MORE THAN CURIOSITY: THE CONSTITUTIONALITY OF STATE LABELING REQUIREMENTS FOR GENETICALLY ENGINEERED FOODS

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INTRODUCTION

Over sixty countries around the world require the labeling of genetically engineered (GE) foods.[1] These countries include the members of the European Union, Russia, China, Saudi Arabia, Japan, Thailand, Australia, India, South Africa, and Venezuela.[2] The United States does not require labeling. However, there is some movement in that direction at the federal level, and labeling bills or referendums have been proposed in over twenty states—including all three of the states within the jurisdiction of the United States Court of Appeals for the Second Circuit.[3] The bills call for raw agricultural commodities and processed foods that have been partially or wholly produced through genetic engineering to be so labeled (for example, with the words "Produced with Genetic Engineering").[4] If any one of these state laws goes into effect—whether in the Second Circuit or elsewhere—there is general agreement that "someone" will sue.

This Article examines the three most likely legal challenges and concludes that, as a legal matter, there is no reason that state labeling laws cannot withstand constitutional challenge. In particular, it explains why labeling legislation should not fail under the First Amendment, with special emphasis on Second Circuit law. The Second Circuit is somewhat unique in that it has an unusual 1996 case striking down a Vermont labeling law for

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1. *International Labeling Laws*, CENTER FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/international-labeling-laws (last visited Nov. 30, 2013).

2. *Who Requires Labels?*, GREEN AM., April/May 2012, *available at* http://www.greenamerica.org/pubs/greenamerican/articles/AprilMay2012/Who-requires-GMO-labels.cfm.

3. H.112, 2013–2014 Leg. Sess. (Vt. 2013), *available at* http://www.leg.state.vt.us/database/status/summary.cfm?Bill=H.0112&Session=2014.pdf; H.B. 6519, Gen. Assemb., Jan. Sess. (Conn. 2013), *available at* http://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=HB06519&which_year=2013; *A03525 Summary*, N.Y. STATE ASSEMBLY, http://assembly.state.ny.us/leg/?default_fld=&bn=A03525&term= 2013&Summary=Y (last visited Nov. 30, 2013). Connecticut actually enacted a GE labeling law on June 25, 2013, but the law has a fairly extensive trigger clause. H.B. 6527, Gen. Assemb. (Conn. 2013), *available at* http://www.cga.ct.gov/2013/ACT/PA/2013PA-00183-R00HB-06527-PA.htm; Amanda Peterka, *Agriculture: Democratic Lawmakers Prepping National GMO Labeling Bill*, GREENWIRE (Feb. 20, 2013), http://www.eenews.net/Greenwire/2013/02/20/6. The Maine legislature has also passed a GE labeling law with a trigger clause. Maggie Caldwell, *Maine is Second State to Pass GMO Labeling Law*, MOTHER JONES (June 14, 2013), http://www.motherjones.com/blue-marble/2013/06/maine-gmo-labeling.

4. H.112, 2013–2014 Leg. Sess. (Vt. 2013), *available at* http://www.leg.state.vt.us/database/status/summary.cfm?Bill=H.0112&Session=2014.pdf; H.B. 6519, Gen. Assemb., Jan. Sess. (Conn. 2013), *available at* http://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=HB06519&which_year=2013; *A03525 Summary*, N.Y. STATE ASSEMBLY, http://assembly.state.ny.us/leg/?default_fld=&bn=A03525&term=2013&Summary=Y (last visited Nov. 30, 2013); H.B. 6527, Gen. Assemb. (Conn. 2013), *available at* http://www.cga.ct.gov/2013/ACT/PA/2013PA-00183-R00HB-06527-PA.htm.

products derived from cows treated with recombinant Bovine Growth Hormone (rBGH) on the ground that the law's only basis was "consumer curiosity."[5] This Article explains that *International Dairy Foods Ass'n v. Amestoy* is significantly distinguishable and should not control a court's analysis of a labeling law for genetically engineered foods. It also explains how Second Circuit law has developed favorably in applying a rational basis-type test to disclosure requirements. Next, the Article discusses why a state genetically engineered labeling-law would not be preempted by federal legislation, and why the law would meet either of the potential tests under the Dormant Commerce Clause. This article does not attempt a factual analysis of a particular proposed labeling bill or legislative record, but it does provide a synopsis of, and references to, scientific materials that identify and explain concerns with genetically engineered foods. It also provides recaps of the rules associated with each legal test discussed—the First Amendment, preemption, and the Dormant Commerce Clause. These recaps can serve as snapshot roadmaps for states or labeling advocates seeking to craft strong GE labeling laws.

Utilizing the constitutional tests depicted here, States can develop and support labeling bills that should withstand the inevitable litigation and seemingly limitless resources of industry opponents.[6] As we explain, there is a valid, supportable basis in the law for these labeling requirements. Further, they reflect the necessary underpinnings of a free and open society. As the United States Supreme Court proclaimed in the first decisive commercial-speech case:

> 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.[7]

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5. *See* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73–74 (2d. Cir. 1996) (citing Riley v. Nat'l Fed'n of the Blind of N.C., 487 U.S. 781, 797–98 (1988)) (holding "consumer curiosity alone" was an insufficient state interest to justify labeling requirement).

6. *See, e.g.*, Tom Philpott, *Could Prop. 37 Kill Monsanto's GM Seeds?*, MOTHER JONES (Oct. 10, 2012), http://www.motherjones.com/environment/2012/10/california-prop-37-monsanto-gmo-labeling (discussing proposed California legislation requiring the labeling of food containing genetically modified ingredients); *Monsanto Threatens to Sue the Entire State of Vermont*, RT USA (Apr. 11, 2012, 8:16 PM), http://rt.com/usa/monsanto-sue-gmo-vermont-478/ (discussing proposed Vermont legislation requiring the labeling of food containing genetically modified ingredients). Also note that the Center for Food Safety has developed a well-analyzed model bill for states.

7. Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 765, 772–73 (1976) (striking down state restriction on advertisement of commercial drug prices).

And, as Thomas Jefferson reflected almost two-hundred years earlier:

> Whenever the people are well informed, they can be trusted with their own government; that whenever things get so far wrong as to attract their notice, they may be relied on to set them to rights.[8]

I. GENETICALLY ENGINEERED FOODS: WHAT THEY ARE AND WHY THEY CAUSE CONCERN

A "genetically engineered" (GE) food is one that has been produced through an alteration of genetic material that would not occur in nature.[9] This can happen through methods involving *in vitro* recombinant DNA technology and direct injection into cells, or hybridization or fusion across taxonomic borders in ways that would not occur through natural hybridization or multiplication.[10] The most common GE foods on the market today derive from corn, soybeans, sugar beets, canola, papayas, and cotton, with an estimated 70% or more of processed foods being derived from genetic engineering.[11]

Over the years, the production and consumption of GE foods have posed a host of concerns to scientists, consumers, environmentalists, farmers, social-justice advocates, and others.[12] On the public-health front, scientists and researchers from within the Food and Drug Administration (FDA) and elsewhere have written comments, conducted studies, and generally warned against the uncertainty regarding health impacts of GE foods—especially given that no safety testing is required for these foods.[13]

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8. Letter from Thomas Jefferson to Richard Price (Jan. 8, 1789), *available at* http://memory.loc.gov/ammem/collections/jefferson_papers/mtjquote.html.

9. *See, e.g.*, H.112, 2013–2014 Leg. Sess. (Vt. 2013) (defining "genetic engineering" as a process by which food is produced involving techniques that overcome natural barriers); *see also* FOOD & AGRIC. ORG. OF THE U.S., PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY 1, 1 (2003) (defining the term "Modern Biotechnology"), *available at* http://www.fao.org/fileadmin/user_upload/gmfp/resources/CXG_044e.pdf.

10. H.112, 2013–2014 Leg. Sess. (Vt. 2013); FOOD & AGRIC. ORG. OF THE U.S., *supra* note 9.

11. About GMOs, CENTER FOR FOOD SAFETY, http://gefoodlabels.org/about/ (last visited Nov. 30, 2013); Vermont Right to Know GMOs, FAQs, http://www.vpirg.org/gmo/faq/ (last visited Nov. 30, 2013).

12. *See generally Our Health: GMOs and Allergies, Irritable Bowls, and Birth Defects*, GREEN AM., April/May 2012, at 14 (discussing the health effects of GMO foods); *Open Letter from World Scientists to All Governments Concerning Genetically Modified Organisms (GMOs)*, INSTITUTE OF SCI. SOC'Y, http://www.i-sis.org.uk/list.php (last visited Nov. 30, 2013).

13. *See, e.g.*, Memorandum from Michael Hansen, Ph.D, Senior Scientist Consumer Reports, to Am. Med. Ass'n Council on Sci. & Pub. Health, Reasons for Labeling of Genetically Engineered Foods 3–4 (Mar. 19, 2012) *available at* http://www.cga.ct.gov/kid/ docs/022813/Tara%20Cook-Littman,%20Fairfield%20CT%20(Attachment)%20(5).pdf (discussing the lack of safety assessment requirements for GE foods in the U.S. and the mitigation of possible deleterious effects by labeling

Studies have shown health effects related to increased allergenicity, damage to vital organ systems, compromised immune responses and metabolic functioning, intestinal damage, and infertility.[14] In addition to these demonstrated risks of harm, GE foods also pose risks related to unintended consequences arising from the imprecise process of genetic manipulation.[15] On the environmental and farming front, impacts include increased herbicide use and "superweeds," transgenic contamination that threatens seed diversity and organic agriculture, loss of soil fertility, and loss of biodiversity.[16] On the social-justice front, suicide rates of farmers struggling to survive in Maharashtra, India continue to rise with "Monsanto's stranglehold on the Indian market."[17] Costly GE seeds, increased needs for water and fertilizer for GE cotton, and compromised GE crops are likely contributors.[18] In Argentina, indigenous communities surrounded by large, aerially sprayed monoculture soybean fields are grappling with birth defects.[19] Against this backdrop of concern, the public has called for labeling.[20]

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foods derived through genetic engineering); Arpad Pusztai, *Can Science Give Us the Tools for Recognizing Possible Health Risks of GM Food?*, 16 NUTRITION AND HEALTH 73, 73 (2002).

14. *See, e.g.*, *Genetically Modified Foods Position Paper*, AM. ACAD. OF ENVTL. MED. (May 8, 2009), http://www.aaemonline.org/gmopost.html (discussing animal studies that indicate a variety of health risks associated with GM food consumption); MICHAEL ANTONIOU ET AL., EARTH OPEN SOURCE GMO MYTHS AND TRUTHS: AN EVIDENCE-BASED EXAMINATION OF THE CLAIMS MADE FOR THE SAFETY AND EFFICACY OF GENETICALLY MODIFIED CROPS 37–63 (June 2012) (providing an in-depth analysis of studies showing that GM foods can be toxic or allergenic), *available at* http://earthopensource.org/index.php/reports/58; Artemis Dona & Ioannis S. Arvanitoyannis, *Health Risks of Genetically Modified Foods*, 49 CRITICAL REVIEWS IN FOOD SCIENCE & NUTRITION 164, 164 (2009).

