

No. 15-1504-CV

In the United States Court of Appeals for the Second Circuit

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

Plaintiffs-Appellants,

v.

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

Defendants-Appellees.

ON APPEAL FROM THE
UNITED STATES DISTRICT COURT FOR THE DISTRICT OF VERMONT
CASE NO. 5:14-cv-117-Cr (HON. CHRISTINA REISS)

**BRIEF OF AMICUS CURIAE DR. RAMON J. SEIDLER, DR. JACK
HEINEMANN, DR. DAVID SCHUBERT, DR. ALLISON K. WILSON, DR.
JOHNATHAN LATHAM, NATIONAL FAMILY FARM COALITION, OUR
FAMILY FARMS COALITION, SIERRA CLUB, AND CENTER FOR
FOOD SAFETY, IN SUPPORT OF DEFENDANTS-APPELLEES AND
AFFIRMANCE OF THE DISTRICT COURT**

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CORPORATE DISCLOSURE STATEMENT

Amicus curiae Center for Food Safety, National Family Farm Coalition, Our Family Farms Coalition, and Sierra Club are nonprofit corporations, have no parent corporations, and do not issue stock.

Dated: August 31, 2015

/s/ George A. Kimbrell

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INTEREST OF AMICUS CURIAE¹

Amicus Center for Food Safety (CFS) is a nonprofit whose mission is to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture.² CFS has 700,000 consumer and farmer members nationwide.

CFS and its members have strong interest in this appeal: A pillar of CFS's mission is protecting the public's right to know how their food is produced. For over two decades, CFS has been the leading U.S. public interest organization working on the issue of genetically engineered organisms. Dist. Ct. Dkt. No. 18-5. CFS has a major program area specific to GE foods and labeling, and numerous staff members—scientific, policy, campaign, and legal—whose work encompasses the topic. *Id.* CFS staff are recognized experts in the field, intimately familiar with the issue of GE crops, the inadequacy of their oversight, their health risks, and their adverse environmental impacts.

¹ No party's counsel authored the brief in whole or part; no party or party's counsel contributed money that was intended to fund the preparation or submission of this brief; and no person—other than Amici, their members, or their counsel—contributed money that was intended to fund preparing or submitting the brief. *See* 2d Cir. R. 29.1(b); Fed. R. App. P. 28(c)(5). All parties have consented to the filing of this brief. *See* Fed. R. App. P. 29(a).

² *See* CFS, www.centerforfoodsafety.org.

In Vermont, CFS worked closely with local allies in supporting Act 120's passage. *Id.* When Appellants filed suit, CFS moved to intervene. Dist. Ct. Dkt. Nos. 18-1, 29. While the court held that CFS had significantly protectable interests in the case, it denied the motion based on the adequacy of the State's representation. Dist. Ct. Dkt. No. 52. Nonetheless the court permitted CFS to participate as Amicus throughout without the need for motions for leave; the organization subsequently did, filing several briefs, including a sixty-eight-page memorandum in support of the State's motion to dismiss and in opposition to Appellants' injunction motion. Dist. Ct. Dkt. No. 64. As Amicus, CFS will provide insight into the specialized legal, scientific, and factual context of genetically engineered crops, in order to aid this Court's review.³

Dr. Ramon J. Seidler, Ph.D. is the former head scientist of the U.S. Environmental Protection Agency's *Genetically Engineered Organism Biosafety Program*. Dr. Seidler wrote the first-ever U.S. government research plan on Genetically Engineered Organism Biosafety. Beginning in 1970, he was also a Professor of Microbiology at Oregon State University, where he taught biology,

³ See also George A. Kimbrell & Aurora L. Paulsen, *The Constitutionality of State-Mandated Labeling for Genetically Engineered Foods: A Definitive Defense*, 39 Vt. L. Rev. 341 (2014).

microbial physiology, and systematic bacteriology, and directed research in those areas.

Dr. Jack Heinemann, Ph.D. is the Director of the *Centre for Integrated Research in Biosafety*, University of Canterbury, New Zealand, where he is also a Professor in the School of Biological Sciences. Since 2009, Dr. Heinemann has served the United Nations Convention on Biological Diversity Secretariat on the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management.

Dr. David Schubert, Ph.D., directs the *Cellular Neurobiology Lab* at the Salk Institute for Biological Studies in La Jolla, CA, and conducts research on neurodegenerative diseases. For over a decade, Dr. Schubert has written extensively about the potential hazards and inadequate regulation of genetically engineered foods.

Dr. Jonathan R. Latham, Ph.D., is the Executive Director of the *Bioscience Resource Project*, a nonprofit specializing in public interest science. He has a Ph.D. in plant virology and was previously a research associate at the University of Wisconsin, Madison.

Dr. Allison K. Wilson, Ph.D., is the Science Director of the *Bioscience Resource Project*. Her previous research was in the plant molecular genetics of auxin and environmental response. For the past nineteen years she has been

researching genetic engineering, biosafety, and their implications for plant breeding and agriculture.

The National Family Farm Coalition is an organization of family farm, fisher, and rural advocacy organizations from across the United States. Its mission is to provide a voice for grassroots groups on farm, food, trade, and rural economic issues to ensure fair prices for family farmers and fishers, safe and healthy food, and vibrant, environmentally sound rural communities in the United States and around the world.

Our Family Farms Coalition is a nonprofit organization of organic and traditional farmers that works to protect traditional crops and agricultural communities from the adverse impacts of genetically engineered crops such as transgenic contamination.

The Sierra Club is the nation's largest and most influential grassroots environmental organization, with more than two million members and supporters, dedicated to exploring and protecting the wild places of the earth. To this end, the Sierra Club's concerns and work have long encompassed genetic engineering and industrial agriculture.

Amici respectfully submit this brief in support of the State of Vermont.

INTRODUCTION AND SUMMARY OF ARGUMENT

Polls regularly show that 90% of Americans support labeling genetically engineered foods,⁴ and are demanding the same labeling that consumers in sixty-four other countries—including all of Europe and Scandinavia, China, Russia, Brazil, Japan, New Zealand, and Australia—already enjoy.⁵ Because our federal government has thus far failed to act, states have stepped into the breach, following the venerable “states-as-laboratories” tradition of American federalism.

