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LEGAL ANALYSIS OF H.R. 1599:

AN ACT TO PREEMPT STATE GMO DISCLOSURE LAWS

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I. SUMMARY

H.R. 1599, the "Safe and Accurate Food Labeling Act of 2015" (SAFLA), expressly preempts State food labeling laws that regulate foods produced from, containing, or consisting of a genetically engineered plant or material ("GMO food"). SAFLA deprives the states and localities of all rights to legislate concerning GMO labeling. It shifts that power to the federal government, permitting only federal regulatory departments and agencies, the Department of Agriculture and the Food and Drug Administration, to regulate "GMO" claims on food labels. The bill employs an express preemption clause—a congressional utility rarely used in the field of nutrition labeling and one that conflicts with historically concurrent governance by federal and state agencies over food labels. In a national arena where many states have enacted GMO labeling laws at the behest of their constituents, SAFLA proposes a model that directly conflicts with those state initiatives and frustrates the will of the people. "[T]he Constitution divides authority between federal and state governments for the protection of individuals. State sovereignty is not just an end in itself. Rather, federalism secures to citizens the liberties that derive from diffusion of sovereign power." *New York v. United States*, 505. U.S. 144, 181 (1992). That core division of power is essential where, as here, the States have spoken on an issue within their traditional powers in response to overwhelming public demand.

The Supremacy Clause is a truism that federal law in pursuance of power specifically delegated to the national government by the Constitution is supreme. But when Congress invokes its preemption powers in excess of delegated powers and to effect an unconstitutional end, the pursuit of that power contravenes Article I, Section 8 limits on legislative authority. No power is delegated which violates the Bill of Rights. Because only those laws enacted in accordance with the Constitution are supreme to State law and because H.R. 1599 imposes both an unconstitutional prior restraint on the right to communicate truthful GMO Free claims as well as on the right of citizens to receive truthful claims concerning GMOs in foods, the bill violates Article I, Section 8. Passage of the SAFLA not only violates the First Amendment as a prohibition on truthful and non-misleading speech, it also improperly applies federal preemption to effect an unconstitutional end, deprivation of individuals' right to receive truthful information concerning the ingredients in food. H.R. 1599 thus constitutionally defective and invites legal challenge.

SAFLA violates the First Amendment by depriving sellers of foods free of genetically engineered ingredients of their right to convey that truthful and non-misleading information on labels or labeling. It also deprives consumers of their right to receive truthful information concerning the presence of genetically engineered ingredients in foods. "Freedom of speech presupposes a willing speaker" and, "where a speaker exists …, the protection afforded is to the communication, to its source and to its recipients both." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 756 (1976). The right to receive information concerning the presence or absence of GMOs in food "is an inherent corollary of the rights of free speech and press that are explicitly, guaranteed by the Constitution" because "the right to receive ideas follows ineluctably from the sender's First Amendment right to send them." *Bd. of Educ., Island Trees Union Free Sch. Dist. Number 26 v. Pico*, 457 U.S. 853, 867 (1982).

Although proponents of H.R. 1599 claim that it promotes accurate food labeling, the legislation in fact codifies information suppression which promotes consumer confusion. It does so by obscuring the fact that genetically engineered ingredients are in foods and by imposing a prior restraint on the right to communicate that products are GMO free. SAFLA simultaneously prevents those who sell foods free of genetically engineered ingredients from communicating that fact without federal authorization, while it relieves those who sell foods containing genetically engineered ingredients from having to disclose that fact on the label. It is thus a content-based and speaker specific regulation of speech in violation of the First Amendment. *Solantic, LLC v. City of Neptune Beach*, 410 F.3d 1250, 1267 (11th Cir. 2005); *Italian Colors Restaurant v. Harris*, -- F. Supp. 2d --, 2015 WL 1405507, at *9 (E.D. Cal. Mar. 26, 2015). Indeed, for the benefit of those who sell genetically engineered ingredients, SAFLA further contributes to consumer confusion by permitting those companies to label their products as "natural."

The vast majority of consumers nationwide want the presence of genetically engineered ingredients in foods disclosed on the label.[1] SAFLA stands between consumers and accurate food labeling disclosures by obscuring the fact of GMO presence in foods. It imposes certification requirements, government pre-market approval requirements, record-keeping requirements, and government fees on those who want to make "non-GMO" or "GMO Free" claims. It imposes no such requirements on those who sell products containing genetically engineered ingredients, establishing instead an entirely "voluntary" labeling system for that preferred industry. It imposes a blanket ban on claims that compare non-GMO foods to GMO counterparts, further contributing to the obscuring of genetically engineered ingredients. While imposing costly and extensive prior restraints on the organic food industry, it establishes a "voluntary" labeling regime for companies that sell genetically engineered foods, enabling them to avoid any disclosure of genetically engineered ingredients if they so wish. The law thus discriminates against organic producers and sellers in favor of GMO food producers and sellers, and it does so based on speech. It is thus a content and speaker specific act of discrimination in violation of the First Amendment.

Proponents of SAFLA have failed to identify a substantial state interest to justify the onerous and discriminatory burdens H.R. 1599 imposes on non-GMO product producers and sellers. They have presented no proof, let alone extensive evidence, of fraudulent "non-GMO" claims in the market. The certification and fee requirements are far in excess of those required to protect against deceptive advertising, particularly where simple disclaimers would suffice and have been used by the FDA in similar circumstances. 21 U.S.C. § 343(r)(6)(C) (2000) ("This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."). Despite granting the Department of Agriculture and the Food and Drug Administration broad new powers over the content of

[1] *See* Gary Langer, *Poll: Skepticism of Genetically Modified Foods*, ABC NEWS (June 19, 2014), http://abcnews.go.com/Technology/story?id=97567 ("Nearly everyone, moreover — 93 percent — says the federal government should require labels on food saying whether it's been genetically modified, or "bio-engineered" (this poll used both phrases).").

protected speech, SAFLA includes no procedural safeguards against abuse of those powers, granting federal regulators unbridled discretion to determine what is and is not verboten speech based on standards called for but left unarticulated in H.R. 1599.

SAFLA allows non-disclosure of GMO ingredients at the expense of consumers' right to know. By rendering the absence of food label transparency the law of the land, SAFLA reverses the trend in the law since the 1970's which has consistently favored ingredient disclosure over suppression, codifying instead new limits on the free-flow of information indispensable to the exercise of informed consumer choice in the market. In that respect, by removing a central underpinning to free market operation (full disclosure), H.R. 1599 ensures that consumers who wish to avoid genetically engineered ingredients will be misled at the point of sale.

Moreover, by masking the presence of GMOs in foods, the law limits traceability of GMOs in commerce. Traceability is essential for food product recalls and for ascertaining the source of food-borne illness. By precluding State labeling initiatives, H.R. 1599 also prevents accurate disclosure of food identities, like transgenic products (including, e.g., vegetables, berries, etc.). The failure to disclose GMO properties can lead to misidentification of many species, which has already occurred in markets for transgenic corn, soy, zucchini, papaya, beets, citrus fruits, berries, and many others. The presence of GMO technologies could feasibly lead to the inclusion of unlabeled allergens. Many foods can be altered fundamentally by cross-breading or other genetic modifications, often to the point where the product adopts different characteristics that may remain unlabeled or undisclosed in the absence of GMO labeling. The SAFLA thus erects a regulatory model ill-equipped to manage emerging technologies and risks ordinarily attendant to innovations in the food market.

The effects of SAFLA are far-reaching. The bill strips states' rights, imposes prior restraints on non-GMO food labeling, engenders consumer confusion, promotes market dysfunction by obscuring information consumers seek at the point of sale, conflicts with state initiatives already enacted, and violates the First Amendment to the United States Constitution. The Bill enacts fees (or taxes) on the use of "non-GMO" or "GMO-free" claims, burdening the GMO-free industry and rendering such products at a competitive disadvantage vis-à-vis genetically engineered food products. For those reasons, explained in further detail below, H.R. 1599 is an unlawful, unworkable, and ill-advised expansion of federal power at the expense of the states, localities, and consumers.

II. THE FIRST AMENDMENT INVALIDITY OF H.R. 1599

The First Amendment guarantees the right to disclose truthful and non-misleading information on food labels. *See, e.g.*, *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). "The party seeking to uphold a restriction on commercial speech carries the burden of justifying it." *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 71, n. 20 (1983). "This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a

material degree." *Edenfield v. Fane*, 507 U.S. 761, 771 (1993) (citations omitted). First Amendment jurisprudence has focused "not only on the role of the First Amendment in fostering individual self-expression but also on its role in affording the public access to discussion, debate, and the dissemination of information and ideas." *First National Bank of Boston v. Bellotti*, 435 U.S. 765, 783 (1978). The government "may not, consistently with the spirit of the First Amendment, contract the spectrum of available knowledge." *Griswold v. Connecticut*, 381 U.S. 479, 482 (1965). The First Amendment "protects the right to receive information and ideas." *Stanley v. Georgia*, 394 U.S. 557, 564 (1972). The rights at stake here include the right of businesses to convey truthful information concerning GMOs, but also consumers' rights to receive that information. That consumers' right to information is specifically guaranteed under the State initiatives that have required GMO labeling disclosures.

To prohibit disclosure of truthful and non-misleading commercial speech, such as suppression of label disclosure of genetically engineered ingredients in foods or the absence thereof, the government must meet its burden under intermediate scrutiny—the four factor test first articulated in *Central Hudson*. *See generally Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 US 557 (1980). The four elements courts evaluate in determining whether government censorship of commercial speech violates the First Amendment are: (1) whether the speech concerns lawful activity and is not misleading; (2) whether the government's interest in prohibiting the speech is "substantial;" (3) whether the prohibition at issue "directly advances the governmental interest asserted;" and (4) whether the prohibition is "more extensive than is necessary to serve that interest." *Coors*, 514 U.S. at 482 (citing *Central Hudson*, 447 US 557 (1980)).