15. *See, e.g.*, Memorandum from Michael Hansen, *supra* note 13, at 4–5.

16. *See, e.g.*, MARGARET MELLON & JANE RISSLER, UNION OF CONCERNED SCIENTISTS, GONE TO SEED: TRANSGENIC CONTAMINANTS IN THE TRADITIONAL SEED SUPPLY, 1–3 (2004) (summarizing study that found transgenic contamination of traditional seeds and implications for organic agriculture); MICHAEL ANTONIOU ET AL., GM SOY: SUSTAINABLE? RESPONSIBLE?, 13–21 (Sept. 2010) (summarizing scientific evidence regarding negative environmental impacts of GM soy); ANTONIOU ET AL., GMO MYTHS AND TRUTHS, *supra* note 14, at 70–99 (discussing the impacts of GM crops on farms and the environment).

17. Tracy Fernandez Rysavy, *Our World: Bitter Seeds: The Human Toll of GMOs*, GREEN AM., April/May 2012, at 17.

18. *Id.*

19. Rysavy, *supra* note 17, at 15.

20. *See, e.g.*, Thomson Reuters, *National Survey of Healthcare Consumers: Genetically Engineered Food* (Oct. 2010), http://www.justlabelit.org/wp-content/uploads/2011/09/NPR_report_GeneticEngineeredFood-1.pdf (64% unsure of safety and 93% calling for labeling); *Omnibus Poll of GMO Opinions*, YouGov (Mar. 1, 2013), http://big.assets.huffingtonpost.com/toplinesbgmo304.pdf (only 21% think safe to eat, only 8% think good for environment, 82% think GE foods should be labeled).

II. THE FIRST AMENDMENT

A. Background: Labels as Commercial Speech Protected under the First Amendment

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.[21] 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.[22] The Court rejected the argument that "unwitting customers" would somehow be harmed by the disclosure of drug prices.[23] It called this approach "highly paternalistic" and noted that persons would "perceive their own best interests only if they [we]re well enough informed."[24] The Court concluded that the best way to achieve this goal was to "open the channels of communication rather than to close them."[25]

The Court also identified some characteristics of commercial 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."[26] 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."[27] Still later, the Court listed other relevant factors that would indicate when speech is "commercial": the speech is intended as an advertisement, the speech references a specific product, and there is an economic motivation behind the speech.[28] However, the Court also noted that "each of [these] characteristics . . . [need not] necessarily be present in order for speech to be commercial."[29]

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21. Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 761–70 (1976).

22. *Id.* at 763–65, 770.

23. *Id.* at 769–70.

24. *Id.* at 770.

25. *Id.*

26. *Id.* at 762 (quoting Pittsburgh Press Co. v. Human Relations Comm'n, 413 U.S. 376, 385 (1973); Roth v. United States 354 U.S. 476, 484 (1957)) (internal quotation marks omitted).

27. Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 455–56 (1978) (internal quotation marks omitted) (citing Va. State Bd. Of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 761 (1976)).

28. Bolger v. Youngs Drug Prod. Corp., 463 U.S. 60, 66–67 (1983) (treating mass advertising mailings by drug company to public as commercial speech).

29. *Id.* at 67 n.14.

In a 1985 case, the Court opined that the "precise bounds of the category of expression that may be termed commercial speech" were subject to doubt.[30] 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."[31]

Second Circuit cases have also treated product labels and the like as "commercial speech."[32] Additionally, the court has explained that "speech does not cease to be commercial merely because it alludes to a matter of public debate."[33] Cases that have held that particular disclosure requirements implicated more than commercial speech and therefore deserved more protection under the First Amendment are distinguishable. For example, in one such case, the Supreme Court held that New

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30. Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 637 (1985) (noting that "advertising pure and simple" would qualify).

31. Rubin v. Coors Brewing Co., 514 U.S. 476, 481 (1995).

32. *See* Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 113 (2d Cir. 2001) (treating labeling of products containing mercury as commercial speech after industry conceded to that characterization); N.Y. Rest. Ass'n v. N.Y. City Bd. of Health, 556 F.3d 114, 131 (2d Cir. 2009) (stating that disclosure of calorie information in connection with "a proposed commercial transaction—the sale of a restaurant meal" is clearly commercial speech (quoting N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health (NYSRA II), No. 08-cv-1000, 2008 WL 1752455, at *1, 6 (S.D.N.Y. Apr. 16, 2008))); Bad Frog Brewery, Inc. v. N.Y. Liquor Auth., 134 F.3d 87, 97 (2d Cir. 1998) (treating beer labels as commercial speech). 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 by* 92 F.3d 67 (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." *Id.* (citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 562 n.5 (1980)). On review, the Second Circuit declined to decide the issue. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 72 (2d Cir. 1996) ("We need not address the controversy concerning the nature of the speech in question—commercial or political—because we find that Vermont fails to meet the less stringent constitutional requirements applicable to compelled commercial speech.").

33. Conn. Bar Ass'n v. United States, 620 F.3d 81, 93–94 (2d Cir. 2010) (citing Supreme Court cases); *see also Bad Frog Brewery, Inc.*, 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.

Id. (citations omitted) (alteration in original) (quoting *Cent. Hudson*, 447 U.S. at 563 n.2) (citing Bd. of Trs. of State Univ. of N.Y. v. Fox, 492 U.S. 469, 474 (1989)).

Hampshire could not require citizens to display the state motto, "Live Free or Die," on license plates, as it was an ideological message that some citizens found morally and religiously repugnant.[34] In another case, the court found that a state statute requiring a newspaper to give equal space to political candidates to respond to attacks infringed on the newspapers' editorial judgment and violated the First Amendment.[35] In a third case, the Court stated, "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."[36]

In upholding a disclosure requirement for attorney advertising, the Court in *Zauderer v. Office of Disciplinary Counsel* 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."[37]

Given these characteristics of commercial speech, the Supreme Court has developed two tests for evaluating commercial speech regulation under the First Amendment, each of them less stringent than a typical heightened-scrutiny test. For restrictions on commercial speech, where that speech is not misleading and does not refer to unlawful activity, the Court generally applies an intermediate-type scrutiny and evaluates the restriction under the four-part test introduced in *Central Hudson Gas & Electric Corp. v. Public Service Commission*.[38] For factual disclosure requirements, the Court generally applies a lesser standard of review and evaluates the requirement under *Zauderer*'s rational basis-type standard.[39] As later discussed, the Second Circuit deviated from this general framework in the 1996

34. Wooley v. Maynard, 430 U.S. 705, 706–07, 715, 717 (1977).

35. Miami Herald Publ'g Co. v. Tornillo, 418 U.S. 241, 243, 258 (1974).

36. W. Va. State Bd. of Educ. v. Barnette, 319 U.S. 624, 642 (1943).

37. Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985) (quoting *Barnette*, 319 U.S. at 642).

38. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980).

39. *See Zauderer*, 471 U.S. at 651 ("[A]n advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers.").

International Dairy case, but that case is of limited precedential value.[40] The tests and their implications for GE labeling bills are presented in full below.

B. The Central Hudson *Test*

For reasons explained below, the *Central Hudson* test should not apply to a GE disclosure requirement. However, this Article discusses the test because there is some possibility that a court might utilize it when evaluating a GE labeling law.[41]

1. 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 First Amendment scrutiny.[42] The Court held that it could not and, in so doing, established the foundational test for determining whether restrictions on commercial speech are constitutional.[43]

New York's Public Service Commission had issued an order prohibiting electric utilities in the state from all promotional advertising.[44] The order was based on a concern that there would be insufficient fuel-stocks to meet customer demand one winter.[45] After the fuel shortage had eased, the Commission extended the promotional-advertising prohibition through a policy statement.[46] The policy statement divided advertising into two categories: "promotional" and "institutional and informational."[47] 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.[48] Central Hudson challenged the prohibition in state court, losing at all three levels.[49] Appeal to the United States Supreme Court ensued.

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40. *See* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 72–74 (2d. Cir. 1996) (applying the *Central Hudson* test and holding Vermont failed to meet the second prong, "namely that its interest is substantial").

41. *See, e.g.*, *id.*

42. *Cent. Hudson*, 447 U.S. at 557–58.

43. *Id.* at 571–72.

44. *Id.* at 558.

45. *Id.* at 559.

46. *Id.*

47. *Id.*

48. *Id.* at 559–60.

49. *Id.* at 560–61.

The Court began its analysis by detailing the evolution of commercial speech's protection under the First Amendment.[50] The Court identified "commercial speech" as "expression related solely to the economic interests of the speaker and its audience."[51] 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."[52] Further, protecting commercial speech helps to "open the channels of communication rather than to close them."[53] It helps to foster the "informational function of advertising."[54] This reasoning is in full accord with the "original" commercial speech decision, which explained that "the free flow of commercial information is indispensable."[55] The dissemination of information—even through advertising—helps to ensure that private economic decisions will be "intelligent and well informed."[56] In other words, the primary basis for protecting commercial speech is to promote the flow of information and communication.

The *Central Hudson* Court then described its test for determining whether New York's prohibition was constitutional.[57] First, the Court determines whether the commercial speech is protected in the first instance.[58] To be protected, it "must concern lawful activity and not be misleading."[59] Second, the government "must assert a substantial interest to be achieved by restrictions on commercial speech."[60] Third, the regulation must "directly advance[] the governmental interest."[61] Finally, the regulation must not be "more extensive than is necessary to serve that interest."[62]

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50. *Id.* at 561–64.

51. *Id.* at 561 (citing Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 762 (1976); Bates v. State Bar of Ariz., 433 U. S. 350, 363–64 (1977); Friedman v. Rogers, 440 U.S. 1, 11 (1979)).

52. *Cent. Hudson*, 447 U.S. at 561–63.

53. *Id.* at 563 (quoting Va. State Bd. Of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976)).

54. *Id.* at 563 (citing First Nat'l Bank of Boston v. Bellotti, 435 U. S. 765, 783 (1978)).

55. *Va. State Bd. of Pharmacy*, 425 U.S. at 765.

56. *Id.*

57. *Cent. Hudson*, 447 U.S. at 564–66.

58. *Id.* at 566.

59. *Id.*

60. *Id.* at 564.

61. *Id.* at 566.

62. *Id.*

i. *Central Hudson* First Prong: Is the Speech Protected?

The Court found that the first prong was met.[63] New York had not argued either that promotional advertising was misleading or that it related to unlawful activity.[64] 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.[65] Thus, any advertising would be useless.[66] 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."[67]

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."[68] It continued, "The 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.[69]

In *Friedman v. Rogers*, the Court upheld a Texas ban on the use of trade names in optometry practices.[70] It reasoned that when there is a "significant possibility" that speech will "mislead the public," the government may properly ban it.[71] 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

63. *Id.* at 568.

64. *Id.* at 566.

65. *See id.* ("Because appellant holds a monopoly over the sale of electricity in its service area, the state court suggested that the Commission's order restricts no commercial speech of any worth.").

