

MEMORANDUM

To: Vermont Public Interest Research Group

**From: Environmental & Natural Resources Law Clinic
Jillian Bernstein & Adam Fryska (Student Clinicians)*
Laura Murphy (Supervising Attorney)**

Re: Constitutionality of GE Labeling Legislation in Vermont

Date: December 7, 2012 Draft

The Environmental and Natural Resources Law Clinic represents the Vermont Public Interest Research Group concerning labeling legislation for genetically engineered (GE) foods in Vermont. We have researched and analyzed challenges that may be raised in opposition to such legislation, and have concluded that Vermont can pass GE labeling legislation that will meet all constitutional requirements.

This memorandum provides a comprehensive description of the law in the three areas of most likely legal challenge: the First Amendment, Preemption, and the Dormant Commerce Clause. We identify and explain the tests that would apply to a GE labeling law under each of these doctrines in order to show that, as a legal matter, there is no reason that Vermont cannot pass a defensible law. In particular, we explain why labeling legislation would not fail under the First Amendment (including why the 1996 case *International Dairy Foods Association v. Amestoy* is distinguishable and would not apply); why a state GE labeling law would not be preempted by federal legislation, and; why the legislation would meet either of the potential tests under the Dormant Commerce Clause. Finally, we provide a brief description of why other conceivable constitutional challenges to GE labeling legislation would not survive, including equal protection, overbreadth, and vagueness.

* Also reflecting the work of ENRLC summer 2012 student clinician Zjok Durst.

TABLE OF CONTENTS

I. <u>SUMMARY</u>	1
A. Vermont’s GE Labeling Bill	1
B. First Amendment Summary.....	1
1. The <i>Zauderer</i> Test.	2
2. The <i>Central Hudson</i> Test.....	2
C. Preemption Summary.....	3
1. Express Preemption Provisions.....	4
2. Implied Preemption.	5
D. Dormant Commerce Clause Summary.....	5
1. First Tier: Laws that Discriminate.....	6
2. Second Tier: Balancing Any Burden with Local Interest.....	6
II. <u>LEGAL DISCUSSION</u>	7
A. The First Amendment	7
1. Commercial Speech	7
a. Background: First Amendment Protection for Commercial Speech.....	7
b. Tests Applicable to Commercial Speech	9
2. The <i>Zauderer</i> Test.....	10
a. Detailed Description of the Test.....	10
b. Evolution of the Test... ..	12
<i>National Electric Manufacturers</i>	13
<i>New York State Restaurant Association</i>	13
c. Recap of <i>Zauderer</i> Rules.	15
3. The <i>Central Hudson</i> Test	16
a. Detailed Description of the Test	16
<i>First Prong – Is the speech protected?</i>	17
<i>Second Prong – Is the State’s interest substantial?</i>	19
<i>Third Prong – Does the restriction directly advance the State’s interest?</i>	19
<i>Fourth Prong – Is the restriction narrowly tailored?</i>	20
b. Distinguishing <i>Int’l Dairy Foods Ass’n v. Amestoy</i>	22
<i>Vermont’s Offerings on the Interest Factor in Int’l Dairy</i>	25
c. The <i>Central Hudson</i> Test Would Not Apply to the Disclosure Requirement.....	26
d. Recap of <i>Central Hudson</i> Rules	27
B. Preemption	30
1. FDA Regulation of Genetically Engineered Foods.....	31
2. Supremacy Clause.....	32
a. No Express Preemption.....	33
<i>Standard of Identity</i>	34

<i>Nutrition Information</i>	35
<i>Nutrition Levels & Health Claims</i>	35
Express Nutrient Content Claims.....	36
Implied Nutrient Content Claims.....	36
Health Claims.....	37
“ <i>Natural</i> ” Prohibition.....	37
b. Recap of Express Preemption Rules	38
c. No Implied Preemption	39
C. The Dormant Commerce Clause	41
1. Overview of Dormant Commerce Clause.....	41
2. Analysis under Dormant Commerce Clause.....	42
a. First Tier: Determining whether Vermont’s Proposed GE Labeling Legislation Would Discriminate against Interstate Commerce.....	43
b. Second Tier: Balancing Any Burden of GE Labeling Legislation on Interstate Commerce with the Local Interest.....	45
<i>First Prong: Burden</i>	46
<i>Second Prong: Interest</i>	47
c. Conclusion.....	49
d. Recap of Dormant Commerce Clause Rules	49
D. Additional Considerations	52
<u>APPENDIX</u>	1
<i>Demonstrated Health Concerns</i>	1
<i>FDA Treatment of Genetically Engineered Foods</i>	2
<i>Distinguishing Genetically Engineered Food Products from Traditional Food Products</i>	2
Polymerase Chain Reaction (PCR) Test.....	3
Lateral Flow Device of Dipstick (Strip Test).....	3
Enzyme-linked Immunosorbent Assay (ELISA Test).....	3
Conclusion.....	3
Index of Authorities – Risks of GE Foods.....	1

I. SUMMARY

A. Vermont's GE Labeling Bill

In the second half of Vermont's 2011-2012 legislative biennium, Representative Kate Webb and others sponsored a bill that would require genetically engineered foods to be labeled as such, and would prohibit the use of the term "natural" on those foods (H.722). The bill was referred to the House Committee on Agriculture and committed to the House Committee on Judiciary. It did not reach the floor for a vote, and there was no parallel bill in the Senate.

H.722 defined genetically engineered food as food produced from an organism whose genetic material had been changed through in vitro nucleic acid techniques or cell fusion or hybridization. It required that all raw agricultural commodities (e.g., potatoes) produced through genetic engineering have the words "genetically engineered" either on the food's packaging or, if there were no packaging, on a label on the retail store shelf or bin. It required that any processed foods produced with genetic engineering have the words "partially produced with genetic engineering" or "may be partially produced with genetic engineering" on the front or back of the food's package. It also prohibited the labels, signage, and advertising or promotional materials for such products from containing the word "natural" or the like. The bill exempted several foods from these requirements, including food derived from animals that were not themselves produced through genetic engineering, medical foods, foods sold in restaurants, federally certified organic food, independently certified food that has been tested according to procedures developed by Vermont's Department of Health, certain beverages, and foods containing less than a certain amount of genetically engineered ingredients.

Because Vermont's legislative biennium ended in the spring of 2012, a new labeling bill will be needed in 2013. Therefore, this memo does not attempt a detailed factual analysis of a particular draft labeling bill or legislative record.

B. First Amendment Summary

The Supreme Court has established that "commercial speech" receives limited First Amendment protection based on society's interest in the free flow of information. *E.g., Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 760-65 (1976); *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 561-66 (1980). "Commercial speech" includes product labels. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481-82 (1995) (beer labels as commercial speech); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 113 (2d Cir. 2001) (mercury product labels as commercial speech).

The Supreme Court framework for First Amendment challenges to state laws that impact commercial speech provides two possible tests that a reviewing court might apply. For legislation that requires the disclosure of factual information, courts evaluate the law under a relatively lenient rational basis-type standard. *See Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 661 (1985). Alternatively, for legislation that restricts commercial speech, where that speech is not misleading and does not refer to unlawful activity,

the courts apply an intermediate-type of scrutiny that involves the four-part test developed in *Central Hudson*. See *Central Hudson*, 447 U.S. at 566.

1. The Zauderer Test

The issue in *Zauderer* was whether a series of disciplinary rules and actions applied against an Ohio attorney were valid under the First Amendment. 471 U.S. at 629. The Court upheld Ohio's disclosure requirement regarding contingent fees, but struck down two restrictions limiting attorney advertising. *Id.* at 646-47, 650, 653.

The *Zauderer* Court began its analysis by providing assurance that commercial speech is protected under the First Amendment. *Id.* at 637 (citations omitted). The Court then set forth the standards it would apply in deciding whether Ohio's actions were constitutional, drawing from the *Central Hudson* test for Ohio's speech restrictions and following a modified test for the disclosure requirement. *Id.* at 638, 650-53. It noted that the advertiser's "constitutionally protected interest in *not* providing any particular factual information" was "minimal." *Id.* at 651.

The Court reasoned that "unjustified or unduly burdensome disclosure requirements" might offend the First Amendment, but that disclosure requirements "reasonably related to the State's interest in preventing deception of consumers" would be valid. *Id.* at 651. Ultimately, the Court concluded that the contingent fee disclosure requirement "easily passe[d] muster" under the new standard. *Id.* at 652.

Although the holding in *Zauderer* concerned Ohio's legitimate interest in preventing deception of consumers, the Second Circuit has interpreted *Zauderer* as applying to a broader set of legitimate state interests, including human health and the environment. See *Nat'l Elec. Mfrs.*, 272 F.3d at 115 (preventing consumer confusion or deception not required per se; State's interest in protecting human health and the environment from mercury poisoning sufficient to uphold mercury disclosure requirement); *N.Y. State Restaurant Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114, 133-34 (2d Cir 2009) (reiterating that rational basis test applies to laws that compel disclosure of "'factual and uncontroversial' information by commercial entities" and holding that preventing obesity was legitimate interest for calorie disclosure requirement) (citations omitted). See also *Pharmaceutical Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 310 n.8 (1st Cir. 2005) (*Zauderer* not limited to consumer deception); *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 564-65 (6th Cir. 2012) (same).

Therefore, because *Zauderer* applies to mandated disclosures and to a broad set of State interests, the *Zauderer* rational basis test would apply to Vermont's GE disclosure requirement.

2. The Central Hudson Test

In *Central Hudson*, the issue was whether New York's total ban on promotional advertising by electric utilities could survive the First Amendment. *Central Hudson*, 447 U.S. at 558. The Court held that it could not and, in so doing, established the foundational, four-part test for determining whether restrictions on commercial speech are constitutional. See *id.* at 566, 571-72. First, a court determines whether the commercial speech is protected in the first instance. *Id.*

at 566. To be protected, it “must concern lawful activity and not be misleading.” *Id.* Second, the government “must assert a substantial interest to be achieved by restrictions on commercial speech.” *Id.* at 564, 566. Third, the regulation must “directly advance[] the governmental interest.” *Id.* Finally, the regulation must not be “more extensive than is necessary to serve that interest.” *Id.*

In the 1996 case *International Dairy Foods Association v. Amestoy*, the Second Circuit applied the *Central Hudson* test to invalidate a Vermont statute that required the labeling of dairy products containing recombinant bovine growth hormone. 92 F.3d 67, 69, 72-74 (2d Cir. 1996). The Court focused its analysis on the second prong of the test – whether the State had a substantial interest to be advanced by the legislation. *Id.* at 73-74. In holding that it did not, the Court found that though the citizens of Vermont had expressed concerns about public health and safety, animal health, and milk economics, the interest of the State itself was based only on “consumer curiosity,” and the State had not “adopted” the concerns of its citizens. *Id.* at 73 n.1. Further, the Court noted that there was “no scientific evidence from which an objective observer could conclude that [rBGH] has any impact at all on dairy products.” *Id.* at 73 (citation and internal quotation marks omitted). And, the Food and Drug Administration had determined that there were “no human safety or health concerns associated with food products derived from cows treated with [rBGH].” *Id.* (internal quotation marks and citation omitted).

Later Second Circuit cases have limited *International Dairy* and held that the *Central Hudson* intermediate scrutiny test applies to disclosure requirements only when the government can provide no greater interest than consumer curiosity. *Nat’l Elec. Mfrs.*, 272 F.3d at 115 n.6 (citation omitted); *N.Y. State Restaurant Ass’n*, 556 F.3d at 134; *Conn. Bar Ass’n v. United States*, 620 F.3d 81, 96 n.16 (2d Cir. 2010). As noted above, disclosure requirements backed by governmental interests such as health, the environment, and preventing consumer deception are reviewed under the *Zauderer* rational basis test.

In Vermont’s case, though the State could meet each of the *Central Hudson* factors for both its disclosure requirement and its “natural” prohibition, it should not be necessary for the State to meet each of these factors for either provision. First, the disclosure requirement would be subject to the *Zauderer* test because it would not be based solely on consumer curiosity. Particularly and as explained below, a GE labeling law would not fail as Vermont’s hormone labeling law did; Second Circuit precedent has meaningfully evolved since the hormone case and, even if the law had not evolved, the regulatory and scientific frameworks for GE products are significantly different from those surrounding the recombinant bovine growth hormone in 1996. (Please refer to the attached Appendix for an explanation of some of these differences.) Second, the “natural” prohibition could survive after application of only the first *Central Hudson* prong through Vermont’s showing that the “natural” label on genetically engineered food products is misleading.

C. Preemption Summary

Under the Supremacy Clause of the Constitution, federal law, as the “supreme law of the land,” may trump state law. U.S. Const. art. VI, § 2; *Gibbons v. Ogden*, 22 U.S. (9 Wheat) 1, 211 (1824). There are three instances when federal law may supersede state law: when there is

express preemption, field preemption, or conflict preemption. See *Hillsborough County Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 713 (1985). In the United States, food labeling is regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FDCA) as amended by the Nutrition Labeling and Education Act of 1990 (NLEA). See generally 21 U.S.C. § 341 *et seq.*; Nutrition Labeling and Education Act, Pub. L. No. 101-535 § 2, 104 Stat. 2353 (1990).

1. Express Preemption Provisions

Under express preemption, Congress explicitly states in a statute that federal law preempts state law. *Hillsborough*, 471 U.S. at 713. When a federal statute contains an express preemption provision, a presumption against preemption exists, requiring courts to read the clause narrowly. See *Medtronic, Inc., v. Lohr*, 518 U.S. 470, 485 (1996). The FDCA as amended by the NLEA contains an express preemption provision, Section 343-1. 21 U.S.C. § 343-1. The preemption section in the NLEA contains multiple provisions, three of which courts typically apply to state labeling laws; these provisions preempt non-identical state requirements concerning standard of identity, nutrition information, and nutrition content and health related claims. See, e.g., *id.*; *N.Y. State Restaurant Ass'n v. New York City Bd. of Health*, 556 F.3d 114, 118-19 (2d Cir. 2009); *Guerrero v. Target Corp.*, No. 12-21115-CIV, 2012 WL 3812324, at * 10 (S.D. Fla. Sept. 4, 2012).

First, any state requirement concerning a standard of identity for which a federal standard of identity exists is preempted unless it is identical. 21 U.S.C. § 343-1(1). The FDA has promulgated several standards of identity, which are codified at 21 C.F.R. Parts 131-169. The regulations provide that “a food does not conform to the definition and standard of identity” if: 1) it “contains an ingredient for which no provision is made in such definition and standard;” 2) it does not contain an ingredient included in the standard of identity, or; 3) the quantity of an ingredient does not conform. 21 C.F.R. § 130.8. A Vermont labeling law requiring that GE foods bear the label “genetically engineered” and that genetically engineered foods not bear the label “natural” would not impact the standard of identity for those foods; e.g., “bread” would still be “bread.” See 21 C.F.R. § 136.110(a) (defining bread). Additionally, state law is not preempted when there is no federal standard of identity with which the state law may conflict. *Guerrero*, 2012 WL 3812324, at *10. There is no standard of identity for genetically engineered or “natural” foods. Thus, a Vermont law would not be preempted under this express preemption provision.

Second, any state requirement for nutrition labeling that is not identical to the federal requirements of Section 343(q) concerning nutrition information is preempted. 21 U.S.C. § 343-1(4). According to FDA regulations, required nutrition information exclusively includes serving size, number of servings, caloric content, and the amounts of these nutrients: fat, cholesterol, sodium, carbohydrates, sugars, protein, dietary fiber, and vitamins and minerals. 21 C.F.R. § 101.9(c); see also 21 U.S.C. § 343(q)(1). A Vermont labeling law would not fall under nutrition information because neither “genetically engineered” nor “natural” is one of the exclusive items that comprise nutrition information. Thus, a Vermont law would not be preempted under this provision.

Finally, any state requirement relating to nutrition level claims or health claims is preempted unless it is identical to the requirements of § 343(r). 21 U.S.C. § 343-1(5). Section 343(r)(1) applies to claims that product labels make about the health benefits or nutrient content of the products. *Id.* § 343(r)(1). A nutrient content claim is a claim that “expressly or implicitly characterize[s] the level of a nutrient required to be in nutrition labeling.” 21 C.F.R. § 101.13(b). Health claims characterize the relationship between any of the nutrients in a food product and a disease or health-related condition. 21 C.F.R. § 101.14(a)(1). Because neither a “genetically engineered” label nor a “natural” label relate to nutrients, a Vermont labeling law would not be a nutrient level or health claim, and therefore would not be preempted by this provision.

2. Implied Preemption

Because a Vermont labeling law would not fall under any of the express preemption provisions, it would not be expressly preempted by the FDCA. Additionally, it would not be impliedly preempted because the Act contains a savings clause, which states, “The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of state law, unless such provision is expressly preempted....” Pub. L. No. 101-535, § 6(c)(1) (21 U.S.C. § 343-1 note).

Even if a court were to ignore the savings clause and perform an implied preemption analysis, a Vermont labeling law would still be upheld. Under the NLEA it is clear that field preemption was not the clear and manifest intent of Congress. *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 337-38 (3d Cir. 2009) (“Congress was cognizant of the operation of state law and state regulation in the food and beverage field, and it therefore enacted limited exceptions in the NLEA.”). Finally, because the FDCA as amended by the NLEA does not contain any requirements or language pertaining to “genetically engineered” or “natural” foods specifically, there is nothing with which the state law may conflict; therefore, it is possible to comply with both federal and state requirements.

D. Dormant Commerce Clause Summary

The dormant commerce clause is an implied restriction on the power of States to enact laws that impose burdens on interstate commerce: “[a]lthough the Commerce Clause is by its text an affirmative grant of power to Congress to regulate interstate and foreign commerce, the Clause has long been recognized as a self-executing limitation on the power of the States to enact laws imposing substantial burdens on such commerce.” *S.–Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 87 (1984) (citations omitted).

The Supreme Court has adopted a two-tiered approach for dormant commerce clause analysis. The first tier considers whether a law discriminates against interstate commerce. If a state law “directly regulates or discriminates against interstate commerce” or has an effect which “favor[s] in-state economic interests over out-of-state interests,” it will be “generally struck down . . . without further inquiry.” *Brown–Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986) (citations omitted). On the other hand, if the “statute has only indirect effects on interstate commerce and regulates evenhandedly,” then courts apply the balancing test described in *Pike v. Bruce Church, Inc.* *Id.* at 579. Under *Pike*, a law will be “upheld unless the burden

imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits.” 397 U.S. 137, 142 (1970) (citation omitted).

1. First Tier: Laws that Discriminate

The first tier of dormant commerce clause analysis is primarily concerned with invalidating overt protectionism: “[s]tate laws that discriminate against interstate commerce face a ‘virtually *per se* rule of invalidity.’” *Granholm v. Heald*, 544 U.S. 460, 473-74, 476 (2005) (citation omitted) (holding that a Michigan law which prohibited the shipment of wine from out-of-state wineries to Michigan consumers discriminated against interstate commerce). The key factor in this determination is whether the law’s language draws distinctions between in-state and out-of-state businesses or products. *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 519 n.1, 522-28 (1935) (reviewing a state law that facially distinguished out-of-state milk and regulated the in-state prices of milk produced out-of-state). On the other hand, regulations are facially neutral if they treat in-state and out-of-state business alike. *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 471-72 (1981) (prohibition on plastic milk containers treated in-state and out-of-state business alike).

Even if facially neutral, laws that have the practical effect of favoring in-state commerce over out-of-state commerce are also discriminatory. *Brown–Forman*, 476 U.S. at 579. The key test is whether the regulation denies out-of-state businesses or products access to the local market. *See C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 386, 394-95 (1994) (finding that a state law requiring all local solid waste to be deposited at a local transfer station had a discriminatory effect on out-of-state companies). Regulations that are protectionist—those that shield local businesses from competition with out-of-state businesses—are also discriminatory. *See Hunt v. Wash. State Apple Advertising Comm’n*, 432 U.S. 333, 351-54 (1977) (finding that a state law requiring a particular labeling system for apples sold in the state had a discriminatory effect on particular out-of-state apple producers).

In Vermont’s case, the GE disclosure requirement and “natural” prohibition would create an evenhanded system of GE labeling requirements that would not discriminate against out-of-state interests. For instance, the labeling scheme would apply equally to both in-state and out-of-state businesses and would not distinguish between in-state and out-of-state food products within the retail market. The regulation would therefore be evaluated under the second tier *Pike* balancing test.

2. Second Tier: Balancing Any Burden with Local Interest

The *Pike* test applies when there is no discrimination against interstate commerce: “[w]here the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.” *Pike*, 397 U.S. at 142 (citation omitted).

One part of the balancing test focuses on how the regulation burdens interstate commerce. The withdrawal of some business from an in-state market, compliance costs, and potential lost profits

are all categories of burdens which have been outweighed by legitimate local interests. *See Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127 (1978) (reviewing a case where out-of-state refinery operators were denied access to portion of the local retail fuel market and holding that exclusion of some out-of-state businesses from in-state markets does not constitute an impermissible burden on interstate commerce); *Clover Leaf Creamery*, 449 U.S. at 472-73 (reviewing a situation where in- and out-of-state plastic manufacturers were excluded from the local milk packaging market; finding that requiring milk to be sold in paper containers actually created opportunities for out-of-state paper companies to sell their products within the state, and inconvenience of having to conform would be “slight”); *Parker v. Brown*, 317 U.S. 341, 355, 367-68 (1943) (holding that California’s in-state raisin marketing program that could limit profits was not an impermissible burden on interstate commerce).

The second part of the balancing test focuses on the local benefits of the regulation. Addressing local environmental concerns, public health and safety concerns, local economic concerns, and consumer information have all been upheld as legitimate local benefits that outweighed incidental burdens on interstate commerce. *Clover Leaf Creamery*, 449 U.S. at 473 (finding that there was a “substantial state interest in promoting conservation of energy and other natural resources and easing solid waste disposal problems”); *Parker*, 317 U.S. at 367-68, 367 (noting the “safety, health and well-being of local communities” and the long term viability of California’s raisin crop as appropriate interests); *S.C. State Highway Dep’t v. Barnwell*, 303 U.S. 177, 195-96 (1938) (upholding a law restricting truck weight and size based on public safety concerns); *Grocery Mfrs. of America, Inc. v. Gerace*, 755 F.2d 993, 1003-04 (2d Cir. 1985) (citing list of local legitimate interests served by regulation prohibiting the misleading labeling of imitation cheese products).

In this case, Vermont’s proposed GE labeling legislation would be upheld under the *Pike* balancing test. It would be motivated by various public health, environmental, and economic concerns among others, all interests that have been upheld as outweighing incidental burdens on interstate commerce.

II. LEGAL DISCUSSION

A. The First Amendment

1. Commercial Speech

a. Background: First Amendment Protection for Commercial Speech

In the first United States Supreme Court case to give commercial speech qualified First Amendment protection, the Court described at length the bases for that protection. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761-70 (1976). In striking down a state restriction on the advertisement of commercial drug prices, the Court explained that society’s interest in the “free flow of commercial information” was paramount. *See id.* at 763-65, 770. The Court reasoned:

So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.

Id. at 765.

The Court also identified some characteristics of such speech: it does “no more than propose a commercial transaction,” and it is “removed from any exposition of ideas, and from truth, science, morality, and arts in general, in its diffusion of liberal sentiments on the administration of Government.” *Id.* at 760-62. Later, the Court noted that there is a “common-sense distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech.” *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 454-57 (1978) (treating solicitation of business by lawyer through direct, in-person communication as commercial speech). Still later, the Court listed other relevant factors that would indicate speech is “commercial:” when the speech is intended as an advertisement, when the speech references a specific product, and when there is an economic motivation behind the speech. *Bolger v. Youngs Drug Product Corp.*, 463 U.S. 60, 66-67 (1983) (treating mass advertising mailings by drug company to public as commercial speech). However, the Court also noted that “each of [these] characteristics . . . [need not] necessarily be present in order for speech to be commercial.” *Id.* at 68 n.14.