SAFLA does not pass muster under the *Central Hudson* test. The bill burdens truthful and non-misleading labeling disclosures without a substantial government interest. The bill does not directly advance a substantial government interest because it effects suppression of information that consumers deem material to a purchase, and the prohibitions on GMO claims, including those on comparative GMO/non-GMO claims—here a blanket ban—are far greater than necessary to serve any reasonable government interest. The bill imposes a content-specific prior restraint on speech without suitable guidelines or prompt access to judicial review. That gives federal regulators unbridled discretion in their application of those premarket restraints.

In understanding the constitutional infirmities, several provisions of SAFLA are relevant. The bill imposes a prior restraint on truthful and non-misleading speech in the form of a system of federal premarket approval, requiring federal government certifications for "non-GMO" claims before they may be made in the market. Section 291A of the Agricultural Marketing Act of 1946[2] (as amended by section 201 of H.R. 1599) requires the Agricultural Marketing Service to "establish a voluntary genetically engineered food certification program." That program is "voluntary" only in that it does not compel genetically engineered food products to be certified. As explained below, however, if the food is to be "*sold or labeled*" as GMO-free or without the use of genetic engineering, federal pre-market certification is not voluntary, it is mandatory.

[2] 7 U.S.C.§ 1621 *et seq.*

Under section 291B(a), a product may be sold or labeled as a food that was produced without the use of genetic engineering *only* if it was, *inter alia*, subject to supply chain process controls and produced and handled in compliance with a non-genetically engineered food plan that was developed and *approved* in accordance with section 291B(c). Thus, under Section 291B(c), a "producer or handler *seeking certification* . . . shall submit a nongenetically engineered food plan to the certifying agent and such plan shall be reviewed by the certifying agent who shall determine if such plan meets the requirements of [section 291B]" (emphasis added). Under sections 291B(c)(2), that plan must contain a description of:

(1) The procedures that will be followed to assure compliance with section 291B;

(2) A description of monitoring records that will be maintained; and

(3) Any corrective actions that will be implemented in the event there is a deviation from the plan.

Because a certifying agent must review and approve a food plan *before* a nongenetically engineered food can be sold or labeled as having been produced without genetic engineering, federal premarket approval is in fact required, is not voluntary, for all GMO-free claims. Indeed, Section 291B(c)(1) requires the submission of information by parties "seeking certification under this section…"

In addition, Section 291G authorizes a $2 million appropriation to the Secretary of Agriculture to establish the genetically engineered food certification program in Section 291A, which is the same certification program required by Section 291B(a) and (c) exclusively for non-GMO foods. Section 291G(b)(1) authorizes the Secretary to "collect fees to cover the estimated costs … of carrying out this subtitle." SAFLA thus not only imposes a prior restraint on non-GMO claims, it also imposes a financial burden for the right to communicate truthful and non-misleading GMO free claims.

Moreover, Section 291F imposes recordkeeping requirements on companies manufacturing or selling non-GMO products. Those requirements increase compliance costs and require production of records upon inspection at any point in time.

Furthermore, Section 291B(b)(3) upsets state regulation and private certifying bodies' successful regulation of organic foods by deeming them indistinguishable from non-GMO foods in general. SAFLA treats non-GMO foods and Organic foods as equivalent, and the bill text imposes nearly identical standards on the two foods. *See also* Section 291E (automatically accrediting certification bodies that are accredited under the Organic Foods Production Act). SAFLA Section 202 requires the Secretary to implement regulations that are, "to the greatest extent practicable," consistent with the "certification programs established" under the Organic Foods Production Act. *See also* Section 204(b) (deeming a product certified if it is "produced by a farm or handling operation that is certified as an organic farm or handling operation under the

Organic Food Production Act of 1990"). The decision to treat non-GMO foods equivalent to organic foods has significant constitutional consequences because, as discussed below, the underlying state interest in strictly regulating Organic foods differs from any purported state interest in the regulation of non-GMO foods in general.

Finally, Section 201(a)(3) prohibits labeling or advertising claims which expressly or implicitly suggests that foods "developed without the use of genetic engineering are safer or of higher quality than [foods] produced from, containing, or consisting of a genetically engineered plant." That provision creates a categorical ban affecting every actual and potential producer of foods in these categories and presupposing there to be no present or future difference for which a comparative claim would be truthful and non-misleading. It is thus an overbroad speech regulation in the form of an absolute prior restraint on the dissemination of truthful information concerning the comparative health benefits or other superiority of any and every nongenetically engineered food as compared to any and every genetically engineered food. There is no foundation for the ban sufficient to pass constitutional muster, no proof that every conceivable comparative difference is mythical, false, and misleading. Significantly, the law provides no exemption from that speech-restriction and, so, should information later emerge showing that GMOs are in any respect inferior to a single non-GMO alternative, manufacturers will have no recourse from the confines of Section 201(a)(3). That information would be shuttered from the market in perpetuity.

The aforementioned provisions are accompanied substantial investigatory powers and penalties. Violations of SAFLA Section 201 carry the potential for civil penalties of up to $10,000 per day. Therefore, independently and in combination, the above legislative provisions create a prior restraint on truthful and non-misleading labeling claims, to wit, the use of "non-GMO" claims on product packaging, the discussion of truthful and nonmisleading science concerning same, and the right to communicate any truthful claims of non-GMO product superiority over a GMO product.

Central Hudson Parts I & II:

Proponents of H.R. 1599 likely cannot identify a "substantial" state interest in support of the law's speech restrictions and penalties. At best, the government interest concerns potential (but unestablished) deception of consumers through potentially false or misleading GMO claims. In its preamble, the authors or H.R. 1599 expressly state that GMO and non-GMO materials are equivalent in that non-GMO products are not "safer or of higher quality than covered products produced from, containing, or consisting of a genetically engineered plant." *See* Section 291B(a)(3). The Bill bans labeling statements that suggest otherwise even if true. By banning GMO free claims, even if true, and GMO product superiority claims, even if true, the bill fosters consumer deception which is an illegitimate state interest, failing to satisfy the "substantial state interest" requirement of *Central Hudson*.

The legislative history of H.R. 1599 contained in House Report 114-208, Part 1 (114th Congress (2015-2016)) explained that the need for legislation stems from the "ever more vocal minority of citizens … creating doubt in the minds of many consumers and policymakers

through misinformation regarding the safety and wise use of genetically engineered inputs." It is thus admittedly speaker specific. The proposed bill, which itself increases costs of business through user fees, ironically seeks to prevent "costly price hikes associated with a patchwork of state labeling laws," thus uniquely discriminating against non-GMO producers in favor of GMO producers. Although H.R. 1599 claims the need to suppress disclosure of genetically engineered ingredients as a means to prevent consumer deception, the legislative history is bereft of detailed findings to prove that disclosure of genetically engineered ingredients on food labels begets consumer deception rather than mitigates it. Indeed, the legislative fact-finding failed to identify any history or common practice of deception among GMO and non-GMO claims.

By contrast, the legislative findings leading to the Organic Foods Production Act contained detailed findings on the percentage of Americans seeking organically grown products and the history of dishonest organic traders. The Senate was specifically concerned with the availability of organic products at market, noting that retailers were "concerned about verifying the authenticity of organic items," which had caused them to "refuse to purchase organic products." *See* S. Rep. 101-357 at *4944-4960. Unlike smaller health food stores, the larger retailers and distributors had been unwilling to work directly with farmers to ensure that products were organic. *Id.* "As a result, consumers [found] little to no organic food in the major shops across the country." *Id.* Thus, the Senate concluded that Organic regulations (including the certification programs that have been referenced in H.R. 1599) were necessary to facilitate the *availability* of products at retail. *Id.* Significantly, and unlike in the legislative history underlying H.R. 1599, the Senate when considering the Organic Foods Production Act noted that the law struck "a delicate balance between a State's right to develop its own organic program and the national need for consistency and labeling standards." *Id.* at *4950.

The federal government's purported interest in preventing deception is entirely bereft of the detailed findings underlying the OFCA in 1990. The risk of deceptive advertising addressed by H.R. 1599 is no different from all labeling risk present on nutrition labeling or food packaging nationwide, which is regulated by the Food and Drug Administration. The FDA imposes almost no premarket approval or certification requirements for the disclosure of nutrition information, including facts like ingredient composition, caloric values, and even comparative health statements like "low fat." The government's interest in preventing deceptive claims like unauthorized Nutrient Content Claims (e.g., "good source of…" or "fortified with…") or allergen warnings is at least as substantial as the interest in maintaining truthful non-GMO claims. Yet the FDA has never required premarket approval or a certification process before sellers can provide consumers with that information. The SAFLA proponents have not explained why non-GMO claims for which there is no evidence of record proving a history of deception must nevertheless be subject to an extensive and costly system of federal prior restraints.

Even if the federal government could establish a substantial state interest in preventing deception—and there is no evidence of that—the means chosen to prevent that deception are grossly disproportionate and not narrowly tailored to achieve the end. H.R. 1599 has no "reasonable fit" between the government's goal and the means chosen to advance the goal. *Pearson*, 164 F.3d at 657. "[W]hen government chooses a policy of suppression over disclosure-at least where there is no showing that disclosure would not suffice to cure misleadingness-

government disregards a 'far less restrictive' means." *Id.* at 658. The SAFLA's prior restraint on speech is far more extensive than necessary to serve the government interest in preventing deception and, indeed, disserves that interest by obscuring through preemption and added regulatory burdens the public's awareness of which foods are genetically engineered and which are GMO-free. To be sure, the state disclosure laws, abide by the judicial requirement of a less restrictive alternative because they expressly authorize placement of a statement revealing FDA's policy position on GMOs (that they are as safe as non-GMO products) on the label revealing the presence of genetically engineered ingredients. That disclosure is an obvious, less speech restrictive alternative to the blanket speech bans brought about by H.R. 1599.