66. *Id.* at 566–67.

67. *Id.* at 567.

68. *Id.* at 563.

69. *Id.* (citing Friedman v. Rogers, 440 U.S. 1, 12–13 (1979); Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 464–65 (1978)).

70. *Friedman*, 440 U.S. at 15–16.

71. *Id.* at 13.

> significant possibility that trade names will be used to mislead the public.[72]

The Court noted that "the possibilities for deception [we]re 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.[73] Texas's law would correct this and still allow optometrists to freely convey factual information to the public, including information about services and prices.[74] 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."[75]

In *Ohralik v. Ohio State Bar Ass'n*, the Court considered whether Ohio could properly discipline an attorney for in-person solicitation of accident victims.[76] 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.[77] In addition, the Court specifically held that proof of "actual injury" was not required.[78] Rather, it is "[t]he State's perception of the potential for harm" that controls, as long as that perception is "well-founded."[79]

In contrast, the Court has found this prong met where the speech in question involved factual statements of information or accurate, illustrative depictions.[80] The Court has also found this prong met where the speech in

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72. *Id.* at 12–13 (footnote omitted).

73. *Id.* at 13.

74. *Id.* at 16.

75. *Id.*

76. Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 449 (1978).

77. *Id.* at 464–67.

78. *Id.* at 465–66 ("[U]nder . . . 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)).

79. *See id.* at 464–65 (describing reasons that concern was well-founded).

80. *See* Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 639–41, 647–49 (1985) (stating that the information about and depiction of Dalkon Shield in attorney advertisement was 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) (finding "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); Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376, 13,389 (April 18, 1986) (in response to comments that required "irradiation" label could be misleading, stating that "any confusion created by the presence of a retail label requirement can be corrected by proper consumer education programs"); Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 769–70

question was only "potentially misleading."[81] 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."[82] However, the Court struck down the particular regulation at issue in that case because there was "no finding" that the restricted speech was misleading.[83] Because the restricted speech was only "potentially misleading," the regulation was subject to the remaining three prongs of the *Central Hudson* test.[84] 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.[85]

Summary Guidance

These cases hold that speech which is inherently misleading, or which has indeed misled, is not entitled to protection.[86] They are relevant because they provide guidelines from which to counter the potential industry argument that a GE label is itself misleading. (And, the argument would go, if the label is misleading and not entitled to protection, the State cannot

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(1976) (rejecting State's argument that disclosure of drug prices would somehow harm "unwitting customers" and calling approach "highly paternalistic").

81. *See In re* R.M.J., 455 U.S. 191, 203 (1982) ("[T]he States may not place an absolute prohibition on certain types of potentially misleading information.").

82. *Id.* at 202. "[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." *Id.* at 203.

83. *Id.* at 206.

84. *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.

Id. (emphasis in original).

85. *See* Bad Frog Brewery, Inc. v. N.Y. Liquor Auth., 134 F.3d 87, 98 (2d Cir. 1998) ("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.'" (quoting Brief for Defendants-Appellees at 24, Bad Frog Brewery, Inc., 134 F.3d 87 (2d Cir. 1998) (No. 97-7949), 1997 WL 34602673, at *24)).

86. *In re* R.M.J., 455 U.S. at 202.

require the label in the first instance.) The cases instruct that labels with "numerous" possibilities for deception and "no intrinsic meaning" can be misleading.[87] In contrast, factual statements such as "rBGH free" are *not* misleading. Further, "potentially" misleading speech is not "misleading," and it is entitled to protection.[88]

ii. *Central Hudson* Second Prong: Is the State's Interest Substantial?

For the second prong, the *Central Hudson* Court easily found that each of New York's asserted interests were "substantial."[89] The Court noted that "no one can doubt the importance of energy conservation."[90] It also found that the State's concern for "fair and efficient" rates was "a clear and substantial governmental interest."[91]

Other cases show that a wide variety of governmental interests qualify as "substantial." In a 1995 case, the Supreme Court held that the United States had a substantial "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."[92] In an earlier case, the Court held that New York had substantial interests in promoting an educational, rather than commercial, atmosphere on college campuses; in promoting security and safety; in preventing commercial exploitation of the student body; and in preserving tranquility in campus residences.[93] The District of Connecticut recently held that the government's interest in "preventing consumer confusion" and "protecting public health" was sufficient to justify a disclaimer requirement on green-tea products making health claims.[94] The outlier Second Circuit

87. *See* Friedman v. Rogers, 440 U.S. 1, 12 (1979) (holding that trade names have "no intrinsic meaning" and therefore may mislead the public); *cf. In re* R.M.J., 455 U.S. at 203–04 (discussing various ways in which an advertisement can be misleading).

88. These cases may also be relevant in states that enact restrictions on use of the term "natural" alongside the disclosure requirements for GE foods—*e.g.*, as Vermont and Connecticut are attempting to do. H.112, 2013–2014 Leg. Sess. (Vt. 2013)); H.B. 6519, Gen. Assemb., Jan. Sess. (Conn. 2013), *available at* http://www.cga.ct.gov/2013/FC/pdf/2013HB-06519-R000576-FC.pdf. They can be used to support the point that use of the term "natural" on GE foods is misleading, and therefore not entitled to any First Amendment protection.

89. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 568 (1980).

90. *Id.*

91. *Id.* at 569.

92. Rubin v. Coors Brewing Co., 514 U.S. 476, 485 (1995).

93. Bd. of Trs. of State Univ. of N.Y. v. Fox, 492 U.S. 469, 475 (1989).

94. Fleminger, Inc. v. U.S. Dep't of Health & Human Servs., 854 F. Supp. 2d 192, 209 (D. Conn. 2012).

case—in which the court held that Vermont's interest in a hormone-labeling requirement was not substantial—is explained in Part II.C below.[95]

Summary Guidance

These cases show that a variety of state interests qualify as "substantial." Not surprisingly, they encompass traditional state powers such as "protecting the health, safety, and welfare" of citizens, preventing alcoholism and its social costs, promoting education, increasing energy conservation, and preventing consumer confusion. Therefore, if a disclosure requirement were subject to the *Central Hudson* test, it would survive this prong if it sufficiently demonstrated similar interests. However, as explained in the *International Dairy* section below, the law could not be based on mere "consumer curiosity" under Second Circuit law.

iii. *Central Hudson* Third Prong: Does the Restriction Directly Advance the State's Interest?

For the third prong, the *Central Hudson* 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.[96] In contrast, the link between the Commission's rate structure and the advertising ban was "tenuous," "highly speculative," and "conditional and remote."[97] Thus, the ban did not "directly advance" the State's 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.[98] For example, in a 2011 Second Circuit case, the court ruled that a Vermont restriction on the transmission of prescriber information to pharmaceutical companies was "not drawn to serve" the State's asserted interest of protecting physician privacy because the information could still be transmitted to other audiences.[99] Also under

95. *See* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73–74 (2d Cir. 1996) (citing Riley v. Nat'l Fed'n of the Blind, 487 U.S. 781, 797–98 (1988)) (holding "consumer curiosity alone" was an insufficient state interest to justify labeling requirement).

96. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 569 (1980).

97. *Id.*

98. Rubin v. Coors Brewing Co., 514 U.S. 476, 489, 491 (1995) (stating 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").

99. Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2668 (2011).

this prong, the harms must be real, and the restriction must "alleviate them to a material degree."[100] Sometimes, "accumulated, common-sense judgments" may be enough.[101]

Summary Guidance

These cases provide that a disclosure requirement subject to *Central Hudson* would need to have an "immediate connection" with the interest it is designed to serve, such that it advances that interest in a "direct and material" way.[102] Credible evidence should support the link—studies, anecdotes, something more than conclusory statements.[103] Further, the "harms" in need of alleviation must be "real," and the disclosure should correct them to a "material degree."[104]

iv. *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.[105] The Court noted that there may be other types of promotional advertising that would not increase net energy consumption (for example, energy-saving tools).[106] The Court also noted that the State had not shown how a more limited restriction would not adequately advance the State's interest.[107] 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]

100. Edenfield v. Fane, 507 U.S. 761, 770–71 (1993) (citing Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 648–49 (1985); Bolger v. Youngs Drug Prods. Corp. 463 U.S. 60, 73 (1983); *In re* R.M.J., 455 U.S. 191, 205–06 (1982)) (holding 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).

101. Metromedia, Inc. v. City of San Diego, 453 U.S. 490, 509 (1981) (upholding San Diego's ban on certain advertising signs and stating: "We likewise 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)).

102. *Edenfield*, 507 U.S. at 767 (citing Bd. of Trs. of State Univ. of N.Y. v. Fox, 492 U.S. 469, 480 (1989)); Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 569 (1980)).

103. *Edenfield*, 507 U.S. at 771 (holding government did not meet burden of justifying restriction on speech when "only suggestion" that ban might advance governmental interest was "series of conclusory statements").

104. *Id.* (citing *Zauderer*, 471 U.S. at 648–49; *Bolger*, 463 U.S. at 73; *In re* R.M.J., 455 U.S. at 205–06).

105. *Cent. Hudson*, 477 U.S. at 571–72.

106. *Id.* at 570.

107. *Id.*

regulation" would be ineffective, the State's prohibition did not survive the fourth prong of the test.[108]

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.[109] In *Lorillard Tobacco Co. v. Reilly,* the Court held that Massachusetts' ban on outdoor advertising for smokeless tobacco and cigars failed this prong for many reasons.[110] The State had banned such advertising within 1,000 feet of schools or playgrounds.[111] The Court did not believe the State had considered the impact of this restriction on major metropolitan areas, finding that "[t]he uniformly broad sweep of the geographical limitation demonstrate[d] a lack of tailoring."[112] The Court also found "the range of communications restricted," including oral communications and signs of any size, "unduly broad."[113] Further, the Court found that some retailers and manufacturers could face "onerous burdens"—for example, because of small advertising budgets or an inability for convenience stores to attract passersby.[114] 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."[115]

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."[116] For instance, in the *Rubin v. Coors Brewing* case, the Court noted that limiting the alcohol content of beers, among other options, could help to prevent alcohol strength wars without limiting speech.[117] The Court has also held that a blanket prohibition on all attorney-advertising information regarding specific legal problems was not "narrowly crafted" and the State should have come up

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108. *Id.* at 570–71.

109. *E.g.*, Greater New Orleans Broad. Ass'n, Inc. v. United States, 527 U.S. 173, 188 (1999); Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 561–62 (2001) (quoting Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 417 (1993)).

110. *See Lorillard Tobacco Co.*, 533 U.S. at 562–67 (describing the burden on communication between tobacco companies and consumers imposed by the law's restriction on advertising).

111. *Id.* at 528.

112. *Id.* at 562–63.

113. *Id.* at 563.

114. *Id.* at 564–65.

115. *Id.* at 565.

