of Vermont has decided that it is in the best interests of the State to require labels on genetically engineered (GE) foods. Underlying this decision are two years of legislative deliberations, at least 52 committee meetings, 136 presentations of testimony, public hearings, extensive studies and factual materials, five pages of carefully detailed legislative Findings, and four explicit State purposes.

Vermont is not alone. Two nearby states have passed GE labeling laws, albeit with contingency clauses. 22 Me. Rev. Stat. §§ 2591-2596 (2013); Conn. Gen. Stat. Ann. § 21a-92c (West 2013). Four other states have had ballot initiatives on GE labeling, with opponents spending over $100 million in efforts to defeat them. Annie Gasparro & Jacob Bunge, *Food Industry Wins Round in GMO-Labeling Fight*, Wall St. J. (Nov. 5, 2014), *available at* http://goo.gl/9jpfX2. Nationwide, bills have been introduced in over 30 states. Center for Food Safety, *State Labeling Initiatives*, http://goo.gl/vOodFl (last visited Aug. 29, 2015). Globally, 64 countries require some form of GE labeling. Just Label It!, *Labeling around the World*, http://goo.gl/zH3cEw (last visited Aug. 29, 2015).

Additionally, national polls consistently show that the great majority of Americans want to know whether the foods they buy are produced with genetic engineering. *See, e.g.*, Allison Kopicki, *Strong Support for Labeling Modified Foods*, N.Y. Times (July 27, 2013) (Dist. Ct. Dkt. 64-5, at 18) (93% of respondents say GE foods should be labeled).

Despite this reality, Appellants attempt to paint Vermont as a fringe State that has given in to the "purported" concerns of its citizens by passing a "first-of-its-kind law" with "no credible basis." Appellants' Br. (Dkt. No. 44) at 3, 23, 48. Appellants appear to fear that "too many unwitting customers" will make bad choices unless "they are not permitted to know" how their food is produced. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 769-70 (1976) (striking down Virginia law restricting pharmacists from advertising prescription drug prices).

Appellants are wrong on both fronts, and their rhetorical flourishes do not change the truth. Vermont's interests in passing Act 120 are legitimate and substantial. This brief will explore those interests, providing supplemental context and detail on the legislative process for Act 120 and spelling out why this case is not *Amestoy II*. As for Appellants' "highly paternalistic approach" toward consumers, the Supreme Court has rejected that approach and declared that "information is not in itself harmful, that people will perceive their own best

interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them." *Id.* at 770.

ARGUMENT

I. Vermont's decision to require labels on genetically engineered foods is grounded in a thorough legislative process and reasonable legislative Findings, to which deference is owed.

Before it became law on May 8, 2014, Act 120 progressed through many legislative committees and public hearings; elicited many rounds of testimony from citizens and science, policy, medical, business, and legal professionals—including opponents of the bill; and drew stacks of studies, reports, and other documents into the legislature's deliberations. *See, e.g.*, Materials from H.112 Bill File (2014) (Dist. Ct. Dkt. 24-3, at 2-34). Act 120 is the result of a thoughtful, thorough process and the legislative judgments it embodies are reasonable, well supported, and entitled to deference.

A. Vermont's legislative decisions are entitled to significant deference.

Legislative judgments receive significant deference. First, courts afford great deference to legislative factual findings: "When Congress makes findings on essentially factual issues . . . those findings are of course entitled to a great deal of deference, inasmuch as Congress is an institution better equipped to amass and evaluate the vast amounts of data bearing on such an issue." *Walters v. Nat'l Ass'n*

of Radiation Survivors, 473 U.S. 305, 330 n.12, 335 (1985) (upholding statutory fee limitation for veteran services under First and Fifth Amendments).

Second, in the rational-basis context, courts must uphold a law "'so long as it bears a rational relation to some legitimate end.'" *Vacco v. Quill*, 521 U.S. 793, 799 (1997) (citation omitted). Under this standard, "any reasonably conceivable state of facts" can provide that rational basis, *Fed. Commc'ns Comm'n v. Beach Commc'ns, Inc.*, 508 U.S. 307, 313 (1993), and a "legislative choice" may be "rational speculation unsupported by evidence or empirical data," *id* at 315. States are not obligated to "convince the courts of the correctness of their legislative judgments." *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 464 (1981). Rather, the court must only find that "it is evident from all the considerations presented to [the legislature], and those of which we may take judicial notice, that the question is at least debatable." *Id.* at 464, 470, 474 (citations and internal quotation marks omitted) (upholding Minnesota law banning plastic milk cartons under Equal Protection and Commerce Clause). And, in its fact-finding role, a district court may not "resolve conflicts in the evidence against the legislature's conclusion or . . . reject the legislative judgment" based on a lack of "convincing statistics" in the record. *Bhd. of Locomotive Firemen & Enginemen v. Chicago, Rock Island, & Pac. R.R. Co.*, 393 U.S. 129, 138-39, 143-44 (1968) (upholding

safety-based state law requiring minimum train crew numbers under Equal Protection, Due Process, and Commerce Clause).