Central Hudson Parts III & IV:

Under the third and fourth prongs of *Central Hudson*, the bill therefore fails because the means chosen to limit deception are far broader than necessary to achieve the ends. The bill categorically bans in perpetuity GMO free and GMO/non-GMO comparative speech that includes truthful and non-misleading communication, and the bill's proponents have disregarded obvious, less speech-restrictive alternatives that do not require speech suppression to achieve their desired end.

First, as discussed *supra*, H.R. 1599 creates a prior restraint on non-GMO claims, allowing such claims only after premarket government certification. Second, the Bill imposes user fees on those making non-GMO claims, meaning that the USDA will charge for the right to make truthful and non-misleading non-GMO claims.

Third, the bill categorically bans any speech concerning the comparative health benefits or superiority of non-GMO foods over GMO foods. That ban is without any exceptions, and enacted in perpetuity. That prohibition is thus a blanket ban on commercial speech presumptively unconstitutional under the commercial speech doctrine. *See*, *e.g.*, *Edenfield v. Fane*, 507 U.S. 761, 767-69 (1993) (blanket ban on direct, in-person, uninvited solicitation by CPA's was unconstitutional as applied to CPA's proposed communication to potential client of truthful, non-deceptive information proposing a lawful commercial transaction).

Fourth, the bill imposes redundant and excessive regulatory burdens which are only mandatory in the case of non-GMO foods which represent the absence of GMOs in labeling. The FDA already has ample authority to address deceptive advertising by pursuing false or misleading labeling statements without need for legislation that discriminatorily targets one industry to benefit another. The federal Food, Drug, and Cosmetic Act ("FDCA") already prohibits food labeling that is false or misleading in any particular, and imposes civil and criminal penalties for violations, making a burdensome certification requirement for all GMO-free claims discriminatory, over-inclusive and, to the extent not discriminatorily enforced, nevertheless redundant. *See* 21 U.S.C. §§ 331, 333, 343(a). H.R. 1599 is thus not narrowly tailored; there is no reasonable relationship between the means chosen and the ends.

Fifth, the bill overlooks or rejects obvious and less-speech restrictive alternatives. Rather than censor truthful claims through Section 201(a)(3) and impose financial burdens on one set of

speakers, those who produce and sell non-GMO foods, Congress could have simply mandated use of suitable disclaimer language on all foods carrying GMO Free claims, for instance: "The FDA has not determined that the use of genetic engineering, by itself, render foods unsafe." Through the use of a disclaimer, the government would satisfy its constitutional burden because "the First Amendment favors speech disclosure over speech suppression" and the government "may not completely ban potentially misleading health claims but should allow such claims with an appropriate disclaimer." *Whitaker v. Thompson*, 239 F. Supp. 2d 43, 47 (D.D.C. 2003) (citing *Pearson v. Shalala*, 164 F.3d 650) (D.C. Cir. 1999)). State laws, like those passed in Vermont, do precisely that by allowing companies to accompany required GMO disclosures with qualifying language. *See, e.g.,* 2014 Vt. Acts & Resolves No. 120, § 3(1) (allowing the Attorney General to promulgate a regulation requiring that the label of genetically engineered food include a disclaimer that the FDA does not consider foods produced from genetic engineering to be materially different from other foods).

As explained above, even under circumstances that raise actual threats to the consumer safety (like allergen disclosures), the FDA has not imposed certification requirements or premarket approval standards for food labels or products. The pathway in H.R. 1599 is therefore an extension of federal power greatly in excess of historical practice. The FDA's approach to hormone-treated cows and milk products is insightful because it proves a far less-restrictive means to regulate claims just like the non-GMO claims addressed in H.R. 1599.

In 1994, the FDA addressed a similar debate concerning milk produced by rBST-treated cows and milk sourced from non-rBST-treated cows. Agricultural entities sought to market milk "sourced from non-rBST-treated cows." As with GMO and non-GMO foods here, the FDA found no material difference between milk from rBST-treated cows and non-rBST treated cows. The FDA released a Guidance document on the "Voluntary Labeling of Milk and Milk Products from Cows That Have Not Been Treated With recombinant Bovine Somatotropin."[3] The FDA maintained that "there is currently no way to differentiate between naturally occurring bST and [r]BST in milk." *See Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 636-37 (6th Cir. 2010).

But the FDA never precluded "non-rBST" claims on milk, creating no barriers to truthful communication of that claim. Rather than construct a system of prior restraint through premarket review for non-rBST milk claims, the FDA simply required a short disclaimer on product packaging informing consumers that the FDA believed "there was no significant difference between the two types of milk." That simple, basic disclaimer disabused consumers of any misleading connotation that could arise from the "rBST-free" claim, while still allowing the free flow of information to consumers who might find the "rBST-free" information helpful. A similar approach here with non-GMO claims at the federal level would also preserve the system of dual sovereignty between the federal and state governments, by promulgating federal policies that would complement state law rather than revoke it.

[3] *Available at*, http://www.fda.gov/OHRMS/dockets/dockets/06p0394/06p-0394-cp00001-15-Tab-13-Farm-Animal-Welfare-01-vol1.pdf (last visited Aug. 4, 2015).

The "rBST-free" example also provides another cautionary note concerning Section 201(a)(3) in H.R. 1599, which includes the categorical prohibition of certain statements about the difference between non-GMO and GMO products. That provision prevents any merchant from claiming that a non-GMO ingredient or food is somehow better, healthier, or safer than a GMO counterpart. For many years the FDA claimed that rBST-free milk was indistinguishable from milk produced by rBST-treated cattle. The FDA used language similar to that featured in H.R. 1599 concerning the lack of material differences. Then, in *Int'l Dairy Foods Ass'n*, the Sixth Circuit found that milk sourced from rBST-treated cows was in fact of lower quality due to increased fat content and decreased protein content, and that rBST-treated cows' milk contains a higher level of somatic cells, which makes milk turn sour faster. *See Int'l Dairy Foods Ass'n*, 622 F.3d at 636-37. Thus, the Court found objectionable any blanket ban on rBST-free claims by those who sold milk from non-rBST treated cows. The court stated:

> A compositional difference thus exists between the two types of milk, although the extent of this difference—namely whether conventional milk does in fact contain rbST—is still very much an open question. As such, the composition claim "rbST free" at best informs consumers of a meaningful distinction between conventional and other types of milk and at worst potentially misleads them into believing that a compositionally distinct milk adversely affects their health. Under these circumstances, we conclude that composition claims like "rbST free" are not inherently misleading.

Id. That *Int'l Dairy* decision illustrates the evolving nature of scientific knowledge and the need to avoid blanket speech bans which do not allow for reasonable product comparisons. Although today the government perceives no material distinction between GMOs and non-GMOs, that official orthodoxy may conflict with new scientific information or product specific findings tomorrow. New GMO products may emerge that possess properties which do indeed establish material differences, rendering their GMO free alternatives superior. SAFLA's Section 201(a)(3) outright prohibits discussion of that science, and provides no exemption or means to introduce any comparative claim of superiority in the market. Note that the prohibition is itself a discriminatory speech ban because it goes but one way: against a claim that a GMO free product is in any way superior to a GMO product (but not the other, that a GMO product is healthier or superior in some way to a non-GMO product). For these additional reasons, as illustrated by the Court in *Int'l Dairy*, H.R. 1599 is unconstitutionally overbroad and should be rejected.

III. THE DEPRIVATION OF STATES' RIGHTS

A "claim of preemption suggests a considered decision by the federal government to prevent the states from operating in a field and thus affect[s] a basic change in the allocation of powers."[4] Unsurprisingly, "[c]omplete preemption is . . . quite rare." *See Johnson v. MFA Petrol. Co.*, 701 F.3d 243, 248 (8th Cir. 2012); *see also Devon Energy Production Co., L.P. v. Mosaic Potash Carlsbad, Inc.*, 693 F.3d 1195, 12014 (10th Cir. 2012) ("Complete preemption is a rare doctrine"); *Cmty. State Bank v. Strong*, 651 F.3d 1241, 1260 n.16 (11th Cir. 2011) (same). Infrequent application of the preemptive power is necessary to preserve in the states the power to uniquely tailor legislation to fit the evolving norms and standards of their constituencies. State and local regulation thus provide three significant advantages: "(1) [they produce] programs tailored to local needs with correspondingly greater ability to response promptly to changes in local needs; (2) [they permit] experimentation with a variety of approaches to regulation; and (3) [they provide] for greater political accountability and legitimacy."[5]

Recognizing the exceptional nature of Congress's preemption power, in 2009 President Obama explained to his executive agencies that principles of federal preemption should be invoked only under extreme circumstances. He instructed that "preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption." *See* Preemption, 74 Fed. Reg. 24693 (May 20, 2009). He continued,

> Executive departments and agencies should be mindful that in our Federal system, the citizens of the several States have distinctive circumstances and values, and that in many instances it is appropriate for them to apply to themselves rules and principles that reflect these circumstances and values. As Justice Brandeis explained more than 70 years ago, "īt is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."

Id., 74 FR at 24693. That policy was consistent with Executive Order 13132, published by President Clinton in 1999, which explained that "[n]ational action limiting the policymaking discretion of the States shall be taken only where there is a constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance." *See* Federalism, 64 Fed. Reg. 43255, 43256 (Aug. 4, 1999). "Any regulatory preemption of State law shall be restricted to the minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated." *Id.* at 43257.

Unsurprisingly, Congress has traditionally let food regulation, including food label regulation, remain with the states alongside the federal regime, a practice that fosters joint enforcement of food laws and thereby better protects the consumer. The FDA depends on companion state models to help enforce its own goals and standards. *See, e.g., Gustavson v. Wrigley Sales Co.*, 961 F.Supp. 2d 1100, 1116-17 (N.D. Cal. 2013) (explaining that California's Sherman Laws are identical to FDA regulations). FDA also works with local governments to

[4] *See* Wolfson, *supra* note 1, at 114.
[5] *See* Gray, *Regulation and Federalism*, 1 Yale J. Reg. 93, 95 (1983).

develop food codes.[6] In that context, use of the federal preemption power for GMO labeling is at odds with the history of dual federalism and unprecedented in this precise context.

