

No. 15-16466

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UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT

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ALIKA ATAY, *et al.*,  
Plaintiffs-Appellants,

v.

COUNTY OF MAUI, *et al.*,  
Defendants-Appellees.

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF HAWAI‘I  
Case No. 1:14-cv-00582-SOM-BMK

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No. 15-16552

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UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT

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ROBERT ITO FARM, INC., *et al.*,  
Plaintiffs-Appellees,

v.

COUNTY OF MAUI,  
Defendant-Appellee,

and

ALIKA ATAY, *et al.*,  
Intervenor-Defendants-Appellants.

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF HAWAI‘I  
Case No. 1:14-cv-00511-SOM-BMK

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**BRIEF OF AMICUS CURIAE CENTER FOR FOOD SAFETY,  
MOMS ON A MISSION (MOM) HUI, MOLOKA‘I MAHI‘AI, AND GERRY  
ROSS IN SUPPORT OF APPELLANTS AND SEEKING REVERSAL OF  
DISTRICT COURT**

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**CORPORATE DISCLOSURE STATEMENT**

Amicus Curiae Center for Food Safety, a non-profit corporation, has no parent corporations, and does not issue stock.

Dated: December 7, 2015

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## INTERESTS OF AMICI CURIAE<sup>1</sup>

Amicus Center for Food Safety (CFS) is a nonprofit whose mission is to empower people, support farmers, and protect the earth from the adverse impacts of industrial agriculture. CFS is the leading U.S. public interest organization working on the issue of genetically engineered organisms. *See* Mot. Leave File Amicus Br. (filed concurrently). Amicus Gerry Ross is a Maui organic farmer who faces pesticide damage and transgenic contamination of his organic crops from genetically engineered crop operations on the island. Amici Moloka‘i Mahi‘ai and Moms On A Mission (MOM) Hui are grassroots organizations of local farmers, food producers, beekeepers, residents, and concerned mothers that live and work on the island of Moloka‘i, the part of Maui County most affected by Appellees’ (Chemical Companies) genetically engineered crop facilities. *See id.*

Amici will provide insight into the specialized legal, scientific, and factual context of genetically engineered crops, aiding this Court’s review.

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<sup>1</sup> 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. Fed. R. App. P. 28(c)(5).

## I. GENETICALLY ENGINEERED CROPS

Genetically engineered (GE) crops have been very controversial since their introduction. One reason is that while traditional plant breeding involves identifying genetically similar plants with useful traits and crossing them, genetic engineering allows scientists to combine genetic material from widely dissimilar, unrelated organisms, producing combinations of genetic material that cannot occur in nature.<sup>2</sup> Another is that the U.S. has never passed a law specifically to regulate GE organisms, their production, or food products created from them, instead applying pre-existing laws, leaving significant oversight gaps.<sup>3</sup> Other reasons include the failure to label GE food products in the U.S., and health unknowns; the Food and Drug Administration makes no finding, and undertakes no independent assessment, of their food safety.<sup>4</sup> But this case, and the two related Hawai‘i

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<sup>2</sup> Allison Snow, *Genetic Engineering: Unnatural Selection*, 424 *Nature* 619 (2003), available at <http://goo.gl/Fn6hs3>, cited in the Brief of Amicus Curie Dr. Ramon J. Seidler, Dr. Jack Heinemann, Dr. David Schubert, Dr. Allison K. Wilson, Dr. Jonathan Latham, National Family Farm Coalition, Our Family Farms Coalition, Sierra Club, and Center for Food Safety, in Support of the State of Vermont, No. 15-1504, 2015 WL 5168442, \*8 (2nd Cir. Aug. 31, 2015) (hereafter Scientists’ Vermont Brief) (Attached as Exhibit A for the Court’s convenience).

<sup>3</sup> George Kimbrell, *State-Mandated Labeling of Genetically Engineered Foods*, 39 *Vermont L. Rev.* 342, 360-362 and n.114-124 (2014) (summarizing academic critiques of federal oversight).

<sup>4</sup> Scientists’ Vermont Brief, *supra* note 2, at \*12-18 and citations therein.

ordinance cases, concern another major reason for the controversy: the significant adverse agronomic, environmental, and health impacts of GE crops' production.<sup>5</sup>

**A. A Pesticide-Promoting Technology.**

The vast majority of GE crops are engineered to produce insecticides and/or withstand direct application of herbicides, two subtypes of pesticides.<sup>6</sup> Nearly all herbicide-resistant crops are Monsanto's "Roundup Ready" varieties, engineered with to resist glyphosate, the active ingredient in Roundup herbicide. *Center for Food Safety (CFS) v. Vilsack*, 718 F.3d 829, 836 (9th Cir. 2013) (describing Monsanto's Roundup Ready "crop system" of the GE crop and associated herbicide).<sup>7</sup> Overall, from 1996 to 2011, an *extra 527 million pounds* of herbicides were sprayed in U.S. agriculture because of GE crops.<sup>8</sup>

The extraordinary pesticide use associated with GE crops has had profound consequences.<sup>9</sup> Glyphosate is frequently detected in the air and water bodies of the U.S., is a leading culprit in pesticide drift injury to crops and wild plants, and a

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<sup>5</sup> *Id.* at \*19-26.

<sup>6</sup> *Id.* at \*19.

<sup>7</sup> *Id.* and n.31-34.

<sup>8</sup> *Id.* and n.35.

<sup>9</sup> *Id.* at \*20-23.

contributing factor in the alarming declines of frogs and monarch butterflies, among other species.<sup>10</sup> Roundup Ready crops are also responsible for an epidemic of “superweeds” that have evolved resistance to glyphosate across 70 million acres in the United States, costing farmers approximately \$1 billion so far.<sup>11</sup> GE crops “stacked” with resistance to multiple herbicides are the industry’s major research and development focus, such as those engineered to also resist Agent Orange component 2,4-D and the closely-related dicamba; these will further vastly increase herbicide use.<sup>12</sup> And as a recent New England Journal of Medicine article concluded, in addition to environmental impacts, “GM foods and the herbicides applied to them may pose hazards to human health that were not examined in previous assessments.”<sup>13</sup>

#### **B. Transgenic Contamination.**

GE crops also contaminate traditional crops and wild plants, through wind- or insect-mediated cross-pollination, seed mixing, faulty or negligent containment, weather events, and other means. *Geertson Seed Farms v. Johanns*, No.

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<sup>10</sup> *Id.* at \*21-23.

<sup>11</sup> *Id.* at \*20.

<sup>12</sup> *Id.* at \*21-22 and n.36-43.