Grocery Manufacturers Association *et al.* (GMA or Appellants) appeal the district court’s rejection of their claim to a First Amendment right to keep consumers in the dark about whether their food products are genetically engineered. They do not have such a right, and this Court should affirm. *Zauderer v. Office of Disc. Counsel of the Sup. Ct. of Ohio*, 471 U.S. 626, 651 (1985) (explaining that a corporation’s “constitutionally protected interest in *not* providing...information in his advertising is minimal”).

At its core, GMA’s appeal questions Vermont’s findings underlying Act 120. Appellants, and their amici, claim Vermont had no cognizable interests in support of requiring labeling; that any such interests are not the State’s; and that, in

⁴ CFS, *U.S. Polls on GE Food Labeling*, <http://goo.gl/jZUfmc> (listing polls).

⁵ CFS, *International Labeling Laws*, <http://goo.gl/nj6g2d>.

any event, any rationale to require labeling is unfounded, because genetically engineered organisms are no different than conventional crops, do not pose any health and environmental risks, are rigorously regulated at the federal level to assure their safety, and anyone questioning their arguments must be scientifically illiterate.

First, there is no need to guess as to what Vermont's substantial interests were in enacting Act 120, or whether they belong to the State or not, because Vermont laid them out, over five pages, in twenty-seven detailed Findings, followed by a summarizing Purpose Section. *See* Act 120, Sections 1-2. Simply put, Act 120's purposes were to (1) reduce consumer confusion and deception regarding genetically engineered foods; and instead (2) to allow consumers to make purchasing decisions in light of the public health concerns and unknowns regarding engineered foods; (3) and in light of the adverse environmental and agronomic impacts caused by their production. *Id.* at Sec. 2.

Second, Appellants may wish to impugn these purposes and interests as merely the public's, and not the State's, but the Act's express language forecloses that argument, repeatedly explaining that "the 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(6) (emphasis added); *see also* Secs. 1 & 1(5). Courts must “assume that the objectives articulated by the legislature are actual purposes of the statute.” *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 463 n.7 (1981).

Third, the State’s substantial purposes are supported by detailed findings about the commercial and scientific reality of GE crops, which resulted from a voluminous administrative record and arduous legislative process. *See* Dist. Ct. Dkt. No. 64 at 1-11 (detailing that process). While Appellants may want to wish away these findings, it is long settled that such governmental findings are entitled to substantial deference in this context. *Columbia Broad. Sys., Inc. v. Democratic Nat. Comm.*, 412 U.S. 94, 102-103 (1973); *Turner Broad. Sys., Inc. v. F.C.C.*, 520 U.S. 180, 195-96 (1997).

Accordingly, the purpose of this brief is to provide this Court further context for the State’s findings, submitted by scientific experts, farmers, and environmental organizations that all support the labeling of genetically engineered foods.

Labeling laws such as Act 120 are fully supported by and further constitutional speech principles, because they simply require companies to disclose factual information about their products, and in so doing, serve substantial state interests in preventing potential consumer deception and confusion, as well as promoting public health and environmental protection.

ARGUMENT

I. Genetic Engineering is Radically Different than Traditional Plant Breeding.

Genetic engineering (GE) is a combination of techniques and processes that cause changes in genes that could only happen through human intervention and never naturally. It is a relatively new technology that is fundamentally different from traditional breeding. Attempting to undermine Vermont's substantial interests and findings, Appellants and their amici repeatedly attempt to conflate GE with classical plant breeding. Brief for Appellants at 6 (Dkt. No. 44); Brief for Amicus Biotech. Indus. Org. (BIO) at 6-9 (Dkt. No. 61). Traditional plant breeding involves identifying genetically similar plants with useful traits and crossing these plants to produce offspring with the desired characteristics. In contrast, genetic engineering allows scientists, for the first time ever, to combine genetic material from widely dissimilar and unrelated organisms—for example, bacterial genes with alfalfa genes or chicken genes with maize genes.⁶ In so doing,

⁶ Allison Snow, *Genetic Engineering: Unnatural Selection*, 424 *Nature* 619 (2003), available at <http://goo.gl/Fn6hs3>.

scientists produce combinations of genetic material that do not—and cannot—occur in nature.⁷

A gene from one organism that scientists insert into another organism is called a transgene, and the host organisms receiving the gene are “transgenic” or “genetically engineered.”⁸ The transgenic construct consists of DNA fragments assembled together in the laboratory. For example, for engineered “Roundup Ready” soybeans (and the overwhelming majority of GE crop acreage is Roundup Ready crops, *see infra*), the main part of the genetic construct—the coding region—is derived from a gene from the soil bacterium *Agrobacterium tumefaciens* that allows plants to survive even when treated with the pesticide glyphosate.⁹ This coding sequence is then fused to gene fragments from other species—cauliflower mosaic virus, petunia, and another strain of *Agrobacterium*—

⁷ Stanley N. Cohen et al., *Construction of Biologically Functional Bacterial Plasmids in Vitro*, 70 Proc. Nat’l Acad. Sci. 3240-44 (1973), available at <http://goo.gl/ils6Ha>.

⁸ *Transgenic Crops: An Introduction and Resource Guide*, Dep’t of Soil and Crop Sci. Colo. St. Univ., <http://goo.gl/L8G7ga>.

⁹ Stephen Powles, *Evolved glyphosate-resistant weeds around the world: lessons to be learnt*, 64 Pest Mgmt. Sci. 360 (2008), available at <http://goo.gl/YeDnQw>.

to control its expression in the host soybean plant.¹⁰ *Scientific American* explains how Monsanto engineered Roundup Ready crops:

A seven-year search for the right gene ended in an outflow pipe from a Monsanto facility in Louisiana. There researchers looking for organisms that could survive amid the glyphosate runoff discovered a bacterium that had mutated to produce a slightly altered form of the EPSPS enzyme. The altered enzyme made the same three amino acids but was unaffected by glyphosate. Scientists isolated the gene that coded for it and, along with various housekeeping genes (for control and insertion of the gene for the enzyme) collected from three other organisms, implanted it in soybean cells with a gene gun.