Third, even in the intermediate-scrutiny context, a court's "sole obligation" is to assess whether the legislature "has drawn reasonable inferences based on substantial evidence." *Turner Broad. Sys., Inc. v. Fed. Commc'ns Comm'n*, 520 U.S. 180, 195 (1997); *Turner Broad. Sys., Inc. v. Fed. Commc'ns Comm'n*, 512 U.S. 622, 666 (1994).[2] In making this assessment, a court does not "reweigh the evidence *de novo*" nor "replace [the legislature's] factual predictions" with its own. 512 U.S. at 666. Instead, a court involves itself in further factual development only where a particular record is insufficient to support a determination that relevant constitutional factors have been met. *See id.* at 668.

Under either form of review, Vermont's legislative judgments are sound. Act 120's Findings and their underlying support are far more than the "rational speculation" required under rational-basis review. At a minimum, they also constitute "reasonable inferences based on substantial evidence," thus meeting intermediate scrutiny as well.

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[2] For the reasons explained by the State, Vermont's disclosure law is subject to the *Zauderer* standard and intermediate scrutiny does not apply. *See also* VPIRG-CFS Reply Support MTD & Response Opp. PI (Dist. Ct. Dkt. 64, at 24-39). However, if the Court were to apply intermediate scrutiny, Act 120's disclosure requirement would survive because the legislature has drawn reasonable inferences based on substantial evidence, *see Turner Broad.*, 512 U.S. at 666, and the disclosure requirement satisfies *Central Hudson*. *See, e.g.*, Dist. Ct. Dkt. 64, at 41-43.

B. Vermont's legislative decisions are reasonable and well supported.

When Representative Kate Webb introduced H.112 to the Vermont House Committee on Agriculture and Forest Products, she explained that the "introduction of genetically engineered foods into our diet has come quietly without mandatory labeling," that GE foods "might increase the risk of long-term health impairment," and that "without our knowledge and consent, we are all participants in this grand experiment." Statement of Representative Kate Webb (Dist. Ct. Dkt. 64-1, at 5). Representative Webb also explained that Vermonters deserve to know whether "the food they purchase poses potential risks to the environment and biodiversity." *Id.* at 5-6.

Over the next month, the House Agriculture Committee heard testimony from 35 individuals, including science and medical professionals, policy experts, attorneys, business owners, and agency personnel. *See* Vt. Legislative Bill Tracking System (Dist. Ct. Dkt. 24-3, at 20-25). The House Committee on Judiciary then spent several days considering the bill and hearing from additional witnesses. *Id.* at 18-19. In the Senate the following year, the Committee on Agriculture worked with the bill for 19 days and heard testimony from 31 witnesses, plus an additional 53 members of the public who testified at a public hearing. *Id.* at 8-17. At its last major stop, the bill garnered testimony from 17 people in the Senate Committee on Judiciary. *Id.* at 5-8.

During its review of H.112, the Vermont legislature made several significant and accurate determinations, which it memorialized in the Findings section of Act 120. *See* 2014 Vt. Acts & Resolves No. 120 (Act 120), Sec. 1. First, the legislature found that federal law does not currently require GE foods to be labeled as such. *Id.* Sec. 1(1). This is correct. *See* Statement of Policy: Foods Derived from New Plant Varieties (1992 Policy Statement), 57 Fed. Reg. 22,984-01, 22,991 (May 29, 1992); U.S. Food & Drug Administration (FDA), *DRAFT Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering* (Jan. 2001), http://goo.gl/es6cOv ("The 1992 policy does not establish special labeling requirements for bioengineered foods as a class of foods.").

Second, the legislature found that federal law does not require independent testing of the safety of foods produced with genetic engineering. Act 120, Sec. 1(2). This also is true. There is no federal statute or regulation that requires either GE companies or FDA to test the safety of GE foods. *See id.* Sec. 1(2)(B); 1992 Policy Statement, 57 Fed. Reg. at 22,989-90 (providing guidance to industry and encouraging "informal consultation"). Rather than independently test GE foods, FDA reviews voluntarily submitted studies that have been financed or conducted primarily by the biotechnology companies themselves. *See* Act 120, Sec. 1(2)(B); Testimony of Robert Merker, Ph.D. (Feb. 19, 2013) (Dist. Ct. Dkt. 64-1, at 11, 20-

21) (testing done by purveyor or manufacturer or labs with which they contract). Then, rather than make safety determinations regarding these products, FDA informs the biotechnology companies that they (the companies) have made safety determinations. *See* Act 120, Sec. 1(2)(B); Testimony of Michael Hansen, Ph.D. (Feb. 7, 2013) (Dist. Ct. Dkt. 64-1, at 50-52); Michael Hansen, Ph.D., *Reasons for Labeling of Genetically Engineered Foods* (Mar. 19, 2012) (Dist. Ct. Dkt. 64-2, at 5-6); William Freese & David Schubert, *Safety Testing & Regulation of Genetically Engineered Foods*, 21 Biotech. & Genetic Eng'g Revs. 5 (2004) (Dist. Ct. Dkt. 64-2, at 23) ("The review process . . . makes it clear that, contrary to popular belief, the FDA has not formally approved a single GE crop as safe for human consumption. Instead, at the end of the consultation, the FDA merely issues a short note summarizing the review process and a letter that conveys the crop developer's assurances that the GE crop is substantially equivalent to its conventional counterpart.").