116. Rubin v. Coors Brewing Co., 514 U.S. 476, 491 (1995).

117. *Id.*

with other means to restrain the misleading advertising.[118] This case also held that the State's blanket ban on illustrations in attorney advertising was over-extensive, that the State had not shown why it was not, and that concerns about misleading illustrations could be better addressed on a case-by-case basis.[119] In a recent case, the Court held that where a State disagreed with the viewpoint of pharmaceutical companies regarding the propriety of influencing prescriber decisions with mined data, the State should have expressed that view through its own speech rather than by indirectly restricting the flow of "truthful information" to physicians.[120]

However, the government need not pursue the least restrictive alternative. The Court has noted that "almost all of the restrictions disallowed under *Central Hudson*'s fourth prong have been substantially excessive," and has required "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.'"[121] Where the

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118. Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 643–45 (1985).

119. *Id.* at 648–49.

120. Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2670–71 (2011) (quoting Thompson v. W. States Med. Ctr., 535 U.S. 357, 374 (2002)).

121. Bd. of Trs. of State Univ. of N.Y. v. Fox, 492 U.S. 469, 479–80 (1989) (quoting Shapero v. Ky. Bar Ass'n., 486 U.S. 466, 476 (1988)); *In re* R.M.J. 455 U.S. 191, 206 (1982); *see also* Fleminger, Inc. v. U.S. Dep't of Health & Human Servs., 854 F. Supp. 2d 192, 196–97 (D. Conn. 2012) (explaining that 2011 case, *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011), did not alter this traditional interpretation of the test). 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. Fleminger v. IMS Health, Inc., 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 Info. Servs., Inc., 903 F. Supp. 2d 303, 308 (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.

Id. (citations omitted) (citing Sorrell v. IMS Health, Inc., 131 S. Ct. 2653, 2664 (2011)); NSK Corp. v. United States, 821 F. Supp. 2d 1349, 1356 (Ct. Int'l Trade 2012) (rejecting argument that *IMS Health* altered *Central Hudson* First Amendment test); Standard Furniture Mfg. Co. v. United States, 823 F. Supp. 2d 1327, 1342 (Ct. Int'l Trade 2012) ("We reject plaintiff's argument that [*IMS Health*] requires

government's belief is reasonable, it should receive some deference.[122] However, the deference is not absolute and broad regulations on truthful, non-misleading advertising are disfavored.[123]

Summary Guidance

To survive the fourth prong of *Central Hudson,* a State should show that a more limited regulation would not suffice to serve its interests and that the regulation does not infringe on additional protected speech. However, current case law indicates that the State need not adopt the least restrictive alternative, and that the State will receive some deference regarding the reasonableness of the fit between the regulation and the State's goal.[124] The State should also consider the costs and benefits of the regulation, including the benefits of the regulated speech.

2. 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 from cows treated with recombinant bovine growth hormone (rBGH).[125] 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.[126]

Vermont had passed a law stating, "If [recombinant bovine somatotropin] rBST has 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."[127] Multiple industry groups filed suit to challenge the

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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. Friendly House v. Whiting, 846 F. Supp. 2d 1053, 1059–60 (D. Ariz. 2012) (quoting Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2667–68 (2011)). Thus any "heightened scrutiny" would not apply to a State's disclosure requirement (which is not a content-based ban on commercial speech).

122. *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)).

123. 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 510 (1996).

124. *Clear Channel Outdoor, Inc.*, 594 F.3d at 111.

125. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 72–73 (2d Cir. 1996).

126. *Id.* at 69, 74.

127. *Id.* at 69 (quoting Vt. Stat. Ann. tit. 6, § 2754(c) (Supp. 1994)).

statute.[128] They claimed, among other things, that the labeling requirement was "not purely commercial because it compel[led] them to convey a message regarding the significance of [rBGH] use that is expressly contrary to their views."[129] 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."[130] Later Second Circuit precedent makes clear that the relative significance of information does not act to make it any less "commercial" or "factual."[131] 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;[132] later cases (discussed below) explicitly limit *International 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.[133] In deciding this, the court relied "only upon those interests set forth by Vermont before the district court."[134] 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' . . . ."[135]

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 *Vermont adopted no such rationales for its statute*. Rather, Vermont's sole expressed interest was, indeed,

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128. *Id.* at 69–70.

129. *Id.* at 71 (quoting Brief for Plaintiffs-Appellants at 21, Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996) (No. 95-7819), 1995 WL 17049817) (internal quotation marks omitted).

130. *Id.* at 72.

131. *See* N.Y. Rest. Ass'n v. N.Y. City Bd. of Health, 556 F.3d 114, 134 (2d Cir. 2009) (analyzing calorie disclosure requirement as "commercial" and finding it "factual" despite plaintiff's position that it did not want to prioritize such information); *see also* cases cited *supra* note 32.

132. 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*, 92 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. Brief for Defendants-Appellees at 30, Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996) (No. 95-7819), 1995 WL 17049818 (arguing *Central Hudson* test applies).

133. *Int'l Dairy*, 92 F.3d at 73–74.

134. *Id.* at 73 ("[T]he *Central Hudson* standard does not permit us to supplant the precise interests put forward by the State with other suppositions." (quoting Edenfield v. Fane, 507 U.S. 761, 766–67 (1993))).

135. *Id.* (quoting Int'l Dairy Foods Ass'n v. Amestoy, 898 F. Supp. 246, 249 (D. Vt. 1995)).

> "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." *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.*[136]

The Court therefore adopted the district court's factual finding that only "consumer curiosity" was at stake.[137]

In contrast, the dissent argued that the district court had recognized several other interests.[138] 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.[139] The State had also offered survey evidence and comments by Vermont citizens with similar concerns.[140] The dissent explained that the district court found most Vermonters did not want to purchase rBGH 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.[141]

Based on these concerns, the district court had found that "Vermont ha[d] a substantial interest in informing consumers of the use of [rBGH] in the production of milk and dairy products sold in the State."[142]

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136. *Id.* at 73 n.1 (emphases added) (citations omitted) (quoting *Int'l Dairy*, 898 F. Supp. at 252).

137. *Id.* at 73–74.

138. *Id.* at 75–76 (Leval, J., dissenting).

139. *Id.* at 75.

140. *See id.* (discussing citizens' comments expressing concern about the safety of rBGH for humans and cows and its potential negative impact on small dairy farmers).

141. *Id.* at 75–76 (quoting Int'l Dairy Foods Ass'n v. Amestoy, 898 F. Supp. 246, 250 (D. Vt. 1995)).

142. *Id.* at 76 (quoting *Int'l Dairy*, 898 F. Supp. at 254).

The dissent attempted to discount the district court's statements along these lines, arguing that the State's interest was broader than consumer information.[143] It stated:

> 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."[144]

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.[145] *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."[146] 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].'"[147] Further, it was "undisputed that neither consumers nor scientists can distinguish [rBGH]-derived milk from milk produced by an untreated cow."[148]

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

143. *Id.*

144. *Id.* at 76 & n.2.

145. *See id.* at 73 n.1, 75–76 (quoting *Int'l Dairy*, 898 F. Supp. at 250) (discussing District Court's findings of reasons why Vermonters did not want to purchase milk products derived from cows treated with rBGH and State's interest behind statute).

146. *Id.* at 73 (internal quotation marks omitted) (citing Edenfield v. Fane, 507 U.S. 761, 770–71 (1993)).

147. *Id.* (quoting *Int'l Dairy*, 898 F. Supp. at 248).

148. *Id.* (citing *Int'l Dairy*, 898 F. Supp. at 248–49).

> 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.[149]

In sum, the court's holding rests on the fact that the district court had identified "consumer curiosity" as the *State's* sole interest in the disclosure requirement.[150] And, in order to justify another type of interest—for example, 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.[151] The court's holding does 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.[152] 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.[153]

i. Differences Between the rBGH Case and GE Labeling

This section draws from the factors set forth in *International Dairy* to provide a brief summary of some of the factual differences that exist between the regulatory and scientific frameworks regarding rBGH and genetically engineered foods. It 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.[154] The FDA has already voiced "human safety or health concerns associated with food products derived from [genetic engineering]."[155] And, "scientists can distinguish [genetically engineered foods] from [foods] produced [without genetic engineering]."[156] GE labeling is therefore already readily

149. *Id.* at 73–74 (citing Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, 512 U.S. 136, 145–46 (1994); Riley v. Nat'l Fed'n of the Blind, 487 U.S. 781, 797–98 (1988)).

150. *Id.* at 74 (citing Riley v. Nat'l Fed'n of the Blind, 487 U.S. 781, 797–98 (1988)).

151. *See id.* at 73 ("It is thus plain that Vermont could not justify the statute on the basis of 'real' harms.") (quoting Edenfield v. Fane, 507 U.S. 761, 770–71(1993)).

152. *See id.* (concluding Vermont's only justification for statute was "'strong consumer interest and the public's right to know'" (quoting *Int'l Dairy*, 898 F. Supp. at 249)).

153. *See id.* (holding only that Vermont failed to establish that "its interest" in labeling requirement was "substantial").

154. *Id.*

155. *Id.*

156. *Id.*

distinguishable from *International Dairy*, and one would expect any GE-labeling bill to reflect these considerations.

a. 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."[157] The record for state GE labeling laws would be far different from the record before the court in *International Dairy.* Since the publication of the FDA's GE draft policy statement over twenty years ago, see Part III.A *infra*, numerous studies have been conducted showing that there are demonstrated health risks associated with consuming genetically engineered food products, and scientists have voiced concerns about unintended consequences common to all GE foods.[158]

b. FDA Treatment of Genetically Engineered Foods

The FDA's actions concerning genetically engineered foods differ greatly from the Agency's actions concerning rBGH in milk products.[159] On November 12, 1993, the FDA approved by final rule a new animal drug application (NADA) for the use of Posilac® (sterile sometribove zinc suspension), a Monsanto rDNA-derived drug, in lactating dairy cows to increase the production of marketable milk.[160] 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."[161] 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 draft policy statement that it would regulate genetically engineered foods within the existing regulatory framework—because genetically engineered foods were "substantially

157. *Id.*

158. *See, e.g.*, sources cited *supra* notes 13–15.

159. 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.

160. Animal Drugs, Feeds, and Related Products, 58 Fed. Reg. 59,946, 59,946 (Nov. 12, 1993) (to be codified at 21 C.F.R. pts. 510 & 522).

161. Interim Guidance on Milk Labeling, 59 Fed. Reg. 6279, 6279–80 (issued Feb. 10, 1994).

similar" to their traditional counterparts—the FDA voiced numerous health and safety risks.[162] 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.[163] Unlike the FDA's rBGH "thorough review," the FDA has neither performed nor evaluated thorough testing on genetically engineered foods.[164] Instead, the FDA accepts a manufacturer's determination that its products are generally recognized as safe (GRAS) based on the producer's own studies and "encourages informal consultation."[165] 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.

c. 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.[166] 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."[167] *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."[168]

In contrast, food products can be tested to determine whether they were produced with genetic engineering.[169] Testing for genetically engineered foods "confirms the identity and nature of the product at every step along

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162. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984–88 (issued May 29, 1992).

163. *Id.* at 22,987–88.

164. *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.").

165. *See id.* at 22,990 (explaining that manufacturers are responsible for conducting safety studies).