This is a brute-force technology in which the selected DNA is wrapped around microscopic specks of gold that are blasted at soybean embryos, in hopes that at least a few will find their way to the right place on a chromosome. Tens of thousands of trials resulted in a handful of plants that could withstand glyphosate and pass the trait down to their descendants. Starting in 1996, Monsanto began selling these soybean seeds as Roundup Ready. Seeds for glyphosate-resistant cotton, canola and corn followed soon after.¹¹

As this explanation illustrates, genetic engineers have been unable to control where they inserted the genes into the genome of existing commercial GE crops.¹² Even

¹⁰ Jerry Adler, *The Growing Menace From Superweeds*, 304 *Sci. Am.* at 78 (May 2011), available at 2011 WLNR 10901996.

¹¹ *Id.*

¹² Martin Dagoberto, *Life, the Remix*, 26 *GeneWatch* 28, 29 (Jan.-Mar. 2013), available at <http://goo.gl/Xyvzww>.

if new more precise techniques replace existing techniques, separate unintended changes will still occur, changes that can interrupt genes or alter their functions.¹³

In short, genetic engineering is very different than traditional breeding.¹⁴ It is an imprecise technology that causes random and, in some cases, large-scale mutations in crop genomes;¹⁵ has a higher potential for generating unintended and potentially adverse human health effects than conventional breeding methods;¹⁶ and is a relatively novel technology with no demonstrated history of safe use.¹⁷

II. Vermont's Public Health Interests.

As Act 120 explains, requiring disclosure labeling is well supported by the potential health risks of GE foods. Act 120, Secs. 1(2)-(4), 2(1). Courts have long held public health interests to be legitimate and substantial. *Rubin v. Coors Brewing, Co.*, 514 U.S. 476, 485 (1995); *Natl. Elec. Mfrs. Ass'n v. Sorrell*, 272

¹³ *Id.*

¹⁴ *See supra* note 6.

¹⁵ Allison K. Wilson et al., *Transformation-induced mutations in transgenic plants: Analysis and biosafety implications*, 23 *Biotech. & Genetic Eng'g Rev.* 209-234 (2006), available at <http://goo.gl/JtDyk8>.

¹⁶ Inst. of Med. & Nat'l Research Counsel of the Nat'l Acads., *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*, 64, 65 n. 3 (2004), available at <http://goo.gl/g9AuE1>.

¹⁷ For these same reasons, labeling foods produced through genetic engineering as “natural” is inherently misleading and deceptive.

F.3d 104, 115 (2d Cir. 2001). These legislative findings are entitled to substantial deference. *Discount Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d 509, 521-22 (6th Cir. 2012); *Kachalsky v. County of Westchester*, 701 F.3d 81, 97 (2d Cir. 2012).

A. Federal Oversight of GE Food Safety is Exceedingly Weak.

Contrary to Appellants' assurances of robust federal oversight assuring safety, the Food and Drug Administration (FDA) neither makes any health and safety approval "finding" for GE foods, nor undertakes any independent analysis of their health risks. *See* Act 120, Sec. 1(2).¹⁸ In reality, federal review is exceedingly weak: The sum of FDA's role is a confidential consultation with industry, where FDA reviews selected summaries of the industry's data, and even that is voluntary. Act 120 Sec. 1(2)(B). Tellingly, the consultation culminates in FDA sending a "no questions" letter conveying the GE food developer's—*not FDA's*— safety assurances.¹⁹ A typical FDA response, from a 2011 letter to Dow Chemical on a corn engineered to be resistant to the pesticide 2,4-D:

¹⁸ William Freese & David Schubert, *Safety Testing and Regulation of Genetically Engineered Foods*, 21 *Biotech. & Genetic Eng'g Revs.* 299, 303-04 (2004), available at <http://goo.gl/B9wSIa>.

¹⁹ *Id.* at 304-05; *Biotechnology Consultations on Food from GE Plant Varieties*, U.S. Food & Drug Admin., <http://goo.gl/2quKHm>.

Based on the safety and nutritional assessment *Dow has conducted*, it is our understanding that *Dow has concluded* that DAS-40278-9 corn is not materially different in any respect relevant to food or feed safety from corn varieties currently on the market and that the genetically engineered corn does not raise issues that would require premarket review or approval by FDA *Based on the information Dow has provided to FDA*, we have no further questions concerning the new corn variety, DAS-40278-9 corn, at this time. However, as you are aware, it is *Dow's continuing responsibility* to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.²⁰

Hence, it is incorrect and misleading to claim, as Appellants and their amici repeatedly do, that FDA “approves” GE foods. Br. for Appellants at 7-8; Br. for Amicus BIO at 4-5, 16-18.

Indeed, there is no U.S. federal law that specifically addresses GE organisms. Like other agencies, FDA applies its pre-existing authority under the Federal Food, Drug and Cosmetic Act of 1938 (FFDCA) to GE foods, but has no specific regulations applying the FFDCA to GE foods. Instead, FDA issued only a “statement of policy,” in 1992.²¹ Pursuant to that guidance, the manufacturer, not

²⁰ Letter from Mitchell A. Cheeseman, Acting Director, Office of Food Additive Safety, to Craig Blewett, Regulatory Leader, Dow AgroSciences LLC (Apr. 13, 2011), *available at* <http://goo.gl/0MKpQL> (emphases added).

²¹ Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,985 (May 29, 1992); *Consultation Procedures under FDA's 1992 Statement of Policy—Foods Derived from New Plant Varieties*, U.S. Food & Drug Admin. (Revised Oct. 1997), <http://goo.gl/AzT5Ob>.

FDA, determines whether a GE substance is “generally recognized as safe,” and any consultation with FDA on that decision is voluntary.