<sup>13</sup> *Id.* at \*16 and n.23.

C 06-01075, 2007 WL 518624, at \*4 (N.D. Cal. Feb. 13, 2007).<sup>14</sup> This “injury has an environmental as well as an economic component.” *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 155 (2010). Transgenic contamination has cost U.S. farmers billions of dollars in rejected sales, lost exports, and closed agricultural markets.<sup>15</sup> Further, once it occurs, it becomes difficult or impossible to contain, depriving farmers and consumers of the ability to choose what they eat and grow.<sup>16</sup> *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.”); *CFS v. Vilsack*, No. C 08-00484, 2009 WL 3047227, at \*8 (N.D. Cal. Sept. 21, 2009). The risk of contamination itself creates costly burdens for organic and traditional farm businesses, such as DNA testing or crop buffer zones. *Monsanto*, 561 U.S. at 154.

Escape of transgenes into related wild plant populations also is irreparable. Oregon continues to find and destroy feral populations of Monsanto’s Roundup

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<sup>14</sup> *Id.* at \*23-26 and n.49-54.

<sup>15</sup> *Id.* at \*24.

<sup>16</sup> *Id.* at \*25.

Ready 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).<sup>17</sup>

Corn, rice, canola, alfalfa, and other crops have all been contaminated. The U.S. Government Accountability Office (GAO) analyzed several major contaminations and concluded that “the ease with which genetic material from crops can be spread makes future releases likely.”<sup>18</sup>

### **C. USDA’s Inadequate Oversight, GE-Free Zones, and Hawai‘i.**

Courts have repeatedly found USDA management of GE crops inadequate and unlawful.<sup>19</sup> Most relevant to federal preemption, the U.S. Department of Agriculture has adopted an extremely narrow interpretation of its authority over GE crops, and based on this view, has simultaneously acknowledged GE crops’ significant harms—in the form of transgenic contamination and increased pesticide use—but refused to regulate to ameliorate those harms, concluding they are not “plant pest” harms. This Court has affirmed that agency interpretation. *CFS*, 718 F.3d at 841.

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<sup>17</sup> *Id.* at \*26 and n.53.

<sup>18</sup> *Id.* at \*26 and n.54.

<sup>19</sup> *Id.* at \*29-30 (citing and summarizing caselaw).

States and counties have stepped into this breach to address GE crops' adverse environmental and agronomic impacts to protect their farmers and environments, creating "GE-free" zones in many states, including California, Oregon, and Washington.<sup>20</sup> These are important safe harbors, providing an alternative to the currently-dominant GE agricultural paradigm in the United States.

Hawai'i has embraced this movement, with three counties in 2013-2014 passing such ordinances. The health and environmental impacts of GE crop production in Hawai'i are particularly severe.<sup>21</sup> On the one hand, it is a small state, where the trade winds carry pesticides and GE pollen to schools, homes, and gardens abutting agricultural fields. On the other, Hawai'i is home to the Chemical Companies' major research and development fields, where they grow GE crops all

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<sup>20</sup> Mendocino County, Cal., Cty. Code § 10A.15 (2004); Marin County, Cal., Cty. Code § 6.92 (2004); Trinity County, Cal., Cty. Code § 8.25 (2004); Santa Cruz County, Cal., Cty. Code § 6.10 (2004); San Juan County, Wash., Cty. Code § 8.26 (2012); Humboldt County, Cal., Genetic Contamination Prevention Ordinance (2014); Jackson Co., Ore., Ordinance 635 (2014); Josephine Co., Ore., Ordinance 2014-007 (2014).

<sup>21</sup> CFS, *Pesticides in Paradise: Hawai'i's Health & Environment at Risk*, <http://goo.gl/SWIpti>; Christopher Pala, *Pesticides in Paradise*, *The Guardian*, August 23, 2015, <http://goo.gl/NRlczd>.



year, and spray unique cocktails of pesticides on pesticide-resistant crops, at a far higher rate than in any other state.<sup>22</sup>

### ARGUMENT

This is the third Hawai‘i case currently before this Court presenting these same preemption issues. *Syngenta Seeds, Inc. v. County of Kaua‘i*, Nos. 14-16833, 14-16848 (9th Cir. 2014); *Hawai‘i Papaya Indus. Ass’n. v. Cty. of Hawai‘i*, Nos. 14-17538; 15-15020 (9th Cir. 2015). Amici respectfully point the Court to their briefing in the two prior cases for longer treatment than space here allows.

Intervenor-Defendants-Appellants’ Opening Br., *Syngenta Seeds, Inc.*, Nos. 14-16833, 14-16848 (9th Cir. Jan. 2, 2015), ECF No. 9-1; Intervenor-Defendant-Appellants’ Reply Br., *Syngenta Seeds, Inc.*, Nos. 14-16833, 14-16848 (9th Cir. May 11, 2015), 2015 WL 2265299; Defendant-Appellant’s Principal Br., *Hawai‘i Papaya Indus. Ass’n.*, Nos. 14-17538; 15-15020 (9th Cir. May 4, 2015), ECF No. 19-1; Defendant-Appellant’s Reply Br., *Hawai‘i Papaya Indus. Ass’n.*, Nos. 14-17538; 15-15020 (9th Cir. Oct. 1, 2015), 2015 WL 5920107.<sup>23</sup>

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<sup>22</sup> *Id.*

<sup>23</sup> See also Laura Murphy, *Seeking Pure Fields: The Case Against Federal Preemption of State Bans on Genetically Engineered Crops*, 49 U.S.F.L. Rev. 503 (2015).

## I. FEDERAL LAW DOES NOT PREEMPT THE ORDINANCE

The district court erred in finding federal preemption by a statute that does not even address genetically engineered crops, applied by an agency that does not address their adverse impacts. And it is important to understand the far-reaching nature of the lower court's error: its sweeping rationale would preempt any county *or even any state* oversight of GE crops differing from USDA's regulation—or lack thereof. Over 130 state statutes, regulations, and county ordinances in 43 states currently regulate GE crops to some extent, which could all be negated.<sup>24</sup>

### A. The PPA Does Not Expressly Preempt Maui's Ordinance.

First, the district judge conflated (1) commercialized, or “deregulated,” GE crops and (2) experimental “regulated article” GE crops for express preemption analysis. Not even the Chemical Companies made this error, having raised express

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<sup>24</sup> Based on review of Westlaw search for state statutes and regulations containing the phrase “genetically engineered” or “genetically modified.” *See* WestlawNext, <https://a.next.westlaw.com/> (enter “advanced: (‘genetically engineered’ ‘genetically modified’)” in the search bar and select “All States,” then filter by “Statutes” or “Regulations.”) (last visited Dec. 7, 2015). For example, in Minnesota, the “Genetically Engineered Organisms Act” gives the state agriculture department the power to require, condition, and deny GE crop planting permits, in order “to protect humans and the environment from the potential for significant adverse effects of those releases.” Minn. Stat. Ann. §§ 18F.01, 18F.07. An Arizona regulation authorizes that state’s agriculture department to restrict or deny a permit for GE crop cultivation, requiring permit applicants to demonstrate various safeguards the state decides, “in addition to USDA’s requirements.” Ariz. Admin. Code § R3-4-901. *See also supra* n.20 (listing county ordinances).

preemption as to only regulated articles, but not commercial crops. 5ER 1126-33. This distinction has tremendous practical importance because, while “regulated article” field trials are more concentrated in Hawai‘i than other states, commercial GE crop acreage dwarfs field trial acreage nationally.