In the *Zauderer* case, the Court acknowledged that the “precise bounds of the category of expression that may be termed commercial speech” were subject to doubt. *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 637 (1985) (noting that “advertising pure and simple” would qualify). Later, in a 1995 case challenging a restriction on listing alcohol content on beer labels, the Court applied a commercial speech test and noted that “[b]oth parties agree that the information on beer labels constitutes commercial speech.” *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481-82 (1995).

Second Circuit cases have also provided guidance in treating product labels or the like as “commercial speech.” See *Nat’l Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104, 113 (2d Cir. 2001) (requiring labeling of mercury-containing products conceded to implicate only commercial speech); *N.Y. State Restaurant Ass’n v. N.Y. City Bd. of Health*, 556 F.3d 114, 131 (2d Cir. 2009) (finding law requiring disclosure of calorie information in connection with “a proposed commercial transaction - the sale of a restaurant meal” to be clearly commercial speech); *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 97 (2d Cir. 1998) (treating beer labels as commercial speech).¹ The Court has also explained that “speech does not cease to be

¹ These cases post-date the *International Dairy* case, in which the District Court had held that Vermont’s labeling law was commercial in nature. *Int’l Dairy Foods Ass’n v. Amestoy*, 898 F. Supp. 246, 253 (D. Vt. 1995) (“The Court . . . finds that, despite the current public debate, the labels required by [Vermont] relate to commercial transactions involving specific products and are therefore commercial speech.”), *overruled on other grounds*, 92 F.3d 67, 72 (2d Cir. 1996). The District Court had also noted that, under Supreme Court law, the “[m]ere fact that products may be tied to public concerns does not transform speech into noncommercial speech.” 898 F. Supp. at 253 (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 562-63 n.5 (1980)). On review, the Second Circuit declined to decide the issue. 92 F.3d 67, 72 (2d Cir. 1996) (“We need not address the controversy concerning the nature of the speech in question—commercial or

commercial merely because it alludes to a matter of public debate.” *Conn. Bar Ass’n v. United States*, 620 F.3d 81, 93-94 (2d Cir. 2010) (listing Supreme Court cases); *see also Bad Frog Brewery*, 134 F.3d at 97 (“We are unpersuaded by Bad Frog’s attempt to separate the purported social commentary in the labels from the hawking of beer. . . . [T]he purported noncommercial message is not so ‘inextricably intertwined’ with the commercial speech as to require a finding that the entire label must be treated as ‘pure’ speech. Even viewed generously, Bad Frog’s labels at most ‘link[] a product to a current debate,’ which is not enough to convert a proposal for a commercial transaction into ‘pure’ noncommercial speech.”) (internal citations omitted).

Cases that have held that particular disclosure requirements implicated more than commercial speech and therefore deserved more protection under the First Amendment are easily distinguished. *See, e.g., Wooley v. Maynard*, 430 U.S. 705, 707, 717 (1977) (New Hampshire could not require citizens to display state motto, “Live Free or Die,” on license plates as it was ideological message which some citizens found morally and religiously repugnant); *Miami Herald Publishing Co. v. Tornillo*, 418 U.S. 241, 243, 258 (1974) (state statute requiring newspaper to give equal space to political candidate to respond to attacks infringed on editorial judgment and violated First Amendment); *W. Va. State Bd. of Education v. Barnette*, 319 U.S. 624, 642 (1943) (“We think the action of the local authorities in compelling the flag salute and pledge transcends constitutional limitations on their power and invades the sphere of intellect and spirit which it is the purpose of the First Amendment to our Constitution to reserve from all official control.”).

The *Zauderer* Court noted the clear distinctions between these cases and a compelled factual disclosure: “[T]he interests at stake in this case are not of the same order as those discussed in *Wooley*, *Tornillo*, and *Barnette*. [The State] has not attempted to ‘prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein.’” 471 U.S. at 651 (citing *Barnette*, 319 U.S. at 642).

b. Tests Applicable to Commercial Speech

The Supreme Court framework for First Amendment challenges to commercial speech requirements provides two possible tests for a reviewing court to apply. For factual disclosure requirements, the court applies a lesser standard of review and evaluates the law under the *Zauderer* rational basis-type standard. *See Zauderer*, 471 U.S. at 651. Alternatively, for restrictions on commercial speech, where that speech is not misleading and does not refer to unlawful activity, the court applies an intermediate-type scrutiny and evaluates the restriction under the four-part analysis developed in *Central Hudson*. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (1980). These tests and their implications for a Vermont labeling bill are presented in full below.

political—because we find that Vermont fails to meet the less stringent constitutional requirements applicable to compelled commercial speech.”).

2. The Zauderer Test

a. Detailed Description of the Test

The issue in *Zauderer* was whether a series of disciplinary rules and actions applied against an Ohio attorney were valid under the First Amendment. *Zauderer*, 471 U.S. at 626, 629. The Court upheld Ohio's disclosure requirement regarding contingent fees, but struck down two restrictions limiting attorney advertising. *Id.* at 646-47, 650, 653.

An Ohio attorney had published a newspaper advertisement soliciting female clients who had been harmed by their use of the "Dalkon Shield Intrauterine Device." The advertisement had a drawing of the Shield and included information about the ills associated with its use. It noted that there may still be time to file suit, and that the attorney's firm was already managing such cases. It also noted that the cases could be handled on a contingent fee basis, and that clients would owe attorney fees only if they won.

Ohio's Office of Disciplinary Counsel filed a complaint against the attorney alleging violations of various Disciplinary Rules. A panel of the Board of Commissioners on Grievances and Discipline of the Ohio Supreme Court heard the complaint and found against the attorney. The Board then recommended indefinite suspension from the practice of law. The Ohio Supreme Court likewise found that the attorney had violated several Disciplinary Rules, and that the application of those rules had not violated the attorney's First Amendment rights. The Court recommended a public reprimand. An appeal to the United States Supreme Court followed.²

The *Zauderer* Court began its analysis by providing assurance that commercial speech is protected under the First Amendment: "There is no longer any room to doubt that what has come to be known as 'commercial speech' is entitled to the protection of the First Amendment, albeit to protection somewhat less extensive than that afforded 'noncommercial speech.'" *Id.* at 637 (citations omitted). As mentioned above, the Court did note that the "precise bounds of the category of expression that may be termed commercial speech" were subject to doubt, but that "advertising pure and simple" would surely qualify. *Id.* Also, speech "proposing a commercial transaction" would qualify. *See id.*

The Court then set forth the standards it would apply in deciding whether Ohio's actions were constitutional, calling the "general approach to restrictions on commercial speech . . . well settled." *Id.* at 638. It drew one test from *Central Hudson*: restrictions on non-misleading commercial speech that concerns a lawful activity must directly advance a substantial governmental interest, and only through means necessary to do so. 471 U.S. at 638 (citing *Central Hudson*, 447 U.S. at 566). The Court would follow a modified test for disclosure requirements. *Id.* at 650-53.

² The complaint against the attorney also alleged violations regarding a drunk-driving advertisement the attorney had previously published. Though the attorney challenged his punishment regarding that violation, it is not included here because it involved due process, not First Amendment, issues. *See Zauderer*, 471 U.S. at 654.

The Court analyzed the two restrictions - one that prohibited attorney advertisements from containing advice and information about specific legal problems, and one that prohibited illustrations in attorney advertising – in much the same way. *Id.* at 639-49. It found that neither was narrowly tailored under *Central Hudson*. *Id.* at 643-45, 48-49. (The Court’s reasoning on this factor is captured below in the *Central Hudson* discussion.)

In turning to the rule that required attorneys to disclose the terms of contingent fees in their advertising, the Court laid out the basis for using a different test than *Central Hudson*. *See id.* at 650-51. It noted that there were “material differences between disclosure requirements and outright prohibitions on speech” and that “Ohio ha[d] not attempted to prevent attorneys from conveying information to the public; it ha[d] only required them to provide somewhat more information than they might otherwise be inclined to present.” *Id.* at 650. It distinguished other cases where disclosure requirements had been subject to full First Amendment protection because the “interests at stake” were of a different order – implicating prescriptions on politics, religion, nationalism, or other matters of opinion. 471 U.S. at 650-51. In contrast, the required speech in this case was “factual and uncontroversial.” *Id.* at 651.

In fact, drawing upon the basis for extending First Amendment protections to commercial speech, the Court noted that the attorney’s constitutionally protected right in this case would be “minimal:”

Because the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, appellant’s constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal.

Id. at 651 (internal citation to *Va. State Bd. of Pharmacy*, 425 U.S. 748, omitted); *see also Va. State Bd. of Pharmacy*, 425 U.S. at 757 (“this Court has referred to a First Amendment right to receive information and ideas, and that freedom of speech necessarily protects the right to receive”) (citations and internal quotation marks omitted).

In a long footnote, the Court explained why disclosure requirements should not be subject to the “least restrictive means” test (prong four of *Central Hudson*). *Id.* n.14. It again made reference to the “substantially weaker” First Amendment interests at stake where disclosure requirements – as opposed to outright suppression - were concerned. *Id.* And, it noted that a State need not address all facets of a problem at once in a disclosure requirement: As a general matter, governments are entitled to attack problems piecemeal, save where their policies implicate rights so fundamental that strict scrutiny must be applied. The right of a commercial speaker not to divulge accurate information regarding his services is not such a fundamental right. *Id.* (internal citations omitted).

The Court reasoned that “unjustified or unduly burdensome disclosure requirements” might offend the First Amendment, but that disclosure requirements “reasonably related to the State’s interest in preventing deception of consumers” would be valid. *Id.* at 651. *See also Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 558 (6th Cir. 2012) (“This Court has also opined on *Zauderer*’s reach and import. We have held that *Zauderer* applies not only when

the required disclosure ‘targets speech that is *inherently* misleading,’ but also ‘where, as here, the speech is *potentially* misleading.’”) (citation omitted). Ultimately, the Court concluded that the contingent fee disclosure requirement “easily passe[d] muster” under the new standard. *Id.* at 652. It was a “commonplace” that members of the public were “often unaware of the technical meanings of such terms as ‘fees’ and ‘costs.’” *Id.* at 652. Therefore, the State’s belief that an advertisement mentioning contingent fees without a specific disclosure about other costs would be deceptive was “self-evident” and “reasonable enough” to support the disclosure requirement. *Id.* at 652-53.

b. Evolution of the Test

Although the holding in *Zauderer* concerned Ohio’s legitimate interest in preventing deception of consumers, the Second Circuit has interpreted *Zauderer* as applying to a broader set of legitimate state interests as well, including human health and the environment.³ *See Nat’l Elec. Mfrs.*, 272 F.3d at 115; *N.Y. State Restaurant Ass’n*, 556 F.3d at 133; *see also Pharmaceutical Care Mgmt. Ass’n v. Rowe*, 429 F.3d 294, 310 n.8 (1st Cir. 2005) (“In its reply brief, [Plaintiff] states that the holding in *Zauderer* is ‘limited to potentially deceptive advertising directed at consumers.’ None of the cases it cites, however, support this proposition, and we have found no cases limiting *Zauderer* in such a way.”) (internal citation omitted); *Tobacco City*, 674 F.3d at 556 (“[*Nat’l Elec. Mfrs.* shows that *Zauderer*’s framework can apply even if the required disclosure’s purpose is something other than or in addition to preventing consumer deception.”).

³ A 2010 Second Circuit case looked at several disclosure requirements in the Bankruptcy Abuse Prevention and Consumer Protection Act. *Conn. Bar Ass’n v. United States*, 620 F.3d 81 (2d Cir. 2010). Following a recent Supreme Court decision that had decided several of the same issues about the Act, the Second Circuit held that the *Zauderer* test was applicable to the disclosure requirements because *Milavetz*, which also reviewed provisions aimed at preventing consumer deception, had applied *Zauderer*. *Id.* at 95-96 (citing *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339 (2010)). However, the Court was very clear in noting that its “own earlier precedent” would have pointed it to this conclusion regardless and described the *Zauderer* test as applying to “‘compelled commercial disclosure cases.’” *Id.* at 96 (citing *Nat’l Elec. Mfrs.*, 272 F.3d at 115, as reviewing a regulation intended to “‘better inform consumers’”). The Court did not hold that “preventing consumer deception” was a prerequisite to applying *Zauderer*, and it did not overrule *Nat’l Elec. Mfrs.* or *N.Y. State Restaurant Ass’n*. The Court stated: “[B]ecause the regulations compel disclosure without suppressing speech, *Zauderer*, not *Central Hudson*, provides the standard of review.” *Id.* at 93. However, because the Court described the *Nat’l Elec. Mfrs.* regulation as one designed to “‘better inform consumers,’” the “‘better information” piece is not unimportant under the *Zauderer* standard. *See id.* at 96 (citing *Nat’l Elec. Mfrs.*, 272 F.3d at 115).

A recent D.C. Circuit case argued that *Zauderer* is limited to requirements designed to correct misleading speech and cited some limited Supreme Court examples of that application. *R.J. Reynolds Tobacco Company v. Food & Drug Admin.*, 2012 WL 3632003, *5, *9 (D.C. Cir., Aug. 24, 2012) (applying *Central Hudson* to requirement that cigarette packaging contain graphic warning labels). However, that case is not binding on the Second Circuit and, as the Second Circuit has previously stated, the Supreme Court has not held that “all other disclosure requirements are subject to heightened scrutiny.” *N.Y. Restaurant Ass’n*, 556 F.3d at 133 (discussed below); *see also Tobacco City*, 674 F.3d at 556 (*Zauderer* applies even if interest is not preventing consumer deception). In any case, an argument could certainly be made that the *absence* of a GE disclosure on a GE product label could deceive consumers; thus the disclosure would be required to prevent consumer deception and *Zauderer* would apply. *See Irradiation in Food*, 51 Fed. Reg. 13,376-01, 13,388, 13,389-90 (April 18, 1986) (in preamble to rule establishing labeling for irradiated foods, stating that “[t]he issue here is whether the irradiation of food is a material fact that must be disclosed to the consumer to prevent deception,” and finding that it was). Further, *R.J. Reynolds* suggests that if a disclosure requirement does not fall under the *Zauderer* test because it is not meant to correct misleading speech, the requirement will nevertheless be reviewed under the *Central Hudson* commercial speech standard – which is a lesser standard than that applied to other types of (more protected) speech, and which Vermont could meet.

National Electric Manufacturers

In *Nat'l Elec. Mfrs.*, which applied *Zauderer* to Vermont's mercury labeling requirement, the Court first held that Vermont's interest in "protecting human health and the environment from mercury poisoning" was a "legitimate and significant public goal." 272 F.3d at 115. (The Vermont statute required manufacturers of some mercury-containing products to label the products and packaging to inform consumers about the presence of mercury and instruct consumers to recycle or dispose of the products as hazardous waste.) The Court also took note of the close link between the State's overall goal and the necessary intermediary goal of increasing consumer awareness. *See id.* at 115 ("Although the overall goal of the statute is plainly to reduce the amount of mercury released into the environment, it is inextricably intertwined with the goal of increasing consumer awareness of the presence of mercury in a variety of products."). It then held that *Zauderer's* "reasonable-relationship rule" was the proper standard under which to determine whether the State statute appropriately advanced the State's interest, and noted that the State's interest need not be to prevent "consumer confusion or deception" per se. *Id.* (quoting *Zauderer*, 471 U.S. at 651).

The Court decided that a "reasonable relationship" was "plain" in the instant case. *Id.* The labeling would likely reduce mercury pollution by encouraging changes in consumer behavior. *Id.* *See also Tobacco City*, 674 F.3d at 557 ("[*Nat'l Elec. Mfrs.*] relied on common sense rather than evidence to conclude that the disclosures would lead some consumers to change their behavior, thereby showing that constitutionality does not hinge upon some quantum of proof that a disclosure will realize the underlying purpose. A common-sense analysis will do."). It did not matter that the requirement would likely be insufficient to eliminate most mercury pollution in the state, as "[s]tates are not bound to follow any particular hierarchy in addressing problems within their borders." *Id.* at 115-16.

The Court closed by cautioning against a First Amendment slippery slope that would unnecessarily restrict regulatory disclosure requirements:

Innumerable federal and state regulatory programs require the disclosure of product and other commercial information. . . . To hold that the Vermont statute is insufficiently related to the state's interest in reducing mercury pollution would expose these long-established programs to searching scrutiny by unelected courts. Such a result is neither wise nor constitutionally required.

Id. at 116.

New York State Restaurant Association

In this case, the Second Circuit followed its reasoning in *Nat'l Elec. Mfrs.* to uphold New York City's calorie disclosure requirements as "reasonably related" to the City's interest in preventing obesity among its residents. *N.Y. State Restaurant Ass'n*, 556 F.3d at 131-36. In doing so, it refuted three of the Restaurant Association's primary arguments, two of which are relevant to the present analysis. *Id.* at 132-34. First, the Association claimed that a 2001 Supreme Court case had limited the rational basis *Zauderer* test to situations where the state's interest was in

preventing consumer deception. *Id.* at 132 (citing *United States v. United Foods, Inc.*, 533 U.S. 405 (2001)). The Court found, instead, that the *United Foods* case simply distinguished *Zauderer*, and did not “provide that all other disclosure requirements [those not aimed at preventing consumer deception] are subject to heightened scrutiny.” *Id.* at 133.⁴ The Second Circuit noted that “this distinction was [not] lost on us in [*Nat’l Elec. Mfrs.*], when we held that *Zauderer’s* holding was broad enough to encompass nonmisleading disclosure requirements.” *Id.* (citation omitted).

The Court then discounted the Association’s argument that, because the significance of the facts it was being asked to disclose were in dispute, *Zauderer* should not apply. *Id.* at 132, 134. The Court reiterated that the rational basis test applies to laws that compel the disclosure of “‘factual and uncontroversial’ information by commercial entities.” 556 F.3d at 134 (citations omitted). It characterized the “question [it] must answer” as one of whether the disclosure requirements were “simply requirements of purely factual disclosures.” *Id.* at 134 (internal quotation marks and citation omitted). It found that the calorie disclosure requirements fell within that category; Plaintiff did not contend that the disclosure of calorie information was not “factual.” *Id.* Rather, the Association argued that member restaurants did not want to prioritize calorie information among other nutrition information. The Court found this unpersuasive, noting that the First Amendment did not bar the City from “compelling such ‘under-inclusive’ factual disclosures.” *Id.* (citing *Zauderer*, 471 U.S. at 651 n.14). Thus, it is the accuracy of the disclosed information that must be “uncontroversial,” not its significance. *See also Tobacco City*, 674 F.3d at 555 (“*Zauderer* relied on the distinction between a fact and a personal or political opinion to distinguish factual, commercial-speech disclosure requirements, to which courts apply a rational-basis rule, from the type of compelled speech on matters of opinion that is ‘as violative of the First Amendment as prohibitions on speech.’”) (citation omitted). *Compare with Entertainment Software Ass’n v. Blagojevich*, 469 F.3d 641, 651-52 (7th Cir. 2006) (discussing *Nat’l Elec. Mfrs.* and noting that “18” sticker requirement on “sexually explicit” video games not purely factual because “sexually explicit” determination is “far more opinion-based than the question of whether a particular chemical is within any given product”).

When the Court went on to apply the test, it found that New York City had “plainly demonstrated a reasonable relationship between the purpose of [the regulation’s] disclosure requirements and the means employed to achieve that purpose.” 556 F.3d at 134. The “Notice of Adoption” that accompanied the regulation had laid out two reasons for the disclosure requirements: “(1) reduce consumer confusion and deception; and (2) ... promote informed consumer decision –making so as to reduce obesity and the diseases associated with it.” 556 F.3d at 134. The “Notice of Adoption” had also identified numerous studies and made multiple findings. *Id.* The findings were: 1) obesity is a serious epidemic and increasing cause of disease; 2) the epidemic is caused primarily by excess calorie consumption in restaurants; 3) food from chain restaurants is associated with weight gain and excess calorie consumption; 4) consumers make unhealthy food choices based on distorted perceptions about calorie amounts;

⁴ After striking down mandatory mushroom handler fees on other First Amendment grounds, the *United Foods* Court noted that, unlike in *Zauderer*, there was also no reason to uphold the fees on the basis of preventing consumer deception. 533 U.S. at 416 (“There is no suggestion in the case now before us that the mandatory assessments imposed to require one group of private persons to pay for speech by others are somehow necessary to make voluntary advertisements nonmisleading for consumers.”).

5) providing calorie information at the point of decision would aid consumers in making healthier and informed food choices; and, 6) voluntary activities by restaurants were inadequate to achieve the desired result. *Id.* at 134-35 (citing “Notice of Adoption”). On this last point, the City had provided a study in which the vast majority of respondents had not noticed calorie information under current practices; the City also noted that leading health authorities recommended calorie disclosure at the point of purchase. *Id.* at 135. The Court specifically stated that this type of information was not necessary for the State to survive the rational basis test. *Id.* n.23. *See also Conn. Bar Ass’n*, 620 F.3d at 97-98 (discussing evidence from congressional hearings – including testimony, doctor survey, and anecdotes – that supported government’s interest in reducing confusion in the bankruptcy process, but noting that “evidence or empirical data” are not necessary to “demonstrate the rationality of mandated disclosures in the commercial context”) (quoting *N.Y. Restaurant Ass’n*, 556 F.3d at 134 n.23).

c. Recap of Zauderer Rules

This section gives a distillation of the most important factors under the *Zauderer* test. Because *Zauderer* applies to mandated factual disclosures and a broad set of legitimate state interests, the *Zauderer* rational basis test would apply to Vermont’s GE disclosure requirement.

First Factor – Disclosed Information Is Factual & Uncontroversial

- Disclosure of factual, uncontroversial information supports First Amendment principles protecting the flow of information. Therefore, a company’s protected interest in *not* disclosing such information is minimal. *Zauderer*, 471 U.S. at 651.
- Calorie information is “factual” information, even though parties disputed the significance of that information. *N.Y. State Restaurant Ass’n*, 556 F.3d at 134.
 - “18” sticker requirement on “sexually explicit” video games not purely factual because “sexually explicit” determination is “far more opinion-based than the question of whether a particular chemical is within any given product”). *Entertainment Software Ass’n*, 469 F.3d at 651-52.

Second Factor – State Must Have Legitimate Interest

- Preventing deception of consumers is legitimate interest. *Zauderer*, 471 U.S. at 651.
- Protecting human health and the environment from mercury poisoning is legitimate interest. *Nat’l Elec. Mfrs.*, 272 F.3d at 115.
 - Later case described this regulation as better informing consumers. *Conn. Bar Ass’n*, 620 F.3d at 96.
- Preventing obesity is legitimate interest. State coupled it with preventing consumer deception. *N.Y. State Restaurant Ass’n*, 556 F.3d at 134.

Third Factor - Requirement Must Be Reasonably Related to State Interest

- Requirement is not subject to the least restrictive means test. *Zauderer*, 471 U.S. at 651 n.14.
- Requirement need not address all facets of problem at once. *Zauderer*, 471 U.S. at 651 n.14.

- Irrelevant that mercury labeling would probably be insufficient to eliminate most mercury pollution in state. *Nat'l Elec. Mfrs.*, 272 F.3d at 115-16.
- Where the problem to be corrected is “commonplace” (lay public’s confusion about the distinction between legal “fees” and “costs”), State’s belief that disclosure would help remedy problem was reasonable. *Zauderer*, 471 U.S. at 652-53.
- Reasonableness was “plain” because labeling would encourage changes in consumer behavior, therefore likely reducing mercury pollution. *Nat'l Elec. Mfrs.*, 272 F.3d at 115.
- Reasonable relationship “plainly demonstrated” where City found that providing calorie information at point of consumption would aid consumers in making healthy food choices, and voluntary efforts were insufficient. *N.Y. State Restaurant Ass’n*, 556 F.3d at 134-35.
 - City provided study showing that vast majority of surveyed did not notice voluntary efforts. *N.Y. State Restaurant Ass’n*, 556 F.3d at 135.
 - City noted that leading health authorities recommended calorie disclosure at point of purchase. *N.Y. State Restaurant Ass’n*, 556 F.3d at 135.
 - But this type of evidence is not necessary to show reasonable relationship. *N.Y. State Restaurant Ass’n*, 556 F.3d at 135 n.23.