Appellants relied on such agency GE policy statements for their implied “obstacle” preemption claims, arguments the district court rejected, since policy statements like FDA’s GE policy do not have the force of law and thus cannot have preemptive effect. Dist. Ct. Dkt. No. 95, at 35-38; *Holk v. Snapple*, 575 F.3d 329, 340 (3d Cir. 2009). Appellants have wisely declined to appeal those holdings. However they fail to see that the same federal oversight inadequacy also belies their remaining 1st Amendment arguments: that federal regulation is robust, assures GE food safety, and hence Vermont’s interests regarding GE crops are not substantial, or the state’s findings unsupported. Br. for Appellants at 37. In reality federal review is the antithesis of robust, a failing that rightly gives consumers pause and supports Vermont’s interests in requiring disclosure through labeling.

B. There Is No “Consensus” that GE Foods Are Safe.

Another myth Appellants and their amici echo is a supposed “consensus” regarding GE foods’ safety. As the State found, there is no such consensus. Act 120, Sec. 1(2)(D). Numerous scientific, health, and legislative bodies have concluded that GE foods have not been proven safe, that mandatory safety

assessments are needed, and that they support labeling.²² *See also* Declaration of Dr. Michael Antoniou (Dist. Ct. Dkt. 63-14 at 15-20) (listing numerous such conclusions, including the British Medical Association: “Many unanswered questions remain, particularly with regard to the potential long-term impact of GM foods on human health and the environment”); European Network of Scientists for Social and Environmental Responsibility (Dist. Ct. Dkt. 64-3 at 114) (“As scientists, physicians, academics, and experts from disciplines relevant to the scientific, legal, social and safety assessment aspects of genetically modified organisms, we strongly reject claims by GM seed developers and some scientists, commentators, and journalists that there is a ‘scientific consensus’ on GMO safety”).

Genetic engineering is a novel technology that may cause unintended consequences and, unlike traditional breeding, does not have a demonstrated history of safe use. *See supra* Sec. I. No long-term or epidemiological studies in the United States have examined the safety of human consumption of genetically engineered foods. Act 120, Sec. 1(2)(E). Indeed, given recent developments (*see*

²² Angelika Hilbeck et al., *No scientific consensus on GMO safety*, *Envtl. Sci. Europe* 27:4 (2015) available at <http://goo.gl/k2f4R6>; Sheldon Krimsky, *An Illusory Consensus behind GMO Health Assessment*, *Sci., Tech., and Human Values* (August 7, 2015), available at <http://goo.gl/5cEHpm>.

infra Sec. III.A), as an August 20, 2015 article in the *New England Journal of Medicine* just concluded: “GM foods and the herbicides applied to them may pose hazards to human health that were not examined in previous assessments.”²³

Without labeling, there is no accountability or traceability to link such foods to proliferating public health problems. *Id.* at 695 (“Labeling...is essential for tracking emergence of novel food allergies and assessing effects of chemical pesticides applied to GM crops.”). Moreover, the studies that have been done on health consequences show conflicting results, with numerous studies showing that GE foods can be toxic. Act 120, Sec. 1(4)(A); *See* Declaration of Dr. Michael Antoniou (Dist. Ct. Dkt. 63-14 at 21-26) (listing numerous such studies).²⁴ And because FDA neither undertakes nor requires any certain analysis, there are significant limits to the types and lengths of studies that are conducted by the manufacturers.

Nor does the State have to conclusively establish the extent of potential health risks in order to require labeling. *Maine v. Taylor*, 477 U.S. 131, 148 (1986)

²³ Philip Landrigan & Charles Benbrook, *GMOs, Herbicides, and Public Health*, at 694, *New Eng. J. of Med.* (August 20, 2015), *available at* <http://goo.gl/uvHoSG> (“We believe that the time has come to thoroughly reconsider all aspects of the safety of plant biotechnology”).

²⁴ Krimsky, *supra* note 22, at 12 (“Thus far, I have identified twenty-six studies in the scientific literature that have reported adverse effects or uncertainties of GMOs fed to animals”); Table 2 (listing studies)).

(States do not have to “sit idly by and wait until potentially irreversible environmental damage has occurred or until the scientific community agrees on what disease organisms are or are not dangerous before it acts to avoid such consequences”). In any event, governments do not simply require labels for food products if they definitively know them to be harmful; if they have such evidence, they pull those foods off the market shelves.

Finally, as Act 120 notes, Act 120 Sec. 1(2)(f), the lack of publicly available health and risk data is not accidental: the industry tightly controls any research through intellectual property. GE seeds are patented: Scientists cannot buy GE seeds for studies, or obtain them from farmers, but instead must seek them directly from the patent holder biotech company, who can refuse a request for any reason.²⁵ Academics deemed critical may be denied permission;²⁶ even if granted, the patent holders retain the right to control and approve studies and any publication.²⁷ In 2009, twenty-six university scientists protested this restricted access in a filing with EPA:

²⁵ Emily Waltz, *Under Wraps*, 27 *Nature Biotech.* 880, 880-82 (2009).

²⁶ Rex Dalton, *Superweed Study Falters as Seed Firms Deny Access to Transgene*, 419 *Nature* 655 (2002).

²⁷ Andrew Pollack, *Crop Scientists Say Biotechnology Seed Companies Are Thwarting Research*, *N.Y. Times*, Feb. 19, 2009, <http://goo.gl/Nz7tWu>.

Technology/stewardship agreements required for the purchase of genetically modified seed explicitly prohibit research. These agreements inhibit public scientists from pursuing their mandated role on behalf of the public good unless the research is approved by industry. *As a result of restricted access, no truly independent research can be legally conducted on many critical questions regarding the technology.*²⁸

III. Vermont's Environmental and Agricultural Interests.

Act 120 also details GE crop production's substantial environmental and agronomic impacts, Act 120 Secs. 1(4)(C)-(E), (6), as another major purpose, *id.* Sec. 2(2). As with health, protection of the environment is a venerable state interest. *Maine*, 477 U.S. at 148, 151-2; *Nat'l Elec. Mfrs.*, 272 F.3d at 115.²⁹ Contrary to the claims of Appellants and their amici, the significant adverse environmental impacts of GE crops are well documented in the legislative record of Act 120, public realm, and the courts.