166. *See Testing Options*, GMO TESTING, http://www.gmotesting.com/Testing-Options.aspx (last visited Nov. 30, 2013) [hereinafter *Testing Options*] (discussing GMO food testing methods and tests).

167. Interim Guidance on Milk Labeling, 59 Fed. Reg. 6,279, 6,280 (Feb. 10, 1994).

168. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73 (2d Cir. 1996) (citing Int'l Dairy Foods Ass'n v. Amestoy, 898 F. Supp. 246, 248–49 (D. Vt. 1995)).

169. GMO TESTING, http://www.gmotesting.com/ (last visited Nov. 30, 2013).

the supply chain."[170] There are at least two methods and three tests for testing for genetic engineering in a food product.[171] The methods include genetic analysis (DNA analysis) and immunological analysis (protein analysis).[172] The three tests are a polymerase chain-reaction (PCR) test, a lateral flow device or dipstick test (strip test), and an enzyme-linked immunosorbent assay (ELISA test).[173]

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 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.

ii. Vermont's Offerings on the Interest Factor in *International Dairy*[174]

This section attempts to show how the State presented its case in *International Dairy* and why the Second Circuit found only "consumer curiosity" was at stake for the State. 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,

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170. *Id.*

171. *Testing Options*, *supra* note 166.

172. *Id.*

173. *Id.*

174. 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 Foods Ass'n v. Amestoy, 898 F. Supp. 246, 248 (D. Vt. 1995). 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. Brief for Defendants-Appellees at 8, 10–12, 14, Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 2009) (No. 95-7819).

it does not appear that the State had actually adopted those concerns as its own or provided scientific evidence regarding the concerns.

a. State's Briefing

- 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]."[175]
- "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."[176]
- "The court below had *ample evidence before it to support its findings that consumers are concerned* that [rBGH] 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."[177]
- "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."[178]

b. District Court Decision

- "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."[179]
- "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."[180]

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175. Brief for Defendants-Appellees, *supra* note 174, at 6 (emphasis added).
176. *Id.* at 7 (emphasis added).
177. *Id.* at 7–8 (emphasis added).
178. *Id.* at 35.
179. *Int'l Dairy,* 898 F. Supp. at 249 (emphasis added).
180. *Id.* (emphasis added).

- "The State believes that this labeling system will *communicate accurate product information to consumers and reduce uncertainty* regarding the use and effect of rBST."[181]
- "The State's surveys show that *Vermont consumers have a high awareness of issues* surrounding the use of rBST and a*re in favor of the type of labeling* required by the 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."[182]
- "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."[183]

3. The *Central Hudson* Test Should Not Apply to the Disclosure Requirement

The *Central Hudson* test is not the proper standard under which to analyze a GE disclosure requirement. Cases following *International Dairy* expressly limited its application to situations where the state could provide no greater interest than "consumer curiosity."[184] In 2001, the court said: "Although we applied the *Central Hudson* test in [*International Dairy*] . . . 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.'"[185] In 2009, the court again distinguished *International Dairy* and applied *Zauderer* to New York City's

181. *Id.* at 250 (emphasis added).
182. *Id.* (emphasis added).
183. *Id.* at 254 (emphasis added).
184. Conn. Bar Ass'n v. United States, 620 F.3d 81, 96 n.16 (2d Cir. 2010) (applying *Zauderer* to disclosure requirements and limiting *International Dairy*).
185. Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 n.6 (2d Cir. 2001) (citing Int'l Dairy Food Ass'n v. Amestoy, 92 F.3d 67, 73 (2d. Cir. 1996)).

requirement that certain restaurants post calorie information on their menus.[186]

In *National Electric Manufacturers Ass'n v. Sorrell*, the issue was the constitutionality of a Vermont requirement that some products have labels to inform consumers that the products contained mercury and should therefore be disposed of as hazardous waste.[187] Following *International 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."[188] 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.'"[189] 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."[190] 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."[191] 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."[192]

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 caloric information on some restaurant menus.[193] Discussing *National Electric Manufacturers*, the court stated: "In light of *Zauderer*, this Circuit thus held that rules 'mandating that commercial

186. N.Y. Rest. Ass'n v. N.Y. City Bd. of Health, 556 F.3d 114, 134 (2d Cir. 2009); *see also* Conn. Bar Ass'n v. United States, 620 F.3d 81, 96 n.16 (2d Cir. 2010) (applying *Zauderer* to disclosure requirements and limiting *Int'l Dairy*).

187. *Nat'l Elec. Mfrs. Ass'n*, 272 F.3d at 107–08.

188. *Id.* at 113, 115 (emphasis added).

189. *Id.* at 113 (quoting Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985)).

190. *Id.* at 113–14.

191. *Id.* at 114.

192. *Id.* at 115 (citing *Zauderer*, 471 U.S. at 651).

193. N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health, 556 F.3d 114, 131–34 (2d Cir. 2009).

actors disclose commercial information' are subject to the rational-basis test."[194] The court further held that *International Dairy* was "inapplicable" because it was "'expressly limited'" to cases where consumer curiosity was the lone state interest.[195] In contrast, in *New York State Restaurant Ass'n v. New York City Board of Health*, New York had an interest in preventing obesity. The court stated:

> [Plaintiff's] claim that this case is more akin to [*International Dairy*], clearly fails. In [*National Electric Manufacturers*], we explained that our decision in [*International 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 . . . [*International Dairy*] is inapplicable.[196]

Therefore, because states would have an interest greater than "consumer curiosity" in GE disclosure requirements, the *Central Hudson* test would not apply.[197]

4. Readers' Guide to the *Central Hudson* Test

This section gives a distillation of the most important factors under each of *Central Hudson*'s prongs, discussed in full above. A state could meet these factors for a GE disclosure requirement in order to ensure that

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194. *Id.* at 132 (quoting *Nat'l Elec. Mfrs. Ass'n*, 272 F.3d at 114–15).

195. *Id.* at 134 (quoting *Nat'l Elec. Mfrs.*, 272 F.3d at 115 n.6).

196. *Id.* (citations omitted) (internal quotation marks omitted) (quoting *Nat'l Elec. Mfrs.*, 272 F.3d at 115 n.6).

197. 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. *See* Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376, 13,388 (April 18, 1986) (to be codified at 21 C.F.R. pt. 179) ("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."). 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 v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 764 (1976) (arguing that society has a "strong interest in the free flow of commercial information"). A similar concept could also be applied to fulfill one of the legitimate state interests under *Zauderer*: the prevention of consumer deception. *See* Irradiation in the Production, Processing, and Handling of Food, 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 supra* Part II.C.1. The point would be that labels for genetically engineered food products without GE disclosures are both misleading and potentially deceptive.

the requirement would survive constitutional challenge. However, a state should not *need* to meet these factors because a disclosure requirement that was not based solely on consumer curiosity would be subject to the *Zauderer* test (discussed in Part II.C *infra*), not the *Central Hudson* test.[198]

i. 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 satisfied.[199]
- Factual statements of information or accurate illustrative depictions are not misleading.[200]
  - Speech with numerous possibilities to deceive is misleading.[201]
  - 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 (for example, 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.[202]
- Speech is misleading if it is "inherently misleading" or the record indicates that it is misleading.[203]
- Fact that other, factual speech would not be restricted lends support to restriction on misleading speech because factual speech would more effectively convey information.[204]

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198. *See* Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985) (requiring only that disclosure requirements be reasonably related to the State's interest in preventing deception of customers).

199. *See* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566–67 (stating prong met where New York had not claimed electric utility advertising was misleading or referred to unlawful activity).

200. *See Zauderer*, 471 U.S. at 639–41, 647–49 (stating that the information about and depiction of Dalkon Shield in attorney advertisement was factually accurate and thus not misleading).

201. Friedman v. Rogers, 440 U.S. 1, 12–13 (1979).

202. *See* Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 464–67 (1978) (holding State's "well founded" "perception of the potential for harm" was sufficient and State did not need to prove actual injury to survive Constitutional inquiry).

203. *In re* R.M.J., 455 U.S. 191, 202 (1982).

204. *See Friedman*, 440 U.S. at 16 (holding optometry practices still allowed to convey practical information about prices, services, etc. to public).

ii. Second Prong: State Must Have Substantial Interest

- Consumer curiosity ("public's right to know" and "consumer concern") is not a substantial interest under *International Dairy*.[205]
  - Consumer's concerns about human health and safety, bovine health, and economics of surplus milk were not adopted by State.[206]
  - State asserted, as *its* interest, providing information to concerned consumers.[207]
  - State interest should be based on a "reasonable concern" about "human health or safety or some other sufficiently substantial governmental concern."[208]
- There must be evidence (for example, scientific evidence) of real harms.[209]
  - Should be some evidence that thing to be disclosed on label has some impact on product (as opposed to "no" evidence and no "impact at all," especially where FDA has concluded otherwise).[210]
  - Consumers or scientists should be able to distinguish product with labeled process from product without labeled process.[211]
- Examples of substantial interests:
  - Energy conservation.[212]
  - Health, safety, welfare (for example, alcoholism and social costs).[213]
  - Promoting educational, rather than commercial, atmosphere on college campuses; promoting security and safety; preventing

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205. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73–74 (2d Cir. 1996) (citing Riley v. Nat'l Fed'n of the Blind, 487 U.S. 781, 797–98 (1988)).

206. *Id.* at 73 & n.1 (quoting Int'l Dairy Foods Ass'n v. Amestoy, 898 F. Supp. 246, 249 (D. Vt. 1995)).

207. *Id.* at 73; Brief for Defendants-Appellees, *supra* note 174 at 6; *Int'l Dairy*, 898 F. Supp. at 249–50, 254 (D. Vt. 1995).

208. *Int'l Dairy*, 92 F.3d at 74.

209. *See id.* at 73 (citing Edenfield v. Fane, 507 U.S. 761, 770–71 (1993) (finding labeling statute unconstitutional because State could not justify "on the basis of 'real' harms").

210. *Id.*

211. *Id.* at 73.

212. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 568 (1980).

213. Rubin v. Coors Brewing Co., 514 U.S. 476, 485 (1995).

commercial exploitation of student body; and preserving tranquility in campus residences.[214]

- Preventing consumer confusion; protecting public health (for example, through disclaimer requirement on green tea health claim).[215]

iii. 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.[216]
  - Link between alcohol content labeling restriction and reduction in strength wars not direct and material.[217]
  - Link between order prohibiting promotional advertising by utilities and State's interest in fair rate structure too tenuous.[218]
  - 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.[219]
- 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."[220]

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214. Bd. of Trs. of State Univ. of N.Y. v. Fox, 492 U.S. 469, 475 (1989).

215. Fleminger, Inc. v. U.S. Dep't of Health & Human Servs., 854 F. Supp. 2d 192, 209 (D. Conn. 2012).

216. *Cent. Hudson*, 447 U.S. at 569.

217. *Rubin*, 514 U.S. at 487, 489.

218. *Cent. Hudson*, 447 U.S. at 569.