3. The Central Hudson Test

a. Detailed Description of the Test

In *Central Hudson*, the issue was whether New York’s total ban on promotional advertising by electric utilities could survive the First Amendment. *Central Hudson*, 447 U.S. at 557-58. The Court held that it could not and, in so doing, established the foundational test for determining whether restrictions on commercial speech are constitutional. *See id.* at 566, 571-72.

New York’s Public Service Commission had issued an order prohibiting electric utilities in the State from all promotional advertising. The order was based on a concern that there would be insufficient fuel stocks to meet customer demand one winter. After the fuel shortage had eased, the Commission extended the promotional advertising prohibition through a Policy Statement. The Policy Statement divided advertising into two categories: “promotional,” and “institutional and informational.” While “institutional and informational” advertising was allowed, “promotional” advertising was banned in order to promote energy conservation and to ensure that rates would be fair – that is, unaffected by the potentially higher cost of producing additional electricity. *Central Hudson* challenged the prohibition in state court, losing at all three levels. Appeal to the United States Supreme Court ensued.

The Court began its analysis by detailing the evolution of commercial speech’s protection under the First Amendment. *Id.* at 561-64. The Court identified “commercial speech” as “expression related solely to the economic interests of the speaker and its audience.” *Id.* at 561 (citing *Va. Bd. of Pharmacy*, 425 U.S. at 762) (other citations omitted). Though commercial speech is afforded “lesser protection” than other “constitutionally guaranteed expression,” it deserves some protection because it “assists consumers and furthers the societal interest in the fullest possible dissemination of information.” *Id.* Further, protecting commercial speech helps to “open the channels of communication rather than to close them.” 447 U.S. at 563 (citations omitted). It helps to foster the “informational function of advertising.” *Id.* at 563 (citation

omitted). This reasoning is in full accord with the “original” commercial speech decision, which explained that “the free flow of commercial information is indispensable.” *Va. Bd. of Pharmacy*, 425 U.S. at 765 (citations omitted). The dissemination of information – even through advertising – helps to ensure that private economic decisions will be “intelligent and well informed.” *Id.* In other words, the primary basis for protecting commercial speech is to promote the flow of information and communication.

Central Hudson then described the test it would apply in order to determine whether New York’s prohibition was constitutional. 447 U.S. at 564-66. First, the Court determines whether the commercial speech is protected in the first instance. *Id.* at 566. To be protected, it “must concern lawful activity and not be misleading.” *Id.* Second, the government “must assert a substantial interest to be achieved by restrictions on commercial speech.” *Id.* at 564, 566. Third, the regulation must “directly advance[] the governmental interest.” *Id.* at 566. Finally, the regulation must not be “more extensive than is necessary to serve that interest.” *Id.*

Central Hudson First Prong – Is the speech protected?

The Court found that the first prong was met. 447 U.S. at 568. New York had not argued either that promotional advertising was misleading or that it related to unlawful activity. Rather, New York seemed to argue that *Central Hudson*’s promotional advertising was not entitled to protection because *Central Hudson* held a monopoly over certain electricity sales. *See id.* at 566-67. Thus, any advertising would be useless. *Id.* The Court rejected this argument by noting several ways in which advertising could in fact be useful, in particular noting that “[e]ven in monopoly markets, the suppression of advertising reduces the information available for consumer decisions and thereby defeats the purpose of the First Amendment.” *Id.* at 567.

The Court provided guidance on this factor by explaining that “there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity.” *Id.* at 563. It continued: “[t]he government may ban forms of communication more likely to deceive the public than to inform it,” and cited two previous Supreme Court cases as examples. *Id.* at 563 (citing *Friedman v. Rogers* and *Ohralik v. Ohio State Bar Ass’n*).

In *Friedman*, the Court upheld a Texas ban on the use of trade names in optometry practice. *Friedman v. Rogers*, 440 U.S. 1, 12-16 (1979). It reasoned that, when there is a “significant possibility” that speech will “mislead the public,” the government may properly ban it. *Id.* In describing why trade names could be misleading, the *Friedman* Court said:

Here, we are concerned with a form of commercial speech that has no intrinsic meaning. A trade name conveys no information about the price and nature of the services offered by an optometrist until it acquires meaning over a period of time by associations formed in the minds of the public between the name and some standard of price or quality. Because these ill-defined associations of trade names with price and quality information can be manipulated by the users of trade names, there is a significant possibility that trade names will be used to mislead the public.

Id. at 12-13 (internal footnote omitted). The Court noted that the “possibilities” for deception were “numerous” and included instances where the trade name of an office may remain the same, but the optometrists practicing under it may have changed unbeknownst to the public. *Id.* at 13. Texas’ law would correct this and would still allow optometrists to freely convey factual information to the public, including information about services and prices. *Id.* at 16. Therefore, the Court held that “[r]ather than stifling commercial speech, [the Texas law] ensures that information regarding optometrical services will be communicated more fully and accurately to consumers than it had been in the past when optometrists were allowed to convey the information through unstated and ambiguous associations with a trade name.” *Id.*

In *Ohralik*, the Court considered whether Ohio could properly discipline an attorney for in-person solicitation of accident victims. 436 U.S. at 449. The Court held that it could, reasoning that the State’s interest in protecting the public from harmful solicitation by lawyers – basically a prophylactic rule – was sufficient under the Constitution. *Id.* at 464-67. In addition, the Court specifically held that proof of “actual injury” was not required. *Id.* at 465-66 (“under . . . adverse conditions the overtures of an uninvited lawyer may distress the solicited individual simply because of their obtrusiveness and the invasion of the individual’s privacy, even when no other harm materializes”) (footnotes omitted). Rather, it is the State’s “perception of the potential for harm” that controls, as long as that perception is “well-founded.” *See id.* at 464-65 (describing reasons that concern was well-founded in those circumstances).

In contrast, the Court has found this prong met where the speech in question involved factual statements of information or accurate illustrative depictions. *See Zauderer*, 471 U.S. at 639-41, 647-49 (information about and depiction of Dalkon Shield in attorney advertisement factually accurate and entitled to protection); *see also Int’l Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 636-37 (6th Cir. 2010) (“rBGH free” and similar composition claims on milk labels not inherently misleading because conventional milk and milk from untreated cows was compositionally different; State’s restriction therefore subject to remainder of *Central Hudson* test).

The Court has also found this prong met where the speech in question was only “potentially” misleading. For example, in a 1982 Supreme Court case, the Court cited both *Friedman* and *Ohralik* and stated: “[T]he Court has made clear . . . that regulation - and imposition of discipline - are permissible where the particular advertising is inherently likely to deceive or where the record indicates that a particular form or method of advertising has in fact been deceptive.” *In re RMJ*, 455 U.S. 191, 202-03 (1982) (“[W]hen the particular content or method of the advertising suggests that it is inherently misleading or when experience has proved that in fact such advertising is subject to abuse, the States may impose appropriate restrictions. Misleading advertising may be prohibited entirely.”). However, the Court struck down the particular regulation at issue in that case because there was “no finding” that the restricted speech was misleading. *Id.* at 205-07 (“There is nothing in the record to indicate that the [restricted speech] was misleading.”). Because the restricted speech was only “potentially misleading,” the regulation was subject to the remaining three prongs of the *Central Hudson* test. *Id.* at 203-06; *see also Alexander v. Cahill*, 598 F.3d 79, 89 (2d Cir. 2010) (“The speech that Defendants’ content-based restrictions seeks to regulate - that which is irrelevant, unverifiable, and non-informational - is not inherently false, deceptive, or misleading. Defendants’ own press

release described its proposed rules as protecting consumers against ‘*potentially* misleading ads.’ This is insufficient to place these restrictions beyond the scope of First Amendment scrutiny.”). Further, this prong can be met even when the speech in question is potentially offensive and does not necessarily convey any useful information, as long as the speech is not misleading. *See Bad Frog Brewery*, 134 F.3d at 98 (“Indeed, although [the State] argues that the labels convey no useful information, it concedes that ‘the commercial speech at issue ... may not be characterized as misleading or related to illegal activity.’”) (citation omitted).

Central Hudson Second Prong – Is the State’s interest substantial?

For the second prong, the Court easily found that each of New York’s asserted interests were “substantial.” *Central Hudson*, 447 U.S. at 568-69. The Court noted that “no one can doubt the importance of energy conservation.” *Id.* It also found that the State’s concern for “fair and efficient” rates was “a clear and substantial governmental interest.” *Id.* at 569.

Other cases show that a wide variety of governmental interests qualify as “substantial.” *See, e.g., Rubin*, 514 U.S. at 485 (substantial government interest in “protecting the health, safety, and welfare of its citizens” by preventing brewers from competing based on alcohol strength because of concerns about greater alcoholism and its attendant social costs); *Bd. of Trustees of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 475 (1989) (substantial interests in promoting educational, rather than commercial, atmosphere on college campuses; in promoting security and safety; in preventing commercial exploitation of student body, and; in preserving tranquility in campus residences); *Fleminger, Inc. v. U.S. Dep’t of Health & Human Svcs.*, 854 F. Supp. 2d 192, 209 (D. Conn. 2012) (government’s interest in “preventing consumer confusion” and “protecting public health” sufficient to justify disclaimer requirement on green tea product making health claim). The Second Circuit’s *International Dairy* case, in which the Court held that Vermont’s interest in a hormone labeling requirement was not substantial, is discussed in full below. *See Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 73-74 (2d Cir. 1996).

Central Hudson Third Prong – Does the restriction directly advance the State’s interest?

For the third prong, the Court found that there was an “immediate connection between advertising and demand for electricity;” therefore the State’s interest in energy conservation was “directly advanced” by the Commission’s order. *Central Hudson*, 447 U.S. at 569. In contrast, the link between the Commission’s rate structure and the advertising ban was “tenuous,” “highly speculative,” and “conditional and remote.” *Id.* Thus, the ban did not “directly advance” the State interest associated with rate structures.

This prong has been fleshed out in other cases as well. It requires the government to show that the regulation advances the government’s interest in a “‘direct and material’” way. *Rubin*, 514 U.S. at 487, 489 (citation omitted) (government’s restriction on alcohol content labeling did not advance interest in curbing alcohol strength wars where government “had failed to present any credible evidence showing that the disclosure of alcohol content would promote strength wars”). *See also Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2668 (2011) (Vermont restriction on transmission of prescriber information to pharmaceutical companies not “drawn” to serve asserted interest of protecting physician privacy because information could still be transmitted to

other audiences). The harms must be real, and the restriction must “alleviate them to a material degree.” *Edenfield v. Fane*, 507 U.S. 761, 771 (1993) (government failed to show that ban on Certified Public Accountant solicitation met this prong; it provided no studies, no anecdotal evidence, only a lone affidavit with conclusory statements). Sometimes, “accumulated, common-sense judgments” may be enough. *Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 509–12 (1981) (upholding San Diego’s ban on certain advertising signs and stating: “We . . . hesitate to disagree with the accumulated, common-sense judgments of local lawmakers and of the many reviewing courts that billboards are real and substantial hazards to traffic safety. There is nothing here to suggest that these judgments are unreasonable.”) (footnote omitted).

Central Hudson Fourth Prong – Is the restriction narrowly tailored?

On the fourth prong, the *Central Hudson* Court found that the Commission’s order was more extensive than necessary to further the State’s interest in energy conservation. 477 U.S. at 570-71. The Court noted that there may be other types of promotional advertising that would not increase net energy consumption (e.g., energy saving tools). *Id.* at 570. The Court also noted that the State had not shown how a more limited restriction would not adequately advance the State’s interest. *Id.* Therefore, because the Commission’s order suppressed speech that would *not* harm the State’s interest, and because the State failed to show that a “more limited speech regulation” would be ineffective, the State’s prohibition did not survive the fourth prong of the test. *Id.* at 570-71.

Other cases have explained that the fourth prong requires a careful calculation of the speech interests involved, including the costs and the benefits of the regulation. *Greater New Orleans Broadcasting Ass’n, Inc. v. United States*, 527 U.S. 173, 188 (1999) (government should “carefully calculate[] the costs and benefits associated with the burden on speech imposed by its prohibition”) (citation and internal quotation marks omitted); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 561-62 (2001). In *Lorillard*, the Court held that Massachusetts’ ban on outdoor advertising for smokeless tobacco and cigars failed this prong for many reasons. 533 U.S. at 562-67. The State had banned such advertising within 1,000 feet of schools or playgrounds. The Court did not believe the State had considered the impact of this restriction on major metropolitan areas, finding that the “uniformly broad sweep of the geographical limitation demonstrate[d] a lack of tailoring.” *Id.* at 563. The Court also found the “range of communications restricted,” including on oral communications and signs of any size, “unduly broad.” *Id.* Further, the Court found that some retailers and manufacturers could face “onerous burdens” – e.g., because of small advertising budgets or an inability for convenience stores to attract passersby. *Id.* at 564-65. The Court concluded: “A careful calculation of the costs of a speech regulation does not mean that a State must demonstrate that there is no incursion on legitimate speech interests, but a speech regulation cannot unduly impinge on the speaker’s ability to propose a commercial transaction and the adult listener’s opportunity to obtain information about products.” *Id.* at 565.

In addition to considering costs and benefits, the State should also consider whether any alternatives could advance its interest in a “manner less intrusive to . . . First Amendment rights.” See *Rubin*, 514 U.S. at 490-91 (noting that limiting alcohol content of beers, among other options, could help to prevent alcohol strength wars without limiting speech). See also

Zauderer, 471 U.S. at 643-45, 48-49 (State’s “prophylactic rule” – a blanket prohibition on all attorney advertising information regarding specific legal problems – was not “narrowly crafted” and State should come up with other means to restrain misleading advertising; State’s blanket ban on illustrations in attorney advertising was also over-extensive, State had not shown why it was not, and concerns about misleading illustrations could be better addressed on a case-by-case basis); *IMS Health*, 131 S. Ct. at 2670-72 (where State disagreed with viewpoint of pharmaceutical companies regarding propriety of influencing prescriber decisions with mined data, State should have expressed that view through its own speech rather than indirectly restricting flow of “truthful information” to physicians) (citation omitted).

However, this does not require that the government pursue the least restrictive alternative. *Bd. of Trustees*, 492 U.S. at 479-80 (noting that “almost all of the restrictions disallowed under *Central Hudson*’s fourth prong have been substantially excessive,” and requiring “a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is ‘in proportion to the interest served’”) (citations omitted); *Fleminger*, 854 F. Supp. 2d at 196-97 (explaining that 2011 case, *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011), did not alter this traditional interpretation of the test).⁵ Where the government’s belief is reasonable, it should receive some deference. *See Clear Channel Outdoor, Inc. v. City of New York*, 594 F.3d 94, 104-05 (2d Cir. 2010) (“Supreme Court precedent instructs that, if the City’s determination about how to regulate outdoor commercial advertising is ‘reasonable’—and we find that it is in this case—then we should defer to that determination.”) (citations omitted). However, the deference is not absolute. *See 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 508-10 (1996) (broad regulations on truthful, nonmisleading advertising disfavored where non-speech-related alternatives are available).

⁵ In the *Fleminger* case, Plaintiff argued that *Sorrell v. IMS Health* had overturned a substantial line of Supreme Court precedent and had modified the test for commercial speech restrictions to require more than a reasonable fit between the government’s means and ends. 854 F. Supp. 2d at 196. The Court rejected this argument in full with a thoughtful and thorough explanation and noted, among other things, that *IMS Health* did not alter the third prong of the *Central Hudson* test, either. *Id.* at 196-97. *Accord, e.g., King v. General Information Svcs., Inc.*, No. 10-6850, 2012 WL 5426742, at *4 (E.D. Pa. 2012) (“Certainly, the [*IMS Health*] decision reaffirms the core meaning of the First Amendment and attempts to guide lawmakers trying to protect privacy interest without unduly suppressing speech. However, the Supreme Court stopped far short of overhauling nearly three decades of precedent, which is clearly demonstrated by the fact that the opinion characterizes commercial speech precedence, including *Central Hudson* itself, for support. . . . This alone is enough to find that the typical commercial speech inquiry under intermediate scrutiny remains valid law. If the Court wished to disrupt the long-established commercial speech doctrine as applying intermediate scrutiny, it would have expressly done so. Absent express affirmation, this Court will refrain from taking such a leap.”) (internal citations omitted); *NSK Corp. v. United States*, 821 F. Supp. 2d 1329, 1353, 1356 (Ct. Int’l Trade 2012) (rejecting argument that *IMS Health* altered *Central Hudson* First Amendment test); *Standard Furniture Mfg. Co., Inc. v. United States*, 823 F. Supp. 2d 1327, 1338, 1340-42 (Ct. Int’l Trade 2012) (“We reject plaintiff’s argument that [*IMS Health*] requires us to apply to the [challenged law] a level of scrutiny different from that applied by the Court of Appeals in [an earlier case applying *Central Hudson*].”). Even if *IMS Health* somehow modified the *Central Hudson* test, any “heightened scrutiny” would nevertheless only apply to “content-based bans on commercial speech” and would require only that the law in question be “drawn to achieve” the government’s interest. *See Friendly House v. Whiting*, 846 F. Supp. 2d 1053, 1059-60 (D. Ariz. 2012). Thus, any “heightened scrutiny” would not apply to Vermont’s disclosure requirement (which is not a content-based ban on commercial speech) or to its natural prohibition (which would be upheld under the first prong of *Central Hudson*).

b. Distinguishing *International Dairy Foods Association v. Amestoy*

In this 1996 case, the Second Circuit applied the *Central Hudson* test to a Vermont statute requiring the labeling of dairy products containing recombinant bovine growth hormone. 92 F.3d 67, 72-73 (2d Cir. 1996). The District Court had denied a preliminary injunction against enforcement of the statute, but the Second Circuit reversed, finding that the statute was likely to be held unconstitutional under the First Amendment. *Id.* at 69, 74.

Vermont had passed a law stating that, if rBGH had been “used in the production of milk or a milk product for retail sale in this state, the retail milk or milk product shall be labeled as such.” *Id.* at 69 (quoting Vt. Stat. Ann. tit. 6 § 2754(c)). Multiple industry groups filed suit to challenge the statute. They claimed, among other things, that the labeling requirement was not “purely commercial” because it compelled them to “convey a message regarding the significance of [rBGH] use that is expressly contrary to their views.” *Id.* at 71-72 (citation and internal quotation marks omitted). As mentioned above, the Court did not decide whether the speech was “commercial or political” because it found that Vermont had failed to meet *Central Hudson’s* “less stringent constitutional requirements applicable to compelled commercial speech.” *Id.* at 72. (Later Second Circuit precedent makes clear that the relative significance of information does not act to make it any less “commercial” or “factual.” *N.Y. State Restaurant Ass’n*, 556 F.3d at 134 - analyzing calorie disclosure requirement as “commercial” and finding it “factual” despite plaintiff’s position that it did not want to prioritize such information.) Additionally, the Court did not discuss, and appears to have merely assumed, that the *Central Hudson* test applied to *disclosure requirements* as well as *restrictions* on speech;⁶ later cases (discussed above) would explicitly limit *Int’l Dairy’s* holding on this issue.

The Court focused its holding and analysis on the second prong of the test – whether the State had a substantial interest to be advanced by the legislation. *Id.* at 73-74. In deciding this, the Court relied “only upon those interests set forth by Vermont before the district court.” 92 F.3d at 73 (citing *Edenfield*, 507 U.S. at 766-67 (“[T]he *Central Hudson* standard does not permit us to supplant the precise interests put forward by the State with other suppositions.”) (internal quotation marks omitted). As characterized by the Second Circuit:

As the district court made clear, Vermont “does not claim that health or safety concerns prompted the passage of the Vermont Labeling Law,” but instead defends the statute on the basis of “strong consumer interest and the public’s ‘right to know’ . . .”

Int’l Dairy, 92 F.3d at 73 (citing District Court, *Int’l Dairy*, 898 F. Supp. at 249). The Court continued:

Although the dissent suggests several interests that if adopted by the state of Vermont *may* have been substantial, the district court opinion makes clear that

⁶ The Court cited *Zauderer* for the propositions that commercial speech is protected and that preventing consumer deception is an appropriate state interest. *Int’l Dairy*, 72 F.3d at 71, 74. It appears the State did not argue that the rational basis test articulated in *Zauderer* should apply to Vermont’s disclosure requirement. *Int’l Dairy Foods Ass’n v. Amestoy*, Brief for Defendants-Appellees, *29-36 (2d Cir.) (analyzing under *Central Hudson* test).

Vermont adopted no such rationales for its statute. Rather, Vermont's sole expressed interest was, indeed, "consumer curiosity." The district court plainly stated that, "Vermont takes no position on whether [rBGH] is beneficial or detrimental. However," the district court explained, "Vermont has determined that its consumers want to know whether [rBGH] has been used in the production of their milk and milk products." 898 F. Supp. at 252 It is clear from the opinion below that the state itself has not adopted the concerns of the consumers; it has only adopted that the consumers are concerned. Unfortunately, mere consumer concern is not, in itself, a substantial interest.

92 F.3d at 73 n.1 (emphases added). The Court therefore adopted the District Court's factual finding that only "consumer curiosity" was at stake. *Id.* at 73-74.

In contrast, the dissent argued that the District Court had recognized several other interests. For instance, the statement accompanying the regulations implementing Vermont's statute had noted that consumers were interested in disclosure because they were concerned about human health and safety, bovine health, and the economics of surplus milk. *Id.* at 75 (Leval, J., dissenting). The State had also offered survey evidence and comments by Vermont citizens with similar concerns. *See id.* The dissent explained that the District Court found most Vermonters did not want to purchase gBGH milk products because:

(1) They consider the use of a genetically-engineered hormone in the production unnatural; (2) they believe that use of the hormone will result in increased milk production and lower milk prices, thereby hurting small dairy farmers; (3) they believe that the use of rBST is harmful to cows and potentially harmful to humans; and, (4) they feel that there is a lack of knowledge regarding the long-term effects of rBST.

Id. at 75-76 (quoting District Court, 898 F. Supp. at 250). Based on these concerns, the District Court had found that Vermont had a "substantial interest in informing consumers of the use of [rBGH] in the production of milk and dairy products sold in the state." *Id.* (quoting District Court, 898 F. Supp. at 254).

The dissent attempted to discount District Court statements along these lines, arguing that the State's interest was broader than consumer information. 92 F.3d at 76, 76 n.2 ("More likely, what Judge Murtha meant was that Vermont does not claim to *know* whether [rBGH] is harmful. . . . When the citizens of a state express concerns to the legislature and the state's lawmaking bodies then pass disclosure requirements in response to those expressed concerns, it seems clear (without the need for a statutory declaration of purpose) that the state is acting to vindicate the concerns expressed by its citizens, and not merely to gratify their 'curiosity.'"). However, without making the dissent's assumption – however logical – that the State had basically "adopted" the concerns of its citizens, the District Court's statements describe a record in which the *citizens'* interests were in public health and safety, animal health, and economics; and the *State's* interest was in providing information to consumers because they were concerned. *This* was the interest that was not good enough.

The majority also noted that Vermont could not have justified the statute on the basis of “real harms” because there was “no scientific evidence from which an objective observer could conclude that [rBGH] has any impact at all on dairy products.” *Id.* at 73 (citation and internal quotation marks omitted). The Food and Drug Administration had “concluded that [rBGH] has no appreciable effect on the composition of milk produced by treated cows, and that there are no human safety or health concerns associated with food products derived from cows treated with [rBGH].” *Id.* (quoting District Court, 898 F. Supp. at 248). Further, it was “undisputed that neither consumers nor scientists can distinguish [rBGH]-derived milk from milk produced by an untreated cow.” *Id.* (citing District Court, 898 F. Supp. at 248-49). Please refer to the attached Appendix for an explanation of some of the factual differences that already exist between the regulatory and scientific frameworks regarding rBGH in *Int’l Dairy*, and those regarding genetically engineered foods in the present case. The Appendix demonstrates that there is already “scientific evidence from which an objective observer could conclude that [genetic engineering] has any impact at all on [food products].” The FDA has already voiced “human safety or health concerns associated with food products derived from [genetic engineering].” And, “scientists can distinguish [genetically engineered foods] from [foods] produced [without genetic engineering].” This case is therefore already readily distinguishable from *Int’l Dairy*.