²⁸ Comment on FIFRA Scientific Advisory Panel Meeting Pertaining to Resistance Risks from Using a Seed Mix Refuge with Pioneer's Optimum® AcreMax™ 1 Corn Rootworm-Protected Corn, <http://goo.gl/yMeeWw> (emphasis added).

²⁹ Because Act 120 mandates disclosure labeling, the proper standard is *Zauderer*, not *Central Hudson*, see *Nat'l Elec Mfrs.*, 272 F.3d at 115, and *Zauderer* is a rational basis test, requiring only legitimate, not substantial state interests, 471 U.S. at 650-51. However even if a substantial interest was required, Vermont's interests here are substantial, as the district court found, Dist. Ct. Dkt. No. 95, at 63.

A. GE Crops Are a Pesticide-Promoting Technology.

Despite two decades of promises about reducing world hunger, ameliorating global malnutrition, or combating global warming,³⁰ biotechnology firms have instead only delivered a handful of GE commodity crops that produce insecticides and/or withstand direct application of herbicides.³¹ Over five of every six acres of transgenic crops worldwide (84%),³² and 94% of soybeans, 89% of cotton, and 89% of corn grown in the United States in 2015 were GE, herbicide-resistant varieties. Nearly all herbicide-resistant crops are Monsanto's Roundup Ready varieties, resistant to glyphosate, the active ingredient in Roundup pesticide.³³ *Ctr. for Food Safety v. Vilsack*, 718 F.3d 829, 836 (9th Cir. 2013) (describing Monsanto's Roundup Ready "crop system" of the GE crop and associated

³⁰ J.A. Heinemann, *Hope Not Hype: The future of agricultural guided by the International Assessment of Agricultural Knowledge, Science and Technology for Development*, (Third World Network, 2009), available at <http://goo.gl/kxAhnB>.

³¹ *Id.* at 63.

³² C. James, *Biotech Traits: Annual Updates 2014*, excerpted from *Global Status of Commercialized Biotech/GM Crops: 2013, ISAAA Brief No. 46.*, ISAAA (2014), available at <http://goo.gl/RX0XPY> (GE crops with herbicide-resistance—alone or stacked with insect-resistance—were grown on 362 million acres of the 433 million global GE crop acres reported in 2013).

³³ William Neuman & Andrew Pollack, *Farmers Cope with Roundup-Resistant Weeds*, N.Y. Times, May 3, 2010, <http://goo.gl/QiIiwW>.

pesticide). The Roundup Ready GE crop system has made glyphosate the most used pesticide in history, with over 280 million pounds applied in U.S. agriculture in 2012 alone.³⁴ Overall, in the sixteen years from 1996 to 2011, an extra 527 million pounds of herbicides were sprayed in U.S. agriculture because of GE crops.³⁵

These Roundup Ready crops are also responsible for an epidemic of “superweeds” that have evolved resistance to glyphosate on 70 million acres in the United States, that have cost U.S. farmers approximately \$1 billion in damages to crops.³⁶ The pesticide firms’ “solution” is a “next-generation” of GE crops “stacked” with resistance to multiple other toxic herbicides, such as Agent Orange component 2,4-D and the closely related dicamba.³⁷ Yet far from providing any

³⁴ Pesticide National Synthesis Project, *Pesticide Use Maps: Glyphosate*, U.S. Geological Survey (2012), <http://goo.gl/hSFYL0>.

³⁵ Charles M. Benbrook, *Impacts of genetically engineered crops on pesticide use in the U.S. – the first sixteen years*, 24 *Envt. Sci. Eur.* 1, 3 (2012) available at <http://goo.gl/RaFkeM>; R. J. Seidler, *Pesticide use on genetically engineered crops*, *Ag/Mag Blog* (Sept. 15, 2014), <http://goo.gl/R7wocn>.

³⁶ Charles Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Thirteen Years*, at 3, 23, 31, 36 (2009) available at <http://goo.gl/AXAo9G>; Mark Koba, *Superweeds Sprout Farmland Controversy Over GMOs*, *NBC News*, September 30, 2014, <http://goo.gl/BuxKR1>.

³⁷ David Mortensen et al., *Navigating a critical juncture for sustainable weed management*, 62 *BioScience* 75-84 (2012), available at <http://goo.gl/RxZVM2>;

panacea, these new GE crops will instead lead to vastly increased herbicide use, such as a three- to seven-fold rise in agricultural use of 2,4-D,³⁸ and increasingly intractable weeds resistant to multiple herbicides.³⁹

Earlier this year the World Health Organization's International Agency for Research on Cancer concluded that glyphosate is probably carcinogenic to humans,⁴⁰ and that 2,4-D is possibly carcinogenic.⁴¹ 2,4-D is linked to higher risk of cancer, Parkinson's disease, and developmental disorders, and is also an environmental toxin.⁴² Increased spraying of 2,4-D-resistant crops will exacerbate

Scott Kilman, *Superweed outbreak triggers arms race*, Wall Street Journal, June 4, 2010, available at <http://goo.gl/Fcolxd>.

³⁸ USDA, *Final Environmental Impact Statement for Determinations of Nonregulated Status for 2,4-D-Resistant Corn and Soybean Varieties*, at 134 (August 2014), available at <http://goo.gl/lbXjeX>.

³⁹ Brandon Keim, *New generation of GM crops put agriculture in a 'crisis situation'*, Wired, Sept. 25, 2014, <http://goo.gl/ejbTLF>.

⁴⁰ World Health Organization, *IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides* (March 20, 2015), available at <http://goo.gl/KRhWNX>.

⁴¹ World Health Organization, *ARC Monographs evaluate DDT, lindane, and 2,4-D* (June 23, 2015), available at <http://goo.gl/XMqbVY>.