219. Sorrel v. IMS Health Inc., 131 S. Ct. 2653, 2668 (2011).

220. *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.[221]

- "Accumulated, common-sense judgments" may be enough.[222]
  - 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."[223]

iv. 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).[224]
- 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 in part because State did not look at more limited regulation.[225]
  - Regulation on alcohol content labeling failed this prong because limiting alcohol content of beers, among other options, could help to prevent alcohol-strength wars without limiting speech.[226]
  - 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.[227]
  - State's blanket ban on illustrations in attorney advertising was over-extensive, State had not shown why it was not, and concerns about

221. Edenfield v. Fane, 507 U.S. 761, 771 (1993).

222. *See* Metromedia, Inc., v. City of San Diego, 453 U.S. 490, 509 (1981) (deferring to the legislature's finding that billboards presented a hazard to traffic safety).

223. *Id.*

224. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 570 (1980).

225. *Id.*

226. Rubin v. Coors Brewing Co., 514 U.S. 476, 491 (1995).

227. Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 643–45 (1985).

misleading illustrations could be better addressed on a case-by-case basis.[228]

- 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.[229]

- But State does not need to pursue least restrictive alternative.[230] Fit need only be reasonable and in proportion to interest served.[231]
  - Reasonable government belief should receive some deference.[232]
  - Deference not absolute where legislature suppresses nonmisleading, truthful information for paternalistic purposes.[233]
- State must carefully consider costs and benefits of regulation.[234]
  - State should consider geographic scope, range of communications restricted, and whether regulated entities would face onerous burdens.[235]
    - Ban on outdoor tobacco advertising near schools covered too much space in major metropolitan areas.[236]
    - Ban on outdoor tobacco advertising covered too many types of speech—oral communications, signs of any size.[237]
    - Ban on outdoor tobacco advertising too onerous for those of limited means or convenience stores with difficulty attracting passersby.[238]

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228. *Id.* at 648–49.

229. Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2670–71 (2011) (quoting Thompson v. W. States Med. Ctr., 535 U.S. 357, 374 (2002)).

230. Bd. of Trs. of State Univ. of N.Y. v. Fox, 492 U.S. 469, 480 (1989) (quoting *In re* R.M.J. 455 U.S. 191, 206 (1982)).

231. *Id.*

232. Clear Channel Outdoor, Inc. v. City of New York, 594 F.3d 94, 104–05 (2d Cir. 2010).

233. 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 507, 510 (1996).

234. Greater New Orleans Broad. Ass'n, Inc. v. United States, 527 U.S. 173, 188 (1999) (quoting Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 417 (1993)).

235. Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 561–67 (2001).

236. *Id.* at 528.

237. *Id.* at 563.

238. *Id.* 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.[239]

C. The Zauderer *Test*

1. 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.[240] The Court upheld Ohio's disclosure requirement regarding contingent fees, but struck down two restrictions limiting attorney advertising.[241]

An Ohio attorney had published a newspaper advertisement soliciting female clients who had been harmed by their use of the "Dalkon Shield Intrauterine Device."[242] The advertisement included a drawing of the Shield and information about the ills associated with its use.[243] It noted that there may still be time to file suit, and that the attorney's firm was already managing such cases.[244] 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. [245]

Ohio's Office of Disciplinary Counsel filed a complaint against the attorney alleging violations of various Disciplinary Rules, and an appeal to the United States Supreme Court ultimately ensued.[246] The 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.'"[247] As mentioned above, the Court did

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239. *Id.* at 565.

240. Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 629 (1985).

241. *Id.* at 646–47, 650, 653.

242. *Id.* at 630.

243. *Id.* at 630–31.

244. *Id.* at 631.

245. *Id.*

246. 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 (addressing appellant's argument that he was denied procedural due process in discipline of drunken driving advertisement).

247. *Id.* at 637 (citing Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60 (1983); *In re* R.M.J., 455 U.S. 191 (1982); Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557 (1980)).

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.[248] Also, speech "proposing a commercial transaction" would qualify.[249]

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."[250] It drew the restrictions 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.[251] The Court would follow a modified test for disclosure requirements.[252]

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.[253] It found that neither was narrowly tailored under *Central Hudson.*[254] (The Court's reasoning on this factor is captured above in Part II.B.1.iv *supra*)

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*.[255] 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."[256] 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.[257] In contrast, the required speech in this case was "factual and uncontroversial."[258]

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248. *Id.*

249. *See id.* (quoting Ohralik v. Ohio State Bar Ass'n., 436 U.S. 447, 455–56 (1978)) (distinguishing speech proposing a commercial transaction from other varieties of speech).

250. *Id.* at 638.

251. *Id.* (citing *Cent. Hudson*, 447 U.S. at 566).

252. *Id.* at 650–53.

253. *Id.* at 639–49.

254. *Id.* at 644, 646 (citing *Cent. Hudson*, 447 U.S. at 565, 569–71).

255. *See id.* at 650–51.

256. *Id.* at 650.

257. *Id.* at 650–51 (citing W. Va. State Bd. of Educ. v. Barnette, 319 U.S. 624, 642 (1943)).

258. *Id.* at 651.

In fact, drawing upon the basis for extending First Amendment protections to commercial speech in the first instance, 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.[259]

In a long footnote, the Court explained why disclosure requirements should not be subject to the "least restrictive means" test.[260] It again made reference to the "substantially weaker" First Amendment interests at stake where disclosure requirements—as opposed to outright suppression—were concerned.[261] 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."[262]

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.[263] Ultimately, the Court concluded that the contingent-fee disclosure requirement "easily passe[d] muster" under the new standard.[264] It was "commonplace that members of the public [were] often unaware of the technical meanings of such terms as 'fees' and 'costs.'"[265] Therefore, the State's belief that an advertisement mentioning

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259. *Id.* at 651 (citation omitted) (citing Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748 (1976)); *see also Va. State Bd. of Pharmacy*, 425 U.S. at 757 ("[T]his Court has referred to a First Amendment right to receive information and ideas, and that freedom of speech necessarily protects the right to receive." (internal quotation marks omitted) (quoting Kleindienst v. Mandel, 408 U.S. 753, 762–63 (1972))).

260. *Zauderer*, 471 U.S. at 651 n.14.

261. *Id.*

262. *Id.* at 251–52 n.14 (citations omitted).

263. *Id.* at 651; *see also* Disc. 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.'" (emphasis in original) (quoting Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 641 (6th Cir. 2010))).

264. *Id.* at 652.

265. *Id.*

contingent-fees, without a specific disclosure about other costs, would be deceptive was "self-evident" and "reasonable enough" to support the disclosure requirement.[266]

2. Evolution of the Test

Since *Zauderer* was decided, the Second Circuit has applied its rational-basis test to disclosure requirements based on a variety of state interests—such as human health and the environment—and has not limited its reach to laws aimed at preventing consumer deception.[267] The First and Sixth Circuits have also endorsed this approach.[268]

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266. *Id.* at 652–53.

267. *See* Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001) (upholding mercury labeling law aimed at increasing consumer awareness and reducing pollution); N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114, 133 (2d Cir. 2009). 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, 81 (2d Cir. 2010). Following a recent Supreme Court decision that decided several of the same issues, 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, 559 U.S. 229, 249 (2010)). However, the court was very clear in noting that its "own earlier precedent would have pointed [it] to that conclusion" and described the *Zauderer* test as applying to "'compelled commercial disclosure cases.'" *Id.* at 96 (quoting and citing Nat'l Elec. Mfrs. Ass'n, 272 F.3d at 115 (2d Cir. 2001)). The court did not hold that "preventing consumer deception" was a prerequisite to applying *Zauderer,* and it did not overrule *National Electric Manufacturers* or *New York State Restaurant Ass'n. Id.* 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 *National Electric Manufacturers* regulation as one designed to "'better inform consumers,'" the "better inform" piece is not unimportant under the *Zauderer* standard. *Id.* at 96 (quoting and citing *Nat'l Elec. Mfrs.*, 272 F.3d at 115). A recent D.C. Circuit case suggested 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 Co. v. FDA, 696 F.3d 1205, 1212–16 (D.C. Cir. 2012) (quoting Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985)) (applying *Central Hudson* to requirement that cigarette packaging contain graphic warning labels). However, 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 (stating that *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 the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376, 13,389 (April 18, 1986) (finding that "the irradiation of food is a material fact that must be disclosed to the consumer to prevent deception"). 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 States could meet.

268. Pharm. 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

i. *National Electric Manufacturers*

In *National Electric Manufacturers,* 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."[269] The court also noted the close link between the State's overall goal and the necessary intermediary goal of increasing consumer awareness.[270] 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."[271]

The court decided that a "reasonable relationship [was] plain" in the instant case.[272] The labeling would likely reduce mercury pollution by encouraging changes in consumer behavior.[273] 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."[274]

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.[275]

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no cases limiting *Zauderer* in such a way.") (citation omitted); *Tobacco City*, 674 F.3d at 556 ("[*National Electric Manufacturers*] 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.").

269. *Nat'l Elec. Mfrs.*, 272 F.3d at 115.

270. *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.").

271. *Id.* (quoting *Zauderer*, 471 U.S. at 651).

272. *Id.*

273. *Id.*; *see also Tobacco City*, 674 F.3d at 557 ("[*National Electric Manufacturers*] 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.").

274. *Nat'l Elec. Mfrs.*, 272 F.3d at 115–16.

275. *Id.* at 116.

ii. *New York State Restaurant Ass'n*

In *New York State Restaurant Ass'n*, the Second Circuit followed its reasoning in *National Electric Manufacturers* to uphold New York City's calorie-disclosure requirements as "reasonably related" to the City's interest in preventing obesity among its residents.[276] In doing so, the court refuted three of the Restaurant Association's primary arguments, two of which are relevant to the present analysis.[277] First, the Association claimed that a 2001 Supreme Court case, *United States v. United Foods, Inc*., had limited the rational-basis *Zauderer* test to situations where the state's interest was in preventing consumer deception.[278] The court found, instead, that *United Foods* simply distinguished *Zauderer*, and did "not provide that all other disclosure requirements [those not aimed at preventing consumer deception] are subject to heightened scrutiny."[279] The Second Circuit noted that "this distinction [was not] lost on us in [*National Electric Manufacturers*], when we held that *Zauderer*'s holding was broad enough to encompass nonmisleading disclosure requirements."[280]

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.[281] The court reiterated that the rational-basis test applies to laws that compel the disclosure of "'factual and uncontroversial' information by commercial entities."[282] It characterized the "question [it] must answer" as one of whether the disclosure requirements were "simply requirements of purely factual disclosures."[283] It found that the calorie disclosure requirements fell within that category; Plaintiff did not contend that the disclosure of calorie information was not "factual."[284] Rather, the Association argued that member restaurants did not want to prioritize

276. *N.Y. State Rest. Ass'n*, 556 F.3d at 136.

277. *Id.* at 132–34.

278. *Id.* at 132 (citing United States v. United Foods, Inc., 533 U.S. 405, 416 (2001)).