The Court concluded:

We are aware of no case in which consumer interest alone was sufficient to justify requiring a product’s manufacturers to publish the functional equivalent of a warning about a production method that has no discernible impact on a final product. . . .

[The] information [must] bear[] on a reasonable concern for human health or safety or some other sufficiently substantial governmental concern. . . .

[C]onsumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement.

Id. at 73-74 (citations omitted).

In sum, the Court’s holding rested on the fact that the District Court had identified “consumer curiosity” as the *State’s* sole interest in the disclosure requirement. And, in order to justify another type of interest – e.g., concerns for human health or safety – the State would need to provide some evidence that products from cows treated with rBGH were worthy of concern and distinguishable from products from non-treated cows. The Court’s holding did not stand for the proposition that all labeling requirements are per se based on consumer curiosity - even those that are based in part on a consumer’s right to know. Similarly, the Court’s holding does not stand for the proposition that a State could not have a valid, constitutional interest in a labeling requirement.

*Vermont's Offerings on the Interest Factor in Int'l Dairy*⁷

The following excerpts from the District Court opinion and the State's brief to the Second Circuit detail how the State had identified "consumer concern" and the public's right to know as its primary goals in passing the legislation (which, in the Second Circuit's opinion, amounted to "consumer curiosity"). The State had produced evidence to prove that consumers were concerned about potential health effects, farming economics, etc. True to the Second Circuit's finding, 92 F.3d at 73, it does not appear that the State had actually adopted those concerns as its own (all emphases added below).

- Vermont passed the law "*in response to widespread consumer concern about th[e] new, bio-engineered product, and to further the goal of providing consumers with truthful information about [rBGH].*" *Int'l Dairy Foods Ass'n v. Amestoy*, Brief for Defendants-Appellees, *6 (2d Cir.).
- "Vermont's [rBGH] labeling law *responds to widespread and deeply felt consumer concern* about injecting cows with a synthetic hormone to induce the cows to produce more milk through agricultural biotechnology." *Id.* *7.
- "The court below had *ample evidence before it to support its findings that consumers are concerned that [gBGH] use (1) will hurt small dairy farmers, (2) will have potentially harmful health effects on humans and cows; and (3) may have long-term health effects that have not been sufficiently studied.*" *Id.* *7-*8.
- "The district court correctly found, based upon the ample record before it, that Vermont's interest in providing consumers with truthful, commercial information concerning the method of production for dairy products sold in the state more than satisfies this test." *Id.* *35 (citation omitted).
- "The defendants assert that the FDA approved the use of rBST, even though the Agency recognized a slight increase in the incidence of mastitis in injected cows. In addition, the *defendants have demonstrated the existence of consumer concern* about the use of rBST." *Int'l Dairy*, 898 F. Supp. at 249.
- "The State does not claim that health or safety concerns prompted the passage of the Vermont Labeling Law. Instead, *it bases its justification for mandatory labeling not otherwise required by the FDA on strong consumer interest and the public's 'right to know' whether a particular dairy product contains milk produced by cows given rBST.*" *Id.*
- "The State believes that this labeling system will *communicate accurate product information to consumers and reduce uncertainty* regarding the use and effect of rBST." *Id.* at 250.
- "The State's surveys show that *Vermont consumers have a high awareness of issues* surrounding the use of rBST and *are in favor of the type of labeling* required by the

⁷ This section explains how the District Court and the State characterized evidence. It is not clear how much of the evidence came from the legislative record. According to the District Court, the evidence it reviewed included two days of testimony at hearing, affidavits, and exhibits. *Int'l Dairy*, 898 F. Supp. at 248. The Court does not really name or describe the evidence. The State's brief to the Second Circuit mentioned several different types of evidence: testimony from the Commissioner of Agriculture, the Plaintiffs' own affidavits, a Government Accountability Office report, a federal government study, and the opinion of a state consumer survey expert. *Int'l Dairy*, 92 F.3d 67, Defendant's Brief at *8-*14.

- Vermont Labeling Statute. Apparently, a majority of Vermonters do not want to purchase milk products derived from rBST-treated cows. Their reasons for not wanting to purchase such products include: (1) They consider the use of a genetically-engineered hormone in the production unnatural; (2) they believe that use of the hormone will result in increased milk production and lower milk prices, thereby hurting small dairy farmers; (3) they believe that use of rBST is harmful to cows and potentially harmful to humans; and, (4) they feel that there is a lack of knowledge regarding the long-term effects of rBST.” *Id.*
- “Vermont has a *substantial interest in informing consumers* of the use of rBST in the production of milk and dairy products sold in the state.” *Id.* at 254.

c. The *Central Hudson* Test Would Not Apply to the Disclosure Requirement

The *Central Hudson* test is not the proper standard under which to analyze the GE disclosure requirement. Though the Second Circuit in *Int’l Dairy* applied *Central Hudson* to Vermont’s milk labeling law, the later Second Circuit decisions discussed above limited that holding to cases where the government could provide no greater interest than consumer curiosity. *Nat’l Elec. Mfrs.*, 272 F.3d at 115 n.6 (“Although we applied the *Central Hudson* test in *IDFA* . . . our decision was expressly limited to cases in which a state disclosure requirement is supported by no interest other than the gratification of ‘consumer curiosity.’”) (citation omitted); *N.Y. State Restaurant Ass’n*, 556 F.3d at 134 (distinguishing *Int’l Dairy* and applying *Zauderer* to New York City’s requirement that certain restaurants post calorie information on their menus); *Conn. Bar Ass’n*, 620 F.3d at 96 n.16 (applying *Zauderer* to disclosure requirements and limiting *Int’l Dairy*).

In *Nat’l Elec. Mfrs.*, the issue was whether a Vermont requirement that some mercury-containing products have labels to inform consumers that the products contain mercury, and that they should be disposed of as hazardous waste, was constitutional. 272 F.3d at 107. Following *Int’l Dairy*, the district court had applied the *Central Hudson* test, but the Second Circuit ruled that the district court had “misperceived the proper standard to apply” and that the “*Central Hudson* test should be applied to statutes that *restrict* commercial speech.” *Id.* at 113, 115. Citing *Zauderer*, the Court noted that “[r]egulations that compel ‘purely factual and uncontroversial’ commercial speech are subject to more lenient review than regulations that restrict accurate commercial speech and will be sustained if they are ‘reasonably related to the State’s interest in preventing deception of consumers.’” *Id.* (citing 471 U.S. at 651). The Court explained that disclosure requirements are treated differently than restrictions because “mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests.” *Id.* at 113-14. Moreover, “[r]equired disclosure of accurate, factual commercial information presents little risk that the state is forcing speakers to adopt disagreeable state-sanctioned positions, suppressing dissent, confounding the speaker’s attempts to participate in self-governance, or interfering with an individual’s right to define and express his or her own personality.” *Id.* at 114 (citation omitted). Therefore, the test for determining whether a disclosure requirement is valid is to determine whether a “rational connection” exists between “the purpose of a commercial disclosure requirement and the means employed to realize that purpose.” *Id.* at 115.

Eight years later, the Second Circuit upheld the application of *Zauderer* to disclosure requirements when a restaurant association challenged New York City’s law requiring calorie information on some restaurant menus. *N.Y. Restaurant Ass’n*, 556 F.3d at 131-34. Discussing *Nat’l Elec. Mfrs.*, the Court stated: “In light of *Zauderer*, this Circuit thus held that rules ‘mandating that commercial actors disclose commercial information’ are subject to the rational basis test.” *Id.* at 132 (citation omitted). The Court further held that *Int’l Dairy* was “inapplicable” because it was “‘expressly limited’” to cases where consumer curiosity was the lone state interest. *Id.* at 134 (quoting *Int’l Dairy*, 272 F.3d at 115 n.6). In contrast, in *N.Y. Restaurant Ass’n*, New York had an interest in preventing obesity. 556 F.3d at 134:

[Plaintiff’s] claim that this case is more akin to [Int’l Dairy], clearly fails. In [Nat’l Elec. Mfrs.] we explained that our decision in [Int’l Dairy] was expressly limited to cases in which a state disclosure requirement is supported by no interest other than the gratification of consumer curiosity. Given New York’s interest in preventing obesity . . . [Int’l Dairy] is inapplicable.

Id. (internal quotation marks and citations omitted) (emphasis added).

Therefore, because Vermont would have an interest greater than “consumer curiosity” in the GE disclosure requirement, the *Central Hudson* test would not apply.⁸

d. Recap of *Central Hudson* Rules

This section gives a distillation of the most important factors under each of *Central Hudson*’s prongs, discussed in full above. Vermont could meet each of these factors for both its disclosure requirement and its “natural” prohibition in order to ensure that these provisions would survive constitutional challenges. However, Vermont should not *need* to meet all of these factors for either provision. First, the disclosure requirement would be subject to the *Zauderer* test because it would not be based solely on consumer curiosity. Second, the “natural” prohibition could survive after application of only the first prong through Vermont’s showing that the “natural” label on genetically engineered products is misleading.

⁸ There could also be an argument that the full *Central Hudson* test would not apply to the disclosure requirement because the first prong – requiring that the protected speech not be misleading – would not be met. In this case, the protected speech would actually be an *absence* of speech (product labels without GE disclosures). The FDA utilized this concept in its rationale for requiring labels on irradiated foods. Irradiation in Food, 51 Fed. Reg. 13,376-01, 13,388, 13,390 (April 18, 1986) (“Irradiation may not change the food visually so that in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed. . . . Thus, the absence of a label statement on retail foods may incorrectly suggest that an irradiated food is essentially unprocessed.”). In response to comments that the “irradiation” label itself could be misleading, the FDA stated that “any confusion created by the presence of a retail label requirement can be corrected by proper consumer education programs.” *Id.* at 13,389; *see also Va. State Bd. of Pharmacy*, 425 U.S. at 769-70 (rejecting State’s argument that disclosure of drug prices would somehow harm “unwitting customers” and calling approach “highly paternalistic”). A similar concept could also be applied to fulfill one of the legitimate state interests under *Zauderer*: the prevention of consumer deception. *See* 51 Fed. Reg. at 13,389 (“The issue here is whether the irradiation of food is a material fact that must be disclosed to the consumer to prevent deception.”); *see also* Part II.A.2.a, *supra*. The point would be that labels for genetically engineered food products without GE disclosures are both misleading and potentially deceptive.

First Prong – Protected Speech Must Not Be Misleading or Relate to Unlawful Activity

- If no one claims the speech is related to an unlawful activity or misleading, this prong is likely to be satisfied. *See Central Hudson*, 447 U.S. at 566-68 (prong met where New York had not claimed electric utility advertising was misleading or referred to unlawful activity).
- Factual statements of information or accurate illustrative depictions are not misleading. *See Zauderer*, 471 U.S. at 639-41, 47-49 (information about and depiction of Dalkon Shield in attorney advertisement factually accurate and entitled to protection).
- Speech with numerous possibilities to deceive is misleading. *Friedman*, 440 U.S. at 12-13.
 - Trade name for optometry practice would not convey factual information about practice (services, prices) and would instead create for public an “ill-defined association” with trade name over time, which may not be accurate (e.g., if optometrist leaves practice but trade name stays the same).
- Proof of actual injury is not required. The State’s well-founded perception of potential for harm is enough. *Ohralik*, 426 U.S. at 464-66.
- Speech is misleading if it is “inherently misleading” or the record indicates that it is misleading. *In re RMJ*, 455 U.S. at 202-03.
- Fact that other, factual speech would not be restricted lends support to restriction on misleading speech because factual speech would be more effective at conveying information. *Friedman*, 440 U.S. at 16 (optometry practices still allowed to convey factual information about prices, services, etc. to public).

Second Prong – State Must Have Substantial Interest

- Consumer curiosity (a.k.a. “public’s right to know” and “consumer concern”) is not a substantial interest. *Int’l Dairy*, 92 F.3d at 73-74.
 - Consumer’s concerns about human health and safety, bovine health, and economics of surplus milk were not adopted by State. *Int’l Dairy*, 92 F.3d at 73 n.1, 75.
 - State asserted, as *its* interest, providing information to concerned consumers. *Int’l Dairy*, 92 F.3d at 73; *Int’l Dairy*, Brief for Defendants-Appellants, *6 (2d Cir.); *Int’l Dairy*, 898 F. Supp. at 249-50, 254.
 - State interest should be based on a “reasonable concern” about “human health or safety or some other sufficiently substantial governmental concern.” *Int’l Dairy*, 92 F.3d at 73-74.
- There must be evidence (e.g., scientific evidence) of real harms.
 - Should be some evidence that ingredient to be disclosed on label has some impact on product (as opposed to “no” evidence and no “impact at all,” especially where Food & Drug Administration has concluded otherwise). *Int’l Dairy*, 92 F.3d at 73.
 - Consumers or scientists should be able to distinguish product with labeled ingredient from product without labeled ingredient. *Int’l Dairy*, 92 F.3d at 73.
- Examples of substantial interests:
 - Energy conservation - *Central Hudson*, 447 U.S. at 568-69.
 - Health, safety, welfare (alcoholism and social costs) - *Rubin*, 514 U.S. at 485.
 - Promoting educational, rather than commercial, atmosphere on college campuses; promoting security and safety; preventing commercial exploitation of student body, and; preserving tranquility in campus residences - *Bd. of Trustees*, 492 U.S. at 475.

- Preventing consumer confusion; protecting public health (through disclaimer requirement on green tea health claim) - *Fleminger*, 854 F. Supp. 2d at 209.

Third Prong – Regulation Must Directly Advance State Interest

- Regulation must advance interest in direct and material way; there should be an immediate connection between the interest and the regulation. Link should not be speculative, remote, or conditional.
 - Order prohibiting promotional advertising by utilities immediately connected to State’s interest in conserving electricity. *Central Hudson*, 447 U.S. at 569.
 - Link between alcohol content labeling restriction and reduction in strength wars not direct and material. *Rubin*, 514 U.S. at 487, 489 (citation omitted).
 - Link between order prohibiting promotional advertising by utilities and State’s interest in fair rate structure too tenuous. *Central Hudson*, 447 U.S. at 569.
 - Restriction on transmission of prescriber information to pharmaceutical companies not “drawn” to serve asserted interest of protecting physician privacy because information could still be transmitted to other audiences. *IMS Health, Inc.*, 131 S. Ct. at 2668.
- State must provide credible evidence that regulation directly advances interest.
 - Government’s restriction on alcohol content labeling did not advance interest in curbing alcohol strength wars where government “had failed to present any credible evidence showing that the disclosure of alcohol content would promote strength wars.” *Rubin*, 514 U.S. at 489.
 - Government failed to show that ban on Certified Public Accountant solicitation met this prong; it provided no studies, no anecdotal evidence, only a lone affidavit with conclusory statements. *Edenfield*, 507 U.S. at 771.
- “Accumulated, common-sense judgments” may be enough.
 - San Diego’s ban on certain advertising signs was in line with “accumulated, common-sense judgments of local lawmakers and of the many reviewing courts that billboards are real and substantial hazards to traffic safety.” *Metromedia*, 453 U.S. at 509–12 (footnote omitted).

Fourth Prong – Regulation Must Be No More Extensive than Necessary

- Regulation must not suppress speech that would *not* harm state’s interest.
 - Ban on all promotional advertising by utilities failed prong; it could also suppress advertising that would not increase net energy consumption (e.g., energy saving tools). *Central Hudson*, 447 U.S. at 570-71.
- State must show that more limited regulation would be ineffective, or at least consider other means.
 - Ban on all promotional advertising by utilities failed prong failed in part because State did not look at more limited regulation. *Central Hudson*, 447 U.S. at 570-71.
 - Failing this prong because limiting alcohol content of beers, among other options, could help to prevent alcohol strength wars without limiting speech. *Rubin*, 514 U.S. at 490-91.

- State’s blanket prohibition on all attorney advertising information regarding specific legal problems was not narrowly crafted and State should come up with other means to restrain misleading advertising. *Zauderer*, 471 U.S. at 643-45, 48-49.
 - State’s blanket ban on illustrations in attorney advertising was also over-extensive, State had not shown why it was not, and concerns about misleading illustrations could be better addressed on a case-by-case basis. *Zauderer*, 471 U.S. at 643-45, 48-49.
 - Where State disagreed with viewpoint of pharmaceutical companies regarding propriety of influencing prescriber decisions with mined data, State should have expressed that view through its own speech rather than indirectly restricting flow of “truthful information” to physicians. *IMS Health*, 131 S. Ct. at 2670-72 (citation omitted).
- But State does not need to pursue least restrictive alternative. Fit need only be reasonable and in proportion to interest served. *Bd. of Trustees*, 492 U.S. at 479-80. (Test still stands after *Sorrell v. IMS Health*. *Fleminger*, 854 F. Supp. 2d at 196-97.)
- Reasonable government belief should receive some deference. *Clear Channel*, 594 F.3d at 104-05.
 - Deference not absolute where legislature suppresses nonmisleading, truthful information for paternalistic purposes. *44 Liquormart*, 517 U.S. at 508-10.
- State must carefully consider costs and benefits of regulation.
- *Greater New Orleans Broadcasting Ass’n*, 527 U.S. at 188 (stating rule).
 - Should consider geographic scope, range of communications restricted, and whether regulated would face onerous burdens. *Lorillard Tobacco*, 533 U.S. at 561-67.
 - Ban on outdoor tobacco advertising near schools covered too much space in major metropolitan areas. *Lorillard Tobacco*, 533 U.S. at 563.
 - Ban on outdoor tobacco advertising covered too many types of speech – oral communications, signs of any size. *Lorillard Tobacco*, 533 U.S. at 563.
 - Ban on outdoor tobacco advertising too onerous for those of limited means or convenience stores with difficulty attracting passersby. *Lorillard Tobacco*, 533 U.S. at 564-65.
 - Does not mean there can be no impingement on speech interests, but it should not unduly impinge actor’s ability to give information or public’s ability to receive it. *Lorillard Tobacco*, 533 U.S. at 566.

B. Preemption

This section will explain why a genetically engineered food labeling law in Vermont would not be preempted by the Federal Food, Drug, and Cosmetic Act, including the 1990 amendments adding the Nutrition Labeling and Education Act. First, this section will provide background information on how the Food and Drug Administration (FDA) regulates biotechnology products. Second, this section will give a brief overview of the preemption doctrine, touching on the three instances when federal law may trump state law. Next, this section will walk through three express preemption provisions of the NLEA and explain why they do not apply. Finally, this section will illustrate why only express preemption can be applied and GE labeling would not be impliedly preempted.

1. FDA Regulation of Genetically Engineered Foods

In the United States, products of biotechnology are regulated under the same laws that govern the “health, safety, efficacy, and environmental impacts of similar products derived by more traditional methods.” *Guide to U.S. Regulation of Agricultural Biotechnology Products*, Pew Initiative on Food and Biotechnology i (Sept. 2011) (Pew Initiative);⁹ *see also* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302-01, 23,302-03 (June 26, 1986). Thus, no new regulatory scheme was created for biotechnology products when the United States announced its first policy in 1986; instead, they were regulated under existing legal frameworks. *Id.*

The Food and Drug Administration regulates the labeling of foods under the Federal Food, Drug and Cosmetic Act (FDCA or Act). *See generally* 21 C.F.R. ch. I. The FDCA prohibits the misbranding of food. 21 U.S.C. § 331(b)(1938); *see also* *N. Y. State Restaurant Ass’n v. New York City Bd. of Health*, 556 F.3d 114, 118 (2d Cir. 2009). Specifically, under the FDCA, the FDA can adopt food definitions and food quality standards; set levels of tolerance for poisonous substances in food; and take enforcement actions on misbranded or adulterated foods. *E.g.*, 21 U.S.C. §§ 334, 341, 346; *see also* *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 331 (3d Cir. 2009). In 1990, Congress amended the FDCA to include the Nutrition Labeling and Education Act (NLEA), which regulates certain aspects of food labeling in concert with the FDCA. Nutrition Labeling and Education Act, Pub. L. No. 101-535 § 2, 104 Stat. 2353 (1990); *see* Dan L. Burk, *The Milk Free Zone: Federal and Local Interests in Regulating Recombinant BST*, 22 Colum. J. Envtl. L. 227, 258 (1997). The NLEA sought to “clarify and strengthen the [FDA’s] legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in food.” *N. Y. State Restaurant Ass’n*, 556 F.3d at 118 (citation omitted). When describing the NLEA, the Court in *Ackerman v. Coca Cola Co.* explained, “[I]t expanded the coverage of nutrition labeling requirements; it changed the form and substance of ingredient labeling on packages; it imposed limitations on health claims; it standardized the definitions of all nutrient content claims; and it required more uniform serving sizes.” No. CV-09-0395, 2010 WL 2925955, at *3 (E.D.N.Y. July 21, 2010) (citation omitted).

As mentioned above, the federal policy stating that no new laws were needed to regulate biotechnology first came about in 1986 in the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework). *See* 51 Fed. Reg. at 23,302-01. The policy was “based on the assumption that the process for biotechnology itself posed no unique or special risks,” and therefore biotechnology products could be regulated under existing federal statutes. Pew Initiative at 1. In addition, the Coordinated Framework explained that a commercial product “should be regulated based on the product’s composition and intended use,” not on its manner of production. Pew Initiative at 1; *see also* Coordinated Framework, 51 Fed. Reg. at 23,304.

In 1992, the FDA published another policy statement regarding food derived from genetically modified plants. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984-01 (May 29, 1992). The policy defined “genetic modification” as “the alteration of the

⁹ http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_0901.pdf

genotype of a plant using any technique, new or traditional.” 57 Fed. Reg. at 22,984 n.3. In the policy statement, the FDA “proposed to consider foods derived from genetically modified plants in the same way that it has traditionally treated foods containing additives developed through more traditional forms of plant breeding.” Pew Initiative at 27; 57 Fed. Reg. at 22,984-85. The FDA “also indicated that most foods derived from genetically modified plants were presumptively GRAS [generally recognized as safe]” and that no prior FDA approval would be required. Pew Initiative at 27; 57 Fed. Reg. at 22,990. Additionally, in its 1992 policy statement the FDA “created a voluntary process under which producers could consult with the agency about safety and regulatory issues prior to marketing food derived from [bio]technology.” Pew Initiative at 28; 57 Fed. Reg. at 22,993-23004. Regarding labeling, the FDA stated that it was not currently aware of any “material” information about GE foods that would require the agency to require labels. 57 Fed. Reg. at 22,991.¹⁰

In 2001, the FDA announced two proposals relating to genetically modified organisms: a proposed rule to submit data to the agency before marketing plant-derived bioengineered foods, and draft guidance for the voluntary labeling of bioengineered foods. 66 Fed. Reg. 4706-01, 4839-01 (Jan. 18, 2001). Both proposals were published in the Federal Register and open for public comment. *Id.* It appears, however, that no regulations were adopted since they have not been codified in the applicable volumes of the Code of Federal Regulations (CFR). Code of Federal Regulations Title 21.

In 2011, the House of Representatives proposed H.R. Bill 3553, the “Genetically Engineered Food Right to Know Act.” H.R. 3553, 112th Cong. (2011). If passed, H.R. 3553 would amend the FDCA to “deem a food misbranded if it contains or was produced with a genetically engineered material unless its labeling contains statements meeting specified requirements.” Open Congress, H.R. 3553, “Official Summary,” <http://www.opencongress.org/bill/112-h3553/show> (last visited Nov. 5, 2012). The bill is currently before the House Subcommittee on Health. The Library of Congress Thomas, Bill Summary & Status, 112th Congress (2011-2012), H.R. 3553, <http://thomas.loc.gov/cgi-bin/thomas> (last visited Nov. 5, 2012).