⁴² Leah Schinasi & Maria E. Leon, *Non-Hodgkin Lymphoma and Occupational Exposure to Agricultural Pesticide Chemical Groups and Active Ingredients: A Systematic Review and Meta-Analysis*, 11 Int'l J. Env'tl. Res. & Pub. Health 4449, 4520 (2014), available at <http://goo.gl/ZHXv5O> (finding that 2, 4-D may be

these impacts. GE crops resistant to multiple herbicides are the industry's major research and development focus, the future of agricultural biotechnology.⁴³

The extraordinary use of pesticides associated with GE crops has had profound consequences. For example, the massive use of glyphosate with Roundup Ready crops has contributed to an alarming decline in the monarch butterfly.⁴⁴ Monarch caterpillars feed only on milkweed plants, once common in corn and soybeans fields. Glyphosate has nearly eradicated milkweed from Midwest cropland, the monarchs' major breeding range, depriving monarch caterpillars of their chief food source.⁴⁵ As a result, the Fish and Wildlife Service

carcinogenic to humans); Caroline M. Tanner, *Occupation and Risk of Parkinsonism*, 66 JAMA Neurology 1106, 1112 (2009), available at <http://goo.gl/InPR87>; Vincent F. Garry, *Pesticide Applicators, Biocides, and Birth Defects in Rural Minnesota*, 104 *Envtl. Health Persp.* 394, 394 (1996), available at <http://goo.gl/HdxSk6>.

⁴³ Emily Waltz, *Glyphosate resistance threatens Roundup hegemony*, 28 *Nature Biotech.* 537-538 (2010), available at <http://goo.gl/Q8BawF>.

⁴⁴ Richard Coniff, *Tracking the causes of sharp decline of the monarch butterfly*, *Yale Environment* 360, Apr. 1, 2013, <http://goo.gl/EBCU33>; J.M. Pleasants, K.S. Oberhauser, *Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population*, 6 *Insect Conservation and Diversity*, 135-144 (2013), available at <http://goo.gl/jHa0nB>.

⁴⁵ Josephine Marcotty, *Calling all milkweed: Federal pollinator plan needs a billion plants for monarch butterflies*, *Minneapolis Star-Tribune*, June 6, 2015, <http://goo.gl/tzzqzP>.

recently concluded that Endangered Species Act protection may be warranted for Monarchs. 79 Fed. Reg. 78,775-78,778 (December 31, 2014).

Glyphosate is also a leading culprit in herbicidal drift injury to sensitive crops,⁴⁶ and also injures wild plants that many other organisms depend upon for food and/or habitat. Glyphosate is frequently detected in the air, rain, and water bodies of the Midwest and South.⁴⁷ Glyphosate-containing Roundup formulations are extremely toxic to tadpoles and frogs, and likely have contributed to the worldwide decline in frog populations.⁴⁸

B. Transgenic Contamination.

Another adverse impact of GE crops recognized by Act 120's findings is transgenic contamination—the unintended, undesired presence of transgenic material in organic or traditional crops, as well as wild plants. *See* Act 120 Sec.

⁴⁶ Assoc. of Am. Pesticide Control Officials, *2005 Pesticide Drift Enforcement Survey Report*, <http://goo.gl/79OliK>.

⁴⁷ Feng-Chih Chang et al., *Occurrence and Fate of the Herbicide Glyphosate and its Degradate Aminomethylphosphonic Acid in the Atmosphere*, 30 *Envtl. Toxicology & Chemistry* 548, 548-50 (2011), available at <http://goo.gl/bZZTve>; Richard H. Coupe et al., *Fate and Transport of Glyphosate and Aminomethylphosphonic Acid in Surface Waters of Agricultural Basins*, 68 *Pest. Mgmt. Sci.* 16, 16-17 (2012), available at <http://goo.gl/WSvHO2>.

⁴⁸ Rick A. Relyea, *The Lethal Impact of Roundup on Aquatic and Terrestrial Amphibians*, 15 *Ecological Adaptions* 1118, 1120-23 (2005), available at <http://goo.gl/ZjYiHG>.

1(4)(D)-(E). Transgenic contamination happens through, among other means, wind- or insect-mediated cross-pollination, seed mixing, faulty or negligent containment, and weather events. *Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624, at *4 (N.D. Cal. Feb. 13, 2007) (“Biological contamination can occur through pollination of non-genetically engineered plants by genetically engineered plants or by the mixing of genetically engineered seed with natural, or non-genetically engineered seed.”).⁴⁹

Harm from transgenic contamination manifests several ways. As the U.S. Supreme Court has explained, this “injury has an environmental as well as an economic component.” *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 155 (2010). The agronomic injury causes significant economic damage to farmers: Over the past decade, transgenic contamination has cost U.S. farmers literally billions of dollars in rejected sales, lost exports, and closed agricultural markets,⁵⁰ with new episodes cropping up regularly.⁵¹

⁴⁹ Michelle Marvier & Rene C. Van Acker, *Can Crop Transgenes Be Kept on a Leash?*, 3 *Frontiers Ecology & Env't* 99, 100-01 (2005), available at <http://goo.gl/m2K6rS>.

⁵⁰ Andrew Harris, *Bayer Agrees to Pay \$750 Million to End Lawsuits Over Gene-Modified Rice*, Bloomberg, July 2, 2011, <http://goo.gl/ymErOa>; K.L. Hewlett, *The Economic Impacts of GM Contamination Incidents on the Organic Sector* (2008), available at <http://goo.gl/jf2F5E>; Stuart Smyth et al., *Liabilities & Economics of Transgenic Crops*, 20 *Nature Biotech.* 537, 537 (2002), available at

Additionally, contamination can be irreparable, because once it occurs, it becomes difficult or impossible to contain, resulting in a fundamental loss of choice for farmers and consumers. *See, e.g., Geertson Seed Farms*, 2007 WL 518624, at *9 (“For those farmers who choose to grow non-genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop.”); *Ctr. for Food Safety v. Vilsack*, No. C 08-00484 JSW, 2009 WL 3047227, at *8 (N.D. Cal. Sept. 21, 2009). Unlike chemical pollution, transgenic contamination can propagate itself over space and time via gene flow. *Geertson Seed Farms*, 2007 WL 518624, at *5 (“Once the gene transmission occurs and a farmer’s seed crop is contaminated with the Roundup Ready gene, there is no way for the farmer to remove the gene from the crop or control its further spread.”).⁵² And the risk of contamination itself creates costly burdens for organic and conventional farmers

<http://goo.gl/KeDRPX>; Carey Gillam, *U.S. Organic Food Industry Fears GMO Contamination*, Reuters, Mar. 12, 2008, <http://goo.gl/nkC52J>.