279. *Id.* at 133 (citing *United Foods*, 533 U.S. at 416). 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. *United Foods*, 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 non-misleading for consumers.").

280. *N.Y. State Rest. Ass'n*, 556 F.3d at 133 (citing Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001)).

281. *Id.* at 132–34.

282. *Id.* at 134 (quoting *Nat'l Elec. Mfrs.*, 272 F.3d at 115) (citing Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 637 (1985).

283. *Id.* (internal quotation marks omitted) (quoting Entm't Software Ass'n v. Blagojevich, 469 F.3d 641, 652 (7th Cir. 2006)).

284. *Id.*

calorie information among other nutrition information.[285] The Court found this unpersuasive, noting that the "First Amendment [did] not bar the City from compelling such 'under-inclusive' factual disclosures."[286] Thus, it is the accuracy of the disclosed information that must be "uncontroversial," not its significance.[287]

When the court applied 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."[288] The "Notice of Adoption" that accompanied the regulation 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."[289] The "Notice of Adoption" also identified numerous studies and made multiple findings.[290] 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) foods from chain restaurants are associated with weight gain and excess calorie consumption; 4) consumers make unhealthy food choices based on distorted perceptions about calorie amounts; 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.[291] On this last point, the City 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.[292] The court specifically stated that this

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285. *Id.*

286. *Id.* (citing *Zauderer*, 471 U.S. at 651 n.14).

287. *Compare* Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 555 (6th Cir. 2012) ("*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.'" (quoting *Zauderer*, 471 U.S. at 650)), *with Entm't Software*, 469 F.3d at 651–52 (discussing *National Electric Manufacturers* 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").

288. *N.Y. State Rest. Ass'n*, 556 F.3d at 134.

289. *Id.*

290. *Id.*

291. *Id.* at 134–35 (citing *Notice of Adoption of a Resolution to Repeal and Reenact § 81.50 of the New York City Health Code* (Jan. 22, 2008)).

292. *Id.* at 135.

type of information was not necessary for the City to survive the rational-basis test.[293]

3. Summary Guidance

The *Zauderer* Court established that a company's interest in *not* disclosing factual information is "minimal."[294] It explained at length why disclosure requirements should be subject to less scrutiny than other commercial speech requirements.[295] Following that reasoning, the Second Circuit has a line of cases applying *Zauderer* to factual disclosure requirements, whether those requirements are aimed at preventing consumer deception or protecting human health and the environment.[296] A "factual" disclosure requirement is one that provides accurate factual information, whether or not parties agree on the information's significance.[297] Therefore, when presented with a GE disclosure law, the Second Circuit would in all likelihood rely upon this precedent to evaluate the law under *Zauderer*'s rational-basis test. In that circumstance, a state law would need to put forward legitimate interests—such as preventing consumer deception and protecting human health—and the labeling requirement would need to be "reasonably related" to achieving those interests.[298] States may draw guidance from the decisions discussed above in supporting their interests—for example, by articulating supported findings as New York did in its "Notice of Adoption" for the calorie disclosure requirement. Once an interest is found, the court may rely upon a "common-sense" analysis to determine that labeling causes changes in human behavior, and is therefore reasonably related to the interest.[299]

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293. *Id.* at 134 n.23 (quoting Lewis v. Thompson, 252 F.3d 567, 582 (2d Cir. 2001)). The Second Circuit similarly noted in a later case that "'evidence or empirical data'" are not necessary to "demonstrate the rationality of mandated disclosures in the commercial context." Conn. Bar Ass'n v. United States, 620 F.3d 81, 97–98 (2010) (quoting *N.Y. State Rest. Ass'n*, 556 F.3d at 134 n.23).

294. Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985).

295. *Id*. at 650–51.

296. *See supra* note 267 (discussing Second Circuit cases finding the *Zauderer* test applicable).

297. *See Zauderer*, 471 U.S. at 639–41, 647–49 (determining that the information about the product in attorney advertisement was accurate and entitled to protection).

298. There may be some uncertainty regarding whether the Supreme Court would apply *Zauderer* to disclosure requirements not aimed at preventing deception. *See supra* note 267. However, given the strong line of reasoning in favor of lessened scrutiny for factual disclosure requirements, this would be an odd result. *See, e.g.*, *Zauderer*, 471 U.S. at 650–53 (discussing the rationale for applying a lower level of scrutiny); Milavetz, Gallop & Milavetz, P.C. v. United States, 559 U.S. 229, 230 (2010) (applying reduced scrutiny to disclosure requirements). In any case, if the state law is properly aimed at preventing consumer deception among other interests, *Zauderer* would apply.

299. *See* Metromedia, Inc. v. City of San Diego, 453 U.S. 490, 509 (1981) (deferring to the legislature's "common-sense" judgment that billboards present a hazard to traffic safety).

4. Readers' Guide to the *Zauderer* Test

This section distills 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 should apply to a state GE disclosure requirement.

i. First Factor: Disclosed Information Is Factual and Uncontroversial

- Disclosure of factual, uncontroversial information supports First Amendment principles protecting the flow of information.[300] Therefore, a company's protected interest in *not* disclosing such information is minimal.[301]
- Calorie information is "factual" information, even though parties disputed the significance of that information.[302]
  - "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."[303]

ii. Second Factor: State Must Have Legitimate Interest

- Preventing deception of consumers is a legitimate interest.[304]
- Protecting human health and the environment from mercury poisoning is a legitimate interest.[305]
  - Later case described this regulation as better informing consumers.[306]
- Preventing obesity is a legitimate interest.[307] State coupled this interest with the additional interest of preventing consumer deception.[308]

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300. *Zauderer*, 471 U.S. at 646.
301. *Id.* at 651.
302. N.Y. Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114, 134 (2d Cir. 2009).
303. Entm't Software Ass'n v. Blagojevich, 469 F.3d 641, 651–52 (7th Cir. 2006).
304. *Zauderer*, 471 U.S. at 651.
305. Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001).
306. Conn. Bar Ass'n v. United States, 620 F.3d 81, 96 (2d Cir. 2010) (quoting *Nat'l Elec. Mfrs.*, 272 F.3d at 115).
307. N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114, 134 (2d Cir. 2009).
308. *Id.*

iii. Third Factor: Requirement Must Be Reasonably Related to State Interest

- Requirement is not subject to the least restrictive means test.[309]
- Requirement need not address all facets of the problem at once.[310]
  - Irrelevant that mercury labeling would probably be insufficient to eliminate most mercury pollution in state.[311]
- 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 the problem was reasonable.[312]
- Reasonableness was "plain" because labeling would encourage changes in consumer behavior, therefore likely reducing mercury pollution.[313]
- Reasonable relationship was "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.[314]
  - City provided study showing that vast majority of surveyed did not notice voluntary efforts.[315]
  - City noted that leading health authorities recommended calorie disclosure at point of purchase.[316]
  - But this type of evidence is not necessary to show reasonable relationship.[317]

III. PREEMPTION

A. 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

309. *Zauderer*, 471 U.S. at 651 n.14.
310. *Id.*
311. *Nat'l Elec. Mfrs.*, 272 F.3d at 115.
312. *Zauderer*, 471 U.S. at 652–53.
313. *Nat'l Elec. Mfrs.*, 272 F.3d at 115.
314. N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114, 134–35 (2d Cir. 2009).
315. *Id.* at 135.
316. *Id.*
317. *Id.* at 134 n.23 (quoting Lewis v. Thompson, 252 F.3d 567, 582 (2d Cir. 2001)).

methods."[318] 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.[319]

The Food and Drug Administration (FDA) regulates the labeling of foods under the Federal Food, Drug, and Cosmetic Act (FDCA).[320] The FDCA prohibits the misbranding of food.[321] 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.[322] 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.[323] The NLEA sought "to clarify and to 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 foods."[324] 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."[325]

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

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318. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, GUIDE TO U.S. REGULATION OF GENETICALLY MODIFIED FOOD AND AGRICULTURAL BIOTECHNOLOGY PRODUCTS 1 (Sept. 2001) [hereinafter PEW INITIATIVE], *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_0901.pdf (footnote omitted); *see also* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302–03 (June 26, 1986) (concluding that existing health and safety laws would sufficiently ensure the safety of biotechnology research and products).

319. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302–03.

320. *See generally* 21 C.F.R. ch. 1 (2013) (detailing labeling and other requirements under the Federal Food, Drug and Cosmetic Act).

321. 21 U.S.C. § 331(b) (1938); *see also* N. Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114, 118 (2d Cir. 2009).

322. 21 U.S.C. §§ 334, 341, 346 (2006); Holk v. Snapple Beverage Corp., 575 F.3d 329, 331 (3d Cir. 2009).

323. Nutrition Labeling and Education Act of 1990, 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).

324. *N.Y. State Rest. Ass'n,* 556 F.3d at 118 (internal quotation marks omitted) (quoting H.R. Rep. No. 101-538, at 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337).

325. Ackerman v. Coca Cola Co., No. CV-09-0395 (JG)(RML), 2010 WL 2925955, at *3 (E.D.N.Y. July 21, 2010).

Framework).[326] The policy was "based on the assumption that the process of biotechnology itself posed no unique or special risks," and therefore biotechnology products could be regulated under existing federal statutes.[327] 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.[328]

In 1992, the FDA published a draft policy statement regarding food derived from genetically modified plants.[329] The draft policy defined "genetic modification" as "the alteration of the genotype of a plant using any technique, new or traditional."[330] In the 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."[331] 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.[332] Additionally, 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."[333] Regarding labeling, the FDA stated that it was not currently aware of any "material" information about GE foods that would require the agency to mandate labels.[334]

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326. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,303 (June 26, 1986).

327. PEW INITIATIVE, *supra* note 318.

328. *Id.*; *see also* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,304 (outlining the jurisdiction of approval over commercial biotechnology products, determined by their use).

329. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984 (May 29, 1992).

330. *Id.* at 22,984 n.3.

331. PEW INITIATIVE, *supra* note 318, at 20; Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,984.

332. PEW INITIATIVE, *supra* note 318, at 20; Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,990.

333. PEW INITIATIVE, *supra* note 318, at 21; Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,993.

334. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,991. This Article does not discuss this policy in its preemption analysis. It is not entitled to preemptive effect. *See, e.g.,* Holk v. Snapple Beverage Corp., 575 F.3d 329, 340–42 (3d Cir. 2009) (stating 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'") (citing Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237, 243–45 (3d Cir. 2008)). Similarly, the FDA's 1992 draft policy was not the result of a "formal, deliberative process" and was issued pre-comment. Also, the 1992 draft does not fall under any of the "express preemption" provisions of the Act. *See infra* Part III.B.1. For the same reasons, the FDA's 2001 notice of a "draft guidance" for voluntary GE labeling is not preemptive.

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.[335] Both proposals were published in the Federal Register and open for public comment.[336] However, no final rules were issued and no regulations were adopted.