Additionally, FDA has no protocol for determining whether studies that are not industry funded would produce different results than FDA's current process. *See* Act 120, Sec. 1(2)(C); Merker Testimony (Dist. Ct. Dkt. 64-1, at 25-26). In fact, non-industry scientists often cannot conduct studies in the United States because industry has restricted the use of patented GE crops in food safety research. *See* Act 120, Sec. 1(2)(F); Freese & Schubert (Dist. Ct. Dkt. 64-2, at 18-

19); Hansen, *Reasons for Labeling* (Dist. Ct. Dkt. 64-2, at 8-9). Relatedly, there have been no long-term or epidemiologic studies in the United States demonstrating that GE foods are safe for human consumption. *See* Act 120, Sec. 1(2)(E); Michael Antoniou et al., *GMO Myths & Truths: An Evidence-Based Examination of the Claims Made for the Safety & Efficacy of Genetically Modified Crops* (June 2012) (Dist. Ct. Dkt. 64-2, at 90-93); European Network of Scientists for Social & Environmental Responsibility (ENSSER), *Statement: No Scientific Consensus on GMO Safety* (Oct. 21, 2013) (Dist. Ct. Dkt. 64-3, at 18), *published in Environmental Sciences Europe* (Hilbeck et al., *No Scientific Consensus on GMO Safety*, 27:4 Envtl. Sci. Eur. (Jan. 2015), *available at* http://goo.gl/IMNLKF).

In a third major Finding, the legislature concluded that there is a lack of consensus regarding the safety of GE foods, and that such foods pose potential risks to human health. Act 120, Sec. 1(2)(D), (4), (6). This too is well founded. The legislature heard testimony regarding potential health effects from highly credentialed professionals on multiple occasions. *See, e.g.*, Testimony of Michael Hansen, Ph.D. (Feb. 7, 2013 & Jan. 29, 2014) (Dist. Ct. Dkt. 64-1, at 40-119); Testimony of David Rogers, Retired Professor (Jan. 10, 2014) (Dist. Ct. Dkt. 64-1, at 120-50); Testimony of Martin Donohoe, M.D. (Jan. 16 & 29, 2014) (Dist. Ct. Dkt. 64-1, at 151-82); Hansen, *Reasons for Labeling* (Dist. Ct. Dkt. 64-2, at 7-15) (describing multiple studies demonstrating unintended effects of genetic

engineering); Letter from Michael Hansen to Carolyn Partridge (Feb. 25, 2013) (Dist. Ct. Dkt. 64-3, at 35-36) (regarding follow-up questions including need to label "highly purified" GE foods). The legislature also had before it at least 47 scientific studies and documents supporting that there are potential health risks with consuming GE foods and that, at the very least, there is a lack of consensus regarding their safety. *See Table of Contents: Health Risks of GE Foods, Volume I* (Dist. Ct. Dkt. 24-3, at 28-29); *Table of Contents: Health Risks of GE Foods, Volume II* (Dist. Ct. Dkt. 24-3, at 30-31); *Table of Contents: GE Labeling-Additional Materials for Vermont Legislature Spring 2014* (Dist. Ct. Dkt. 24-3, at 33). For example:

- We feel compelled to issue this statement because the claimed consensus on GMO safety does not exist. The claim that it does exist is misleading and misrepresents the currently available scientific evidence and the broad diversity of opinion among scientists on this issue. Moreover, the claim encourages a climate of complacency that could lead to a lack of regulatory and scientific rigour and appropriate caution, potentially endangering the health of humans, animals, and the environment. ENNSER, *No Scientific Consensus* (Dist. Ct. Dkt. 64-3, at 17).

- Based on the scientific uncertainty surrounding both the molecular characterization of genetically engineered (GE) crops as well as the detection of potential allergenicity, there is more than enough uncertainty to decide to require labeling of foods produced via GE as a risk management measure as a way to identify unintended health effects that may occur post approval. If foods are not labeled as to GE status, it would be very difficult to even identify an unexpected health effect resulting from a GE food. Hansen, *Reasons for Labeling* (Dist. Ct. Dkt. 64-2, at 4).

- In the preceding paragraphs, we have described the US regulatory system for GE foods, and with specific examples pointed out serious deficiencies in both regulatory oversight and corporate testing procedures. It is clear that the US regulatory process must be made mandatory, as well as more stringent and transparent. Freese & Schubert, *Safety Testing & Regulation* (Dist. Ct. Dkt. 64-2, at 34).