The district court grossly erred in applying the Plant Protection Act’s (PPA’s) express preemption provision to commercial GE crops. Among other prerequisites, the PPA’s preemption provision requires that USDA be regulating a plant as a “plant pest” or “noxious weed” and have “issued an order to prevent the dissemination” of that plant. 7 U.S.C § 7756(b)(1). Yet the USDA’s deregulation decisions commercializing GE crops under 7 C.F.R. § 340.6 are the *exact opposite* of what Section 7756(b)(1) requires: in deregulation, USDA (1) determines that a GE crop is definitively *not* a plant pest, and (2) *allows* its commercialization without any further restrictions or monitoring. *CFS*, 718 F.3d at 835, 842 (“[O]nce APHIS concluded that [the GE plant] was not a plant pest because it did not cause plant pest injury to plants, the agency had no jurisdiction to continue regulating the crop.”).

Unlike the district court here, the lower court in the County of Hawai‘i’s case properly distinguished between regulated articles and commercial crops, noted that the Chemical Companies did not bring an express preemption claim to commercial crops, only an implied “obstacle” preemption claim, and then rejected

that implied preemption claim in its entirety. *Hawai‘i Floriculture and Nursery Ass’n v. County of Hawai‘i*, No. 14-00267, 2014 WL 6685817, \*7, \*10 (D. Haw. Nov. 26, 2014). The Chemical Companies dropped their cross-appeal of that decision. Order, *Hawai‘i Floriculture and Nursery Ass’n*, No. 14-17538 (9th Cir. Aug. 18, 2015), ECF No. 40.

The district court also erred in finding the PPA’s express preemption clause applies to experimental GE crop field trials. Section 7756(b)(1) is narrowly drafted and has numerous missing prerequisites. Each is a necessary precondition, but not alone sufficient, for preemption.

*First*, the provision applies only to some regulation of “plant pests” and “noxious weeds,” and experimental GE crops are neither—they are “regulated articles.” *Compare* 7 C.F.R. § 340.1 (definitions). The lower court erred in assuming regulated articles are *ipso facto* plant pests, but their definitions show the difference. Regulated articles are GE crops that the agency has “reason to believe” *might* present a plant pest risk, but has not determined do so. *Id.* 73 Fed. Reg. 60008, 60009 (October 9, 2008) (“Regulated articles are essentially GE organisms which might pose a risk as a plant pest.”). This presumption is usually based on the fact that genetic engineering is typically performed using genes from *agrobacterium*, a plant pest organism. The “regulated article” classification allows USDA to control GE crops’ dissemination while their pest status is determined.

As this Court explained, USDA does not normally make a ‘plant pest-no plant pest’ decision until the later, petition for deregulation stage. *CFS*, 718 F.3d at 835 (“When such a [deregulation] petition is filed, the agency determines whether a presumptive plant pest is an actual plant pest within the meaning of the term in the PPA”). A regulated article could theoretically be a plant pest, if USDA determines it is. But USDA’s deregulation record is revealing: USDA has *never* determined that a GE crop is a plant pest; of the 117 applications for deregulation since 1992, USDA has granted all of them, finding that none were plant pests.<sup>25</sup> Nor has the agency ever declared a GE crop to be a noxious weed, and restricted it on those grounds. 7 C.F.R. Part 360.200 (listing all federal noxious weeds).

Thus, unless USDA finds a particular regulated article to be an actual plant pest, the preemption provision cannot apply. This is what the court held in *Hawai‘i Floriculture and Nursery Ass’n.*, 2014 WL 6685817 at \*8 n.7 (holding that “not every regulated article is a plant pest or noxious weed,” and the provision is satisfied only “to the extent a regulated article is a plant pest or noxious weed”); *id.* at \*9 (“Conversely, the Ordinance’s ban on field testing of plants that are not

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<sup>25</sup> USDA, *Petitions for Determination of Nonregulated Status*, [http://www.aphis.usda.gov/biotechnology/petitions\\_table\\_pending.shtml](http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml).

plant pests or noxious weeds regulated under Part 340 is not preempted by the PPA”).

The only other court to address PPA preemption held similarly. Farmers have responded to transgenic contamination episodes costing them rejected sales and closed markets with state-law-based class action litigation, and PPA preemption of those claims has been rejected, even if the contaminating GE crop was a regulated article. *In re Genetically Modified Rice Litig.*, No. 4:06-MD-01811-CDP, 2011 WL 339168, \*2 (E.D. Mo. Feb. 1, 2011) (rejecting PPA preemption defense because “Bayer has not shown that its genetically modified rice constitutes a ‘plant pest’ under the statute”).

*Second*, the preemption provision takes into account the local law’s intent, by including the words “in order to,” 7 U.S.C. § 7756(b)(1); Maui’s Ordinance does not regulate “in order to” address “plant pests” or “noxious weeds,” but to address GE crops. The difference between these purposes is revealed by the harms Maui County intended to address: transgenic contamination and increased pesticide exposure. 1ER 014-16.

The lower court concluded that, because Maui acted to prevent transgenic contamination, it “inherently” must be acting to address a plant pest or noxious weed. 1ER 038. This was error, as this Court has held exactly the opposite, affirming USDA’s interpretation that transgenic contamination and GE crops’

pesticide impacts *are not* “*plant pest*” harms. *CFS*, 718 F.3d at 840 (USDA “has never classified a plant as a ‘plant pest’ based on such cross-pollination effects” because “it does not consider such alteration to be a plant pest harm within the meaning of the statute.”); *id.* at 841 (holding transgenic contamination is “not the result of plant pest harms as defined under the PPA” and explaining, as to GE crop pesticide impacts, “[t]he environmental harms the plaintiffs cite are not plant pest harms.”). Nor does USDA apply its noxious weed authority in its Part 340 GE crop process, *CFS*, 718 F.3d at 843, and it has never regulated a GE crop as a noxious weed. The lower court’s view cannot be reconciled with the controlling precedent.