Where the FDA has traditionally relied on cooperative efforts in the states, H.R. 1599 would instead demand exclusive federal GMO certification programs and enforcement of GMO marketing. Section 291G authorizes the Secretary of Agriculture to collect fees from regulated industry members in an effort to cover the "estimated costs to the Secretary of carrying out" H.R. 1599. SAFLA is thus a hidden tax on businesses manufacturing GMO-free products. Those additional costs are passed to consumers, which will make GMO-free products less marketable and less desirable. H.R. 1599 is justified in part based on the argument that it curbs rising costs to GMO and non-GMO entities, yet by its own terms it only imposes mandatory prior restraints on GMO free producers, thus saddling them with costs to the competitive advantage of GMO food producers and sellers.

A. Dual Sovereign System

The U.S. Constitution contemplates "a system of dual sovereignty." *Printz v. U.S.*, 521 U.S. 898, 918 (1997) (internal quotations omitted). "Although the States surrendered many of their powers to the new Federal Government, they retained 'a residuary and inviolable sovereignty.'" *Id*. (quoting The Federalist No. 39, at 245 (J. Madison)). The Constitution's text reflects this principle of federalism. *See, e.g.*, U.S. Const., Art. IV, § 3 (prohibiting any involuntary reduction or combination of a State's territory); *id*. at Art. III, § 2 (the Judicial Power Clause); *id*. at Art. IV, § 2 (the Privileges and Immunities Clause); *id*. at Art. V (requiring the votes of three-fourths of the States to amend the Constitution; *id*. at Art. IV, § 4 (the Guarantee Clause); *id*. at Art. I, § 8 (conferring upon Congress only discrete, enumerated powers). The Tenth Amendment further establishes the sovereignty of the States by asserting that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." *See also Lane Cnty. v. State of Oregon*, 74 U.S. 71, 76 (1868) ("To [the States] nearly the whole charge of interior regulation is committed or left; to them and to the people all powers not expressly delegated to the national government are reserved.").

The Framers embraced "a system in which the State and Federal Government would exercise concurrent authority over the people," and "rejected the concept of a central government that would act upon and through the States." *Id*. at 919-20. *See also Lane Cnty.* 74 U.S. at 76 ("Both the States and the United States existed before the Constitution. The people, through that instrument, established a more perfect union by substituting a national government, acting, with ample power, directly upon the citizens, instead of the Confederate government, which acted with powers, greatly restricted, only upon the States.").

[6] *See* FDA, "Real Progress in Food Code Adoption" (Oct. 2013), *available at*, http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM230336.pdf (last visited Aug. 4, 2015).

Although States have residual sovereignty, they "have no power, reserved or otherwise, over the exercise of federal authority within its proper sphere." *U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 841 (1995) (Kennedy, A., concurring). Similarly, Congress "has no ability to require States to govern according to Congress' instructions." *N.Y. v. U.S.*, 505 U.S. 144, 162 (1992). *See also Hodel v. Va. Surface Mining & Reclamation Assn., Inc.,* 452 U.S. 264, 288 (1981) (noting that Congress cannot "commandee[r] the legislative process of the States by directly compelling them to enact and enforce a federal regulatory program").

Because the Framers "split the atom of sovereignty," our country today continues to have "two orders of government, each with its own direct relationship, its own privity, its own set of mutual rights and obligations to the people who sustain it and are governed by it . . ." *U.S. Term Limits, Inc.*, 514 U.S. at 838-39 (Kennedy, A., concurring). Historically, health and safety regulation has been the province of the states and localities, and the federal government has been loath to pre-empt state and local health and safety ordinances. *See, e.g.*, *Metro. Life Ins. Co. v. Mass*., 471 U.S. 724, 756 (1985) ("States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.") (internal quotations omitted); *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993) ("[A] court interpreting a federal statute pertaining to a subject traditionally governed by state law will be reluctant to find pre-emption."); West's ALR Digest States k18.3, ALRDG 360K18.3 ("A court interpreting a federal statute pertaining to a subject traditionally governed by state law will be reluctant to find preemption.") (citing *Rushing v. Kan. City Southern Ry. Co*., 185 F.3d 496, (5th Cir. 1999).

B. Preemption in General

One way in which a federal law preempts state law is through express preemption.[7] *English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990). Express preemption occurs when Congress "define[s] explicitly the extent to which its enactments pre-empt state law." *Id*. In such an instance, Congress is said to have "unmistakably ordained that its enactments alone are to regulate [an aspect of activity]" and, thus, "state laws regulating that aspect . . . must fail." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (internal citation and quotations omitted).

When Congress invokes its express preemption powers pursuant to one or more of its constitutionally enumerated powers, the U.S. Supreme Court upholds the validity of those actions, *see, e.g., Pacific Gas & Elec. v. Energy Res. Comm'n*, 461 U.S. 190, 203-04 (1983), unless the federal law is unconstitutional, in which case it can have no preemptive effect. *See, e.g., U.S. v. Lopez*, 514 U.S. 549, 566 (1995) (holding a statute unconstitutional on the ground

[7] The other two ways in which a federal law may preempt a State law are: (1) field preemption, in which a federal law preempts a State law that attempts to regulate "conduct in a field that Congress intended the Federal Government to occupy exclusively"; and (2) conflict preemption, in which the State law conflicts with federal law, making it impossible for a party to comply with both laws. *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990); *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

that it was not within Congress's enumerated power to regulate commerce among the several states).

C. H.R. 1599 Improperly Preempts State GMO Labeling Laws

The use of an express preemption clause to accomplish an otherwise unconstitutional end violates Article I, Section 8. The State GMO disclosure laws directly advance the rights of consumers to receive information material to them at the point of sale. Those laws further the constitutional objective of information disclosure over suppression, which is mandated by the First Amendment commercial speech doctrine. Moreover, the federal pre-emption brought about by H.R. 1599 not only blocks the states from requiring truthful ingredient disclosures, it also forbids GMO free claims unless federal prior restraints are satisfied. It thus achieves a dual content and speaker specific discrimination in violation of the First Amendment. That violation is imposed through H.R. 1599 preemption, an improper use of the pre-emption power.

"Health and safety issues have traditionally fallen within the province of state regulation. This is true of the regulation of food and beverage labeling and branding." *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3d Cir.2009). Nonetheless, under its enumerated power "to regulate commerce . . . among the several states," Congress has enacted several laws that contain an express preemption provision concerning the labeling of any food in interstate commerce, such as the National Labeling and Education Act of 1990 ("NLEA"),[8] the Federal Meat Inspection Act ("FMIA"), and the Poultry Products Inspection Act ("PPIA").[9]

Like the NLEA, the FMIA, and the PPIA, H.R. 1599 expressly preempts State laws concerning the labeling of foods in interstate commerce.[10] Specifically, Sections 203 and 303

[8] The NLEA created a system of national, uniform nutrition labeling. It amended the federal Food, Drug, and Cosmetic Act ("FDCA"), which charges the Food and Drug Administration ("FDA") with protecting the public health by ensuring that "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). Congress intended the NLEA "to clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods." H.R. Rep. No. 101–538, at 7 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3337. The NLEA expressly preempts State food labeling laws that are that are not identical to specific labeling requirements. Congress, however, did not intend for the NLEA to *impliedly* preempt State food labeling laws. *See* Pub. L. No. 101-535, § 6(c)(1) ("The [NLEA] shall not be construed to preempt any provision of State law, unless such provision is *expressly preempted* under section 403A of the [FDCA]."") (emphasis added). Further, Congress carved out an exemption from the NLEA's express preemption clause for warnings concerning the safety of food or a component of food, including pesticide and cancer warnings. *See id*. at § 6(c)(2) (noting that it "shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food").

[9] The U.S. Department of Agriculture administers the FMIA and the PPIA. Both laws contain similar express preemption language that permits some concurrent State enforcement but prohibits State marking, labeling, packing, or ingredient requirements that are in addition to, or different than, those mandated by these federal laws. *See* 21 U.S.C. §§ 467e, 678.

[10] Additionally, Section 113 of H.R. 1599 also expressly preempts State laws that establish "any requirement with respect to the sale or offering for sale in interstate commerce of a genetically engineered

expressly preempt State laws that establish labeling requirements for genetic engineering and "natural claims, respectively. Thus, SAFLA prohibits all State laws requiring mandatory labeling of any food that was developed using genetic engineering.

An example of a State law that the SAFLA will preempt is Vermont's Act 120. Act 120 requires, *inter alia*, that manufacturers and retailers identify whether a raw or processed food sold in Vermont is produced in whole or in part through genetic engineering. *See* V.S.A. § 3043(b)(1) (requiring GE manufacturers to clearly and conspicuously label a "packaged raw agricultural commodity" with "produced with genetic engineering"); *id*. at § 3043(b)(2) (requiring a GE retailer to "post a label" on the shelf or bin of a "raw agricultural commodity" that is not sold separately packaged "with the clear and conspicuous words 'produced with genetic engineering'"); *id*. at § 3043(b)(3) (requiring GE manufactures of packaged processed foods to label them as: "partially produced with genetic engineering," "may be produced with genetic engineering," or "produced with genetic engineering"). Vermont's law also prohibits manufacturers from labeling or advertising GMO foods as "natural," "naturally made," "naturally grown," "all natural," or "any words of similar import." *Id*. at § 3043(c).