- An increasing body of evidence shows the disruptive effect of the GM transformation process and clear signs of toxicity in well-controlled animal feeding studies even of a short-term nature. . . . Based on available evidence and inadequacy of the tests required by regulators, at present no GM crop and food can be categorically stated as safe to consume, especially on a long-term, life-long basis. Michael Antoniou, *Sources & Mechanisms of Health Risks from Genetically Modified Crops & Foods*, Biosafety Briefing-Third World Network (Sept. 2013) (Dist. Ct. Dkt. 64-3, at 32).

- With the precautionary principle in mind, because GM foods have not been properly tested for human consumption, and because there is ample evidence of probable harm, the AAEM asks . . . [f]or a moratorium on GM food, implementation of immediate long term independent safety testing, and labeling of GM foods, which is necessary for the health and safety of consumers. American Academy of Environmental Medicine, *Genetically Modified Foods* (May 8, 2009) (Dist. Ct. Dkt. 64-3, at 38).

- The results of most studies with GM foods indicate that they may cause some common toxic effects such as hepatic, pancreatic, renal, or reproductive effects and may alter the hematological, biochemical, and immunologic parameters. However, many years of research with animals and clinical trials are required for this assessment. Artemis Dona & Ioannis S. Arvanitoyannis, *Health Risks of Genetically Modified Foods*, 49 Critical Revs. Food Sci. & Nutrition 164 (2009) (Dist. Ct. Dkt. 64-3, at 40).

- Taking into account the increased risk of human and animal exposures to significant levels of these toxins, especially through diet, our results suggest that further studies are required to clarify

> the mechanism involved in the hematotoxicity found in mice, and to establish the toxicological risks to non-target organisms, especially mammals, before concluding that these microbiological control agents are safe for mammals. Belin Poletto Mezzomo et al., *Hematotoxicity of Bacillus thuringiensis as Spore-crystal Strains Cry1Aa, Cry1Ab, Cry1Ac or Cry2Aa in Swiss Albino Mice*, J. Hematology & Thromboembolic Diseases (2013) (Dist. Ct. Dkt. 64-3, at 59).

A recent article in the *New England Journal of Medicine* affirms the wisdom of GE labeling, highlighting that the pesticides applied to GE crops create risks of their own. *See* Philip J. Landrigan, M.D. & Charles Benbrook, Ph.D., *GMOs, Herbicides,& Public Health*, 373 N.E. J. Med. 693 (Aug. 20, 2015), *available at* http://goo.gl/lDgByY. The article notes that earlier recommendations by the National Academy of Sciences (NAS) have largely gone unheeded, even given the potential for GE foods to "produce unanticipated allergens or toxins" and "alter the nutritional quality of food." *Id.*[3] And, new developments "raise fresh concerns about the safety of [GE] crops"—a new combination herbicide containing 2, 4-D, and the designations of glyphosate as a "probable human carcinogen" and 2, 4-D

[3] In 2004, the NAS had made several recommendations for improving GE safety assessment, stating that "there remain sizeable gaps in our ability to identify compositional changes that result from genetic modification of organisms intended for food; to determine the biological relevance of such changes to human health; and to devise appropriate scientific methods to predict and assess unintended adverse effects on human health." National Academies Press, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* 8-15 (2004), *available at* http://goo.gl/QyAeZo.

as a "possible human carcinogen." *Id.* (citing links to malignant tumors in animals and, for glyphosate, increased non-Hodgkin's lymphoma in humans).

In its fourth Finding, the legislature found that GE crops pose potential risks to the environment, which also is accurate. Act 120, Sec. 1(4). For example, GE crops contaminate wild plants and non-GE crops. *See id.* Sec. 1(4)(D)-(E). A 2004 report found that traditional varieties of seeds used by United States farmers are "pervasively contaminated with low levels of DNA sequences originating in genetically engineered varieties of those crops." Margaret Mellon & Jane Rissler, *Gone to Seed-Transgenic Contaminants in the Traditional Seed Supply* (2004) (Dist. Ct. Dkt. 64-3, at 68); *see also* Doug Gurian-Sherman, *Contaminating the Wild? Gene Flow from Experimental Field Trials of Genetically Engineered Crops to Related Wild Plants* (2006), *available at* http://goo.gl/K1SByY. A more recent study identified genetically modified cotton genes in wild populations in Mexico. A. Wegier et al., *Recent Long-Distance Transgene Flow into Wild Populations Conforms to Historical Patterns of Gene Flow in Cotton (Gossypium hirsutum) at Its Centre of Origin*, 20 Molecular Ecology 4182 (2011) (Dist. Ct. Dkt. 64-4, at 46-50). Another concluded that feral populations of canola were "large and widespread" based on a roadside survey of canola plants that found two GE varieties growing in the wild, as well as "novel combinations of transgenic forms." Meredith G. Schafer et al., *The Establishment of Genetically Engineered Canola*

Populations in the U.S., PLoS one 6(10): e25736.doi:10.1371/ journal. pone. 0025736 (2011) (Dist. Ct. Dkt. 64-4, at 53).