2. Supremacy Clause

The Supremacy Clause of the Constitution states that the “Constitution, and the Laws of the United States ... shall be the supreme Law of the Land.” U.S. Const. art. VI, § 2. Under the Supremacy Clause, state laws that “interfere with, or are contrary to the laws of Congress, made in pursuance of the constitution” must “yield” to the laws of Congress. *Gibbons v. Ogden*, 22 U.S. (9 Wheat) 1, 211 (1824). Congressional intent to preempt state law may be seen in a statute’s “express language” or through its “structure or purpose.” *Altria Group, Inc. v. Good*, 555 U.S. 70, 76 (2008) (citation omitted). Federal law may preempt state law in three circumstances: when there is express preemption, field preemption, or conflict preemption. *See*

¹⁰ We do not discuss this policy in our preemption analysis. It is not entitled to preemptive effect. *See, e.g., Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 341-42 (3rd Cir. 2009) (FDA policy on use of the term “natural” not entitled to preemptive effect because, among other things, it had not undergone notice and comment and was not product of “formal, deliberative process”) (citation omitted). Similarly, the FDA’s 1992 policy was not the result of a “formal, deliberative process” and was issued pre-comment. Also, the 1992 policy does not fall under any of the “express preemption” provision of the Act, discussed *infra*. For the same reasons, the FDA’s 2001 notice of a “draft guidance” for voluntary GE labeling is not preemptive.

Hillsborough County Fla. v. Automated Medical Laboratories, Inc., 471 U.S. 707, 713 (1985) (citations omitted). Under express preemption, Congress explicitly states in a statute that federal law preempts state law. *Id.* Absent express language, Congressional intent to preempt all state law in a particular area may be inferred where the scheme of federal regulation is so pervasive that it has left no room for state regulation. *Id.* In addition, state law may be preempted when compliance with both state and federal law is physically impossible. *Id.* As the Supreme Court has explained, “The nature of power exerted by Congress, the object sought to be obtained, and the character of the obligations imposed by the law are all important in considering the question of whether supreme federal enactments preclude enforcement of state laws on the same subject.” *Hines v. Davidowitz*, 312 U.S. 52, 70 (1941).

a. No Express Preemption

Under express preemption, Congress may withdraw specified powers from states by enacting laws with express preemption provisions. *Arizona v. United States*, 132 S. Ct. 2492, 2500-01 (2012). Simply because the federal statute contains an express preemption clause, however, does not mean that the state law is automatically preempted; “[t]he question of the substance and scope of Congress’ displacement of state law still remains.” *See Altria*, 555 U.S. at 76-87 (interpreting specific terms in express preemption provision of federal Cigarette Labeling & Advertising Act and holding they did not preempt state fraud claim). When a federal statute contains an express preemption provision, a presumption against preemption exists, requiring courts to read the clause narrowly. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Additionally, “in areas of traditional state regulation, [courts] assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest.” *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005); *see also Holk*, 575 F.3d at 334 (“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.”) (citation omitted).

The FDCA as amended by the NLEA contains an express preemption provision, Section 343-1. 21 U.S.C. § 343-1. Because the Act contains an express preemption provision, the court must first focus on the plain meaning of the clause to determine what exactly is preempted. *See 23-34 94th St. Grocery Corp. v. New York City Bd. of Health*, 685 F.3d 174, 181 (2d Cir. 2012) (citations omitted). The preemption provision in the NLEA contains three provisions which courts typically apply to state labeling laws. *See N. Y. State Restaurant Ass’n*, 556 F.3d at 118-19 (explaining that §§ 343-1(a)(4) and (a)(5) concerning nutrition information and nutrient content/health claims were the provisions applicable to New York City’s calorie disclosure requirement); *Guerrero v. Target Corp.*, No. 12-21115-CIV, 2012 WL 3812324, at *10 (S.D. Fla. Sept. 4, 2012) (determining that Florida’s labeling standard was not preempted by the standard of identity preemption provision because there was no federal standard of identity for honey).¹¹

¹¹ The other sections of the Act with which state laws need to be identical concern food sold under another name, imitation food, misleading containers, prominence of information on labels, standard of quality, fill of container, unidentified foods with multiple ingredients, artificial flavoring and coloring, chemical preservatives, and allergens. 21 U.S.C. § 343(b), (c), (d), (e), (f), (h), (i), (k), (w), (x); 21 U.S.C. § 343-1. These would not be applicable in our situation, either. For instance, Vermont’s law would not seek a label about “artificial flavoring and coloring” or the names of allergy-causing foods or food allergens, or the identification of “chemical preservatives” (which,

First, section 343-1(1) of the NLEA preempts any state requirement regarding standard of identity that is not identical to the federal standard. 21 U.S.C. § 343-1(1). Second, section 343-1(4) preempts any state requirement for food nutrition labeling that is not identical to the federal requirements of section 343(q) (nutrition information). *Id.* at § 343-1(4). Finally, section 343-1(5) preempts any requirement relating to nutrition levels and health claims that is not identical to those set out in 343(r). *Id.* at § 343-1(5). As explained below, Vermont’s labeling law would not fall under any of the three specified preemption provisions.¹²

Standard of Identity

The express preemption provision of the Act prohibits states from establishing “any requirement for a food which is the subject of a standard of identity established under section 341 of [the Act],” which requirement is not “identical to such standard of identity” or to the “requirement of section 343(g).” 21 U.S.C. § 343-1(1). Courts have interpreted this provision to mean that Congress has only prohibited standards of identity which conflict with established federal standards. *Guerrero*, 2012 WL 3812324, at * 10 (“the only State requirements that are subject to preemption are those that are affirmatively different from the Federal requirements”) (citations and internal quotation marks omitted). Section 341, titled “Definitions and standards for food,” authorizes the Secretary of the FDA to promulgate regulations “fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity.” 21 U.S.C. § 341. The Secretary has promulgated several standards of identity

interestingly, do not include “chemicals applied for their insecticidal or herbicidal properties”). *See* 21 U.S.C. § 343(w), (x); 21 C.F.R. § 101.22(a)(5).

¹² Neither the recent Second Circuit decision in *23-34 94th St. Grocery Corp. v. New York City Board of Health* nor the Supreme Court decision in *National Meat Association v. Harris* would be an obstacle to a Vermont labeling law. In the Second Circuit case, the Court determined that a Board of Health regulation requiring the display of signs featuring images of the negative health effects associated with smoking was preempted by the Federal Cigarette Labeling and Advertising Act (Labeling Act) because it was a content-based requirement related to promotional materials. *Grocery Corp.*, 685 F.3d 174, 179, 184-86 (2d Cir. 2012) (where Labeling Act’s preemption provision prohibited states from regulating content of advertising or promotion of cigarettes). In the Supreme Court case, the Court ruled that a California Penal Code provision prohibiting the receipt, processing, or sale of meat or meat products of nonambulatory animals for human consumption, and requiring immediate euthanization of nonambulatory animals, was preempted by the Federal Meat Inspection Act (FMIA) because California’s statute substituted its own regulatory scheme for that created under the FMIA. *Nat’l Meat*, 132 S. Ct. 965, 970-71 (2012) (finding that “[t]he FMIA’s preemption clause sweeps widely—and in so doing, blocks the applications of [the statute] challenged here. The clause prevents a State from imposing any additional or different—even if non-conflicting—requirements that fall within the scope of the Act and concern a slaughterhouse’s facilities or operations. And at every turn [the statute] imposes additional or different requirements on swine slaughterhouses: It compels them to deal with nonambulatory pigs on their premises in ways that the federal Act and regulations do not. In essence, California’s statute substitutes a new regulatory scheme for the one the FSIS uses. Where under federal law a slaughterhouse may take one course of action in handling a nonambulatory pig, under state law the slaughterhouse must take another.”). Like in the NLEA, Congress included an express preemption provision in both the Labeling Act and the FMIA. However, the NLEA’s preemption provision only prohibits state regulation of specific forms of food labeling such as to standard of identity and nutrition. *See generally* 21 U.S.C. § 343-1. Unlike the Labeling Act and the FMIA, the NLEA’s prohibition is smaller in scope, listing out specific sections of the broader legislation that are preempted. *Id.* Even the labeling requirements that are preempted may be regulated by the states so long as those regulations are identical to the federal requirements. *See* 21 U.S.C. § 343-1. Unlike the City’s regulation in the *Grocery Corp.* case and California’s Penal Code provision, and for the reasons discussed in this section, Vermont’s law would not fall under any of the relevant Act’s express preemption provisions.

codified in Title 21 of the CFR Parts 131-169. Similarly to the FDCA, the regulations do not mention genetically engineered foods; therefore, there is no standard of identity specifically for genetically engineered foods. In *Guerrero v. Target Corp.*, the Florida district court logically determined that there can be no conflict between state and federal laws when there is no federal standard of identity. 2012 WL 3812324, at *10. Because there is no federal standard of identity for genetically engineered foods, there is no standard with which the state requirements may conflict, and, therefore, a Vermont law would not be preempted by the standard of identity preemption provision.

Additionally, requiring a label stating that a product was made with genetic engineering would not alter how the food is identified as “identity” is contemplated under the regulations. The regulations provide that “a food does not conform to the definition and standard of identity” if: 1) it “contains an ingredient for which no provision is made in such definition and standard” (with some exceptions for additives); 2) it does not contain an ingredient included in the standard of identity, or; 3) the quantity of an ingredient does not conform. 21 C.F.R. § 130.8. For example:

Bread, white bread, and rolls, white rolls, or buns, and white buns are the foods produced by baking mixed yeast-leavened dough prepared from one or more of the farinaceous ingredients... and one or more of the moistening ingredients... and one or more of the leavening agents.... Each of the finished foods contains not less than 62 percent total solids....

Id. § 136.110(a). Requiring a label stating “genetically engineered” would not alter the standard of identity or common name of the food product; it would still be labeled “bread” so long as it met the above requirements.

Nutrition Information

Any state requirement for nutrition food labeling that is not identical to the federal requirement of Section 343(q) concerning nutrition information is preempted under the express preemption provision of the Act. 21 U.S.C. § 343-1(4). Section 343(q) requires food labels to contain information about serving size, number of servings, total calories per serving, and amounts of the following nutrients per serving: fat, cholesterol, sodium, carbohydrates, sugars, fiber, and protein. *Id.* § 343(q)(1); *see also* 21 C.F.R. § 101.9(c) (also requiring information for vitamins and minerals). According to the regulation, “[n]o nutrients or food components other than those listed . . . as either mandatory or voluntary may be included within the nutrition label.” *Id.*

Requiring foods to bear a label stating that they were produced with genetic engineering does not constitute “nutrition information” as described in the Act. Thus, the state labeling requirement would not fall under the jurisdiction of 343(q) and would not be preempted by the express preemption provision.

Nutrition Levels and Health Claims

The express preemption provision also prohibits “any requirement respecting any claim of the type described in section 343(r)(1)” if it is not “identical to the requirement of section 343(r).”

21 U.S.C. § 343-1(5). Section 343(r)(1) covers nutrition level claims and health-related claims. *Id.* at § 343(r)(1). It applies to claims that product labels make about the health benefits or nutrient content of the products. *Id.* “Nutrient content claims” are claims that “expressly or implicitly characterize the level of a nutrient required to be in nutrition labeling.” 21 C.F.R. § 101.13(b); *see also* 21 U.S.C. § 343(r)(1)(A) (nutrition claim “characterizes the level of any nutrient which is of the type required by [subsection q] to be in the label”). “Health claims” are claims made “on the label of a food . . . that expressly or by implication . . . characterize[] the relationship of any substance to a disease or health-related condition.” 21 C.F.R. § 101.14(a)(1); *see also* 21 U.S.C. § 343(r)(1)(B) (health claims characterize “the relationship of any nutrient which is of the type required by [subsection q] to be in the label . . . to a disease or a health-related condition”).

Using the regulations as guidance, the nutrition levels and health claims section of the FDCA can be characterized as regulating three specific kinds of claims: express nutrient content claims, implied nutrient content claims, and health-related claims. 21 C.F.R. §§ 101.13(b), 101.14(a)(1); *see also Ackerman*, 2010 WL 2925955, at *3. As explained below, a Vermont labeling law would not fall under any these categories.

Express Nutrient Content Claims

An express nutrient content claim is a direct statement about the level or range of a nutrient in a food (which nutrient is required to be on the label). 21 C.F.R. § 101.13(b), (b)(1). An example of an express nutrient content claim is “contains 100 calories” printed on food packages which contain 100 calories, or “low sodium.” *Id.* Because a “genetically engineered” label would not be a statement about the level of any nutrient required to be on the label, or any “nutrient” in the product at all, Vermont’s labeling requirement would not be an express nutrient content claim. The required label would say nothing about the level of nutrients within the food product, e.g. carbohydrates, sodium, or fiber. *See* 21 U.S.C. § 343(q)(1), 21 C.F.R. § 101.9(c) (listing nutrients). *See also N.Y. State Restaurant Ass’n*, 556 F.3d at 127-28, 137 (in holding New York City’s calorie disclosure requirement not preempted, explaining that even quantitative information about a particular nutrient (where information about that nutrient is required on the nutrition panel) can be a “claim” if it falls outside nutrition panel).

Implied Nutrient Content Claims

An implied nutrient content claim “describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount, e.g., ‘high in oat bran.’” *Id.* at § 101.13(b)(2)(i) (as opposed to “high in *fiber*,” the actual nutrient). Or, it “suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., ‘healthy, contains 3 grams (g) of fat’).” *Id.* § 101.13(b)(2)(ii). Vermont’s “genetically engineered” labeling requirement would not be an implied nutrient content claim for the same reason it is not an express nutrient content claim. Labeling that a food product was produced by genetic engineering provides no information as to the nutrient content of that food.

Health Claims

Health claims characterize the relationship between any of the nutrients in a food product and a disease or health-related condition. 21 C.F.R. § 101.14(a)(1). Additionally, the FDA has advised that health claims are “limited to claims about disease risk reduction, and cannot be claims about the diagnosis, cure, mitigation, or treatment of disease.” FDA, Food Labeling Guide-Claims, Answer H.1.¹³ Health claims, unlike express or implied nutrient content claims, are required to be reviewed or approved by the FDA prior to use on a label. *Id.*; 21 C.F.R. § 101.14(e); 21 U.S.C. § 343(r)(3)(c). Examples of health claims include: a heart symbol, the statement that “[d]iets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease,” and the phrase “may reduce the risk of breast or prostate cancer.” 21 C.F.R. § 101.14(a)(1); Food Labeling Guide-Claims, Answer H.4; *Fleminger, Inc. v. U.S. Dep’t of Health & Human Servs.*, 854 F. Supp. 2d 192, 195 (D. Conn. 2012). Vermont’s “genetically engineered” labeling requirement would not be a health claim. It would not attempt to link the nutrients in the food product to any health condition or disease.

“Natural” Prohibition

In addition to the “genetically engineered” disclosure requirement, Vermont’s labeling law would prohibit any product that was made using genetic engineering from bearing the label “natural” or the like. A Vermont law prohibiting the labeling of products as “natural” if they were produced by genetic engineering would not be expressly preempted by the Act’s preemption provisions for the same reasons Vermont’s disclosure requirement of “genetically engineered” would not be preempted.

First, like genetically engineered foods, there is no standard of identity for “natural” food products. In addition, after an extensive comment period in 1993, the FDA stated in the Federal Register that due to resource limitations and other agency priorities, the agency would not be undertaking rulemaking to establish a definition for “natural.” Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 58 Fed. Reg. 2302-01, 2407 (Jan. 6, 1993). Thus, Vermont’s labeling prohibition is not preempted by the first express preemption provision.

Second, the term “natural” does not fit into the nutrition information preemption provision, as a label bearing the word “natural” provides no information as to the quantity of specific nutrients in the product. Finally, “natural” labeling does not fit into the third category: nutrition levels and health-related claims. Again, the term “natural” does not provide any information about the nutrients or the level of nutrition provided in the food product. A label bearing the word “natural” is not a health-related claim since it does not link the food or nutrients in the food to a health condition or disease. Thus, Vermont’s labeling prohibition of “natural” if the food was produced using genetic engineering would not be preempted by any of the express preemption provisions of the Act.

¹³<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064908.htm#health>.

Additionally, courts have quickly dismissed express preemption arguments where challenges to use of the term “natural” did not fit clearly into any of the express preemption provisions. *See Holk*, 575 F.3d at 329, 336 n.3 (noting that claim against Snapple for using “natural” label on products with high fructose corn syrup (HFCS) would likely not fall under express preemption provision regarding “artificial flavoring” because FDA regarded HFCS as “sweetener,” and federal artificial flavoring disclosure was requirement, not restriction on commercial marketing); *Lockwood v. Conagra Foods Inc.*, 597 F. Supp. 2d 1028, 1031 (N.D.Cal. 2009) (determining that express preemption provision did not apply to plaintiffs’ claim that “natural” should not be on pasta sauce made with HFCS, since plaintiffs did not allege that sauce contained artificial flavoring, coloring, or chemical preservative, or that sauce was an imitation); *Hitt v. Arizona Beverage Co., LLC*, No. 08cv809, 2009 WL449190, at *4 (S.D. Cal. 2009) (not expressly preempted where neither party asserted that use of term “natural” on fruit juice with HFCS fell under any express preemption provision). Similarly in this case, Vermont’s regulation of the term “natural” would not implicate “artificial flavoring” or coloring, chemical preservatives, or imitation food. And, as explained above, it would not implicate other express preemption provisions such as nutrition information and health claims.

b. Recap of Express Preemption Rules

This section gives a distillation of the most important factors under an express preemption analysis. Most of the same factors would apply to the disclosure requirement and the “natural” prohibition.

General Rules

- Under express preemption, Congress explicitly states in a statute that federal law preempts state law. *Hillsborough County*, 471 U.S. at 713 (citations omitted).
- When a federal statute contains an express preemption provision, a presumption against preemption exists, requiring courts to read the clause narrowly. *See Medtronic, Inc.*, 518 U.S. at 485.
- The FDCA as amended by the NLEA contains an express preemption provision, Section 343-1. 21 U.S.C. § 343-1.
- The preemption provision in the NLEA contains three provisions which courts typically apply to state labeling laws (below). *See N. Y. State Restaurant Ass’n*, 556 F.3d at 118-19; *Guerrero*, 2012 WL 3812324, at *10.
- Courts dismiss express preemption arguments where challenges to use of the term “natural” do not fit clearly into any of the express preemption provisions. *Holk*, 575 F.3d at 336 n.3; *Lockwood*, 597 F. Supp. 2d at 1031; *Hitt*, 2009 WL449190, at *4.

Express Preemption Provision- Standard of Identity

- Any state requirement concerning a standard of identity for which a federal standard of identity exists is preempted unless it is identical. 21 U.S.C. § 343-1(1).
- The Secretary has promulgated several standards of identity, which are codified at 21 C.F.R. Parts 131-169.

- The regulations provide that “a food does not conform to the definition and standard of identity” if: 1) it “contains an ingredient for which no provision is made in such definition and standard” (with some exceptions for additives); 2) it does not contain an ingredient included in the standard of identity, or; 3) the quantity of an ingredient does not conform. 21 C.F.R. § 130.8.
- State law is not preempted when there is no federal standard of identity with which the state law may conflict. *Guerrero*, 2012 WL 3812324, at *10.

Express Preemption Provision- Nutrition Information

- Any state requirement for nutrition labeling that is not identical to the federal requirements of Section 343(q) concerning nutrition information is preempted. 21 U.S.C. § 343-1(4).
- Required nutrition information exclusively includes serving size, number of servings, caloric content, and the amounts of: fat, cholesterol, sodium, carbohydrates, sugars, protein, dietary fiber, vitamins, and minerals. 21 U.S.C. § 343(q)(1); 21 C.F.R. § 101.9(c).

Express Preemption Provision- Nutrition Levels and Health Claims

- Any state requirement relating to nutrition level claims or health claims is preempted unless it is identical to the requirements of § 343(r). 21 U.S.C. § 343-1(5).
- Section 343(r) covers nutrition level claims and health-related claims and applies to claims that product labels make about the health benefits or nutrient content of the products. 21 U.S.C. § 343(r)(1).
- A nutrient content claim is a claim that “expressly or implicitly characterize[s] the level of a nutrient required to be in nutrition labeling.” 21 C.F.R. § 101.13(b); *see also* 21 U.S.C. § 343(r)(1)(A).
- An express nutrient content claim is any direct statement about the level or range of a nutrient in a food (which nutrient is required to be on the label). 21 C.F.R. § 101.13(b), (b)(1).
- An implied nutrient content claim “describes the food or an ingredient therein in a manner that suggests that a nutrient [which nutrient is required to be on the label] is absent or present in a certain amount, e.g., ‘high in oat bran.’” 21 C.F.R. § 101.13(b), (b)(2)(i).
- Health claims characterize the relationship between any of the nutrients in a food product and a disease or health-related condition. 21 C.F.R. § 101.14(a)(1); 21 U.S.C. § 343(r)(1)(B).

c. No Implied Preemption

In addition to containing an express preemption provision, the NLEA has a savings clause, which states, “The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of state law, unless such provision is expressly preempted under Section 403A of the Federal Food, Drug, and Cosmetic Act.” Pub. L. No. 101-535, § 6(c)(1) (21 U.S.C. § 343-1 note). (Section 403A is 21 U.S.C. § 343-1(a), the Act’s express preemption provision discussed

above.) This means that anything not expressly preempted in the express preemption provision of the FDCA is not to be considered preempted. Thus, under the Act, preemption analysis ends with the express preemption provisions. *See, e.g., Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 532 (1992) (“We resort to principles of implied pre-emption—that is, inquiring whether Congress has occupied a particular field with the intent to supplant state law or whether state law actually conflicts with federal law—only when Congress has been silent with respect to pre-emption.”) (Blackmun, J., concurring) (internal citation omitted). Since Vermont’s labeling law would fit none of those provisions, it would not be preempted.

Even if a court ignored the savings clause and performed an implied preemption analysis, a Vermont labeling law would not be preempted. Under the NLEA, it is clear that field preemption was not the clear and manifest intention of Congress as evidenced by the fact that the savings clause explicitly leaves some labeling to the states, such as safety warnings. Pub. L. No. 101-535, § 6(c)(2). Even the express preemption provision is very narrow; it only applies to certain distinct areas and it leaves room for states to regulate even in those areas so long as their requirements are identical to their federal counterparts. *See* 21 U.S.C. § 343-1. Additionally, as a result of food labeling traditionally falling to the states to regulate under their police powers, it would be difficult to argue that the federal interest dominates that of the state. *See N. Y. State Restaurant Ass’n*, 556 F.3d at 130. Finally, because the Act does not contain any language pertaining to “genetically engineered” or “natural” foods specifically, there is nothing with which the state law may conflict; therefore, it is possible to comply with both federal and state requirements.

The narrow language of the express preemption provision, the savings clause, and the fact that there is no general preemption provision of the FDCA all demonstrate that “Congress was cognizant of the operation of state law and state regulation in the food and beverage field, and it therefore enacted limited exceptions in the NLEA.” *Holk*, 575 F.3d at 337-38. In *Holk*, the Third Circuit determined that even if one looks beyond the language of the NLEA there is still no implied preemption. *Id.* at 337-38 (explaining that there was no express preemption provision in the FDCA prior to enactment of the NLEA and that the FDCA contains no general preemption provision). The Court reiterated the presumption against preemption and “the Supreme Court’s direction that we should not infer field preemption from the comprehensiveness of a regulatory scheme alone” to hold that “neither Congress nor the FDA intended to occupy the fields of food and beverage labeling and juice products.” *Id.* at 339. The Court also held that Plaintiffs’ challenge to Snapple’s use of the word “natural” was not preempted under implied conflict preemption because the FDA’s policy on use of the term “natural” lacked the force of law. *Id.* at 340-42 (“there is no conflict in this case because there is no FDA policy with which state law could conflict”). Other cases have thrown out implied preemption claims in the food labeling context on similar grounds. *See, e.g., Lockwood*, 597 F. Supp. 2d at 1031-34 (no implied preemption under FDCA for labeling); *Hitt*, 2009 WL 449190, at *4 (same); *Wright v. General Mills, Inc.*, No. 08cv1532, 2009 WL 3247148, at *2-3 (S.D. Cal. 2009) (same). As the Supreme Court explained in *Wyeth v. Levine*, “[t]he case for federal preemption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.” 555 U.S. § 555, 575 (2009) (citation and internal quotation marks omitted). These authorities show that Vermont’s labeling law would survive any implied preemption

challenge.¹⁴

C. The Dormant Commerce Clause

1. Overview of Dormant Commerce Clause

The Constitution grants Congress power “[t]o regulate Commerce with foreign Nations, and among the several States.” U.S. Const. art. I, § 8, cl. 3. In addition to this affirmative power, the commerce clause implies a corresponding restriction on the power of States to enact laws that impose burdens on interstate commerce—this restriction exists even in the absence of a conflicting federal statute. *See, e.g., Gibbons v. Ogden*, 22 U.S. (9 Wheat) 1, 199-200, 227, 239-40 (1824) (holding that New York law prohibiting vessels from traveling on state waterways where vessels had federal licenses was unconstitutional because it interfered with interstate commerce); *Wilson v. Black-Bird Creek Marsh Co.*, 27 U.S. 245, 250-52 (1829) (analyzing state law under this doctrine and finding it valid: “We do not think that the act empowering the Black Bird Creek Marsh Company to place a dam across the creek, can, under all the circumstances of the case, be considered as repugnant to the power to regulate commerce in its dormant state, or as being in conflict with any law passed on the subject.”). The Supreme Court has held that this restriction does not require any prior action on the part of Congress: “[a]lthough the Commerce Clause is by its text an affirmative grant of power to Congress to regulate interstate and foreign commerce, the Clause has long been recognized as a self-executing limitation on the power of the States to enact laws imposing substantial burdens on such commerce.” *S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 87 (1984) (citations omitted).