Vermont's authority to enact Act 120 derived from its general police power "to prevent inadvertent consumer deception, prevent potential risks to human health, protect religious practices, and protect the environment." 2014 Vt. Acts & Resolves No. 120, § 1(5), (6). *See also Plumley v. Mass.*, 155 U.S. 461, 472 (1894) ("If there be any subject over which it would seem the states ought to have plenary control . . . it is the protection of the people against fraud and deception in the sale of food products."); *Me. v. Taylor*, 477 U.S. 131, 138 (1986) ("The limitation imposed by the Commerce Clause on state regulatory power 'is by no means absolute,' and 'the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected.'") (quoting *Lewis v. BT Inv. Managers, Inc.*, 447 U.S. 27, 36 (1980)).

Vermont's law is one example among several statutes adopted or pending in the states that promote the free flow of information to consumers the marketplace. Those laws are very similar in content and, thus, defy the charge that they constitute a diverse patchwork of regulation. Instead, they form a highly complementary and similar system of disclosure laws which effect the simple requirement that food products made with genetically engineered ingredients disclosure that fact on the label. The Vermont law, for example, favors disclosure over suppression, and allows those companies labeling "GMO" products to provide disclaimer language explaining that the product is materially indistinguishable from non-GMO alternatives, if truthful. That law was favored by Vermont citizens, and represents the type of state-level experimentation traditionally protected in a federalist system of government. SAFLA deprives

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plant for use or application in food that is not identical to the requirement of section 461 of the Plant Protection Act (as added by section 111 of [H.R. 1599])." Section 461 of the Plant Protection Act establishes premarket notification requirements for selling, or offering to sell, in interstate commerce: (1) a nonregulated genetically engineered plant for use or application in food; or (2) a food product produced from, containing, or consisting of a nonregulated genetically engineered plant. Thus, under H.R. 1599, State laws that enact different premarket notification requirements for genetically engineered foods in interstate commerce are void.

the states not only of their ability to respond to local citizen needs but also of their right to regulate within the field.

D. State GMO-Labeling Initiatives Do Not Create Inconsistent Compliance Costs

Proponents of SAFLA allege that State-level GMO initiatives impose compliance burdens on industry, which threaten to increase GMO and non-GMO prices. Those advocates claim that the "bill will prevent the costly price hikes associated with a patchwork of state labeling laws." *See* House Rep. 114-208, Part 1 (114th Congress (2015-2016)). Those conclusions are not supported by sound empirical evidence and are illogical. In fact, State GMO laws are consistent in all material respects. Concerning GMO disclosure requirements, the laws are satisfied by the simple addition of "produced with genetic engineering," a phrase that is not unlike phrases required for the listing of expiration dating, statements of identity, recommended uses, or allergy warnings which manufacturers routinely modify on labels to satisfy regulatory requirements without adding more than a negligible increase to the price of goods in the market. In short, modest label changes are a common expense that adds little, if anything, to the price of finished goods.

In most instances, companies can satisfy the various state laws through changes so modest that they have but a trivial effect on price. Labeling changes to the color and commercial content of packaging is customary and considered an ordinary cost of doing business in highly competitive markets, like food markets.

Moreover, the modest label changes required by the State GMO disclosure laws are also trivial when compared to other state food and labeling laws that have historically imposed higher variable cost obligations on industry. A certain level of heterogeneity among the state food laws has always existed, and those various laws have been upheld against constitutional challenges regardless of the burdens imposed on interstate commerce. Proposition 65 in California, for example, requires labeling disclosures for certain ingredients and warnings concerning the risk of certain diseases (e.g., cancers) stemming from exposure to those ingredients. *See, e.g.,* Cal. Health & Safety Code §§ 25180, 25180.7, 25192, and 25249.5-25249.13. Those labeling burdens differ from, and are in excess of, any other state or federal labeling laws. The California authorities have required disclosures for the presence of ingredients at levels far below those mandate under federal laws. Prop 65 requires every business selling product in California to affix labeling content to their products that substantially differs from the labeling content appearing on products sold into any of the remaining forty-nine states. No court has overturned Proposition 65.

Many similar state laws have been enacted that impose divergent standards on food manufacturers, including labeling regulations. Examples include, but are not certainly limited to, the following:

- Alaska Stat. Ann. § 17.20.045: Prohibiting any food fish product from being designated as halibut unless that fish is of the species Hippoglossus or Hippoglossus Stenolepsis.

- Ark. Code Ann. § 20-57-402: Regulating the labeling of "honey" products.

- Conn. Gen. Stat. Ann. § 21a-104a: Requiring an allergen warning for a sulfating agent present in bulk, unpackaged food.

- Del. Code Ann. tit. 16, § 4312: Requiring carbonated beverages that contain artificial sweeteners to be labeled as "DIETETIC."

- Iowa Code Ann. § 189.14(3): Prohibiting labeling of a liquid or semisolid product as sorghum unless the product states that the product is sorghum syrup.

- La. Rev. Stat. Ann. 56:578.11(A): Requiring any catfish or catfish product to be labeled to indicate that it was farm-raised or naturally produced.

- Me. Rev. Stat. tit. 22, § 2157(14): Requiring fresh produce treated with post-harvest chemicals to be labeled as such when sold or offered for sale at retail outlets.

- Md. Code Ann., Health-Gen. § 21-210(b)(11): Declaring a food misbranded if it was frozen and then offered for sale in an unfrozen state, unless the labeling clearly and conspicuously states that it was previously frozen and should not be re-frozen.

- Mass. Gen. Laws Ann. ch. 94, § 77G: Requiring containers of dead lobster processed by a rapid freezing method to bear a plainly marked label that included the date of processing.

- Minn. Stat. Ann. § 30.49: Regulating the labeling of wild rice.

- N.Y. Agric. & Mkts. Law § 204-a: Requiring olive oil mixtures to be labeled with the specific percentage of olive oil.

- R.I. Gen. Laws Ann. § 21-18-2: Requiring closed packages of apples to bear certain labeling statements.

- Wis. Stat. Ann. § 97.13: Prohibiting the sale of any food intended for human consumption that contains fish flour unless its package bears a statement declaring that it was made only from the edible portions of the fish.

State food labeling laws, like those identified above, are generally upheld. Under the Dormant Commerce Clause, when federal law is silent on a matter, state action could nonetheless be unlawful if it burdens interstate commerce. *See, e.g., Hughes v. Oklahoma*, 441 U.S. 322, 326 (1979); *Oklahoma Tax Commn. v. Jefferson Lines, Inc*., 514 U.S. 175, 179 (1995). The Dormant Commerce Clause tolerates State food labeling laws that do not discriminate on their face against interstate commerce in favor of intrastate commerce. *See Fulton Corp. v. Faulkner*, 516 U.S. 325 (1996) ("State laws discriminating against interstate commerce on their face are virtually *per se* invalid.") (internal quotations removed). Additionally, the State law cannot have a practical effect of extraterritorial regulation of commerce entirely outside the borders of the state adopting such a law. *See Freedom Holdings, Inc. v. Spitzer*, 357 F.3d 205, 219 (2d Cir. 2004) ("[A] state statute will be invalid *per se* . . . if it has the practical effect of controlling commerce occurring wholly outside that State's borders."). Lastly, the State law cannot burden interstate commerce disproportionately to the state's benefits. *See Pike v. Bruce Church, Inc*., 397 U.S. 137, 142 (1970). Applying that analysis, the nuanced state regulations have survived judicial review. The GMO disclosure laws do not create a dormant commerce clause problem because they do not discriminate against out of state producers in favor of in state ones.

E. State GMO Laws Do Not Burden Industry or Increase Prices

Food manufacturers, distributors, and retailers are accustomed to tailoring product labels to State-specific labeling requirements. Heightened public awareness of the importance of discerning what ingredients are in foods to make informed selections makes ingredient listing a common and expected characteristic of food marketing. The food industry is well-equipped to handle, financially and otherwise, State laws requiring genetically engineered ingredients to be labeled. State-level GMO labeling laws, like federal ingredient labeling requirements, do not impose standards that are materially different from those expected by industry and already incorporated into food labels.

States such as Connecticut, Maine, and Vermont have enacted laws that require a disclosure statement for genetically engineered foods and prohibit the use of "natural" claims for such products. Those laws impose consistent obligations and, therefore, do not create a divergent patchwork of laws.[11] In fact, the statutes in Maine and Connecticut are not effective until other contiguous states adopt similar laws, thus ensuring that any burdens on commerce are reduced or eliminated by dependence on laws of the same kind adopted throughout the region.[12] All State

[11] *See , e.g*., 2014 Vt. Acts & Resolves No. 120, § 3(2) (allowing the Attorney General of Vermont to adopt by rule a requirement that a label identify a food produced entirely or in part from genetic engineering in a manner consistent with requirements in other jurisdictions for the labeling of food, including the labeling of food produced with genetic engineering); see also n. 1, *supra* (discussing how Connecticut's and Maine's laws only become effective if contiguous states enact consistent mandatory labeling laws for genetically engineered foods.

[12] Vermont's law, as it concerns the labeling of food produced with genetic engineering, will be effective on July 1, 2016. 2014 Vt. Acts & Resolves No. 120, § 7(b). Connecticut's and Maine's laws

laws require food that was partially or entirely produced with genetic engineered to be designated with a short labeling statement: "Produced with Genetic Engineering." Put simply, each state requires a short labeling disclosure informing consumers that the food contains a genetically engineered ingredient. And that requirement essentially satisfies all compliance obligations.

In Connecticut, a food that is intended for human consumption which is entirely or partially genetically engineered[13] must be designated as a food "Produced with Genetic Engineering."[14] Conn. Gen. Stat. Ann. § 21a-92c(a). The placement of that labeling statement depends on the manner in which the food is sold. Specifically, Section 21a-92c(a) provides:

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will only become effective if a requisite number of states enact consistent laws. *See* An Act To Protect Maine Food Consumers' Right To Know About Genetically Engineered Food, 2014 Me. Laws, 2 (making the act effective 30 days after the Commissioner of Agriculture, Conservation and Forestry certifies to the Secretary of State and the Revisor of Statutes that legislation requiring mandatory labeling of genetically engineered foods has been adopted by at least 5 contiguous states, including Maine); Conn. Gen. Stat. Ann. § 21a-92c(a) (requiring mandatory labeling on "October first following the date that the Commissioner of Consumer Protection recognizes the occurrence of both of the following: (1) Four states, not including [Connecticut], enact a mandatory labeling law for genetically-engineered foods that is consistent [Connecticut's law], provided one such state borders Connecticut; and (2) the aggregate population of such states located in the northeast region of the United States that have enacted a mandatory labeling law for genetically-engineered foods that is consistent with this subsection exceed twenty million based on 2010 census figures).").