The legislature also found that the use of GE crops in commodity agriculture may contribute to a loss of biodiversity and increased vulnerability of crops to pests and other factors. *See* Act 120, Sec. 1(4)(C). For instance, a 1992 paper explained how then-newer herbicides intended for herbicide-resistant GE plants "could lead to increased incidence of weeds," potentially toxic effects on fish fry, and glyphosate accumulation in plant foods. Rebecca J. Goldburg, *Environmental Concerns with the Development of Herbicide-Tolerant Plants*, 6 Weed Tech. 647 (1992) (Dist. Ct. Dkt. 64-4, at 61). More recently, scientists have raised concerns about GE crops and the decline in monarch butterfly populations. *See* John M. Pleasants & Karen S. Oberhauser, *Milkweed Loss in Agricultural Fields Because of Herbicide Use: Effect on the Monarch Butterfly Population*, Insect Conservation & Diversity (2012) (Dist. Ct. Dkt. 64-4, at 64) ("results strongly suggest that a loss of agricultural milkweeds is a major contributor to the decline in the monarch population"); *see also* Andrew Pollack, *In Midwest, Flutters May Be Far Fewer,* N.Y. Times (July 11, 2011), *available at* http://goo.gl/8ar3kf; Jim Robbins, *The Year the Monarch Didn't Appear,* N.Y. Times (Nov. 22, 2013), *available at* http://goo.gl/cU2aUZ. GE crops also threaten soil health and non-target species. *See* Tanya E. Cheeke at al., *Evidence of Reduced Arbuscular Mycorrhizal Fungal*

Colonization in Multiple Lines of Bt Maize, 99 Am. J. Botany 700 (2012) (Dist. Ct. Dkt. 64-4, at 80) (finding reduced soil fungi colonization in roots of multiple Bt maize lines, potentially leading to "negative effect on the abundance or diversity" of soil fungi); Michael Antoniou et al., *GM Soy, Sustainable? Responsible?* (Sept. 2010) (Dist. Ct. Dkt. 64-2, at 59-61) (describing concerns about nutrient uptake, crop yields, and plant diseases).

Additionally, the use of GE crops in agriculture has substantially increased—not reduced—the use of herbicides. Charles M. Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use in the U.S.—the First Sixteen Years*, Envtl. Sci. Eur. (2012) (Dist. Ct. Dkt. 64-4, at 82) ("Contrary to often-repeated claims . . . the spread of glyphosate-resistant weeds in herbicide-resistant weed management systems has brought about substantial increases in the number and volume of herbicides applied.").[4] This is especially troubling given that glyphosate and 2, 4-D are possible and probable human carcinogens. *See* Landrigan & Benbrook, *supra*, at http://goo.gl/lDgByY.

[4] Set against these harms, GE crops have not increased yields. *See, e.g.*, John Fagan et al., *GMO Myths & Truths* 297 (2d ed. 2014), *available at* http://goo.gl/daQ6Ph ("GM crops do not increase yields. Nor are there any GM crops that are better than non-GM crops at tolerating poor soils or challenging climate conditions."); Doug Gurian-Sherman, *Failure to Yield: Evaluating the Performance of Genetically Engineered Crops* 33 (2009), *available at* http://goo.gl/udnoxU (studying thirteen years of GE crops and concluding that GE crops have not increased intrinsic agricultural yields while traditional breeding methods have).

Finally, the Vermont legislature found that the absence of GE labels created not only the potential for, but also the reality of, consumer confusion and deception. *See* Act 120, Sec. 1(5)(A)-(B). Specifically, polling "by the New York Times indicated that many consumers are under an incorrect assumption about whether the food they purchase is produced from genetic engineering." *Id.* Sec. 1(5)(B); *see* Kopicki, *Strong Support for Labeling* (Dist. Ct. Dkt. 64-5, at 18) (fewer than half polled knew large amount of processed foods they buy at supermarkets is GE; almost half thought most or a lot of their produce was GE). Another survey showed that only 69.2% of those polled knew that some of the food available in stores had been genetically engineered; for those earning less than $25,000/year, only 51.3% were aware of this fact. Thomson Reuters, *National Survey of Healthcare Consumers: Genetically Engineered Food* (Oct. 2010) (Dist. Ct. Dkt. 64-5, at 25). As a University of Vermont professor testified, foods produced with genetic engineering are "credence goods," which means that "even after consumers use that product, they have no idea what they were eating . . . . [A]nd that's when labeling comes in and helps consume[r]s to understand what is in the product in the absence of no other way to know." Testimony of Jane Kolodinsky, Ph.D. (Jan. 31, 2014) (Dist. Ct. Dkt. 64-1, at 194-95). And, knowing is relevant; the legislature correctly found that "a large majority of Vermonters want foods produced with genetic engineering to be labeled as such." Act 120,

Sec. 1(5)(A); *see* Jane Kolodinsky, *Vermonter's Views on GMO Labeling* (Jan. 29, 2014) (Dist. Ct. Dkt. 64-5, at 27) ("Over the 13 year period, on average 88.9 percent of Vermonters agree there should be GMO labeling.").