*Third*, the provision applies only to regulation of “movement in interstate commerce,” 7 U.S.C. § 7756(b)(1), but experimental regulated articles cannot lawfully be “in commerce.” 7 C.F.R. §§ 340.0, .3-.4; *CFS v. Vilsack*, 636 F.3d 1166, 1169 (9th Cir. 2011). Also, the Ordinance regulates only *intra-county* planting, not “interstate” activity. 7 U.S.C. § 7702(7) (definition of “interstate commerce”). There is no basis to find Congressional intent that “movement in interstate commerce” should mean in-field, intra-county, experimental, non-commercial planting, contrary to the statute’s plain language. *FMC Corp. v. Holliday*, 498 U.S. 52, 57 (1990) (Courts assume the “ordinary meaning of the language accurately expresses the legislative purpose”).

The lower court repeatedly applies the wrong standard, relying on broader PPA language elsewhere (7 U.S.C. § 7701(9)), regarding actions that may “*affect*” interstate commerce, believing this was enough to preempt. 1ER 037, 042-43 (“Nor is the court persuaded by SHAKA’s argument that, because the Ordinance governs GE organisms only in Maui County, interstate commerce is not *affected*.”) (emphasis added). It missed the import of this difference: USDA’s overall authority is broad, but the preemption provision—using only “in” but not “affecting” interstate commerce—is intentionally narrower. Field trials of experimental regulated articles might “*affect*” interstate commerce, 7 U.S.C. § 7701(9), but they are not “*in*” it, *id* § 7756(b)(1).

**B. Federal Law Does Not Impliedly Preempt Maui’s Ordinance.**

The court’s implied preemption conclusion has no legal support. The PPA’s preemptive scope is circumscribed by its detailed preemption clause. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995). However, even applying implied preemption standards beyond the express provision’s scope shows the Chemical Companies’ “obstacle” arguments to be meritless. The touchstone to preemption claims is Congressional intent, *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1039 (9th Cir. 2015), which must be “clear and manifest,” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), and obstacle preemption requires a particularly “high threshold,” *Chamber of Commerce v. Whiting*, 131 S.Ct. 1968, 1985 (2011).



The only objectives relevant to obstacle preemption are those Congress established in the PPA, which does not speak to GE crops at all, let alone promote unbridled GE crop commercialization or planting. *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990) (explaining that the alleged “obstacle” must be to “the accomplishment and execution of the full purposes and objectives of Congress”). “Mere silence in this context cannot suffice to establish a ‘clear and manifest purpose’ to pre-empt local authority.” *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 607 (1991). Further, once GE crops are deregulated, they are completely unregulated at the federal level. *CFS*, 718 F.3d at 842. There is simply no federal law with which state or county regulation can conflict, or to which it can stand as an obstacle.

USDA’s GE crop regulations at 7 C.F.R. Part 340 do not have a preemption provision. Nor do they even implicitly reflect any Congressional purpose behind the PPA, because they were not promulgated pursuant to it: they were promulgated in the 1980s, 52 Fed. Reg. 22,908 (June 16, 1987) and last updated in the 1990s, *predating* the PPA of 2000. In fact, Congress never expressed any intention to apply USDA authority to GE crops at all; this was done by executive policy. *CFS*, 718 F.3d at 832 (citing Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986) (Coordinated Framework)). In any event, the Part 340 regulations cannot preempt local regulation of harms beyond their

authority, namely, non-plant-pest harms like transgenic contamination or increased pesticide exposures. *New York v. Fed. Energy Regulatory Comm'n*, 535 U.S. 1, 18 (2002) (“[A]n agency literally has no power to act, let alone preempt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it.”).

Finally, the Chemical Companies have alleged local regulation is an obstacle to federal goals stemming from the 1986 Coordinated Framework. Even if that were true, the framework cannot support preemption: it is a thirty-year-old *policy* document. *Fellner v. Tri-Union Seafoods*, 539 F.3d 237, 243 (3d Cir. 2008) (“[I]t is federal *law* which preempts contrary state law; nothing short of federal law can have that effect.”); *Found. on Econ. Trends v. Johnson*, 661 F. Supp. 107, 109 (D.D.C. 1986) (“The Framework ... [is] set forth to guide policymaking, not to regulate.”). The framework is also an *executive* branch policy document, neither established by, nor representing, any congressional purpose or directive. No statute’s language or legislative history even mentions the framework. Because the framework was not issued pursuant to any *congressional* delegation of authority, it is irrelevant to preemption analysis. The District of Vermont recently so held:

Plaintiffs’ reliance on a 1986 policy statement by the Office of Science and Technology Policy entitled “Coordinated Framework for Regulation of Biotechnology,” 51 Fed. Reg. 23,302 (June 26, 1986), is misplaced because the Coordinated Framework has no preemptive effect. *See Holk [v. Snapple Beverage Corp.]*, 575 F.3d 329, 341 (3rd Cir. 2009)] (observing that the “FDA’s policy statement” is “not

entitled to preemptive effect”). There also is no basis for finding the Coordinated Framework reflects *Congress’s* objectives with regard to the labeling of GE foods.

*Grocery Manufacturers Ass’n v. Sorrell*, No. 5:14–CV–117, 2015 WL 1931142, at \*21 (D. Vt. April 27, 2015).

In conclusion, a few years ago, public interest advocates were before this Court, arguing that USDA should regulate GE crops to address transgenic contamination and GE-crop-caused pesticide impacts. USDA disavowed authority to do so, and instead told this Court such impacts could be addressed through local regulations. Br. of Federal Appellees at 29, *CFS*, 718 F.3d 829 (9th Cir. June 6, 2012), 2012 WL 2313232 (cross-pollination risks “can be addressed by state and local regulations on planting”). This Court affirmed USDA’s view that USDA lacked authority over these impacts. *CFS*, 718 F.3d at 840-42. It would be beyond unjust for the Court to now find that states and counties still cannot regulate these impacts, despite the federal void, ensuring they are never addressed.

## II. HAWAI‘I LAW DOES NOT PREEMPT THE ORDINANCE

The district court concluded Hawai‘i law impliedly preempts the Ordinance based on the following reasoning:

(1) the Hawai‘i Department of Agriculture has general authority to regulate agricultural matters; and

(2) Hawai‘i has a quarantine law restricting entry of certain plant pests, and another regulating “noxious weeds,” which might allow the Department to some day regulate GE crops.