[13] "Genetic engineering" means:

> a process by which a food or food ingredient that is produced from an organism or organisms in which the genetic material has been changed through the application of: (A) In vitro nucleic acid techniques, including recombinant DNA (deoxyribonucleic acid) techniques and the direct injection of nucleic acid into cells or organelles; or (B) fusion of cells, including protoplast fusion, or hybridization techniques that overcome natural physiological, reproductive or recombination barriers, where the donor cells or protoplasts do not fall within the same taxonomic group, in a way that does not occur by natural multiplication or natural recombination[.]

Conn. Gen. Stat. Ann. § 21a-92b(2). An exception is provided, however, for a processed food that would otherwise have been subject to the disclosure requirement "solely because one or more processing aids or enzymes were produced or derived from genetic engineering." Conn. Gen. Stat. Ann. § 21a-92c (a).

[14] The following foods are not subject to the disclosure requirements: (1) alcoholic beverages; (2) non-alcoholic malt beverages; (3) food intended for human consumption that is not packaged for retail sale and that is either a processed food prepared and intended for immediate consumption or a food that is served, sold or otherwise provided in any restaurant or other food facility that is primarily engaged in the sale of food prepared and intended for immediate consumption; (4) farm products a farmer (or the farmer's agent) sells to consumers at a pick-your-own farm, roadside stat, on-farm market, or farmer's market; and (5) food consisting entirely of, or derived entirely from, an animal that was not genetically engineered even if the animal was fed or injected with any genetically-engineered food or any drug that was produced through means of genetic engineering. Conn. Gen. Stat. Ann. § 21a-92c(b)(1)-(5).

> (i) In the case of such food that is sold wholesale and is not intended for retail sale, on the bill of sale accompanying such food during shipping, with the clear and conspicuous words: "Produced with Genetic Engineering"; (ii) in the case of such food for retail sale contained in a package, with the clear and conspicuous words: "Produced with Genetic Engineering"; [and] (iii) in the case of such food that is a raw agricultural commodity, on the package offered for retail sale or, in the case of any such commodity that is not separately packaged or labeled, on the bill of sale or invoice for such commodity and on the retail store shelf or bin that holds such commodity displayed for sale with the clear and conspicuous words: "Produced with Genetic Engineering"[.]

Additionally, the disclosure statements must be "displayed in the same size and font as the ingredients in the nutritional facts panel on the food label." *Id*. "Any person selling, offering for sale or distributing in [Connecticut] any food . . . required to be labeled as provided in [section 21a-92c] shall be responsible for ensuring that such food . . . is so labeled." *Id*. at § 21a-92c(c). Knowingly violating section 21a-92c exposes a person to liability "for a civil penalty not to exceed one thousand dollars per day, per product." *Id*. at § 21a-92c(e).[15] A food intended for human consumption is misbranded if it is genetically engineered and does not bear the labeling section 21a-92c requires.[16] *See id*. at § 21a-102(a)(12). Finally, Connecticut law excludes food that has been genetically engineered from the definition of "natural food." Conn. Gen. Stat. Ann. § 21a-92 (17).

Similarly, under Maine law, "any food[17] offered for retail sale that is genetically engineered[18] must be accompanied by a conspicuous disclosure that states 'Produced with Genetic Engineering.'" Me. Rev. Stat. tit. 22, § 2593(1). That statement must be placed on the package of packaged food or, if the food is unpackaged, on a card or label on the store shelf or

[15] Connecticut does not allow the civil penalty to be multiplied per package. *See* Conn. Gen. Stat. Ann. § 21a-92c (e) ("Calculation of such civil penalty shall not be made or multiplied by the number of individual packages of the same product displayed or offered for retail sale. Civil penalties assessed under this section shall accrue and be assessed per each uniquely named, designated or marketed product."). A retailer is only liable for failure to label in violation of section 21a-92c(c), however, if: (q) the retailer is the producer or the manufacturer of the genetically engineered food and sells it under a brand the retailer owns; or (2) the retailer's failure to label was knowing and willful. *See* Conn. Gen. Stat. Ann. § 21a-92c(f).

[16] A food is not misbranded under that provision, however, if: (1) it was produced without the producer's knowledge that it was genetically engineered; or (2) it is a processed food that is subject to the labeling requirements solely because it contains one or more materials that have been produced with genetic engineering and such materials do not, in the aggregate, account for more than nine-tenths of one percent of the total weight of the processed food. *See* Conn. Gen. Stat. Ann. § 21a-102(a)(12).

[17] "Food" is limited to "food intended for human consumption." Me. Rev. Stat. tit. 22, § 2592(2). Thus, the law is inapplicable to animal food.

[18] For purposes of Maine's law, "genetically engineered" means "the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid and direct injection of nucleic acid into cells or organelles, or the fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection." Me. Rev. Stat. tit. 7, § 1051.

bin in which the food is displayed.[19] *See id*. Again, that law requires nothing fundamentally different than the other regional laws. Failure to include the requisite disclosure statement misbrands the genetically engineered food.[20] *See id*. at § 2593(3). Maine law also prohibits use of the term "natural" to describe genetically engineered foods. *See id*. at § 2593(2). A violation of Maine's genetic engineering law constitutes a civil violation subject to a fine not to exceed $1,000 per day per misbranded product per sales location. *See id*. at § 2595(3).

Like Connecticut and Maine, Vermont requires food intended for human consumption and offered for sale by a retailer to be labeled as produced entirely or in part from genetic engineering if it is offered for retail sale in Vermont and is entirely or partially produced with genetic engineering.[21] *See* Vt. Stat. Ann. tit. 9, §§ 3042(3), 3043(a)(1)-(2). Vermont also takes in account how the food is sold. Its law states:

> If a food is required to be labeled under subsection (a) of this section, it shall be labeled as follows:
>
> (1) in the case of a packaged raw agricultural commodity, the manufacturer shall label the package offered for retail sale, with the clear and conspicuous words "produced with genetic engineering";
>
> (2) in the case of any raw agricultural commodity that is not separately packaged, the retailer shall post a label appearing on the retail store

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[19] Eating establishments, alcoholic beverages, and medical foods are example from the disclosure requirement, however. *See* Me. Rev. Stat. tit. 22, § 2594(2)-(3).

[20] A genetically engineered food is not misbranded, however, if: (1) a sworn statement attests that it was not knowingly genetically engineered or commingled with a genetically engineered food; (2) it is a food product derived from an animal that was not genetically engineered but was fed genetically engineered food; and (3) it is a packaged process food and the total weight of it that was genetically engineered is less than 0.9% of the total weight of the processed food. *See* Me. Rev. Stat. tit. 22, § 2593(3)(A)-(C).

[21] For purposes of Vermont's law, "genetic engineering" means:

> a process by which a food is produced from an organism or organisms in which the genetic material has been changed through the application of:
>
> (A) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) techniques and the direct injection of nucleic acid into cells or organelles; or
>
> (B) fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells or protoplasts do not fall within the same taxonomic group, in a way that does not occur by natural multiplication or natural recombination.

Vt. Stat. Ann. tit. 9, § 3042(4).

> shelf or bin in which the commodity is displayed for sale with the clear and conspicuous words "produced with genetic engineering"; or
>
> (3) in the case of any processed food that contains a product or products of genetic engineering, the manufacturer shall label the package in which the processed food is offered for sale with the words: "partially produced with genetic engineering"; "may be produced with genetic engineering"; or "produced with genetic engineering."

Id. at § 3043(b).[22] Again, the labeling disclosure is entirely consistent with other regional laws. The Attorney General of Vermont may adopt by rule a requirement for, *inter alia*, that the label required for food produced from genetic engineering include a disclaimer that the Food and Drug Administration does not consider foods produced from genetic engineering to be materially different from other foods. *See* 2014 Vt. Acts & Resolves No. 120, § 3. Additionally, a "manufacturer of a food produced entirely or in part from genetic engineering shall not label the product on the package, in signage, or in advertising as 'natural,' 'naturally made,' 'naturally grown,' 'all natural,' or any words of similar import that would have a tendency to mislead a consumer." *Id*. at § 3043(c). A violation of Vermont's genetic engineering law exposes a person to liability for a civil penalty not to exceed $1,000 per day per product. *See id*. at § 3048(a).[23]

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[22] Section 3043(b) does not, however, subject the following foods to its labeling requirements: (1) food consisting entirely of or derived entirely from an animal what was not itself produced with genetic engineering, even if the animal was fed or injected with any food, drug, or other substance produced with genetic engineering; (2) a "raw agricultural commodity or processed food that was grown, raised, or produced without the knowing or intentional use of food or seed produced with genetic engineering"; (3) any processed food that would normally be subject to the labeling requirements solely because it includes one or more processing aids or enzymes produced with genetic engineering; (4) alcoholic beverages; (5) any processed food that would normally be subject to the labeling requirements solely because it includes one or more materials that have been produced with genetic engineering so long as such materials do not, in the aggregate, account for more than 0.9 percent of the total weight of the processed food; (6) food that has been independently verified as not having been knowingly or intentionally produced from genetic engineering; (7) food that is not packaged for retail sale and is either a processed food intended for immediate human consumption or a food that is served, sold, or otherwise provided in any restaurant or other food establishment that is primarily engaged in the sale of food prepared and intended for immediate human consumption; and (8) medical foods. Vt. Stat. Ann. tit. 9, § 3044(1)-(8). Vermont has left open the possibility that milk or milk products should be subject to labeling requirements though. *See* 2014 Vt. Acts & Resolves No. 120, § 6.