The Supreme Court has adopted a two-tiered approach for dormant commerce clause analysis. The first tier considers whether a law discriminates against interstate commerce. If a state law “directly regulates or discriminates against interstate commerce” or has an effect which “favor[s] in-state economic interests over out-of-state interests,” it will be “generally struck down . . . without further inquiry.” *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986) (citations omitted). The only exception is for laws which are necessary to achieve an important government purpose, and even then the law must be the least restrictive alternative. *See, e.g., Fort Gratiot Sanitary Landfill, Inc. v. Mich. Dep’t of Natural Resources*, 504 U.S. 353, 361, 367-68 (1992) (holding that a law requiring county approval for the importation of out-of-county solid waste – including out-of-state waste - was unconstitutional because the state failed to show that its interest in protecting public health and safety could not

¹⁴ A recent news article discussing possible legal challenges to California’s Proposition 37 mentioned a recent Ninth Circuit case, *Pom Wonderful LLC v. Coca-Cola Company*, to suggest the state law would be preempted. However, that case neither conducted a preemption analysis nor ruled on preemption. *Pom Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1179 (9th Cir. 2012). Instead, it held that Pom Wonderful could not sue Coca-Cola under the federal Lanham Act for false labeling because the FDA had comprehensive requirements regarding the specifics of Pom’s labeling claim, and the FDA was the best entity to interpret and enforce those requirements. *Id.* at 1176-78 (both plaintiff’s claim and FDA’s regulations related to specific requirements such as the name and type-size of juice(s) that could or must be displayed based on volume of product ingredients). In contrast, the FDA has no regulations regarding the labeling of genetically engineered foods or use of the term “natural.” Additionally, Pom’s claims appear to fall under the Act’s express preemption provisions regarding standard of identity and fruit juices. *See* 21 U.S.C. § 343(g), (i). As explained above, this would not be the case with Vermont’s law.

be met in a less discriminatory manner); *Maine v. Taylor*, 477 U.S. 131, 133, 152-52 (1986) (holding that a state law restricting the importation of baitfish was constitutional because there was no less discriminatory alternative for addressing the legitimate local interest of protecting native fisheries). The burden to prove discrimination “rests on the party challenging the validity of the statute.” *Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979).

The second tier is applied to nondiscriminatory laws. If the “statute has only indirect effects on interstate commerce and regulates evenhandedly,” *Brown–Forman*, 476 U.S. at 579, then courts apply the balancing test described in *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). Under *Pike*, such a law will be “upheld unless the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits.” *Id.* at 142 (citation omitted).¹⁵

According to this analytical framework, the GE labeling bill introduced by Vermont last year would survive a constitutional challenge based on the dormant commerce clause. Vermont’s proposed legislation would create an evenhanded system of GE labeling requirements that does not discriminate against out-of-state interests. Under the dormant commerce clause doctrine, evenhanded regulations are evaluated under the *Pike* balancing test; such regulations enjoy a presumption of constitutionality and are upheld if the local interest outweighs any incidental burdens on interstate commerce. *See generally* Erwin Chemerinsky, *Constitutional Law: Principles & Policies* 429-39 (3rd ed. 2006). In this case, Vermont’s legitimate interests in addressing concerns such as health, the environment, and the economy among others would outweigh any incidental burdens on interstate commerce.

2. Analysis under Dormant Commerce Clause

The threshold issue in any dormant commerce clause analysis is whether the state law in question affects interstate commerce. *See Brown–Forman*, 476 U.S. at 578-79. Interstate commerce is an extremely broad category of economic activity; the Supreme Court has held that “[a]ll objects of interstate trade merit Commerce Clause protection.” *Philadelphia v. New Jersey*, 437 U.S. 617, 622 (1978) (reviewing a state law that prohibited the importation of most solid waste originating outside the state). The *Gibbons* court described commerce as all phases of business, including the traffic of goods. *See Gibbons*, 22 U.S. at 193-96. In this case, Vermont’s labeling statute would be aimed at food products, a type of good that is regularly bought and sold across state lines; these products are clearly within the scope of interstate commerce. Furthermore, courts have specifically reviewed food labeling requirements under the dormant commerce clause. *See Grocery Mfrs. of America, Inc. v. Gerace*, 755 F.2d 993, 1003-

¹⁵ There are also two exceptions to the standard dormant commerce clause analysis. First, Congress can utilize its plenary power to regulate commerce among the states to authorize laws that would otherwise violate the dormant commerce clause. *See, e.g., Prudential Ins. Co. v. Benjamin*, 328 U.S. 408, 429–31 (1946) (holding that a state tax leveled on out-of-state insurance companies was constitutional because Congress had authorized state action by statute and with knowledge of state systems). Second is the “market participant” exception, which allows states to favor their own citizens when providing benefits from government programs or engaging in business as a market participant. *See, e.g., White v. Mass. Council of Constr. Employers, Inc.*, 460 U.S. 204, 214-15 (1983) (holding that an executive order requiring the City of Boston to hire a certain percentage of city residents for construction projects funded by the city was constitutional because the city was expending its own funds and was therefore entitled to the same privileges as any other market participant). Neither of these possibilities applies in regard to Vermont’s proposed GE labeling scheme.

05 (2d Cir. 1985) (reviewing a state statute requiring substitute cheese products to be labeled as “imitations”). In that case, in-state and out-of-state food producers were required to adhere to labeling requirements in order to sell their products within New York. *Id.* at 995-96, 1003. Similarly, Vermont’s proposed labeling scheme would require all genetically engineered food products, including those produced out-of-state, to disclose that information on labels and to avoid use of the term “natural.” We can conclude that GE labeling legislation would affect interstate commerce.

a. First Tier: Determining whether Vermont’s Proposed GE Labeling Legislation Would Discriminate against Interstate Commerce

The first tier of dormant commerce clause analysis is primarily concerned with invalidating overt protectionism: “[s]tate laws that discriminate against interstate commerce face a ‘virtually *per se* rule of invalidity.’” *Granholm v. Heald*, 544 U.S. 460, 473-74, 476 (2005) (citation omitted) (holding that a Michigan law which prohibited the shipment of wine from out-of-state wineries to Michigan consumers discriminated against interstate commerce). *Brown–Forman* identified two basic categories of regulations that discriminate against interstate commerce: (1) regulations that facially discriminate against out-of-state interests; and (2) regulations that, while facially neutral, still have the effect of favoring in-state commerce at the expense of interstate commerce. *See Brown–Forman*, 476 U.S. at 579. Additionally, courts have consistently struck down laws aimed at “regulating conduct occurring wholly outside the state.” *See, e.g., U. S. Brewers Ass’n v. Healy*, 692 F.2d 275, 282 (2d Cir. 1982) (holding that a Connecticut price affirmation statute violated the dormant commerce clause because it prevented brewers from raising prices for their products in other states so long as a higher price was being charged within the state); *Brown–Forman*, 476 U.S. at 581-82 (holding that a New York price affirmation statute violated the dormant commerce clause because it regulated entirely out-of-state commercial activity).

The first category of regulations that implicate protectionism are those which facially discriminate between in-state and out-of-state interests. A key factor is whether the law draws distinctions between in-state and out-of-state businesses or products. *See, e.g., Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 519 n.1, 522-28 (1935) (reviewing a state law that facially distinguished out-of-state milk and regulated the in-state prices of milk produced out-of-state); *Philadelphia*, 437 U.S. at 621-23, 625 (reviewing a state law that, on its face, prevented the importation of out-of-state waste to in-state landfills). If no such distinctions are found, then the law is likely facially neutral.

This first level of analysis is illustrated in a 1981 case where milk producers challenged a Minnesota statute prohibiting them from selling their products in plastic containers. *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 458–59 (1981). The producers argued that the law discriminated against interstate commerce because out-of-state milk producers using plastic containers would have to conform to Minnesota’s packaging requirements. *See id.* at 472-73. However, the Supreme Court held that the regulation was evenhanded—not “simple protectionism”—because it applied to all retailers, regardless of whether the milk, containers, or sellers were from out-of-state. *Id.* at 471-72. The same issue was considered in a Second Circuit case considering a New York law requiring the labeling of products resembling or intending to replace traditional cheese products. *Gerace*, 755 F.2d at 996. In the course of its dormant

commerce clause analysis, the Court concluded that the law was evenhanded because it applied equally to products originating both in-state and out-of-state. *Id.* at 1003 (analyzing menu, sign, and container provisions of law). Similarly, Vermont’s GE disclosure requirement and “natural” prohibition would be facially neutral. The legislation would apply to all food products sold within the state, regardless of whether the products or manufacturers were from out-of-state.

While a law may be facially neutral, it may still be found to discriminate against interstate commerce if it has the practical effect or purpose of favoring in-state economic interests over out-of-state economic interests. *See, e.g., C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 386, 394-95 (1994) (finding that a state law requiring all local solid waste to be deposited at a local transfer station had a discriminatory effect on out-of-state companies); *Hunt v. Wash. State Apple Advertising Comm’n*, 432 U.S. 333, 351-54 (1977) (finding that a state law requiring a particular labeling system for apples sold in the state had a discriminatory effect on particular out-of-state apple producers). The major factor in this analysis is whether there is actual proof of a discriminatory impact. *See Carbone*, 511 U.S. at 390-91.

In the *Carbone* case, a town ordinance required all non-recyclable waste to be processed at a local plant before leaving town. *Id.* at 387-88. While the law made no facial distinction between in-state and out-of-state facilities, the Supreme Court found that the law had the practical effect of discriminating against interstate commerce because out-of-state waste processing facilities were effectively denied access to the local market. *Id.* at 392. In the *Hunt* case, a North Carolina law prohibited any labels except for those indicating the U.S. grade or standard (or lack thereof) on all containers of apples sold or shipped into the state, regardless of whether the apples were produced in-state or out-of-state. 511 U.S. at 339. While this requirement was facially neutral—it applied to both in-state and out-of-state producers—the Court found that the law was discriminatory because of its effect on the sale of Washington apples. *Id.* at 350-51. Washington had a more rigorous and well-known system of inspection and labeling for apples, but Washington growers were prohibited from using their labeling system when selling in North Carolina. *Id.* The law thus had the effect of “leveling” the apple market to the advantage of North Carolina’s apple producers. *Id.* Not only were local apple producers shielded from competition with Washington growers, but the actual costs of doing business were raised for out-of-state producers while leaving in-state producers unaffected (since in-state producers were already using only the U.S. grade labeling system). *Id.*

In contrast to these cases, the Vermont legislation would not have any characteristics which could lead to either the complete exclusion of out-of-state business from the local market, nor an advantage specifically for Vermont businesses. It would create no barriers against interstate food producers entering Vermont, would not prohibit the flow of interstate food products (labeled foods could enter the marketplace regardless of their state of origin), would not place additional costs specifically upon interstate food products (in-state companies would face the same costs as out-of-state companies), and it would not distinguish between in-state and out-of-state food products within the retail market.

Finally, the Supreme Court has also consistently struck down state laws that are entirely extraterritorial in effect. *Healy v. Beer Inst.*, 491 U.S. 324, 335-37 (1989) (citing cases); *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 528 (1945). In one such case, a New York law

required liquor distributors to file a monthly price schedule for their products, and to guarantee that they would not charge a lower price for those products anywhere else in the United States. *Brown-Forman*, 476 U.S. at 575. The Court reasoned that this requirement had “the practical effect of . . . control[ing] liquor prices in other states.” *Id.* at 583. Once a price affirmation was filed, liquor distributors were effectively forced to seek the approval of the New York State Liquor Authority before they would be able to lower the price of that item in an entirely different state. *Id.* The Court noted that “[f]orcing a merchant to seek regulatory approval in one State before undertaking a transaction in another directly regulates interstate commerce.” *Id.* at 582 (citations omitted). In a particularly relevant example concerning labeling, the Sixth Circuit recently examined a law allegedly aimed at preventing the misleading advertising of dairy products that was challenged on extraterritorial effect grounds. *Int’l Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 632, 646 (6th Cir. 2010). In this case, dairy producers argued that Ohio’s labeling requirements would force them to adopt a new nationwide label, thus projecting the effects of the legislation outside the state of Ohio. *See id.* at 647. The Court disagreed, concluding that Ohio’s labeling requirement had no direct effect on producers’ out-of-state conduct; the producers remained free to pursue other labeling conduct outside of Ohio, and compliance with Ohio’s requirement would not violate the labeling requirements of any other state. *Id.* The law did not purport to “regulate conduct occurring wholly outside the state.” *Id.* (citation omitted). Similarly, Vermont’s proposed GE labeling bill would not regulate conduct wholly outside of the state. Food producers would remain free to implement other labeling systems outside of Vermont, and meeting Vermont’s requirements would not violate the labeling requirements of any other state.

In sum, the GE labeling system would survive the threshold first tier of dormant commerce clause analysis. Vermont’s proposed legislation would not be overtly protectionist; the law would require identical labeling requirements for food products originating both in-state and out-of-state. Furthermore, there is nothing to suggest that the law would have the practical effect of favoring in-state food producers at the expense of out-of-state food producers, nor would it be attempting to regulate conduct occurring wholly outside of Vermont. We can conclude that Vermont’s proposed GE labeling bill and “natural” labeling prohibition would be non-discriminatory, and thus subject to the *Pike* balancing test.

b. Second Tier: Balancing Any Burden of GE Labeling on Interstate Commerce with the Local Interest

The *Pike* test applies when there is no discrimination against interstate commerce: “[w]here the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.” *Pike*, 397 U.S. at 142 (citation omitted). Courts have consistently used their discretion to uphold laws that reach this second tier of analysis. *See, e.g., Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127 (1978) (holding that exclusion of some out-of-state businesses from in-state markets does not constitute an impermissible burden on interstate commerce); *Parker v. Brown*, 317 U.S. 341, 367-68 (1943) (holding that a state law that regulated California’s in-state raisin marketing program was not an impermissible burden on interstate commerce). There is no standard formula for comparing the burden to the benefits; courts are, after all, comparing two very different things. *See, e.g., Pike*,

397 U.S. at 142. However, reviewing courts' treatment of several common categories of burdens and benefits shows that Vermont's legitimate local interests in GE labeling would outweigh any incidental effects on interstate commerce.

First Prong: Burden

One component of the balancing test focuses on the burdens a law places upon interstate commerce. One recognized burden is the withdrawal of some business from an in-state market: the Supreme Court addressed this issue when upholding a restriction preventing refinery owners from also operating filling stations within Maryland. *Exxon*, 437 U.S. at 119-20. The plaintiffs in that case claimed that the law imposed a heavy burden on interstate commerce because some refiners would have to withdraw entirely from the Maryland retail market. *Id.* at 127. However, the Court concluded that the law had a minimal effect on interstate commerce because other out-of-state companies would still be able to operate retail locations in Maryland, provided they were not refinery operators: "interstate commerce is not subjected to an impermissible burden simply because an otherwise valid regulation causes some business to shift from one interstate supplier to another." *Id.* A similar situation was considered in the *Clover Leaf Creamery* case; a Minnesota law prohibited milk from being sold in plastic containers, and many out-of-state milk producers faced exclusion from the in-state market unless they conformed to Minnesota's packaging requirements. *Clover Leaf Creamery*, 449 U.S. at 472-73. Once again, the Court dismissed this burden by noting that requiring milk to be sold in paper containers actually created opportunities for out-of-state paper companies to sell their products within the state. *Id.*

Of course, Vermont's law would not overtly prevent any out-of-state companies from doing business in the state; any company wishing to sell its products would simply have to meet the labeling requirements by disclosing that they are genetically engineered and abstaining from using the word "natural" to describe the products. Furthermore, the labeling system would be upheld even if it somehow discouraged some food producers from doing business in Vermont, as business would be able to shift to other out-of-state companies—particularly those not dealing with genetically engineered foods. In fact, the labeling requirement would potentially provide an opportunity in Vermont for all out-of-state organic and non-GE food businesses. Finally, any food producer would also be free to bypass the labeling requirement entirely simply by sourcing GE free ingredients.

Another broad set of burdens reviewed by the Supreme Court are those with financial effects such as increased costs of business, compliance costs, or lost profits. In *Parker v. Brown*, a California statute required two-thirds of the yearly state raisin crop to be sold through a California agency at a fixed price. *Parker*, 317 U.S. at 348. This imposed a burden on raisin producers by limiting their ability to compete and limiting their potential profits. *Id.* at 348-49, 355. However, the Court held that California's interest—in this case, concern over the long term economic viability of an important crop—outweighed the burden. *Id.* at 367. The Court stated that "[t]he program was not aimed at nor did it discriminate against interstate commerce, although it undoubtedly affected the commerce by increasing the interstate price of raisins and curtailing interstate shipments to some undetermined extent." *Id.* Such costs are tolerable when balanced against legitimate local interests. *See id.* at 367-68; *see also Clover Leaf Creamery*, 449 U.S. at 473 ("the inconvenience of having to conform to different packaging requirements in

Minnesota and the surrounding States should be slight”) (citation omitted); *American Trucking Ass’n, Inc. v. Mich. Pub. Serv. Comm’n*, 545 U.S. 429, 431, 438 (2005) (upholding Michigan law that charged \$100 fee for vehicles making intrastate trips – “that is, trucks that undertake point-to-point hauls between Michigan cities” – as neither discriminatory nor burdensome).

While Vermont’s labeling system would potentially raise costs for businesses that would be required to adhere to the new labeling requirements, the above cases indicate that this neutral burden would be permissible under the dormant commerce clause.

Second Prong: Interest

The second component of the balancing test focuses on the local benefits provided by the law in question. In *Clover Leaf Creamery*, the Court found that the “substantial state interest in promoting conservation of energy and other natural resources and easing solid waste disposal problems” outweighed the burdens on interstate commerce. *Clover Leaf Creamery*, 449 U.S. at 473. Minnesota relied on evidence demonstrating that preventing the introduction of plastic products into the local marketplace would address these specific environmental concerns. *Id.* at 465-70, 473 (applying same interest to dormant commerce clause analysis as Equal Protection analysis). The environmental issue of conservation has been addressed by the Court in other instances as well; reviewing a case involving the transport of minnows, the Court said “[w]e consider the States’ interests in conservation and protection of wild animals as legitimate local purposes similar to the States’ interests in protecting the health and safety of their citizens.” *Hughes*, 441 U.S. at 336-37 (citation omitted) (noting *Pike* test but finding that law in question overtly discriminated against interstate commerce). Finally, the Supreme Court has expressly held that states may choose to address environmental risks that are still not clearly understood, even if the state’s law is discriminatory (first tier, above). *Taylor*, 477 U.S. at 138, 148. In that case, the Court acknowledged “substantial scientific uncertainty” and said that the state had “a legitimate interest in guarding against imperfectly understood environmental risks, despite the possibility that they may ultimately prove to be negligible.” *Id.* at 148. It continued: “[T]he constitutional principles underlying the commerce clause cannot be read as requiring the State of Maine to sit idly by and wait until potentially irreversible environmental damage has occurred or until the scientific community agrees on what disease organisms are or are not dangerous before it acts to avoid such consequences.” *Id.* (citation omitted).

As stated in *Hughes*, public health and safety is another legitimate local interest that justifies incidental burdens on interstate commerce. *See id.*; *see also Parker*, 317 U.S. at 362 (noting the “safety, health and well-being of local communities” as an appropriate interest). Courts may look at specific examples of how a regulation benefits the local community. *See, e.g., United Haulers Ass’n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 347 (2007). In that case a local ordinance regulated the collection and disposal of solid waste; the Court noted that incentives for recycling and increasing enforcement of recycling laws “conferr[ed] significant health and environmental benefits upon the [local] citizens.” *Id.* at 346-47. In the *Gerace* labeling case, the Second Circuit cited a list of local legitimate interests served by a regulation prohibiting the misleading labeling of imitation cheese products, including health, consumer information, preventing deception, and permitting consumers to clearly discern what type of product they were purchasing. *Gerace*, 755 F.2d at 1003-04 (where “record shows that

health and nutrition professionals strongly disagree about the intrinsic value of the federal nutritional guidelines applied to alternative cheese products,” the “very existence of [the] controversy” meant that New York’s labeling law was not unreasonable).

Many of the public health and safety cases have examined trucking restrictions designed to protect public safety on highways. *See, e.g., S.C. State Highway Dep’t v. Barnwell*, 303 U.S. 177, 195-96 (1938) (upholding a law restricting truck weight and size based on public safety concerns). In these cases courts have examined the factual record to determine whether the public safety contributions are substantial enough to justify the corresponding burden on interstate commerce, particularly when the burden restricts the interstate movement of goods. *See Raymond Motor Transp., Inc. v. Rice*, 434 U.S. 429, 444-48 (1978). In *Raymond*, the Supreme Court ruled that Wisconsin had “failed to make even a colorable showing that its regulations contribute to highway safety.” *Id.* at 447-48. The Wisconsin law appeared to arbitrarily ban certain sizes of trucks on state highways, but failed to offer evidence that these bans provided any particular safety benefits. *Id.* at 444-46. While deferential, the Court clearly requires at least a basic showing of factual support behind health and safety regulations to justify any resulting substantial burdens on interstate commerce. *Id.* at 445-46 (listing factors contributing to “substantial” burden).

Finally, addressing local economic concerns has repeatedly been upheld as a legitimate local interest that outweighs any incidental burdens on interstate commerce. *See Parker*, 317 U.S. at 367-68. As discussed above, the *Parker* Court held that protecting the long term viability of California’s raisin crop was a legitimate local purpose. *Id.* In the *Gerace* labeling case, the Second Circuit noted that preventing unfair competition and promoting consumer information were legitimate local purposes (among others). *Gerace*, 755 F.2d at 1003-04. Finally, even local revenue generation has been upheld as a legitimate local purpose. *See United Haulers*, 550 U.S. at 346. The Court noted that while local revenue generation cannot justify regulations that discriminate against interstate commerce, “it is still a cognizable benefit for purposes of the *Pike* test.” *Id.* (upholding law that gave localities means to finance waste disposal services). In other words, while States cannot discriminate against interstate commerce for the purpose of increasing local revenue, the fact that a regulation benefits local businesses is still a legitimate local benefit for purposes of the balancing test.