Finding implied preemption based on these factors is contrary to Hawai‘i law.

To establish Hawai‘i law impliedly preempts the Ordinance, the Chemical Companies had the burden to prove:

(1) Hawai‘i has a statute covering the *same subject matter* as the Ordinance;

(2) the statute is a *comprehensive statutory scheme*; and

(3) the legislature *intended* that statute to *exclusively* regulate the Ordinance’s subject matter.

*Pac. Int’l. Serv. Corp. v. Hurip*, 873 P.2d 88, 94 (Haw. 1994). The State’s intent to preempt is the “critical determination,” *id.* at 94, and it must be “clear.”

*Hawai‘i Gov’t Emp.’ Ass’n v. Maui*, 576 P.2d 1029, 1038 (Haw. 1978) (legislature must “clearly intend[] to preempt the field of regulation.”).

Absent proof of preemption, the County’s authority for the Ordinance is unassailable: the legislature gave it the power to “enact ordinances deemed necessary to protect health, life, and property” “on *any subject* or matter not inconsistent with, or tending to defeat, the intent of *any* state statute where the statute . . . disclose[s] an express or implied intent” to be exclusive throughout the state. H.R.S. § 46-1.5(13) (emphases added). The district court failed to identify any Hawai‘i statute meeting these requirements.

**A. Hawai‘i Law Does Not Address the Ordinance’s Subject Matter.**

GE crops are arguably the most controversial modern agricultural subject. Eight years ago, two Hawai‘i counties passed ordinances—never challenged—prohibiting certain GE crops.<sup>26</sup> Multiple bills seeking statewide regulation of such crops are introduced and debated every legislative session. A GE crop plainly is not regarded as just another plant.

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<sup>26</sup> Hawai‘i Cty. Code § 14-92 (“It shall be unlawful for any person to test, propagate, cultivate, raise, plant, grow, introduce or release genetically engineered (transgenic) or recombinant DNA taro (kalo).”); *id.* § 14-93 (same, for coffee); Maui Cty. Code § 20.38.030 (“It is unlawful for any person to test, propagate, cultivate, raise, plant, grow, introduce, transport, or release genetically engineered kalo.”).

Yet Hawai‘i has no law even mentioning them, nor any legislative history suggesting any intent to address them. The district court therefore posited the existence of a comprehensive regulatory scheme with a drastically-expanded “subject matter,” regulating all “plants that may harm agriculture, the environment, or the public.” 1ER 053. Hawai‘i courts analyzing implied preemption do not construe “same subject matter” in this expansive manner. Rather, they examine whether a particular statute occupies the ordinance’s field, defined narrowly and specifically. Even where there is some overlap, Hawai‘i courts examine closely whether there are any differences or state law gaps. When they find them, they conclude the state and county laws do not share the “same subject matter,” or the state law is not comprehensive, leaving room for local regulation. They do not, as the court below did here, strain to find intent to preempt the broadest conceivable field.

In *Richardson v. City and County of Honolulu*, 868 P.2d 1193 (Haw. 1994), Hawai‘i’s leading preemption case, the plaintiff alleged that seven state statutes preempted a county ordinance providing for condemnation of a lessor’s interest in condominiums and other developments, and the transfer of fee simple interests to the lessees. The court examined state laws addressing, among other matters:

- eminent domain;
- involuntary lease-to-fee conversions of certain real property;
- disclosure requirements and provisions for mandatory arbitration of rent renegotiations;

- renegotiation of leases;
- governance and management of condominiums;
- registration of condominium projects;
- disclosure and other requirements designed to protect condominium purchasers; and
- formation of limited-equity housing cooperatives.

868 P.2d at 1206, 1211.

The Hawai‘i Supreme Court acknowledged Hawai‘i’s eminent domain laws “relate generally to the subject matter of the counties’ power of condemnation by eminent domain,” *id.* at 1195, but rather than lump these related laws together as evidence of a comprehensive scheme, like the court below did here, it did exactly the opposite. It examined each law individually, and concluded each, while “uniform throughout the state,” was not “comprehensive.” *Id.* at 1209. It observed the eminent domain laws control “the mechanics of the taking process,” but found them not preemptive because, unlike the ordinance, they did not specifically address “rights of lessees to lease-to-fee conversion via the mechanism of the counties’ (and therefore the City’s) power of condemnation ....” *Id.* at 1196, 1209. That the ordinance and the eminent domain laws shared the same subject matter “generally” was insufficient to support finding the eminent domain laws comprehensive or exclusive. *Id.* at 1195, 1197, 1210.

The court acknowledged the six other laws also touched on the ordinance’s subject matter, but none specifically regulated it. For example, one specifically

addressed involuntary lease-to-fee conversions of certain residential real property, but did not expressly extend to condominiums. *Id.* at 1210-11. The court held: where the ordinance’s provisions “have no counterparts” in the state laws, “the state statutory scheme encompassed therein does not, and indeed cannot, ‘indicate a legislative intention to be the exclusive legislation applicable to’ the domain of the ordinances.” *Id.* at 1210.

The court below did not identify any statute that comprehensively and exclusively regulates GE crops or even all “potentially harmful plants.” Instead, it cited a statute allowing the Hawai‘i Department of Agriculture to regulate “noxious weeds,” H.R.S. ch. 152, but that law does not regulate GE crops. First, GE crops are not “weeds,” but commercial biotechnology products, created to be intentionally cultivated. They are patented intellectual property, for which growers pay patent holders. *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1764 (2013).

Nor do GE crops fit the Department of Agriculture’s noxious weed definition. The lower court found some suggestive regulatory descriptions, 1ER 053, but a noxious weed must meet “all of the criteria in [Hawai‘i Administrative Rules] §4-68-4 through §4-68-8.” H.A.R. § 4-68-3. A noxious weed must, at a minimum, be one “capable of *competing with cultivated crops* for nutrients, water or sunlight,” or “that becomes established and forms dense stands in pasture lands, forests, lawns, landscape gardens, and recreational areas and conservation districts



and is capable of *shading and crowding ou[t] forage plants, native plants, and other desirable plants.*” H.A.R. § 4-68-5 (emphases added). GE crops are “cultivated crops,” and none “crowds out” desirable plants; they are the types of plants the noxious weed law was intended to protect from being “crowded out.”