[23] The civil penalty is not multiplied per product. *See* Vt. Stat. Ann. tit. 9, § 3048(a) ("Calculation of the civil penalty shall not be made or multiplied by the number of individual packages of the same product displayed or offered for retail sale. Civil penalties assessed under this section shall accrue and be assessed per each uniquely named, designated, or marketed product."). A retailer, however, will not be held liable for failing to label a processed food if the retailer is not the producer or manufacturer of the processed food. *See* Vt. Stat. Ann. tit. 9, § 3045(a). Nor will a retailer be held liable for failure to label a raw agricultural commodity if the retailer has or obtains a sworn statement that the raw agricultural commodity has not been knowingly or intentionally produced with genetic engineering and has been segregated from and has not been knowingly or intentionally commingled with food that may have been produced with genetic engineering at any time. *See id*. at § 3045(b).

The following table summarizes the similarities between the laws:

Applicable Clause	CT	ME	VT
Requires partially or entirely GE foods to be identified as "Produced with Genetic Engineering"	Conn. Gen. Stat. Ann. § 21a-92c(a)	Me. Rev. Stat. tit. 22, § 2593(1)	Vt. Stat. Ann. tit. 9, § 3043(a)(1)-(2), (b)
Exempts certain foods from the disclosure requirement, such as alcoholic beverages	Conn. Gen. Stat. Ann. §§ 21a-92c(b)(1)-(5), 21a-102(a)(12)	Me. Rev. Stat. tit. 22, §§ 2593(A)-(C), 2594(2)-(3)	Vt. Stat. Ann. tit. 9, § 3044(1)-(8)
Declares food that does not bear required GE labeling to be misbranded	Conn. Gen. Stat. Ann. § 21a-102(a)(12)	Me. Rev. Stat. tit. 22, § 2593(3)	N/A
Prohibits "natural" claims for GE foods	Conn. Gen. Stat. Ann. § 21a-92 (17)	Me. Rev. Stat. tit. 22, § 2593(2)	Vt. Stat. Ann. tit. 9, § 3043(c)
Assesses civil penalties for violations and limits how such penalties may be calculated	Conn. Gen. Stat. Ann. § 21a-92c(e)	Me. Rev. Stat. tit. 22, § 2595(3)	Vt. Stat. Ann. tit. 9, § 3048(a)
Limits liability of retailers or others	Conn. Gen. Stat. Ann. § 21a-92c(f)	Me. Rev. Stat. tit. 22, § 2593(3)(A)-(C).	Vt. Stat. Ann. tit. 9, § 3045(a)-(b)

Because those State GMO labeling laws are similar in all material respects, regulatees can easily comply with each through simple, uniform changes to product labeling. Again, those uniform changes are not unlike the nuanced state laws that have mandated labeling changes for decades, e.g., California's Proposition 65. For most genetically engineered foods, the disclosure requirements are satisfied by placing "Produced with Genetic Engineering" on a store shelf or bin. Accordingly, GMO foods do not require different labeling or packaging because of the States' mandatory genetic engineering labeling laws.

IV. FRUSTRATION OF FEDERAL ADVERSE EVENT REPORTING, SOURCE IDENTIFICATION, AND RESULTING CONSUMER CONFUSION

SAFLA encumbers adverse event reporting associated with GMO foods. It impedes the ability of manufacturers and consumers to identify source ingredients or contaminants in GM foods. It increases the costs of business for companies marketing non-GMO foods which, in turn, reduces the supply of those products. Finally, the SAFLA actually increases consumer confusion by hiding the presence of genetically engineered ingredients and by allowing the term "natural" to be used on GMO food labels.

A. Frustration of Adverse Event Reporting and Ingredient Disclosures

By allowing GMO Food producers and sellers to avoid disclosure of genetically engineered ingredients, SAFLA renders it far more difficult for medical experts and government agencies to track adverse events that may be associated with those ingredients. As with all innovations in the food supply, GMO foods are likely not insulated from the need to conduct recalls related specifically to GMO food product production and distribution. Awareness of that need ordinarily arises from adverse event reporting first to physicians and then, from them, to government agencies. If a problem is associated with a genetically engineered ingredient in a food, the failure to identify such ingredients on the label can delay or prevent identification of the specific GMO food problem.

Many food and dietary supplement products pass through multiple manufacturing steps before reaching consumers, particularly non-perishable goods. The stream of commerce involves source manufacturers, packagers, labeler, distributors, retailers, and many others in the linear path from manufacture to consumption. Downstream manufacturers commonly rely on certificates of analysis to evaluate the quality, purity, and composition of source ingredients. Those companies frequently sample and verify incoming lots or batches. But the presence of GMO-sourced or –containing ingredients may not be detectable or apparent. For instance, a lot containing certain forms of corn could also contain transgenic variants or corn modified to increase plant based pesticides. Verification sampling may only reveal the presence of the bulk corn ingredient, without revealing that a certain percentage of the lot contained GMO ingredients. A downstream manufacturer might only discover the presence of those components if the source manufacturer included a GMO statement on the certificate of analysis that accompanies the product in transit.

Here SAFLA is problematic because it renders GMO disclosures *voluntary* only. Manufacturers would never be obligated to include GMO disclosures in their certificates of analysis. That means the presence of GMOs remains undisclosed even during the manufacturing process. The State GMO laws, by contrast, compel disclosure of GMO content, which would therefore require source manufacturers to similarly identify the presence of GMOs so that middle manufacturers or private labelers could comply with applicable law.

The distinction between the two systems raises concerns over the traceability of technologies in the market. Consider the following hypothetical which illustrates the problems in SAFLA's non-disclosure regime. Suppose that in four years a manufacturer genetically engineers strawberry crops to include a new protein that renders the crop pest-resistant. Under

SAFLA, that protein remains undeclared in the stream of commerce when the farm-grown strawberries are later delivered to a packaging plant that freeze-dries the berries for use in packaged dessert products. Because SAFLA renders GMO disclosures voluntary, the original manufacturer is not obligated to disclose the presence of GMOs on its Certificate of Analysis, meaning that no party in the stream of commerce (other than the source manufacturer) knows that the new protein was used in the strawberry crop. The packager has no cause or method to test for that protein, which remains undeclared and unknown. By all other measures, the strawberries are equivalent to conventional strawberries grown and sold at market.

The packaged dessert travels through three layers of a distribution network before a consumer purchases the product at a local grocer. The protein triggers an acute, but non-serious, adverse reaction presenting as an allergic response in a small fraction of consumers who ingest the product. Those affected consumers are not otherwise allergic to strawberries and, so, the fruit component (or the dessert itself) is not easily identified as the root cause. Those consumers are unable to adequately report the presence of a non-serious adverse event to the manufacturer or the FDA. Moreover, the strawberries within that dessert, which contained multiple ingredients, are not considered to be causal agents because the consumers lack a history with strawberry products.

The consumer may nonetheless report the non-serious event to the manufacturer. The FDA, for its part, rarely receives those adverse events because manufacturers or merchants are generally not required to report non-serious adverse events to the FDA. *See* 21 U.S. C. § 379aa-1.[24] Consumer reports filed directly with the distributor or manufacturer are unlikely to reach the FDA unless reviewed during a facility inspection. Moreover, the FDA's process of GRAS self-affirmance for food additives allows manufacturers to formulate and include the new GMO protein in the food market without first notifying the FDA or seeking premarket approval. 21 CFR §170.30(c).[25] So the chain continues, and without a significant number of reports, or an otherwise clear justification, neither the FDA nor health authorities will likely uncover the connection between the new protein and non-serious allergic reactions.[26]

The result, thus fostered by SAFLA's non-disclosure regime (or "voluntary" disclosure system) might enable an undetected food allergy to persist until detected much later, after a substantial volume of exposures, and, at worst, never attributed to the proper causal ingredient.

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[24] A "serious adverse event" is any health-related event associated with the use of a dietary supplement that is adverse and results in: (1) death; (2) a life-threatening experience; (3) inpatient hospitalization; (4) a persistent or significant disability or incapacity; or (5) a congenital anomaly or birth defect. 21 U.S.C. § 37911-1(a)(2).

[25] *See* How U.S. FDA's GRAS Notification Program Works (December 2005/January 2006), http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/ucm083022.htm#authors ("Put simply, substances that are GRAS under conditions of their intended use are not food additives and do not require premarket approval by FDA.").

[26] *See* Julie A. Nordlee, Steve L. Tyler, Jeffrey A. Townsend, Laurie A. Thomas & Robert K. Bush, *Identification of a Brazil-nut allergen in transgenic soybeans*, N. Engl. J. Med., 334:688–92 (1996) (finding that Brazil nut protein introduced to improve the genetic quality of engineered soybeans could produce an allergic reaction in people with Brazil nut allergies).

In sum, whether GMO products present a risk to safety or health is immaterial. The problem lies in the inherent lack of disclosure or traceability that would otherwise allow FDA or consumers to react efficiently if a safety issue ever arises. For those cautionary reasons, federal food safety laws like the Food Safety Modernization Act (FSMA), 21 U.S.C. §§ 2201 *et seq*., have included prophylactic measures to facilitate traceability and enable recalls when necessary to protect public health. SAFLA shuns those measures and, instead, strictly regulates only those companies that voluntarily choose to disclose the presence of GMO ingredients or that make any non-GMO claims. But what of the majority of companies that will likely choose not to disclose the presence of potentially troubling GMO ingredients? SAFLA actually limits government oversight for those ingredients by failing to include them within the statutory framework. The State GMO regulations had mandated the disclosure of those GMOs, which would at least clue customers and regulators into the need for possible investigation in circumstances that would warrant a recall.