For all of these reasons and more, the State of Vermont determined that it is in the best interests of the State to require labels on foods produced with genetic engineering. Act 120, Sec. 1(6). Vermont's decision to give Vermonters the benefits of this factual information is sound, and Act 120 is constitutional.

II. Vermont's interests in passing Act 120 are legitimate and substantial, and this case is not *Amestoy II*.

Act 120 is based on four substantial governmental interests that are stated in the Act itself and, as described above, are supported by extensive legislative Findings grounded in a robust legislative record.[5] Appellants' attempt to invoke *Amestoy* and conjure up "consumer curiosity"— by claiming that the State's concerns about GE foods have "no credible basis" and that, in any case, the State's concerns are not actually the State's—ignores the reality of Act 120 and the teachings of *Amestoy*.

[5] The Second Circuit repeatedly has characterized the *Zauderer* interest as "legitimate." *See Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001) ("legitimate and significant public goal"); *Conn. Bar Ass'n v. United States*, 620 F.3d 81, 101 (2d Cir. 2010) (applying *Zauderer* and dismissing plaintiffs' claims where government had "legitimate" interest). However, Appellants' preference for "substantial" over "legitimate" is irrelevant because Vermont's interests in Act 120 are both legitimate and substantial.

A. Vermont's interests in passing Act 120 are not "consumer curiosity" because Vermont has set forth its interests, Vermont's concerns about genetically engineered foods are reasonable, and these interests and concerns are indeed Vermont's.

In *Amestoy*, there were essentially three factors relevant to the Court's decision that only "consumer curiosity" was at play, none of which are present here.[6] First, the *Amestoy* Court relied "only upon those interests set forth by Vermont before the district court." *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 73 (2d Cir. 1996). And, as the District Court made clear in that case, Vermont "'d[id] not claim that health or safety concerns prompted the passage of the Vermont Labeling Law.'" *Id.* (quoting District Court). In sharp contrast, in this case, the State set forth four state interests before the District Court, interests that are at the heart of Act 120 and explicitly stated therein, and that include health and safety concerns. *See* Defs. Reply Support MTD & Response Opp. PI (Dist. Ct. Dkt. 63, at 20-26, 37-41); *see also* Act 120, Sec. 2, § 3041(1)-(4).

[6] It was this decision—that Vermont's only interest was "consumer curiosity"—that led the Court to apply *Central Hudson* in the *Amestoy* case, and to determine that Vermont's interest was not "substantial." *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 73-74 (2d Cir. 1996); *Nat'l Elec. Mfrs.*, 272 F.3d at 115 n.6 ("our [*Amestoy*] decision was expressly limited to cases in which a state disclosure requirement is supported by no interest other than the gratification of 'consumer curiosity'") (citation omitted). Since *Amestoy*, this Court has emphasized that *Zauderer* is the proper standard to apply to disclosure requirements absent limited narrow circumstances. *See, e.g., id.* at 115 ("*Zauderer*, not [*Central Hudson*], describes the relationship between means and ends demanded by the First Amendment in compelled commercial disclosure cases."); *Safelite Grp., Inc. v. Jepsen*, 764 F.3d 258, 263 (2d Cir. 2014).

Second, the *Amestoy* Court reasoned that companies could not be required to disclose information absent "some indication that th[e] information bears on a reasonable concern for human health or safety, or some other sufficiently substantial governmental concern." 92 F.3d at 74. Relevant to the Court's inquiry on this point was whether the record contained any "scientific evidence from which an objective observer could conclude that rBST has any impact at all on dairy products." *Id.* at 73. The answer in that case was no, but the answer in this case is yes.

The legislative record for Act 120—not to mention the declarations submitted by the State below—contains ample scientific evidence supporting Vermont's determinations that GE foods pose potential health risks, and that no consensus of safety exists. *See supra* pp. 7-14. This evidence was not fabricated by hack scientists as Appellants would have the Court believe, but includes peer-reviewed articles, testimony from highly credentialed experts, and position statements from professional associations. *See id.* Vermont has a "reasonable concern for human health or safety."