Under Hawai‘i’s detailed definition, a noxious weed must also be incapable of being “effectively controlled by present day technology or by available herbicides,” or controlled only by “extraordinary efforts.” H.A.R. § 4-68-7(1), (2). It must also occur “only in isolated or limited areas,” H.A.R. § 4-68-8, unlike GE crops, which are cultivated on thousands of acres throughout the Hawaiian islands. The Department of Agriculture thus has never viewed GE crops as “noxious weeds” within the meaning of the statute, let alone designated any of them as such. There is no evidence any legislator or regulator ever imagined the noxious weed law governed GE crops.

Nor is Hawai‘i’s Plant Quarantine Law, H.R.S. ch. 150A, a comprehensive regulatory scheme exclusively governing the Ordinance’s subject matter. It was intended to govern plants that “may be likely to spread an infestation or infection of an insect, pest, or disease that is detrimental or potentially harmful to agriculture, horticulture, the environment, or animal or public health”—not patented, genetically engineered plants grown commercially. H.R.S. § 150A-6.1. It was intended to control introduction of pests into Hawai‘i, not where a farmer

may grow a crop. S. Stand. Comm. Rep. No. 377, in 1973 Senate Journal, at 807 (“The purpose of this bill is to provide for more effective control of the introduction of plants, animals, insects, diseases, and other organisms into the State ....”). As discussed above the U.S. Department of Agriculture has *never* found a genetically engineered plant to be a “plant pest” in any deregulation.

GE crops thus are “distinct” from the subject matters of both the noxious weed and quarantine laws. *Richardson*, 868 P.2d at 1211. But even if the statutes encompassed GE crops, the existence of two statutes, rather than one, establishes neither does so “comprehensively” or “exclusively,” as Hawai‘i law requires for implied preemption. *Hurip*, 873 P.2d at 96 (legislature’s failure to repeal a statute when enacting one with overlapping subject matter demonstrates that newer law is not intended to be comprehensive and preemptive). These laws cannot demonstrate clear legislative intent to create a comprehensive and exclusive regulatory scheme regulating GE crops.

Other states have noxious weed and quarantine statutes, yet none has deemed them to impliedly preempt, or even govern, GE crops. California has comprehensive quarantine and noxious weed laws, Cal. Food & Agric. Code §§ 5301-5852; §§ 7270-7276, yet Mendocino County for a decade has had an ordinance prohibiting genetically engineered crops, which has never been challenged as preempted. Mendocino Cty. Code § 10A.15. Oregon also has such

laws, see O.R.S. ch. 569 (noxious weeds), O.R.S. ch. 570 (quarantine), yet recently deemed it necessary to expressly preempt county regulation in a new law, after one county enacted a GE crop prohibition, O.R.S. § 633.738 (2013), added by 2013 Or. Laws 1st Sp. Sess. Ch. 4, eff. Oct. 8, 2013 (exempting Jackson County). *Schultz v. Jackson County*, 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 as not preempted by Oregon state law).

**B. The Hawai‘i Department of Agriculture’s Authority Does Not Impliedly Preempt the Ordinance.**

Since no statute impliedly preempts the Ordinance, the district court found intent to create a “comprehensive statutory scheme” exclusively governing plants throughout Hawai‘i in the Hawai‘i Department of Agriculture’s general agriculture authority. But although the Department has never regulated GE crops, nor ever claimed it could, the district court reasoned that if its authority were broad enough that it someday *could* do so, the legislature must have intended to preempt all county authority to address a topic the Department never has. Evidence of such intent is the antithesis of “clear,” and the court’s theory that unimplemented general authority trumps the counties’ express police powers is contrary to Hawai‘i law.

The lower court moored its decision to the Department of Agriculture being “vested with authority” to address agriculture, 1ER 051, 056, but that is a far cry

from meeting Hawai‘i’s implied preemption test. The court also noted the legislature did not expressly grant the counties such authority. 1ER 056 (“[S]tate law does not speak to county involvement in rulemaking, oversight, or enforcement relating to that scheme.”). This is not so, and if it were, it would be irrelevant.

First, Hawai‘i statutes expressly contemplate the counties’ participation in regulating agricultural matters. H.R.S. chapter 205, part III, regarding identifying and preserving important agricultural lands, acknowledges the counties’ role repeatedly. H.R.S. §§ 205-43 (describing policy that “[s]tate *and county* agricultural policies, tax policies, land use plans, ordinances, and rules shall promote the long-term viability of agricultural use of important agricultural lands”) (emphasis added), -46 (requiring counties to ensure their agricultural development, land use, water use, regulatory, tax, land protection policies, and permitting procedures promote agricultural sustainability), -47 (describing counties’ roles in identifying important agricultural lands), -50 (describing criteria for county rezoning of agricultural lands). *Syngenta Seeds Inc.*, 2014 WL 4216022, at \*4 (D. Haw. Aug. 25, 2014) (observing “the legislature has expressly recognized that the counties have some role to play in enacting regulations that affect the field of agriculture,” citing H.R.S. § 205-43).

Second, Maui County needed no such express authorization beyond the police powers Hawai‘i’s legislature gave it in H.R.S. § 46-1.5(13), granting counties power to “enact ordinances deemed necessary to protect health, life, and property” “on *any subject* or matter not inconsistent with, or tending to defeat, the intent of *any* state statute where the statute . . . disclose[s] an express or implied intent” to be exclusive throughout the state. *Syngenta Seeds, Inc.*, 2014 WL 4216022, at \*4 (“Neither [Hawai‘i Constitution Article XI, § 1 nor Article XI, § 5] indicates that the counties have any role to play [in regulating public health or housing, respectively], but this does not preclude the counties from enacting ordinances affecting either area where an ordinance falls under the counties’ generally granted powers.”) (*citing Richardson*, 868 P.2d at 1212-13).

Third, an agency’s general authority over a broad field does not preempt county police power. Every state has a Department of Agriculture that can regulate some plants in some circumstances, including some that could cause problems. Yet the Hawai‘i Department of Agriculture’s general mandate to “[p]romote the conservation, development, and utilization of agricultural resources in the State,” H.R.S. § 26-16(c)(1), in no way suggests intent to reserve to the Department exclusive power to regulate plants throughout the State, any more than the Hawai‘i Department of Health’s grant of “general charge, oversight, and care of the health and lives of the people of the State,” H.R.S. § 321-1(a), eliminates

two-thirds of the counties' police power to "enact ordinances deemed necessary to protect health, life, and property." H.R.S. § 46-1.5(13). *Hawai'i Gov't Employees' Ass'n*, 576 P.2d at 1038 (legislature must "clearly intend[] to preempt the field of regulation"); *Hurip*, 873 P.2d at 94 (State's intent to preempt is the "critical determination.").