To conclude, Vermont’s proposed GE labeling legislation would be upheld under the *Pike* balancing test. Once found to be non-discriminatory, a law enjoys a presumption of constitutionality, with courts balancing the legitimate local interest against the burden on interstate commerce. In this case, Vermont’s law would be motivated by various public health, environmental, and economic concerns among others, all interests that have been upheld as outweighing incidental burdens on interstate commerce.¹⁶

¹⁶ Despite the overwhelming trend to uphold laws which are found non-discriminatory, there are some cases where such laws have been ruled unconstitutional. In *Bibb v. Navajo Freight Lines*, 359 U.S. 520, 529-30 (1959), the Supreme Court invalidated a law requiring a particular type of mudguard on trucks entering Illinois. The stated goal of the law was to improve road safety, yet the record suggested that the mudguards offered no safety benefits, and may even have increased certain hazards. *Id.* at 525 (noting that it was “conclusively shown” the law would not provide safety benefits) (citation and internal quotation marks omitted). Additionally, the banned mudguards were legal in most other states, and one other state banned the type of mudguard required in Illinois; the patchwork of requirements created a significant burden for interstate commerce. *Id.* at 525-28. The Court noted that it was “one

c. Conclusion

GE labeling legislation in Vermont would be valid under the dormant commerce clause. The key issue is whether the law is equal in its treatment of in-state and out-of-state businesses and products. The legislation would satisfy this condition by requiring identical labeling for food products originating both in-state and out-of-state, and avoiding effects that favor in-state food producers at the expense of out-of-state food producers. Since the law would succeed in adopting an evenhanded approach, it would enjoy a strong presumption of constitutionality under the *Pike* test; the law would be upheld because legitimate local interests would outweigh any incidental effects on interstate commerce.

d. Recap of Dormant Commerce Clause Rules

This section reviews the various rules for both tiers of dormant commerce clause analysis, discussed in full above. The same factors would apply to an evaluation of Vermont's disclosure requirement and "natural" prohibition.

- Labeling requirements for trade goods are a type of regulation that may affect interstate commerce. *See Gerace*, 755 F.2d at 1003-05 (reviewing a statute requiring substitute cheese products to be labeled as "imitations").

First Tier: Laws that Discriminate

- A law is usually *per se* invalid if it discriminates against interstate commerce. *Granholm*, 544 U.S. at 476.
- Laws that facially discriminate against interstate commerce are discriminatory. *Brown-Forman*, 476 U.S. at 579.
 - The key factor is whether the law's language draws distinctions between in-state and out-of-state businesses or products.
 - *Baldwin*, 294 U.S. at 519 n.1, 522-28 (reviewing a state law that facially distinguished out-of-state milk and regulated the in-state prices of milk produced out-of-state).
 - *Philadelphia*, 437 U.S. at 621-23, 625 (reviewing a state law that, on its face, prevented the importation of out-of-state waste to in-state landfills).
 - Regulations are facially neutral if they treat in-state and out-of-state business alike.
 - *Clover Leaf Creamery Co.*, 449 U.S. at 471-72 (prohibition on plastic milk containers treated in-state and out-of-state business alike).

of those cases-few in number-where local safety measures that are nondiscriminatory place an unconstitutional burden on interstate commerce." *Id.* at 529. The Court also specifically noted that a conflict between state regulations would not automatically invalidate a state law under the commerce clause. *See id.* Nevertheless, Vermont's proposed GE labeling scheme would be distinguishable from the facts of *Bibb*. It would not conflict with other states' labeling requirements; no state restricts GE information from appearing on food labels or requires "natural" on certain labels, and Vermont's requirement would be complimentary to similar labeling efforts being undertaken by several other states.

- *Gerace*, 755 F.2d at 1003-05 (statute requiring substitute cheese products to be labeled as “imitation” on menus, etc., did not facially distinguish between in-state products and out-of-state products).
- Even if facially neutral, laws that have the practical effect of favoring in-state commerce over out-of-state commerce are discriminatory. *Brown–Forman*, 476 U.S. at 579.
 - The key test is whether the regulation denies out-of-state businesses or products access to the local market. *Carbone*, 511 U.S. at 386, 394-95 (finding that a state law requiring all local solid waste to be deposited at a local transfer station had a discriminatory effect on out-of-state companies).
 - Regulations that are protectionist—those that shield local businesses from competition with out-of-state businesses—are also discriminatory. *Hunt*, 432 U.S. at 351–54 (finding that a state law requiring a particular labeling system for apples sold in the state had a discriminatory effect on particular out-of-state apple producers).
- The Supreme Court has also consistently struck down laws that attempt to regulate conduct occurring entirely outside the state.
 - *United States Brewers Ass’n*, 692 F.2d at 282 (holding that a Connecticut price affirmation statute violated the dormant commerce clause because it prevented brewers from raising prices for their products in other states so long as a higher price was being charged within the state).
 - *Brown–Forman*, 476 U.S. at 581-82 (holding that a New York price affirmation statute violated the dormant commerce clause because it regulated entirely out-of-state commercial activity).
 - Food labeling requirement that had no direct effect on producers’ out-of-state conduct; where producers remained free to pursue other labeling conduct outside of Ohio; and where compliance with state requirement would not violate the labeling requirements of any other state did not fall within this category, even if out-of-state food manufacturers argued they would be required to change their labels in other states. *Boggs*, 622 F.3d at 647 (reviewing a milk labeling regulation).

Second Tier: Balancing Any Burden with Local Interest

- The *Pike* test applies when there is no discrimination against interstate commerce: “[w]here the statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.” *Pike*, 397 U.S. at 142.
- Non-discriminatory laws enjoy a presumption of constitutionality. *See generally* Chemerinsky at 429-39.
- Burden analysis:
 - Withdrawal of some business from an in-state market may be outweighed by legitimate local interests.
 - *Exxon Corp.*, 437 U.S. at 127 (reviewing a case where out-of-state refinery operators were denied access to portion of the local retail fuel market and holding that exclusion of some out-of-state businesses from in-state markets did not constitute an impermissible burden on interstate commerce).

- *Clover Leaf Creamery*, 449 U.S. at 472-73 (reviewing a situation where in- and out-of-state plastic manufacturers were excluded from the local milk packaging market and finding that requiring milk to be sold in paper containers actually created opportunities for out-of-state paper companies to sell their products within the state).
- Financial effects such as compliance costs or lost profits for interstate businesses may be outweighed by legitimate local interests.
 - *Parker v. Brown*, 317 U.S. at 367-68 (holding that regulating California’s in-state raisin marketing program was not an impermissible burden on interstate commerce).
 - *Clover Leaf Creamery*, 449 U.S. at 473 (“the inconvenience of having to conform to different packaging requirements in Minnesota and the surrounding States should be slight”).
- Benefit analysis:
 - Addressing environmental concerns is a legitimate local interest.
 - *Clover Leaf Creamery*, 449 U.S. at 473 (finding that there was a “substantial state interest in promoting conservation of energy and other natural resources and easing solid waste disposal problems”).
 - *Hughes*, 441 U.S. at 336-37 (holding that conservation is a legitimate local interest).
 - Public health and safety are legitimate local interests.
 - *Parker*, 317 U.S. at 362 (noting the “safety, health and well-being of local communities” as an appropriate interest).
 - *United Haulers*, 550 U.S. at 346-47 (finding that incentives for recycling and increasing enforcement of recycling laws “conferr[ed] significant health and environmental benefits upon the [local] citizens”).
 - *Gerace*, 755 F.2d at 1003-04 (citing list of local legitimate interests served by a regulation prohibiting the misleading labeling of imitation cheese products, where “record shows that health and nutrition professionals strongly disagree about the intrinsic value of the federal nutritional guidelines applied to alternative cheese products,” the “very existence of [the] controversy” meant that New York’s labeling law was not unreasonable).
 - *S. C. State Highway Dep’t*, 303 U.S. at 195-96 (upholding a law restricting truck weight and size based on public safety concerns).
 - Consumer information, preventing deception, and permitting consumers to clearly discern what type of products they purchase are legitimate local interests. *Gerace*, 755 F.2d at 1003-04.
 - Addressing local economic concerns is a legitimate local interest.
 - *Parker*, 317 U.S. at 367-68 (protecting the long term viability of California’s raisin crop was a legitimate local purpose).
 - *Gerace*, 755 F.2d at 1003–04 (preventing unfair competition and promoting consumer information legitimate local purposes).
 - *United Haulers*, 550 U.S. at 346 (upholding law that gave localities means to finance waste disposal services).

- Local benefits may be found illegitimate if it is conclusively shown that the regulation does not further the benefits and the burdens are severe. *Bibb*, 359 U.S. at 525-28 (striking down a regulation requiring certain mudguards for trucks).

D. Additional Considerations

This memo does not discuss every potential challenge to a Vermont labeling law. If the law were upheld under the First Amendment and the Dormant Commerce Clause, it would necessarily survive the constitutional “rational basis” test more generally. *See, e.g., Dunagin v. City of Oxford, Miss.*, 718 F.2d 738, 752-53 (5th Cir. 1983) (holding that, in commercial speech case, consumers are relevant class under Equal Protection and government need only meet rational basis test); *Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico*, 478 U.S. 328, 345 n.9 (1986) (“If there is a sufficient ‘fit’ between the legislature’s means and ends to satisfy the concerns of the First Amendment, the same ‘fit’ is surely adequate under the applicable ‘rational basis’ equal protection analysis.”), *abrogated in part on other grounds by 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 509-10 (1996).

Also, the overbreadth doctrine should not apply to commercial speech. *See, e.g., Bates v. State Bar of Ariz.*, 433 U.S. 350, 380-81 (1977) (explaining why overbreadth doctrine is not well-suited to commercial speech and “declin[ing] to apply it to professional advertising”); *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 463 n.20 (1978) (noting that attorney challenging Ohio restriction could not “make a successful overbreadth argument” in view of *Bates*, and that “[c]ommercial speech is not as likely to be deterred as noncommercial speech, and therefore does not require the added protection afforded by the overbreadth approach”); *Jacobs v. The Fla. Bar*, 50 F.3d 901, 907 (11th Cir. 1995) (noting that “the Supreme Court has held the overbreadth doctrine inappropriate in commercial speech cases”) (footnotes and citations omitted). *But see Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 481-86 (1989) (opining that overbreadth doctrine could be applied to commercial speech). However, if it did, satisfaction of the fourth prong of *Central Hudson* would satisfy any overbreadth concern. *See id.* at 482. Finally, Vermont would ensure that its provisions were sufficiently defined in order to avoid being unconstitutionally vague. *See generally Posadas de Puerto Rico*, 478 U.S. at 347-48 (holding advertising restriction was not unconstitutionally vague where court decisions had narrowed its construction); *Jacobs*, 50 F.3d at 907 (commercial speech rules are subject to vagueness attacks).

APPENDIX

This Appendix provides a basic overview of the scientific and regulatory frameworks regarding genetically engineered (GE) foods. It explains that they are readily distinguishable from those concerning rBGH in *International Dairy Foods Association v. Amestoy*. First, there is already scientific evidence pointing to demonstrated health and other concerns associated with the consumption of genetically engineered foods. Second, the Food & Drug Administration (FDA) has formally voiced health and safety concerns concerning risks associated with genetically engineered foods; and it has not conducted the “thorough review” it did in the rBGH matter, which produced a Final Rule. Third, foods can be tested to determine whether they have been produced with genetic engineering, as well as how much of the food was produced with genetic engineering. For any one of these reasons, a Vermont law requiring a “genetically engineered” label would be easily distinguished from the labeling law struck down in *International Dairy*.

Demonstrated Health Concerns

In *International Dairy*, the Court declared that the “extensive record in this case contains no scientific evidence from which an objective observer could conclude that [rBGH] has any impact at all on dairy products.” 92 F.3d 67, 73 (2d Cir. 1996). This decision came just three years after the FDA determined that rBGH was safe for human consumption. *See* Animal Drugs & Related Products, 58 Fed. Reg. 59,946-02 (Nov. 12, 1993). The record for a Vermont labeling law would be far different from the record before the Court in *International Dairy*. Since the publication of the FDA’s GE policy statement over twenty years ago, numerous studies have been conducted showing that there are demonstrated health risks associated with consuming genetically engineered food products. *See* attached *Index of Authorities – Risks of GE Foods*.

In addition, and similar to the agency’s approval process for rBGH, people who work within the FDA have disagreed with the agency’s determination that genetically engineered foods are “substantially similar” to their traditional counterparts and doctors have voiced concerns about the safety of consuming genetically engineered foods. *See, e.g.*, Dr. Louis J. Pribyl, “Comments on Biotechnology Draft Document, 2/27/92” 1 (March 6, 1992) (“[t]here is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering”); Comments from Dr. Linda Kahl, FDA compliance officer, to Dr. James Maryanski, FDA Biotechnology Coordinator, about the Federal Register document “Statement of Policy: Foods from Genetically Modified Plants” 2 (Jan. 8, 1992) (“The processes of genetic engineering and traditional breeding are different, and according to the technical experts in the agency, they lead to different risks.”); *see also* Declaration of Dr. Richard Lacey, M.D., Ph.D. 1-2 (May 28, 1999) (“Recombinant DNA technology is an inherently risky method for producing new foods. . . . Further, whether singular or multi-faceted, the disruptive influence could well result in the presence of unexpected toxins or allergens or in the degradation of nutritional value. Further, because of the complexity and interactivity of living systems -- and because of the extent to which our understanding of them is still quite deficient -- it is impossible to predict what specific problems could result in the case of any particular genetically engineered organism.”). In contrast to the rBGH process, however, the FDA has not conducted a “thorough review” regarding the safety of genetically engineered foods (see below).

FDA Treatment of Genetically Engineered Foods

The FDA's actions concerning genetically engineered foods differ greatly from the agency's actions concerning growth hormone in milk products.¹ On November 12, 1993, the FDA approved by Final Rule a new animal drug application (NADA) for the use of Posilac(R) (sterile somatotrophic zinc suspension), a Monsanto rDNA-derived drug, in lactating dairy cows to increase the production of marketable milk. 58 Fed. Reg. at 59,946-47. Later, the FDA said that it "approved the product because [it] had determined after a thorough review that [rBGH] is safe and effective for dairy cows, that milk from [rBGH]-treated cows is safe for human consumption, and that production and use of the product do not have a significant impact on the environment." Interim Guidance on Milk Labeling, 59 Fed. Reg. 6279-04, 6279-80 (Feb. 10, 1994). In this case, there is no Final Rule - there is not even a proposed Rule - attesting to the safety of GE foods.

Instead, after explaining in its 1992 policy statement that it would regulate genetically engineered foods within the existing regulatory framework - because genetically engineered foods were "substantially similar" to their traditional counterparts - the FDA voiced numerous health and safety risks. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984-01, 22,984, 22,986-87 (May 29, 1992). It pointed out, among other things, potential unexpected effects; increased toxicity; alteration in the level of nutrients; the creation of new substances; allergenicity; and antibiotic resistance. *Id.* at 22,986-88. Unlike the FDA's [rBGH] "thorough review," the FDA has neither performed nor evaluated thorough testing on genetically engineered foods. *See id.* at 22,988 ("[The] FDA has not found it necessary to conduct, prior to marketing, routine safety reviews of whole foods derived from plants."). Instead, the FDA accepts a manufacturer's determination that its products are generally recognized as safe (GRAS) based on its own studies and encourages "informal consultation." *See id.* at 22,989-90. Therefore, unlike the rBGH milk at issue in *International Dairy*, the FDA has not "determined" that foods produced with genetic engineering are safe for human consumption. And, unlike the Final Rule in the rBGH case, the statements the FDA has made regarding genetic engineering lack the force of law.

Distinguishing Genetically Engineered Food Products from Traditional Food Products

Unlike milk produced with rBGH in the *International Dairy* case, scientists can distinguish GE foods from foods produced without genetic engineering. *See* GMO Testing-Testing Options, <http://www.gmotesting.com/Testing-Options.aspx> (last visited Dec. 3, 2012). In 1994, the FDA stated that "[t]here is currently no way to differentiate analytically between naturally occurring bST and recombinant bST in milk, nor are there any measurable compositional differences between milk from cows that receive supplemental bST and milk from cows that do not." 59 Fed. Reg. at 6280. *International Dairy* echoed this statement in 1996, finding it "undisputed that neither consumers nor scientists can distinguish [rBGH]-derived milk from milk produced by an untreated cow." 92 F.3d at 73 (citation omitted).

¹ We do not attempt to assess the adequacy of FDA's review and approval of rBGH, or to suggest that the presence of a Final Rule is determinative. Our point here is that, in the *Int'l Dairy* case, FDA had conducted a "review" and promulgated a Final Rule regarding rBGH - circumstances not present in the genetically engineered foods context.

In contrast, food products can be tested to determine whether they were produced with genetic engineering. Testing for genetically engineered foods confirms the “identity and nature of the product at every step along the supply chain.” GMO Testing, <http://www.gmotesting.com/> (last visited Dec. 3, 2012). There are two methods and three tests for testing for genetic engineering in a food product. Testing Options, *supra*. The methods include genetic analysis (DNA analysis) and immunological analysis (protein analysis). *Id.* The three tests are a polymerase chain reaction (PCR) test, a lateral flow device or dipstick (strip test), and an enzyme-linked immunosorbent assay (ELISA test). *Id.*

Polymerase Chain Reaction (PCR) Test

DNA analysis consists of a PCR test, which “copies a specific section of a plant’s DNA billions of times in order to detect and quantitate foreign DNA [genetically modified organism] (GMO) inserted into the plant’s genome.” *Id.* PCR tests may include broad-spectrum GMO tests, event-specific and construct-specific GMO tests, or a combination of broad-spectrum and specific GMO tests. GMO Testing – Genetic Analysis, <http://www.gmotesting.com/Testing-Options/Genetic-analysis.aspx> (last visited Dec. 3, 2012). A PCR test is appropriate for qualitative and quantitative testing and can be used to detect GMOs in finished food products. DNA GMO Testing of Seed, Grain, Feed and Food, <http://www.biogeneticservices.com/dnagmo.htm> (last visited Dec. 3, 2012); Testing Options, *supra*.

Lateral Flow Device or Dipstick (Strip Test)

The strip test is one of the tests under the immunological analysis method. Testing Options, *supra*. The strip test is a “rapid antibody-based method used for measuring GMO protein in unprocessed material such as seed, grain, or leaves.” *Id.* The test uses a detection surface made up of “immobilized GMO protein-specific antibodies on a solid strip” and is appropriate for qualitative and semi-quantitative testing. *Id.*

Enzyme-linked Immunosorbent Assay (ELISA Test)

The ELISA test is another antibody-based method for measuring GMO protein and is used for unprocessed material. *Id.* The test “uses a detection surface comprised of immobilized GMO protein-specific antibodies in a multi-well solid plate format.” *Id.* The ELISA test is appropriate for qualitative or quantitative testing and is performed in a laboratory setting. *Id.*

Conclusion

Because there is significant scientific evidence of the health and other risks associated with consuming genetically engineered foods, because the FDA has not made a safety statement with the force of law and has formally voiced its own health and safety concerns about GE foods, and because food products can be tested to determine if they were genetically engineered, a Vermont law requiring genetically engineered foods to be labeled would be easily distinguished from the labeling law at issue in *International Dairy*. Any one of these factors is sufficient to draw a clear distinction; the presence of all three even more.

Index of Authorities-Risks of GE Foods

Food Allergies:

- Michael Antoniou, Claire Robinson, and John Fagan, *GMO Myths and Truths: An Evidence-Based Examination of the Claims Made for the Safety and Efficacy of Genetically Modified Crops*, Earth Open Source, Chapter 5 (2012).

This report covers a wide range of issues pertaining to genetically modified organisms, including food allergies. The report explains that genetic engineering changes the DNA of a food, and that altered DNA can in turn create new proteins. Thus, according to the report, GM foods could create new allergies in two ways: first, the new proteins could cause allergic reactions (be “allergens”) themselves, or second, the new proteins could sensitize people to existing food proteins. The report concludes that there should be more preliminary research into the allergenicity of GM foods before they enter the market.

- Michael Antoniou, *GM Soy, Sustainable? Responsible?: A Summary of Scientific Evidence Showing that Genetically Modified (GM) Soy and the Glyphosate Herbicide it is Engineered to Tolerate are Unsustainable From the Point of View of Farming, the Environment, Rural Communities, Animal and Human Health, and Economies*, GLS Bank (2010).

This report covers a broad range of issues pertaining to genetically modified soy. The report states, “GM RR soy was found to contain a protein that differed from the protein in wild type soy, raising the possibility of allergenic properties. One of the human experimental subjects in the study showed an immune response to GM soy but not to non-GM soy.”

- *Statement of Policy-Foods Derived from New Plant Varieties*, U.S. Food and Drug Administration (1992).

In 1992 the FDA came out with a policy statement describing how the agency would regulate genetically engineered foods. The policy statement explains, “The FDA’s principal concern regarding allergenicity is that proteins transferred from one food source to another, as is possible with recombinant DNA and protoplast fusion techniques, might confer on food from the host plant the allergenic properties of food from the donor plant.” Additionally, the FDA describes that “if the allergen were moved into a variety of a plant species that never before produced that allergen, the susceptible population would not know to avoid food from that variety.”

- *State-of-the-Science on the Health Risks of GM Food*, Institute for Responsible Technology.

This report provides an overview of health risks associated with GM foods. A section titled “GM Crops Trigger Immune Reactions and May Cause Allergens” discusses that allergic reactions occur when the body responds to something foreign, and that all GM foods contain something that is foreign. The section also discusses how it is difficult to pinpoint allergic reactions

triggered by GM food consumption because “few countries conduct regular studies or keep careful records.”

- V. Prescott, P. Campbell, A. Moore, et al. *Transgenic expression of bean alpha-amylase inhibitor in peas results in altered structure and immunogenicity*. *Journal of Agricultural and Food Chemistry*. 53(23): 9023–9030 (2005).

This study found that mice fed GE peas developed an immune response against the genetically engineered protein, leading to an allergic reaction. The mice also developed a similar immune reaction to chicken egg white protein. The authors concluded that the GE protein made the mice more susceptible to developing immune reactions and allergies to normally non-allergenic foods.

Food Intolerance and Sensitivity:

- Roberto I. Vásquez-Padrón, *Cry1Ac Protoxin from Bacillus Thuringiensis sp. Kurstaki HD73 Binds to Surface Proteins in the Mouse Small Intestine*, *Biochemical and Biophysical Research Communications* (2000).

This study “demonstrate[s] that Cry1Ac protoxin (pCry1Ac) binds to the mucosal surface of the mouse small intestine... The data obtained indicate a possible interaction *in vivo* of Cry proteins with the animal bowel which could induce changes in the physiological status of the intestine.”

- S. Kroghsbo, C. Madsen, M. Poulsen, et al. *Immunotoxicological studies of genetically modified rice expressing PHA-E lectin or Bt toxin in Wistar rats*. *Toxicology*. 245(1-2): 24-34 (2008).

This study found a Bt immune response occurring in both rats which had been fed GE Bt rice, as well as a control group that had been fed non-GE rice. The authors concluded that the control group had inhaled powdered particles of the GE feed, leading to the immune response.

General Health:

- A. Finamore, M. Roselli, S. Britti, et al. *Intestinal and peripheral immune response to MON810 maize ingestion in weaning and old mice*. *The Journal of Agricultural and Food Chemistry*. 56: 11533–11539 (2008).

This study examined the effects of a genetically engineered maize diet on both young and old populations of mice. The authors observed disturbances in the immune cells of the mice, as well as changes in biochemical activity. They concluded that “[t]hese results suggest the importance of the gut and peripheral immune response to GM crop ingestion as well as the age of the consumer in the GMO safety evaluation.”

Available at: <http://pubs.acs.org/doi/abs/10.1021/jf802059w?prev>

- A. Kilic, M. Akay. *A three generation study with genetically modified Bt corn in rats: Biochemical and histopathological investigation*. *Food and Chemical Toxicology*. 46(3): 1164–1170 (2008).

A multi-generational study examined the effects of a genetically engineered corn diet on rats. The authors observed “histopathological changes in liver and kidney,” as well as “[c]hanges in creatinine, total protein and globulin levels.” This indicates that identifiable and measurable biochemical changes occur as several generations of rats are exposed to a GE diet.

- Artemis Dona, Ioannis S. Arvanitoyannis. *Health risks of genetically modified foods*. *Critical Reviews in Food Science and Nutrition*. 49(2): 164–175 (2009).

This broad survey paper reviews a number of studies that have identified health concerns associated with GE foods. It highlights a trend of toxic effects of GE foods on various organs, and makes the claim that many current studies have been too short to determine whether GE foods have any adverse effect. “The results of most studies with GM foods indicate that they may cause some common toxic effects such as hepatic, pancreatic, renal, or reproductive effects and may alter the hematological, biochemical, and immunologic parameters. However, many years of research with animals and clinical trials are required for this assessment.”