Additionally, unlike the products at issue in *Amestoy*, FDA has not determined that GE foods are safe. In *Amestoy*, FDA had "'concluded'" after "exhaustive studies" that "'there [we]re no human safety or health concerns'" with rBST-derived products. 92 F.3d at 73 (citation omitted). This conclusion was

memorialized in a Rule. *See* Final Rule: Sterile Sometribove Zinc Suspension, 58 Fed. Reg. 59,946-02 (Nov. 12, 1993) (approving drug); Voluntary Labeling of Milk & Milk Products, 59 Fed. Reg. 6279-04, 6279 (Feb. 10, 1994) (explaining FDA had approved rBST because it "had determined after a thorough review" that product was safe). With GE foods, there is no Rule, no thorough review, and FDA has never made a determination of safety. *See supra* pp. 8-10. Rather, in the decades-old GE foods statement that FDA *has* issued—i.e., a policy statement pre-public notice and comment—the agency raised several concerns regarding potential negative health effects. 1992 Policy Statement, 57 Fed. Reg. at 22,985-88 (e.g., unexpected effects, toxicants, allergenicity, antibiotic resistance). Thus, to the extent FDA has any views on the subject, they do not undermine Vermont's reasonable concerns.[7]

The third "consumer curiosity" factor in the *Amestoy* case was the Court's conclusion that Vermont had not "adopted" the concerns of consumers, but "only adopted that the consumers [we]re concerned." 92 F.3d at 73 n.1. In an astonishing example of selective discernment, Appellants claim that the same is

[7] The *Amestoy* Court also noted that "neither consumers nor scientists [could] distinguish rBST-derived milk from milk produced by an untreated cow." 92 F.3d at 73. Though that turned out to be untrue, *see Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 636 (6th Cir. 2010) ("a compositional difference does exist"), this is another difference between *Amestoy* and the present case. *See* Non-GMO Project, *About GMO Testing*, http://goo.gl/UMZZ9G (last visited Aug. 29, 2015) (describing testing for GMO contamination).

true here, that Act 120 is fatally flawed because it seeks to give information to consumers. Dkt. No. 44, at 40-42. However, disclosure requirements *always* seek to give information to consumers. Appellants do not cite one example of a disclosure requirement whose first purpose is not to give information to consumers.

Further, Vermont *has* adopted the concerns of its citizens, Vermont shares those concerns, they are Vermont's. The legislature worked on H.112 for two years, held at least 52 committee meetings, heard at least 136 testimonies, and meticulously detailed five pages of Findings. *See* H.112 Bill File (Dist. Ct. Dkt. 24-3, at 2-34); Act 120, Sec. 1. These are not the actions of a disinterested, unconcerned legislature. Act 120 is explicit:

> For multiple health, personal, religious, and environmental reasons, *the State of Vermont finds* that food produced from genetic engineering should be labeled as such, as evidenced by the following . . . .
>
> [T]he State should require food produced with genetic engineering to be labeled as such *in order to serve the interests of the State*, notwithstanding limited exceptions, to prevent inadvertent consumer deception, prevent potential risks to human health, protect religious practices, and protect the environment.

Id. Sec. 1(5), (6) (emphases added). In other words, Vermont seeks to give information to consumers because it has concerns about GE foods, and toward the end of enabling its citizens to avoid the foods giving rise to those concerns. *See id.* Secs. 1 & 2.

B. Vermont's interests in passing Act 120 are valid, recognized State interests.

Appellants do not seriously dispute that Vermont's asserted Purposes are valid governmental interests. Rather, they take issue with the "health and safety" Purpose because it addresses a "potential risk." Dkt. No. 44, at 40. This argument is flawed for two reasons. First, it ignores that public health and food safety is but one of the Purposes underlying Act 120. Second, it relies on the wrong benchmark for determining when a health and safety interest becomes sufficient—which is not *after* GE foods have been proven harmful to human health.

1. Act 120 is based on substantial governmental interests in addition to public health and food safety.

Among other things, Act 120 seeks to prevent consumer confusion and deception. Act 120, Sec. 2, § 3041(3). Given that so many Vermonters want to know whether their foods are produced with GE, that Vermonters do not currently have the information necessary to determine this fact, and that polls show consumers often have *inaccurate* assumptions about whether foods are GE, Vermont's interest in preventing consumer confusion and deception is certainly well supported. *See supra* pp. 17-18; *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 23 (D.C. Cir. 2014) (citing "demonstrated consumer interest" in country-of-origin labeling as factor contributing to government's substantial interest). This interest alone is sufficient to survive First Amendment scrutiny. *See, e.g.*,

Zauderer v. Office of Disciplinary Council of the Sup. Ct. of Ohio, 471 U.S. 626, 650-53 n.15 (1985) (noting "the reasonableness of the decision that appellant's omissions created the potential for deception of the public"); *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 252-53 (2010) (upholding bankruptcy disclosure where government interest was in preventing consumer deception); *Evergreen Ass'n, Inc. v. City of New York*, 740 F.3d 233, 248-49 (2d Cir. 2014) (upholding medical provider disclosure under strict scrutiny where disclosure "support[ed] the state interest in informing consumers and combating misinformation").