⁵¹ Tom Polansek, *China rejections of GMO U.S. corn cost up to \$2.9 billion*, Reuters, Apr. 16, 2014, <http://goo.gl/5Nc6Ub>.

⁵² Rachel Bernstein, *Study Details Wild Crop of Genetically Modified Canola*, Pittsburgh Post-Gazette, Aug. 14, 2010, <http://goo.gl/GrfjcK>.

and businesses, such as the need for DNA testing or crop buffer zones. *Monsanto*, 561 U.S. at 154.

Additionally, escape of transgenes into related wild plant populations is, in most cases, irreparable. Oregon, for example, continues the Sisyphean task of trying to find and destroy feral populations of Monsanto's Roundup Ready GE bentgrass that escaped field trials there over a decade ago. *Int'l Ctr. for Tech. Assessment v. Johanns*, 473 F. Supp. 2d 9, 13, 29 (D.D.C. 2007).⁵³

Transgenic contamination incidents have not been limited to a single crop; corn, rice, canola, alfalfa, grasses, and other crops have all been contaminated. In 2008, the U.S. Government Accountability Office (GAO) analyzed several major contaminations, found that they had caused over a billion dollars in damages,⁵⁴ and concluded that "the ease with which genetic material from crops can be spread makes future releases likely." *Id.* at 3.

⁵³ Mitch Lies, *Bentgrass Eradication Plan Unveiled*, Capital Press, June 16, 2011, <http://goo.gl/JIQwms>; Mitch Lies, *Feds Mum on GMO Spread*, Capital Press, Nov. 18, 2010, <http://goo.gl/NN5FR1>.

⁵⁴ U.S. Gov't Accountability Office, *Genetically Engineered Crops: Agencies Are Proposing Changes to Improve Oversight, But Could Take Additional Steps to Enhance Coordination and Monitoring*, at 1, 14-16, 44 (Nov. 2008) available at <http://goo.gl/tjBJEd>.

C. Industry's Claims of GE Crop Yield Increases Are Baseless.

Juxtaposed against these significant adverse impacts, independent studies have concluded that GE crops have not resulted in yield increases, whereas traditional breeding has increased yields.⁵⁵ A 2014 USDA report summarizing GE crop production stated: “over the first 15 years of commercial use, GMO seeds have not been shown to definitively increase yield potentials, and in fact, the yields of herbicide-tolerant or insect-resistant seeds may be occasionally lower than the yields of conventional varieties.”⁵⁶

Nor have GE crops benefited farmers financially: USDA's report goes on to say that several researchers have found “no significant differences” between the net financial returns to farmers who use GE crops and those who use traditional.⁵⁷ Contrary to Appellants' claims, GE crop adoption by farmers is attributable to several factors, including that pesticide/chemical companies have acquired a

⁵⁵ Doug Gurian-Sherman, Union of Concerned Scientists, *Failure to Yield: Evaluating the Performance of Genetically Engineered Crops*, at 1-5 (April 2009), available at <http://goo.gl/Y7xNIA>; Jack A. Heinemann, *Reply to comment on sustainability and innovation in staple crop production in the US Midwest*, Int'l J. of Ag. Sustainability, 12:4, 387-390 (2014), available at <http://goo.gl/GruWvv>.

⁵⁶ USDA, *Genetically Engineered Crops in the United States*, at 12, 41 (Feb. 2014) available at <http://goo.gl/iV9rX3>.

⁵⁷ *Id.* at 22.

substantial portion of the world's seed firms and leave farmers with little choice in the marketplace, and the high risk of being contaminated, even if they were to choose traditional.⁵⁸

D. USDA Oversight Is Wholly Inadequate.

Appellants and their amici also trumpet U.S. Department of Agriculture (USDA) oversight, the main federal agency overseeing GE crops' impacts, yet, in reality USDA oversight is exceedingly weak. While USDA does formally “deregulate,” or approve, some GE crops before commercialization (unlike FDA), GE crop developers increasingly evade USDA regulation entirely by genetically engineering plants without inserting transgenes from a listed “plant pest” such as *Agrobacterium*. See 7 C.F.R. Part 340, *id.* § 340.2. USDA has declared these GE crops beyond its authority, and thus they receive no federal oversight.⁵⁹

For those GE crops USDA does regulate, it has adopted an extremely narrow interpretation of its authority. Based on this self-cabined view, the agency has

⁵⁸ Hubbard, K., *Out of Hand: Farmers Face the Consequences of a Consolidated Seed Industry*, National Family Farm Coalition (Dec. 2009), available at <http://goo.gl/0IyPEX>; Philip H. Howard, *Visualizing Consolidation in the Global Seed Industry: 1996-2008*, 1 Sustainability 1266-1287 (2009) available at <http://goo.gl/Ty52va>.

⁵⁹ See, e.g., USDA APHIS, *Regulated Letters of Inquiry*, <http://goo.gl/qDnTId>; USDA, *Am I Regulated?*, <http://goo.gl/D6E4Le>; Andrew Pollack, *U.S.D.A. Ruling on Bluegrass Stirs Cries of Lax Regulation*, N.Y. Times, July 6, 2011, <http://goo.gl/9e2ah1>.

simultaneously acknowledged the significant harms of GE crops—in the form of transgenic contamination and increased pesticide use—but refused to regulate them to ameliorate those harms. *Ctr. for Food Safety*, 718 F.3d at 841 (recognizing the impacts of transgenic contamination and increased herbicide use from the USDA approval of Roundup Ready alfalfa, but affirming USDA’s refusal to regulate the crop based on those harms because they were not “plant pest” harms).