Importantly, even if it were assumed the Department of Agriculture's authority extends to whether GE crops may be grown, it has never sought to implement such authority in any regulation, and under Hawai'i law mere authority, unimplemented, does not preempt. In *State v. Ewing*, 914 P.2d 549 (Haw. App. 1996), the court held a statute empowering a state agency to regulate "vehicular noise" did not preempt an ordinance regulating noise from vehicular sound systems, because the agency had not enacted any preemptive regulation. *Id.* at 556. The statute encompassed the same type of noise the ordinance regulated, and gave the Department of Health authority to promulgate rules that *could have* preempted it. *Id.* at 555 ("The noise prohibited under [the ordinance] plainly comes within one of the definitions of 'excessive noise' as used in H.R.S. § 342F-20(b)"). Although the statute allowed counties to enact ordinances not inconsistent with the statute or Department of Health rules, *id.* at 553, this was not controlling; as discussed, H.R.S. § 46-1.5(13) already provides counties this power generally. *Ewing*, 914 P.2d at 557 and n.11 (the ordinance fell within the scope of

the county's police power). The court's holding of no preemption instead was premised on its close analysis of the "same subject matter" element of the implied preemption test, and its conclusion that the agency's rules governing "vehicular noise" did not "extend to sounds reproduced by an automobile's stereo and regulated under [the county ordinance]." *Id.* at 555-556. While the agency *could have* regulated the ordinance's specific subject matter, it *had not done so, id.* at 555-56, just as the Department of Agriculture has no regulation addressing GE crops. *Id.* at 554 (holding any county may adopt an ordinance "so long as the matters regulated *are not already governed by* a department rule or *inconsistent with*" a statute.).

**C. Hawai'i's Supreme Court Has Never Found Preemption in an Analogous Circumstance.**

The district court cited two implied preemption cases, *Application of Anamizu*, 481 P.2d 116 (Haw. 1971) and *Citizens Utilities Co. v. County of Kaua'i*, 814 P.2d 398 (Haw. 1991). Neither supports its conclusion of preemption.

In *Anamizu*, the State had established a clearly-defined scheme requiring contractors throughout the state to obtain a license issued by the Hawai'i Contractors License Board. 481 P.2d at 118. A county prohibited duly-licensed contractors from practicing there without an additional credential, "severely diluting the value of a uniform state licensing system." *Id.* at 119.

In *Citizens Utilities*, the State granted the Public Utilities Commission (PUC) exclusive authority over “all public utilities,” 814 P.2d at 400 (quoting H.R.S. § 269–6), and the PUC issued an order governing “all overhead electric line construction in the State of Hawai‘i.” *Id.* The county passed a pole height ordinance flatly contradicting this order. The court found “[a]dherence to the height limits in the [county development plan and zoning ordinance] would not permit Citizens Utilities to comply with the minimum standards contained in the PUC guidelines.” *Id.* at 399.

In both cases, the court was able to easily discern both (1) legislative intent to grant the state exclusive authority over the relevant subject matter, and (2) a law or regulation addressing the ordinance’s specific subject matter implementing that exclusive authority. In both cases, the ordinance interfered with the intended regulatory scheme.

Those scenarios are not this case. The legislature has not enacted any analogous preemptive statute regulating genetically engineered crops (or even “potentially harmful plants”). It has not granted the Department of Agriculture exclusive specific authority comparable to a licensing board or public utilities commission. Nor has the Department issued any regulation finding any GE crop to be a noxious weed or a plant pest, or controlling whether a genetically engineered crop (or any commercial crop) can be grown. In *Richardson*, the Hawai‘i Supreme



Court expressly cited the ordinances' interference with exclusive statewide schemes in distinguishing *Anamizu* and *Citizens Utilities*. 868 P.2d at 1208. The County has done nothing resembling the counties' interfering actions in *Anamizu* and *Citizens Utilities*.

Finally, even assuming the State entered the Ordinance's field, Hawai'i law does not preclude county regulation in every field the State enters. Rather, H.R.S. § 46-1.5(13) *grants* the County authority on any subject unless the legislature demonstrates *intent* to preclude it—any subject “not inconsistent with, or tending to defeat, the intent of any state statute” that the State intended to be exclusive and uniform throughout the state. *See, e.g., Central Maine Power Co. v. Town of Lebanon*, 571 A.2d 1189, 1194-95 (Me. 1990) (“Finally, and of greatest importance, the Lebanon ordinance does not frustrate the purposes of the two Maine pesticide acts.... By requiring a more stringent review process for certain types of pesticide use than that found in the two Maine pesticide acts, the Lebanon ordinance shares and advances these same purposes.”); *Commonwealth v. Do, Inc.*, 674 S.W.2d 519, 522 (Ky. 1984) (“The mere fact that the State has made certain regulations does not prohibit local government from establishing additional requirements as long as there is no conflict between them.”); *Maryland & District of Columbia Rifle & Pistol Ass'n v. Washington*, 442 F.2d 123, 130 (D.C. Cir. 1971) (“The important consideration ... is not whether the legislature and

municipality have both entered the same field, but whether in doing so they have clashed.”) Here, the State neither clearly demonstrated any intent to preclude county regulation of plants, nor does the Ordinance undermine any scheme the State enacted.

Dated: December 7, 2015      Respectfully Submitted,

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## STATEMENT REGARDING RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, Amicus Curiae certify that there are three cases related to the instant appeal.

First, two appeals pending in the Ninth Circuit are related to the instant case as they raise the same state and/or federal preemption issues regarding county regulation of genetically engineered organisms. They are titled *Syngenta Seeds, Inc. v. County of Kaua‘i*, Nos. 14-16833, 14-16848 (9th Cir. 2014) and *Hawai‘i Papaya Indus. Ass’n. v. Cty. of Hawai‘i*, Nos. 14-17538; 15-15020 (9th Cir. 2015).

In *Syngenta Seeds*, the District of Hawai‘i entered judgment against the County of Kaua‘i on August 25, 2014, declaring that the Kaua‘i Ordinance is impliedly preempted by Hawai‘i state law and therefore invalid. Order and Judgment, *Syngenta Seeds, Inc. v. County of Kaua‘i*, No. 14-00014 BMK (D. Haw. Aug. 25, 2014), ECF Nos. 135-136. The district court however, rejected arguments of federal preemption, a decision not cross-appealed. Briefing of the appeal before this Court was completed in July 2015.