The legislature also intended to "[i]nform the purchasing decisions of consumers who are concerned about the potential environmental effects of the production of food from genetic engineering." Act 120, Sec. 2, § 3041(2). A similar but more attenuated interest was recently upheld by the D.C. Circuit. *See Am. Meat Inst.*, 760 F.3d at 23-24. There, the Court specifically referenced legislative statements that "identified the statute's purpose as enabling customers to make informed choices based on characteristics of the products they wished to purchase." *Id.* at 24. The Court explained: "Even though the production steps abroad for food imported into the United States are to a degree subject to U.S. government monitoring . . . it seems reasonable for Congress to anticipate that many consumers may prefer food that had been continuously under a particular

government's direct scrutiny." *Id.* (citation omitted). Similarly here, the Vermont legislature recognized that consumers may prefer to avoid purchasing GE foods based on concerns about the environment. Additionally, environmental protection is a well-established governmental interest. *See, e.g.*, *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 568 (1980) (conserving energy); *Maine v. Taylor*, 477 U.S. 131, 148 (1986) ("guarding against imperfectly understood environmental risks, despite the possibility that they may ultimately prove to be negligible"); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001) (reducing mercury pollution).

2. Vermont's public health and food safety interest is substantial because it is based on reasonable concerns.

Another primary Purpose of Act 120 is "[p]ublic health and food safety"—in particular, to "[e]stablish a system by which persons may make informed decisions regarding the potential health effects of the food they purchase and . . . avoid potential health risks of food produced from genetic engineering." Act 120, Sec. 2, § 3041(1). Like the other Purposes described above, promoting public health and food safety is a valid state interest. *See, e.g.*, *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995) (promoting "health, safety, and welfare" is substantial interest); *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 556 F.3d 114, 134 (2d Cir. 2009) (preventing obesity is valid interest).

Appellants are mistaken that GE foods must be proven harmful before Vermont can have a valid health or safety interest in requiring labeling. The potential for something to go awry justifies a disclosure requirement. In *American Meat Institute*, the Court had no trouble relying on "a congressional decision to empower consumers to take *possible* country-specific differences in safety practices into account" as a factor in upholding country-of-origin labeling. 760 F.3d at 25 (emphasis added). And, in *CTIA*, the Court held that a local government could require factual disclosures regarding cell phone emissions on the basis of a potential health risk.[8] *See CTIA—The Wireless Ass'n v. City & Cnty. of S.F., Ca.*, 827 F. Supp. 2d 1054, 1060-61 (N.D. Ca. 2011) ("[a] government may impose, out of caution, at least some disclosure requirements based on nothing more than the possibility that an agent may (or may not) turn out to be harmful"), *vacated on other grounds by* 494 Fed. Appx. 752, 753-54 (9th Cir. 2012).[9]

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

[9] The Ninth Circuit did not overrule the District Court's conclusion that a government could require a disclosure based on a potential health risk, but rather held that the Fact Sheet in question was not "purely factual and uncontroversial" because it contained "*San Francisco's* recommendations as to what consumers should do if they want to reduce exposure to . . . emissions." 494 Fed. Appx. at

Appellants conflate the "interest" factor with the "fit" factor here, arguing that because Vermont's health and safety interest is based on potential risks, there is not a reasonable relationship between that interest and the disclosure requirement. Dkt. No. 44, at 48-50. But, as noted above, the point of a label is to give consumers information in order to achieve some end. *See, e.g., Nat'l Elec. Mfrs.*, 272 F.3d at 115 ("the compelled disclosure at issue here . . . [is] intended . . . to better inform consumers about the products they purchase []though the overall goal of the statute is plainly to reduce the amount of mercury released into the environment"). If the "end" is valid, the disclosure requirement is almost always bound to achieve that end. *See Am. Meat Inst.*, 760 F.3d at 26 ("The self-evident tendency of a disclosure mandate to assure that recipients get the mandated information may in part explain why, where that is the goal, many such mandates have persisted for decades without anyone questioning their constitutionality."). Here, the State has a substantial interest in enabling its citizens to avoid the potential health risks of GE foods, and labeling achieves that end. *See N.Y. State*

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753 (emphasis added). That there was a scientific debate about health risks was not relevant to the validity of the governmental interest, but to whether it was proper for San Francisco to include *its own* recommendations in the compelled disclosure. *See id.* at 753-54. Thus, the decision does not apply here in *either* the "substantial interest" *or* the "uncontroversial" context. Vermont's law requires a short statement of fact about the product to which the statement refers, plain and simple. *See* Act 120, Sec. 2, § 3043(b).

Rest. Ass'n, 556 F.3d at 134 (enabling New Yorkers to avoid consuming too many calories—at certain restaurants—through calorie disclosure requirements).

Finally, Act 120 passes muster under *Amestoy's* guidance that a state interest in human health or safety be based on a "reasonable concern" in order to be substantial. 92 F.3d at 74. As detailed above, Vermont's interest in human health and safety is based on reasonable concerns, and it is substantial.

CONCLUSION

For the reasons explained above, Appellants' First Amendment claim against Vermont's disclosure requirement is without merit, and this Court should uphold the District Court's denial of a preliminary injunction.

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Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE WITH FRAP 32(A)

1) This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and 29(d) because this brief contains 6992 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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 this brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14-point Times New Roman.

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