B. SAFLA Increases Costs for Industry and Consumers

SAFLA increases costs for consumers and merchants of GMO-free products by imposing premarket compliance costs on those companies seeking to market products with "GMO-free" or "non-GMO" claims. *See* H.R. 1599, 114th Cong., § 201 (authorizing the Secretary of Agriculture to charge and collect fees to cover the estimated costs of implementing the SAFLA certification program). The bill appropriates only $2 million dollars to the GMO food certification program, but then contemplates that the balance of funding—likely far in excess of the $2 million initial appropriation—will come from the GMO-free industry.[27] SAFLA also requires businesses to develop supply chain process controls, nongenetically engineered food plans, and recordkeeping practices specific to non-GMO products. The fees assessed under SAFLA Section 201 do not include costs of compliance with those new regulatory obligations.[28] Section 291F(b)(1) authorizes "investigations" of regulated firms to verify the accuracy of information contained in those compliance plans. Administrative officers have power of compulsory process, which includes authority to "require the production of any records required to be maintained under this subtitle…" *See* H.R. 1599, Section 291F(b)(2)(E).

[27] H.R. 1599 does not authorize appropriations for the FDA or USDA to carry out the statutory mandate, which includes the promulgation of regulations for "natural" claims, and the review or assessment of certain GMO products. The FDA has most recently faced litigation for its failure to implement the Food Safety Modernization Act. The FDA had claimed a lack of funding to achieve those goals. Implementing those regulations requires time and money. The SAFLA will become yet another unfunded administrative obligation which the agency cannot meaningfully enforce absent additional fees on industry or more money from Congress. State enforcement could alleviate the federal enforcement burden, but the SAFLA stripped states of their right to participate through the express preemption clause.

[28] *See* Dr. Andrew Dyke and Robert Whelan, ECONorthwest, *GE Foods Labeling Cost Study Findings* (September 12, 2014), https://consumersunion.org/wp-content/uploads/2014/09/GMO_labeling_cost_findings_Exe_Summ.pdf (last accessed July 31, 2015) (explaining that labeling burdens are not significant).

Those increased compliance costs are barriers to market entry for companies producing non-GMO products. SAFLA does not preclude the sale of non-GMO products, but it does limit the marketability of those products by constricting claim language that truthfully describes the manufacturing process. SAFLA therefore strips the value from non-GMO farming practices, which require considerable effort, care, and expense. The increased industry burdens also offset the value of "non-GMO" claims. Ultimately the end-consumer shoulders the impact of those costs, either through increased prices, increased search costs attendant to confusion arising from non-disclosure, reduced market supply, or some combination thereof.

SAFLA therefore creates market costs for consumers in two critical ways. First, the bill will likely reduce market supply and increase prices for consumers seeking "non-GMO" foods. Second, the bill reduces the free flow of information deemed material by consumers. In December 2014, according to an Associated Press-GfK consumer poll, forty (40) percent of Americans felt that disclosure of genetically engineered ingredients in foods was extremely important, and sixty-six (66) percent favored mandatory GMO labeling.[29] Limiting information at retail leads to uninformed purchases and a decrease in consumer confidence within the relevant market.

Moreover, increased GMO-free prices could depress the market demand for those products, shrinking the GMO-free food industry to a niche product rarely available through larger retail outlets. Notably, Congress's impetus for the Organic Foods Production Act of 1990 was specifically to support the availability of organic food products. *See* S. Rep. 101-357 at *4944 (July 6, 1990). H.R. 1599 is likely to have the opposite effect. In this way, while H.R. 1599 artificially inflates the market for genetically engineered foods by obfuscating the fact that genetically engineered ingredients are in foods, it correspondingly artificially depresses the market for non-GMO foods by establishing costly prior restraints as conditions precedent to the making of GMO free and Non-GMO claims.

A diminution of the GMO-free market is likely to yield a commensurate increase in the supply of GMO-containing foods, including genetically engineered crops, which increases the likelihood of cross-pollination, another significant threat to the organic food industry. The effects are circular, in part, because an increase in the aggregate environmental presence of GMO-containing crops also increases the costs of production for GMO-free crops as farmers must increase safeguards and controls to maintain a GMO-free crop. Certain states, or political subdivisions thereof, have enacted "GMO-free" zoning laws. But as the number of genetically engineered crops enlarges, those zoning ordinances lose their efficacy. SAFLA therefore imperils those local zoning ordinances, maximizing the disruption of state and local government.

C. H.R. 1599 Increases Consumer Confusion and Deception

[29] *See* Mary Clare Jalonick, *AP-GfK Poll: An appetite for labeling genetically modified foods* (Jan. 13, 2015), http://ap-gfkpoll.com/featured/ap-gfk-poll-an-appetite-for-labeling-genetically-modified-foods (last accessed July 30, 2015).

H.R. 1599 increases consumer confusion and deception by impeding the disclosure of genetically engineered foods on the label, and by permitting companies to label genetically engineered foods counterintuitively, as "natural." The Vermont legislature expressly found that use of the term "natural" on GMO-containing foods could potentially mislead consumers:

> Because genetic engineering . . . involves the direct injection of genes into cells, the fusion of cells, or the hybridization of genes that does not occur in nature, labeling foods produced with genetic engineering as 'natural,' 'naturally made,' 'naturally grown,' 'all natural,' or other similar descriptors is inherently misleading, poses a risk of confusing or deceiving consumers, and conflicts with the general perception that 'natural' foods are not genetically engineered.

See 2014 Vt. Acts & Resolves No. 120, § 1(5)(C)" 2014 Vt. Acts & Resolves No. 120, § 1(5)(C). "Polling by the *New Your Times* indicated that many consumers are under an incorrect assumption about whether the food they purchases is produced from genetic engineering . . ." *Id.* at § 1(5)(B). The Vermont General Assembly concluded, therefore, that "labeling food as produced from genetic engineering will reduce consumer confusion or deception regarding the food they purchase" and "allow consumers to make informed decisions." *Id*. at § 1(3), (5)(B).

Unlike Vermont's statute, however, SAFLA permits GMO foods to be labeled "natural." *See* H.R. 1599, 114th Cong. § 301 (July 23, 2015) (prior to the finalization of FDA regulations concerning the use of "natural" claims, the use of any "natural" claim for a food is allowed if consistent with FDA's current policy for such claims). Under FDA's existing policy, use of the term "natural" on food means that "**nothing artificial or synthetic** (including color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food." 58 Fed. Reg. 2302, 2407 (1993) (emphasis added). Yet the agency has "decline[d] to make a determination . . . regarding whether and under what circumstances food products containing ingredients produced using genetically engineered ingredients may or may not be labeled 'natural.'" Ltr. from FDA to Hon. Judges Gonzalez Rogers, White, and McNulty (Jan. 6. 2014).[30] Thus, GMO foods may be deceptively labeled "natural" under SAFLA.

Although FDA has authority to enact regulations concerning the use of "natural" claims under SAFLA, FDA has publicly stated that GMO-containing foods are materially indistinct from GMO-free foods. *See* FDA, *Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not been Developed Using Biotechnology*, (Jan. 2001) ("FDA has concluded that the use or absence of use of bioengineering in the production of a food or ingredient does not, in and of itself, mean that there is a material difference in the food.").[31]

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[30] *Available at* http://www.hpm.com/pdf/blog/FDA%20Lrt%201-2014%20re%20Natural.pdf (last accessed July 27, 2015).

[31] *Available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm (last accessed Aug. 3, 2015).

FDA would act inconsistently if it now concludes that GMO-containing foods could not be deemed "natural" products. Concerning GMO-containing foods, use of a "natural" claim is at least *potentially* misleading under current FDA's policies, because technologically engineered components would likely be considered "artificial" or "synthetic" by most consumers. The definition of "artificial" appears to contrast with the FDA's policy, and seems to characterize GMO-containing products: "humanly contrived often on a natural model."[32]

The FDA has authority under SAFLA to require GMO disclosure where there exists a "material difference in the functional, nutritional, or compositional characteristics, allergenicity, or other attributes between the food so produced and its comparable food." H.R. 1599, 114th Cong. § 424(A) (2015). But the FDA is unlikely to review (or even detect) the large majority of GMO components, particularly without premarket review or notification requirements for those technologies. As discussed *supra*, FDA is likely to detect issues with GMO-containing ingredients only under extreme circumstances where there are multiple adverse events of a serious nature.

Nearly two-thirds of consumers want GMO-related food disclosures. Whether a food was produced using genetic engineering is thus material to purchasing decisions. Yet SAFLA's "voluntary" disclosure of GMO-containing foods assures that no GMO manufacturer will disclose information that could potentially influence profit margins. Thus, regardless of whether genetically engineered foods are different from comparable foods, the omission of the material GMO information contributes to consumer deception. *See, e.g.*, 21 U.S.C. § 321(n) (in determining whether a label is misleading, the FDA must consider material omissions). The policies undergirding SAFLA are therefore contrary to public preference, and would promote consumer misinformation and deception.

To prevent consumer deception regarding whether a food is natural or was produced using genetic engineering, and to ensure that consumers can exercise informed choice at the point of sale and that the FDA receives adverse event reports for genetically engineered foods, SAFLA (H.R. 1599) must not become law.

V. CONCLUSION

SAFLA deprives States of their right to help citizens identify the presence of genetically engineered ingredients in foods. It violates the First Amendment by erecting regulatory barriers to the communication of GMO-free claims. That information is truthful and non-misleading and, as such, is protected by the First Amendment. SAFLA imposes an unconstitutional prior restraint on truthful speech. Moreover, as a means to effect an unconstitutional end, SAFLA is an unlawful and inappropriate use of federal pre-emption power. By pre-empting GMO disclosure laws in states like Vermont, Maine, and Connecticut, as well as all similar laws in

[32] *See* Merriam-Webster Online Dictionary, "artificial," *available at*, http://www.merriam-webster.com/dictionary/artificial (last visited Aug. 5, 2015).

future, and by allowing GMO products to be termed "natural," H.R. 1599 increases consumer confusion and deception at the point of sale. SAFLA should therefore not become law.