Available at: <http://www.tandfonline.com/doi/full/10.1080/10408390701855993>

- F. Brasil, L. Soares, T. Faria, G. Boaventura, F. Sampaio, C. Ramos. *The impact of dietary organic and transgenic soy on the reproductive system of female adult rat*. *The Anatomical Record*; 292(4): 587–594 (2009).

This study examined the effects of a genetically engineered soy diet on the reproductive system of rats. The authors conclude that “both GMSG and OSG diets resulted in decreased body weight and lower serum triglyceride and cholesterol levels, and alterations in uterine and ovarian morphology were also observed.” “The prolonged use of soybased diets and their relation to reproductive health warrants further investigation.”

- G. Séralini, R. Mesnage, E. Clair, et al. *Genetically modified crops safety assessments: Present limits and possible improvements*. *Environmental Sciences Europe*. 23(10) (2010).

The authors of this study re-examined the results of prior studies involving genetically engineered soy and maize trials on various mammals. Their analysis of the data indicated an increase in liver and kidney abnormalities, an effect which may indicate toxic effects and that can be a marker for the onset of chronic diseases. The authors urge further long-term studies to evaluate these risks.

- Michael Antoniou, *GM Soy, Sustainable? Responsible?: A Summary of Scientific Evidence Showing that Genetically Modified (GM) Soy and the Glyphosate Herbicide it is Engineered to Tolerate are Unsustainable From the Point of View of Farming, the Environment, Rural Communities, Animal and Human Health, and Economies*, GLS Bank (2010).

This report is a “summary of scientific evidence showing that genetically modified (GM) soy and the glyphosate herbicide it is engineered to tolerate are unsustainable from the point of view of farming, the environment, rural communities, animal and human health, and economies.” The report states that “[scientific] findings suggest that GM RR soy could pose serious health risks to humans.” The study also suggests that “the fact that differences were found between GM fed and non-GM-fed animals contradicts the FDA’s assumption that GM soy is substantially equivalent to non-GM soy.”

- M. Malatesta, et al. *A long-term study on female mice fed on a genetically modified soybean: effects on liver ageing*. *Histochem Cell Biology*. 130: 967–977 (2008).

This study found that mice which were fed GE soybeans over their entire lifetimes had greater signs of aging in their livers than mice which were fed a non-GE soybean: “[s]everal proteins belonging to hepatocyte metabolism, stress response, calcium signaling and mitochondria were differentially expressed in GM-fed mice, indicating a more marked expression of senescence markers in comparison to controls. Moreover, hepatocytes of GM-fed mice showed mitochondrial and nuclear modifications indicative of reduced metabolic rate. This study demonstrates that GM soybean intake can influence some liver features during ageing and, although the mechanisms remain unknown, underlines the importance to investigate the long-term consequences of GM-diets and the potential synergistic effects with ageing, xenobiotics and/or stress conditions.”

- M. Poulsen, S. Kroghsbo, M. Schrøder, et al. *A 90-day safety study in Wistar rats fed genetically modified rice expressing snowdrop lectin Galanthus nivalis (GNA)*. *Food and Chemical Toxicology*. 45(3): 350-363 (2007).

This study examined various clinical, biological, immunological, microbiological and pathological parameters in rats fed GE rice compared to rats fed non-GE rice. A number of significant differences were recorded. Although the differences were not determined to be adverse, the authors conclude that the short length of the study (90 days) was insufficient to make a final conclusion about the safety of GE foods.

- M. Schrøder, M. Poulsen, A. Wilcks, et al. *A 90-day safety study of genetically modified rice expressing CryIAb protein (Bacillus thuringiensis toxin) in Wistar rats*. *Food and Chemical Toxicology*. 45(3): 339-349 (2007).

This study also examined various biochemical parameters, and a number of significant differences were observed between rats fed GE rice and those fed non-GE rice. Organ weights varied between the two groups, and GE-fed rats had significantly higher levels of certain gut

bacteria. While the findings were not adverse, the authors noted that the short length of the study again precluded a determination that the GE rice was safe, and further research was called for.

- M. Trabalza-Marinucci, G. Brandi, C. Rondini, et al. *A three-year longitudinal study on the effects of a diet containing genetically modified Bt176 maize on the health status and performance of sheep*. *Livestock Science*. 113(2): 178–190 (2008).

This study examined the effects of a genetically engineered corn diet on ewes and their lambs. The authors concluded that there were no direct adverse health effects observed, but they did observe changes in the functioning of the digestive system and cellular changes in the liver and pancreas of the lambs.

- R. Tudisco, P. Lombardi, F. Bovera, et al. *Genetically modified soya bean in rabbit feeding: Detection of DNA fragments and evaluation of metabolic effects by enzymatic analysis*. *Animal Science*. 82: 193–199 (2006).

This study examined possible effects of a GE diet on cell metabolism. The authors found that rabbits fed GE soy had disturbances in the enzyme functions in the kidney and heart: “a significant increase of lactic dehydrogenase . . . was found in particular in kidney and heart but not in the muscle, thus suggesting a potential alteration in the local production of the enzyme.”

- *State-of-the-Science on the Health Risks of GM Food*, Institute for Responsible Technology.

This report provides an overview of health risks associated with consuming GM food. The report explains that “GMOs have been linked to thousands of toxic or allergic-type reactions, thousands of sick, sterile, and dead livestock, and damage to virtually every organ and system studied in lab animals.” The report gives a detailed account of each of the previously mentioned health effects.

Increased Toxic Pesticide/Herbicide Use- Birth Defects:

- Alberto Finamore, et al., *Intestinal and Peripheral Immune Response to MON810 Maize Ingestion in Weaning and Old Mice*, *Journal of Agricultural and Food Chemistry* (2008).

This study evaluated the gut and peripheral immune response to genetically modified (GM) maize in mice in vulnerable conditions. Weaning and old mice were fed a diet containing MON810 or its parental control maize or a pellet diet containing a GM-free maize for 30 and 90 days. The results suggest the importance of the gut and peripheral immune response to GM crop ingestion as well as the age of the consumer in the GMO safety evaluation.

- Alejandra Paganelli, et al., *Glyphosate-Based Herbicides Produce Teratogenic Effects on Vertebrates by Impairing Retinoic Acid Signaling*, *Chemical Resources Toxicology* (2010).

This study took an “embryological approach to explore the effects of low doses of glyphosate in development.” The treated embryos were highly abnormal with “marked alterations in cephalic

and neural crest development and shortening of the anterior-posterior axis. The direct effect of glyphosate on early mechanisms of morphogenesis in vertebrate embryos raises concerns about the clinical findings from human offspring in populations exposed to glyphosate-based herbicides in agricultural fields.”

- Dr. A. Velimirov, et al., *Biological Effects of Transgenic Maize NK603xMON810 Fed in Long Term Reproduction Studies in Mice* (2008).

The aim of this study was to “examine chronic feed effects of GM maize in mice.” Most studies only look for effects which take place in 90 days; however, chronic effects might only become evident in longer lasting multi-generational studies. The study showed time related negative reproductive effects of the GM maize under the given experimental conditions.

- Aziz Aris and Samuel Leblanc, *Maternal and Fetal Exposure to Pesticides Associated to Genetically Modified Foods in Eastern Townships of Quebec, Canada*, *Reproductive Toxicology* (2011).

The aim of this study was to “evaluate the correlation between maternal and fetal exposure levels of herbicides such as glyphosate.” Blood of 30 pregnant women and 39 non-pregnant women were studied. This was the first study to “reveal the presence of circulating pesticides associated with genetically modified foods in women with or without pregnancy.”

- B. Davis, R. Scott, J. Norsworthy, K. Smith. *Effects of Low Rates of Glyphosate and Glufosinate on Rice*. *AAES Research Series 581*, 156–159 (2009).

Researchers applied low doses of Roundup and Liberty herbicides (used with GE soy varieties) to non-GE rice crops, simulating the effect of these common herbicides affecting off-target plants. They found that the pesticides had a substantial effect on the non-GE rice: “[r]ice grain yield was reduced up to 80% with either herbicide.”

- César Paz-y-Miño, et al., *Evaluations of DNA Damage in an Ecuadorian Population Exposed to Glyphosate*, *Brazilian Society of Genetics* (2007).

This study “analyzed the consequences of aerial spraying with glyphosate added to a surfactant solution in the northern part of Ecuador. A total of 24 exposed and 21 unexposed control individuals were investigated using the comet assay. The results showed a higher degree of DNA damage in the exposed group...compared to the control group...These results suggest that in the formulations used during aerial spraying glyphosate has a genotoxic effect on the exposed individuals.”

- G. Séralini, D. Cellier, J. Spiroux de Vendomois. *New analysis of a rat feeding study with a genetically modified maize reveals signs of hepatorenal toxicity*. *Archives of Environmental Contamination and Toxicology*. 52(4): 596–602 (2007).

The authors re-analyzed the results of a Monsanto study of an insecticide-producing genetically engineered Maize fed to rats. Their analysis shows that the rats suffered significant abnormalities

in growth and showed signs of hepatorenal toxicity. They concluded that further studies were necessary before the genetically modified crop could be declared safe.

- J. Cummins. *New GM Crops Tolerant To Old Toxic Herbicides a Step Backwards*. ISIS Report 09/02/12 (2012).

The author discusses the implications of the introduction of a new variety of genetically engineered corn that is tolerant to an older variety of herbicide. He argues that “[t]he development of 2,4-D resistant crops will greatly increase the use of the herbicide and greatly amplify the environmental pollution associated with this old herbicide.”

Available at: http://www.i-sis.org.uk/New_GM_Crops_Tolerant_To_Old_Toxic_Herbicides.php

- Memorandum from Dr. Edwin J. Matthews to the Toxicology Section of the Biotechnology Working Group. Subject: “Analysis of the Major Plant Toxicants.” Dated Oct. 28, 1991.

In his memorandum, Dr. Edwin J. Matthews explains that genetically modified plants could contain unexpected high concentrations of plant toxicants. He also states that “the task of assessing the presence or absence of expected or unexpected plant toxicants in genetically modified plants and the control plant could be very difficult, because thousands of plant biochemicals have been shown to have toxic effects on animals and microorganisms.”

- Memorandum from Dr. Samuel I. Shibko to Dr. James Maryanski, FDA Biotechnology Coordinator. Subject: "Revision of Toxicology Section of the *Statement of Policy: Foods Derived from Genetically Modified Plants*." Dated January 31, 1992.

In his memorandum, Dr. Samuel I. Shibko states that at the time the FDA policy statement was being drafted, “it [was] unlikely that molecular and compositional analysis [could] reasonably detect or predict all possible changes in toxicant levels or the development of new toxic metabolites as a result of genetic modifications introduced by the new methods of biotechnology.”

- Mikael Eriksson, et al., *Pesticide Exposure as Risk Factor for Non-Hodgkin Lymphoma Including Histopathological Subgroup Analysis*, International Journal of Cancer (2008).

This study, performed in Sweden, examined exposure to pesticides as a risk factor for non-Hodgkin lymphoma (NHL). The study confirmed an association between exposure to phenoxyacetic acids and NHL. Based on the study, “the NHL association with glyphosate was considerably strengthened.”

- R.C. Lajmanovich, et al., *Induction of Mortality and Malformation in Scinax nasicus Tadpoles Exposed to Glyphosate Formulations*, Bulletin of Environmental Contamination and Toxicology (2003).

The “objective of this study was to investigate, under laboratory conditions, the acute toxicity of commercial glyphosate formulations (GLY-F) in *S. nasicus* tadpoles, through their survival and larvae malformation.” The study showed that differences between the control and exposed tadpoles, specifically, “hyobranchial skeletons of *S. nasicus* tadpoles exposed to GLY-F show alterations in their cartilage structure consistent with disruption of collagen formation.”

- R. Mesnage, et al., *Cytotoxicity on Human Cells of CryIAb and CryIAc Bt Insecticidal Toxins Alone or With a Glyphosate-Based Herbicide*, Journal of Applied Toxicology (2011).

This study explains that “pesticides residues co-occur in the plants as they are synthesized by the plant itself, by the expression of the inserted transgene or through external pesticide treatment facilitated by the transgene-dependent tolerance to herbicides.” The study tested for the first time the effects of CryIAb and CryIAc alone and combined with Roundup on human cells. The study found that CryIAb can induce cytotoxic effects.

Contamination of Other Crops:

- Margaret Mellon and Jane Rissler, *Gone To Seed, Transgenic Contaminants in the Traditional Seed Supply*, Union of Concerned Scientists (2004).

In this report, the Union of Concerned Scientists (UCS) examines the contamination of traditional seeds by DNA sequences derived from genetically engineered crop varieties. Most of the transgenes used by genetic engineers are new to foods and some are not intended for use in foods at all. The study found that the seeds of traditional varieties bought from the same retailers used by U.S. farmers are pervasively contaminated with low levels of DNA sequences originating in genetically engineered varieties of those crops. The implications of this contamination could be severe. First, transgenic traits will be perpetuated and accumulate over time in plants where they are not expected and could be difficult to control. Second, seeds provide the only safety net if it becomes clear that genetically engineered crops are unsafe; if all seeds are contaminated our food supply could be in trouble.

- Michael Antoniou, *GM Soy, Sustainable? Responsible?: A Summary of Scientific Evidence Showing that Genetically Modified (GM) Soy and the Glyphosate Herbicide it is Engineered to Tolerate are Unsustainable From the Point of View of Farming, the Environment, Rural Communities, Animal and Human Health, and Economies*, GLS Bank (2010).

This report describes numerous negative impacts of the production of GM roundup resistant (RR) soy. Included in the report is a discussion of non-target plant disease as a result of the production of GM RR soy. The report states, “Glyphosate applied to GM RR soy exudes into the rhizosphere (the area of soil around the roots), inhibiting the uptake of important nutrients by

non-target plants. These include nutrients essential to plant disease resistance – manganese, zinc, iron, and boron.”

- *Monsanto Co. v. Geertson Seed Farms*, 130 S.Ct. 2743, 2755 (2010).

In this case, the Supreme Court acknowledged that gene flow between genetically engineered alfalfa plants and organic and conventional alfalfa plants constituted a substantial risk that would harm organic and conventional alfalfa growers in significant ways.

- S. Heuberger, C. Ellers-Kirk, B. Tabashnik, Y. Carrière. *Pollen- and Seed-Mediated Transgene Flow in Commercial Cotton Seed Production Fields*. PLoS ONE 5(11): e14128. doi:10.1371/journal.pone.0014128 (2010).

This paper analyzes how genes can “flow” from one crop to another. It concludes that genetic contamination of related crops is likely to occur regardless of efforts to physically separate the two, particularly due to human factors such as seed sorting, seed handling, and harvesting techniques.

Environmental Impacts:

- A. Wegier, et al. *Recent long-distance transgene flow into wild populations conforms to historical patterns of gene flow in cotton (*Gossypium hirsutum*) at its centre of origin*. *Molecular Ecology*, 20: 4182–4194 (2011).

Researchers identified genetically modified cotton genes in wild populations of cotton in Mexico. Almost a quarter of the wild cotton seeds examined contained genetically engineered genes that had been modified for pest or herbicide resistance.

Available at: <http://onlinelibrary.wiley.com/doi/10.1111/j.1365-294X.2011.05258.x/abstract>

- Michael Antoniou, Claire Robinson, and John Fagan, *GMO Myths and Truths: An Evidence-Based Examination of the Claims Made for the Safety and Efficacy of Genetically Modified Crops*, Earth Open Source, Chapter 5 (2012).

The report explains how GM herbicide-tolerant crops have caused an over-reliance on a single herbicide, glyphosate, leading to the emergence of resistant “superweeds,” causing farmers to use more toxic herbicides. Additionally, “Roundup used on GM herbicide-tolerant plants persists in the environment and has toxic effects on wildlife as well as humans.” Roundup “increases plant diseases, notably Fusarium, a fungus that causes sudden death and wilt in soy plants and is toxic to humans and livestock.”

- Michael Antoniou, *GM Soy, Sustainable? Responsible?: A Summary of Scientific Evidence Showing that Genetically Modified (GM) Soy and the Glyphosate Herbicide it is Engineered to Tolerate are Unsustainable From the Point of View of Farming, the Environment, Rural Communities, Animal and Human Health, and Economies*, GLS Bank (2010).

This report discusses some of the environmental impacts associated with roundup resistant soy production in Argentina. The report describes, “GM RR soy production in Argentina...has caused serious ecological and agronomic problems, including: the spread of glyphosate-resistant weeds, erosion of soils, loss of soil fertility and nutrients, dependence on synthetic fertilizers, deforestation, potential desertification, and loss of species and biodiversity.”

- *Monsanto Co. v. Geertson Seed Farms*, 130 S.Ct. 2743, 2755 (2010).

In this case, the Supreme Court recognized that “the risk that the RRA [roundup resistant alfalfa] gene conferring glyphosate resistance will infect conventional and organic alfalfa is a significant environmental effect within the meaning of NEPA.”

- M. Schafer, A. Ross, J. Londo, et al. *The Establishment of Genetically Engineered Canola Populations in the U.S.*. PLoS ONE 6(10): e25736. doi:10.1371/journal.pone.0025736 (2011).

Researchers conducted a roadside survey of Canola plants to determine the extent that genetically engineered varieties have escaped and hybridized with wild plants. They found two GE varieties growing in the wild, as well as a number of hybridizations between wild varieties and GE varieties. The authors concluded that “feral populations are large and widespread.”

- Rebecca J. Goldberg, *Environmental Concerns with the Development of Herbicide-Tolerant Plants*, Weed Technology, Vol. 6, No. 3, pp. 647-652 (1992).

This study examines the extent of research to develop herbicide-tolerant plants, the environmental effects of herbicides, and the environmental consequences of developing herbicide-tolerant plants. The study explains that over the years a number of herbicides have been implicated as chronic toxins. Environmental concerns include agricultural chemicals in drinking water, surface water contamination, occupational risks to farmers and farmworkers, and hazards to wild plants and animals. Additionally, herbicides applications may pose hazards to fish and wildlife populations, and alter plant community composition.

- Tanya E. Cheeke, Todd N. Rosenstiel, Mitchell B. Cruzan. *Evidence of reduced Arbuscular Mycorrhizal Fungal Colonization in multiple lines of BT Maize*. American Journal of Botany 99(4): 700–707 (2012).

This study analyzes the effect of GE crop cultivation on soil fungi. The authors conclude that Bt crops have a negative effect on colonization by the fungi, an effect that may have broader effects on soil micro-organisms and fertility.

Available at: <https://www.ncbi.nlm.nih.gov/pubmed/22473978>

Species Habitat:

- John M. Pleasants and Karen S. Oberhauser, *Milkweed Loss in Agricultural Fields Because of Herbicide Use: Effect on the Monarch Butterfly Population*, Insect Conservation and Diversity (2012).

This study investigates “whether the decline in the size of the overwintering population can be attributed to a decline in monarch production owing to a loss of milkweeds in agricultural fields in the Midwest.” There has been a large decline in milkweed in agricultural fields in the Midwest over the last decade, which coincides with the increased use of glyphosate herbicide in conjunction with increased planting of genetically modified glyphosate-tolerant corn and soybeans. “The smaller population size that has become the norm will make the species more vulnerable.”

Economic:

- *Monsanto Co. v. Geertson Seed Farms*, 130 S.Ct. 2743, 2755 (2010).

In this case, the Supreme Court recognized that organic and conventional alfalfa growers’ injury was economic as well as environmental. The Court quoted declarations from farmers, which state that the farmers “would have to conduct testing to find out whether and to what extent their crops had been contaminated.” Additionally, the Court cites that the “risk of gene flow will cause [the farmers] to take certain measures to minimize the likelihood of potential contamination and to ensure an adequate supply of non-genetically-engineered alfalfa.”

Other Sources:

- Arpad Pusztai, *Can Science Give Us the Tools for Recognizing Possible Health Risks of GM Food?*, Nutrition and Health, pp.73-84 (2002).

Explains that “novel toxicological/nutritional methods need to be developed or present methods improved to be able to screen for the potential harmful consequences on human/animal health of GM food crops before these are allowed to enter the human food chain either directly or indirectly.”

- Comments from Division of Food Chemistry and Technology and Division of Contaminants Chemistry. “Points to Consider for Safety Evaluation of Genetically Modified Foods. Supplemental Information.” Dated Nov. 1, 1991.

In its comments, the Divisions of Food Chemistry and Technology and Contaminants Chemistry explain that “all of the marker genes produce proteins that are new with respect to plants” and that “they should be considered to be new proteins in the human diet and be subjected to safety evaluation.” The comments forewarn that “some undesirable effects such as increased levels of known naturally occurring toxicants, appearance of new, not previously identified toxicants,

increased capability of concentrating toxic substances from the environment ...and undesirable alterations in the levels of nutrients may escape breeders' attention unless genetically engineered plants are evaluated specifically for these changes." Additionally, the comments recommend that such evaluations be performed on a case-by-case basis before any product enters the marketplace.

- Comments from Dr. Carl B. Johnson on the "draft statement of policy 12/12/91." Dated Jan. 8, 1992.

In his comments, Dr. Carl B. Johnson presents the fact pattern of DNA from a non-food source being inserted into a food product and encoding a protein product that is toxic to certain organisms. Dr. Johnson then goes on to question whether knowledge of the toxicity of the protein would be necessary to ensure the safety of the food product. Dr. Johnson also points out the lack of scientific evidence provided to support the FDA's conclusions.

- Comments from Dr. Linda Kahl, FDA Compliance Officer, to Dr. James Maryanski, FDA Biotechnology Coordinator, on the "Statement of Policy: Foods from Genetically Modified Plants." Dated Jan. 8, 1992.

In her comments concerning the FDA's 1992 Policy Statement, Dr. Linda Kahl describes the policy statement as trying to fit a square peg into a round hole because the processes of genetic engineering and traditional breeding are different, and "according to the technical experts in the agency, they lead to different risks." Additionally, Dr. Kahl questions that the approach of at least part of the document is to use a scientific analysis of the issues, but no data is provided.

- Comments from Dr. Louis J. Pribyl re: the "Biotechnology Draft Document, 2/27/92." Dated Mar. 6, 1992.

In his comments, Dr. Louis J. Pribyl describes the draft policy statement as a "what do I have to do to avoid trouble-type document." He explains that the document is inconsistent in that it states that there are no differences between traditional breeding and genetic engineering, yet the FDA makes a distinction when it discusses consultations and premarket approvals. Pribyl also questions why companies should need to conduct safety tests if there are, as the FDA states, no differences between traditional foods and those produced by modern technology.

- Kaiser Permanente, "What you need to know about GMOs," Partners in Health Newsletter Fall 2012.

In its newsletter, Kaiser Permanente, the largest managed healthcare organization in the United States, warns consumers of health risks associated with consuming GMOs. The newsletter explains that little research has been conducted on the long-term health effects of genetically engineered foods, but that independent research has found that GMOs caused organ damage in rats, with other studies finding potential reproductive problems. The organization offered advice on how to avoid consuming GMOs.

- Memorandum from Dr. Gerald B. Guest, Director of the Center for Veterinary Medicine, to Dr. James Maryanski, Biotechnology Coordinator. Subject: "Regulation of Transgenic Plants--FDA Draft Federal Register Notice on Food Biotechnology." Dated Feb. 5, 1992.

In his memorandum, Dr. Gerald B. Guest explains that the Center for Veterinary Medicine believes that animal feeds derived from genetically modified plants present unique animal and food safety concerns. He states, "It has always been our position that the sponsor needs to generate the appropriate scientific information to demonstrate product safety to humans, animals, and the environment."

- Memorandum from Dr. Mitchell Smith, Head, Biological and Organic Chemistry Section, to Dr. James Maryanski, Biotechnology Coordinator, "Comments on Draft Federal Register Notice on Food Biotechnology, Dec. 12, 1991 draft." Dated Jan. 8, 1992.

In his memorandum, Dr. Mitchell Smith articulates that "the statement 'organisms modified by modern molecular and cellular methods are governed by the same physical and biological laws as are organisms produced by classical methods' is somewhat erroneous because in the former, natural biological barriers to breeding have been breached." Dr. Smith also explains, "It is immaterial that the FDA doesn't believe methods of genetic modifications are material information important to consumers if regulations do indeed indicate that the former will be a material fact when consumers view such information as important."