Courts have repeatedly found USDA management of GE crops inadequate and unlawful. *See, e.g., CFS v. Johanns*, 451 F. Supp. 2d 1165, 1182-85 (D. Haw. 2006) (USDA’s approval of GE crop experimental field tests violated environmental laws, describing USDA’s arguments as “utterly without merit,” its actions as evincing “utter disregard,” and constituting an “unequivocal violation of a clear congressional mandate,” and “abdication” of its responsibilities); *ICTA*, 473 F. Supp. 2d at 29 (vacating USDA approval of another GE crop experimental field trial, finding the record “devoid of any evidence” that USDA had analyzed environmental risks); *Geertson Seed Farms*, 2007 WL 518624, at **7, 10 (N.D. Cal. Feb. 17, 2007) (In a GE crop approval, finding USDA’s attitude toward risk assessment as “cavalier,” and concluded that USDA “simply ignore[d]” the risks in question or “refused” to analyze them); *CFS v. Vilsack*, 734 F. Supp. 2d 948, 953 (N.D. Cal. 2010) (vacating another GE crop approval as unlawful, finding USDA’s position showed an “apparent perception that conducting the requisite

comprehensive review is a mere formality, caus[ing] some concern that Defendants are not taking this process seriously”). Remarkably, in approving dozens of transgenic crops planted on millions of acres, USDA had never analyzed their impacts under the National Environmental Policy Act’s requirements for an Environmental Impact Statement until required to do so by court orders. *Geertson Seed Farms*, 2007 WL 518624; *CFS*, 2009 WL 3047227.

Supplemental oversight by EPA (the third federal agency with authority to regulate GE crops) also has proved exceedingly weak: EPA reviews only a small subset of GE crops that produce their own pesticides, provides no oversight of pesticide-resistant superweeds, and fails to analyze GE crop-specific changes to pesticide use. Thus it is left to states and counties to regulate the adverse environmental and agronomic impacts of GE crops. *See, e.g., Schulz v. Jackson County*, No. 14–cv–01975, 2015 WL 3448069 (D. Or. May 29, 2015) (upholding Oregon county ordinance prohibiting the growing of GE crops in order to protect farmers from transgenic contamination). In sum, labeling allows consumers to decide if they wish to avoid supporting the significant environmental and agronomic degradation that GE crop production causes, and states have a substantial interest in providing their citizens that information.

IV. Vermont's Interests in Ameliorating Potential Consumer Deception and Confusion.

Finally, for over a century the Supreme Court has emphasized the importance of allowing states to protect their citizens from fraud and deception, especially in food products. *Plumley v. Massachusetts*, 155 U.S. 461, 472 (1894). Where, as here, the omission of information would potentially result in consumer confusion or deception, courts have upheld mandated factual disclosures. *Milavetz, Gallop & Milavetz, P.A. v. U.S.*, 559 U.S. 229, 249-253 (2010); *Spirit Airlines, Inc. v. U.S. Dept. of Transp.*, 687 F.3d 403, 413-415 (D.C. Cir. 2012); *U.S. v. Wenger*, 427 F.3d 840, 849-851 (10th Cir. 2005). This type of interest is not the *sin qua non* of *Zauderer* review, see, e.g., *Nat'l Elec. Mfrs.*, 272 F.3d at 115, but even if it was, Vermont has such interests here. As Act 120 found, polls show that “many consumers are under an incorrect assumption about whether the food they purchase is produced from genetic engineering.” Act 120, Sec. 1(5)(B). Further, under *Zauderer* review, a disclosure need only relate to a non-speculative “likelihood of deception,” or a “tendency to mislead.” *Milavetz*, 559 U.S. at 251; *Zauderer*, 471 U.S. at 652–53.

There is little question that the omission of GE labeling is misleading and confusing to consumers. While approximately 80% of processed foods contain GE ingredients, a 2013 New York Times poll (cited in the Act 120 findings), found that less than half of Americans are aware that such a large percent of processed

foods contain GE ingredients.⁶⁰ Other surveys have found that over half of Americans are unaware that GE foods are currently sold in grocery stores, and even fewer (25%) believe they have ever eaten GE food.⁶¹ Only about a quarter of Americans realize that current national regulations do not require labeling of GE foods.⁶² Among the half who are aware of the presence of GE food in stores, there is significant (40%) confusion over which foods are genetically engineered, including mistaken beliefs that some foods are GE which are not.⁶³ Hence the failure to label a food as genetically engineered demonstrably leads to consumer confusion and deception as to which foods are genetically engineered, harms that Act 120's mandated labeling disclosures are aimed at alleviating.

CONCLUSION

For the foregoing reasons, the district court should be affirmed.

⁶⁰ Allison Kopicki, *Strong Support for Labeling Modified Foods*, N.Y. Times, July 27, 2013 (Dist. Ct. Dkt. 64-5 at 18); Act 120, Section 1(5)(B).

⁶¹ The Pew Initiative on Food and Biotechnology, *Recent Findings: Americans Continue to Know Relatively Little About Genetically Modified Foods And Biotechnology* at 2 (Nov. 7, 2005), available at <http://goo.gl/5zKng6>; William K. Hallman et al., *Public Perceptions of Labeling Genetically Modified Foods: Working Paper 2013-01* at 3-4, Rutgers (2013), available at <http://goo.gl/B5aqdD>.

⁶² Hallman et al., *supra* note 61, at 4.

⁶³ *Id.* at 4-5; Kopicki, *supra* note 60.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), this brief contains 7,000 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), according to the word count feature of Microsoft Word 2010, and therefore complies with the 7,000 word limit for amicus briefs.

I further certify that this Brief complies with the Times New Roman 14-point font typeface requirements under Fed. R. App. P. 32(a)(5) and the type style requirements under Fed. R. App. P. 32(a)(6).

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