In *Hawai‘i Papaya Indus. Ass’n.*, the District of Hawai‘i entered judgment against Hawai‘i County on November 26, 2014, finding the Hawai‘i Ordinance is impliedly preempted by Hawai‘i state law and expressly preempted by federal law as applied to experimental GE crop field trials, but only in part, as to GE crops that are both regulated articles and plant pests. Order, *Hawai‘i Floriculture and*

*Nursery Ass'n. v. Cty. of Hawai'i*, No. 14-00267 BMK (D. Haw. Nov. 26, 2014), ECF No. 70. The district court rejected the federal implied preemption claims in full. That decision was initially cross-appealed, but then voluntarily dismissed. Order, *Hawai'i Floriculture and Nursery Ass'n. v. Cty. of Hawai'i*, No. 14-17538 (9th Cir. August 18, 2015), ECF No. 40. Briefing of the appeal before this Court was completed in October 2015.

The third related case is Amicus Curie's appeal from a denial of intervention by the District of Hawai'i in the instant action, appeal titled *Robert Ito Farm, Inc. v. County of Maui v. The Moms on a Mission (MOM) Hui, et al.*, No. 15-15246 (9th Cir. 2015). Briefing of the appeal before this Court was completed in July 2015.

/s/ George A. Kimbrell

**CERTIFICATE OF COMPLIANCE**

Pursuant to Fed. R. App. P. 32(a)(7)(C), this brief is proportionately spaced, has typeface of 14 points or more and contains 6,998 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

/s/ George A. Kimbrell

**Exhibit A**

Brief of Amicus Curiae Center for Food Safety, Moms On A Mission (MOM) Hui,  
Moloka'i Mahi'ai, And Gerry Ross in Support of Defendants-Appellees and  
Seeking Reversal of District Court

# No. 15-1504-CV

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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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August 31, 2015

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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

George A. Kimbrell

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## INTEREST OF AMICUS CURIAE<sup>1</sup>

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.<sup>2</sup> 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.

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<sup>1</sup> 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).

<sup>2</sup> *See* CFS, [www.centerforfoodsafety.org](http://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.<sup>3</sup>

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,

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<sup>3</sup> 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,<sup>4</sup> 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.<sup>5</sup> 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

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

<sup>5</sup> 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.<sup>6</sup> In so doing,

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<sup>6</sup> 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.<sup>7</sup>

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.”<sup>8</sup> 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.<sup>9</sup> This coding sequence is then fused to gene fragments from other species—cauliflower mosaic virus, petunia, and another strain of *Agrobacterium*—

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<sup>7</sup> 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>.

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

<sup>9</sup> 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.<sup>10</sup> *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.<sup>11</sup>

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

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

<sup>11</sup> *Id.*

<sup>12</sup> 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.<sup>13</sup>

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

## 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

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<sup>13</sup> *Id.*

<sup>14</sup> *See supra* note 6.

<sup>15</sup> 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>.

<sup>16</sup> 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>.

<sup>17</sup> 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).<sup>18</sup> 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.<sup>19</sup> A typical FDA response, from a 2011 letter to Dow Chemical on a corn engineered to be resistant to the pesticide 2,4-D:

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<sup>18</sup> 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>.

<sup>19</sup> *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.<sup>20</sup>

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.<sup>21</sup> Pursuant to that guidance, the manufacturer, not

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<sup>20</sup> 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).

<sup>21</sup> 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.<sup>22</sup> *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*

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<sup>22</sup> 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.”<sup>23</sup>

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).<sup>24</sup> 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)

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<sup>23</sup> 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”).

<sup>24</sup> 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.<sup>25</sup> Academics deemed critical may be denied permission;<sup>26</sup> even if granted, the patent holders retain the right to control and approve studies and any publication.<sup>27</sup> In 2009, twenty-six university scientists protested this restricted access in a filing with EPA:

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

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

<sup>27</sup> 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.*<sup>28</sup>

### 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.<sup>29</sup> 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.

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<sup>28</sup> 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).

<sup>29</sup> 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,<sup>30</sup> biotechnology firms have instead only delivered a handful of GE commodity crops that produce insecticides and/or withstand direct application of herbicides.<sup>31</sup> Over five of every six acres of transgenic crops worldwide (84%),<sup>32</sup> 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.<sup>33</sup> *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

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<sup>30</sup> 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>.

<sup>31</sup> *Id.* at 63.

<sup>32</sup> 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).

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

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.<sup>34</sup> 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.<sup>35</sup>

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.<sup>36</sup> 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.<sup>37</sup> Yet far from providing any

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

<sup>35</sup> 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>.

<sup>36</sup> 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>.

<sup>37</sup> 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,<sup>38</sup> and increasingly intractable weeds resistant to multiple herbicides.<sup>39</sup>

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

<sup>38</sup> 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>.

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

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

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

<sup>42</sup> 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.<sup>43</sup>

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.<sup>44</sup> 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.<sup>45</sup> 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>.

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

<sup>44</sup> 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>.

<sup>45</sup> 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,<sup>46</sup> 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.<sup>47</sup> Glyphosate-containing Roundup formulations are extremely toxic to tadpoles and frogs, and likely have contributed to the worldwide decline in frog populations.<sup>48</sup>

## **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.

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

<sup>47</sup> 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>.

<sup>48</sup> 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.”).<sup>49</sup>

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,<sup>50</sup> with new episodes cropping up regularly.<sup>51</sup>

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<sup>49</sup> 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>.

<sup>50</sup> 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.”).<sup>52</sup> And the risk of contamination itself creates costly burdens for organic and conventional farmers

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

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

<sup>52</sup> 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).<sup>53</sup>

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,<sup>54</sup> and concluded that "the ease with which genetic material from crops can be spread makes future releases likely." *Id.* at 3.

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<sup>53</sup> 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>.

<sup>54</sup> 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.<sup>55</sup> 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.”<sup>56</sup>

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.<sup>57</sup> Contrary to Appellants’ claims, GE crop adoption by farmers is attributable to several factors, including that pesticide/chemical companies have acquired a

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<sup>55</sup> 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>.

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

<sup>57</sup> *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.<sup>58</sup>

#### **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.<sup>59</sup>

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

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<sup>58</sup> 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>.

<sup>59</sup> 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.<sup>60</sup> 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.<sup>61</sup> Only about a quarter of Americans realize that current national regulations do not require labeling of GE foods.<sup>62</sup> 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.<sup>63</sup> 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.

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<sup>60</sup> 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).

<sup>61</sup> 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>.

<sup>62</sup> Hallman et al., *supra* note 61, at 4.

<sup>63</sup> *Id.* at 4-5; Kopicki, *supra* note 60.

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/s/ George A. Kimbrell

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