B. 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."[337] 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.[338] Congressional intent to preempt state law may be seen in a statute's "express language" or through its "structure and purpose."[339] Federal law may preempt state law in three circumstances: when there is (1) express preemption, (2) field preemption, or (3) conflict preemption.[340] Under express preemption, Congress explicitly states in a statute that federal law preempts state law.[341] 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.[342]

In addition, state law may be preempted when compliance with both state and federal law is physically impossible.[343] As the Supreme Court has explained, "The nature of the power exerted by Congress, the object sought to be obtained, and the character of the obligations imposed by the law are

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335. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4,706, 4,708 (Jan. 18, 2001); Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4,839 (Jan. 18, 2001).

336. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4,706, 4,708 (Jan. 18, 2001); Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4,839 (Jan. 18, 2001).

337. U.S. CONST. art. VI, § 2.

338. Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 211 (1824).

339. Altria Group, Inc. v. Good, 555 U.S. 70, 76 (2008) (citing Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977)).

340. *See* Hillsborough Cnty Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947); Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963)) (citing Jones v. Rath Packing Co., 420 U.S. 519,525 (1977); Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)) (detailing the three ways federal law can preempt state law).

341. *Hillsborough*, 471 U.S. at 713.

342. *Id.*

343. *Id.*

all important in considering the question of whether supreme federal enactments preclude enforcement of state laws on the same subject."[344]

1. No Express Preemption

Under express preemption, Congress may withdraw specified powers from states by enacting laws with express preemption provisions.[345] Simply because the federal statute contains an express preemption clause, however, does not mean that the state law is automatically preempted; "The question of the substance and scope of Congress' displacement of state law still remains."[346] When a federal statute contains an express preemption provision, a presumption against preemption exists, requiring courts to read the clause narrowly.[347] Additionally, "[i]n 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.'"[348]

The FDCA, as amended by the NLEA, contains an express preemption provision, 21 U.S.C. § 343-1.[349] Because the NLEA contains an express preemption provision, the court must first focus on the plain meaning of the clause to determine what exactly is preempted.[350] The preemption provision in the NLEA contains three provisions which courts typically apply to state labeling laws.[351]

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344. Hines v. Davidowitz, 312 U.S. 52, 70 (1941) (citing Prigg v. Pennsylvania, 41 U.S. 539, 622, 623 (1842)).

345. Arizona v. United States, 132 S. Ct. 2492, 2500–01 (2012).

346. Altria Group, Inc. v. Good, 555 U.S. 70, 76–81, 87 (2008) (interpreting specific terms in express preemption provision of federal Cigarette Labeling & Advertising Act and holding they did not preempt state fraud claim).

347. *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (adhering to *Cipollone*, in which the Court declared a "'presumption against the pre-emption of state police power regulations' to support a narrow interpretation of [a preemption provision]" (quoting Cipollone v. Liggett Group, Inc., 505 U.S. 504, 518 (1992))).

348. Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005) (quoting N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995)); *see also* Holk v. Snapple Beverage Corp., 575 F.3d 329, 334 (3d Cir. 2009) ("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." (citing Plumley v. Massachusetts, 155 U.S. 461, 472 (1894))).

349. 21 U.S.C. § 343-1 (2006).

350. *See* 23-34 94th St. Grocery Corp. v. N.Y.C. Bd. of Health, 685 F.3d 174, 181 (2d Cir. 2012) (stating that "[w]hen Congress expressly codifies its preemptive intent in statutory form, our analysis begins with the language of the statute" (quoting Jones v. Vilsack, 272 F.3d 1030, 1034 (8th Cir. 2001)) (internal quotation marks omitted)).

351. *See* N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114, 118 (2d Cir. 2009) (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., 889 F. Supp. 2d 1348, 1362 (S.D. Fla. 2012) (determining that Florida's labeling standard was not preempted by the standard of identity preemption provision because there was no federal

First, § 343-1(1) of the NLEA preempts any state requirement regarding standard of identity that is not identical to the federal standard.[352] Second, § 343-1(4) preempts any state requirement for food nutrition labeling that is not identical to the federal requirements of § 343(q) (nutrition information).[353] Finally, § 343-1(5) preempts any requirement relating to nutrition levels and health claims that is not identical to those set out in § 343(r).[354] As explained below, state labeling laws would not fall under any of the three specified preemption provisions.[355]

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standard of identity for honey). 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)–(f), (h)–(k), (w), (x); *id.* § 343-1. These would not be applicable, either. For instance, state laws would not seek a label about "artificial flavoring and coloring" or the names of allergy-causing foods or food allergens, or specific ingredients, or the identification of "chemical preservatives" (which, interestingly, do not include "chemicals applied for their insecticidal or herbicidal properties"). *See* 21 U.S.C. § 343(w), (x) (requiring labels for ingredients containing allergens); 21 C.F.R. § 101.22(a)(5) (2013) (defining "chemical preservative"). Note that the draft bills in some states include specific instructions that they are not meant to regulate ingredient or common name labeling. *See, e.g.*, H.112, 2013-2014 Gen. Assemb. (Vt. 2013) (not requiring the listing of any ingredient that was genetically engineered or the term "genetically engineered" immediately preceding a common name of a food).

352. 21 U.S.C. § 343-1(a)(1).

353. *Id.* § 343-1(a)(4).

354. *Id.* § 343-1(a)(5).

355. 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 Ass'n v. Harris* would change this analysis. 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. 23-34 94th St. Grocery Corp., 685 F.3d 174, 179, 184–86 (2d Cir. 2012) (concluding that the 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 Ass'n v. Harris, 132 S. Ct. 965, 970 (2012).

> The 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.

i. Standard of Identity

The express preemption provision of the NLEA prohibits states from establishing "any requirement for a food which is the subject of a standard of identity established under section 341 of this title," which is "not identical to such standard of identity" or to the "requirement of section 343(g)."[356] Courts have interpreted this provision to mean that Congress has only prohibited standards of identity which conflict with established federal standards.[357] 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."[358] The Secretary has promulgated several standards of identity codified in 21 C.F.R. Parts 131-169.

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.[359] 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

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Id. 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 the standard of identity and nutrition. *See* 21 U.S.C. § 343-1 (addressing national uniform nutritional labeling). 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. 21 U.S.C. § 343-1. Unlike the City's regulation in the *Grocery Corp.* case and California's Penal Code provision—which did fall under federal preemptive provisions—a state labeling law would not.

356. 21 U.S.C. § 343-1(a)(1).

357. *See* Guerrero v. Target Corp., 889 F. Supp. 2d 1348, 1362 (S.D. Fla. 2012) ("[T]he only State requirements that are subject to preemption are those that are affirmatively different from the Federal requirements." (internal quotation marks omitted) (quoting Chavez v. Blue Sky Natural Beverage Co., 268 F.R.D. 365, 372 (N.D. Cal. 2010))).

358. 21 U.S.C. § 341 (2006).

359. 21 C.F.R. § 130.8 (1981).

> the leavening agents . . . . Each of the finished foods contains not less than 62 percent total solids . . . .[360]

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.

Additionally, 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.[361] 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, state laws would not be preempted by the standard of identity preemption provision.

ii. Nutrition Information

Any state requirement for nutrition food labeling that is not identical to the federal requirement of § 343(q) concerning nutrition information is preempted under the express preemption provision of the Act.[362] 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.[363] 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."[364]

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, a state labeling requirement would not fall under the jurisdiction of 343(q) and would not be preempted by the express preemption provision.

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360. *Id.* § 136.110(a).

361. *Guerrero*, 889 F. Supp. 2d at 1362.

362. 21 U.S.C. § 343-1(a)(4).

363. *Id.* § 343(q)(1); *see also* 21 C.F.R. § 101.9(c) (2013) (requiring information for vitamins and minerals).

364. 21 C.F.R. § 101.9(c).

iii. 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)."[365] Section 343(r)(1) covers nutrition-level claims and health-related claims.[366] It applies to claims that product labels make about the health benefits or nutrient content of the products.[367] "Nutrient content claims" are claims that "expressly or implicitly characterize[] the level of a nutrient . . . required to be in nutrition labeling."[368] "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."[369]

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.[370] As explained below, a state labeling law would not fall under any of these categories.

a. Express Nutrient Content Claims

An express nutrient-content claim is a direct statement about the level or range of a nutrient in a food (where "nutrient" means those nutrients that are required to be on the label).[371] An example of an express nutrient-content claim is "contains 100 calories" printed on food packages which contain 100 calories.[372] 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, a state labeling requirement would not be an express nutrient-content claim. The required label would say nothing

365. 21 U.S.C. § 343-1(a)(5).

366. *Id.* § 343(r)(1).

367. *Id.*

368. 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").

369. 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.").

370. 21 C.F.R. § 101.13(b)(1); *see also* Ackerman v. Coca Cola Co., No. CV-09-0395 (JG)(RML), 2010 WL 2925955, at *3 (E.D.N.Y. July 21, 2010) (stating that the FDA regulates three types of claims: express nutrient-content, implied nutrient-content, and health related claims).

371. 21 C.F.R. § 101.13(b)(1).

372. *Id.*

about the level of nutrients within the food product, for example, carbohydrates, sodium, or fiber.[373]

b. Implied Nutrient Content Claims

An implied nutrient-content claim "[d]escribes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (for example, 'high in oat bran')."[374] Or, it "[s]uggests 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 (for example, 'healthy, contains 3 grams (g) of fat')."[375] A State'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.

c. Health Claims

Health claims characterize the relationship between any of the nutrients in a food product and a disease- or health-related condition.[376] 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."[377] 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.[378] 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."[379] A

373. *See* 21 U.S.C. § 343(q)(1); 21 C.F.R. § 101.9(c) (listing nutrients); *see also* N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114, 127–28, 137 (2d Cir. 2009) (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).

374. 21 C.F.R. § 101.13(b)(2)(i) (as opposed to "high in *fiber*," the actual nutrient).

375. *Id.* § 101.13(b)(2)(ii).

376. *Id.* § 101.14(a)(1).

377. FDA, GUIDANCE FOR INDUSTRY: A FOOD LABELING GUIDE (8. CLAIMS) Answer H.1 (Oct. 2009), *available at* http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatory information/labelingnutrition/ucm064908.htm.

378. *Id.*; 21 C.F.R. § 101.14(e); 21 U.S.C. § 343(r)(3)(c) (2006).

379. 21 C.F.R. § 101.14(a)(1); FDA, *supra* note 377, at Answer H.4; Fleminger, Inc. v. U.S. Dep't of Health & Human Servs., 854 F. Supp. 2d 192, 195 (D. Conn. 2012).

State'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.

2. Readers' Guide to Express Preemption Rules

This section contains a distillation of the relevant express preemption factors in the FDCA. As explained above, properly drafted state legislation would not implicate any of these factors.

i. General Rules

- Under express preemption, Congress explicitly states in a statute that federal law preempts state law.[380]
- When a federal statute contains an express preemption provision, a presumption against preemption exists, requiring courts to read the clause narrowly.[381]
- The FDCA, as amended by the NLEA, contains an express preemption provision, § 343-1.[382]
- The preemption provision in the NLEA contains three provisions which courts typically apply to state labeling laws (discussed below).[383]
- Courts dismiss express preemption arguments where challenges to use of the term "natural" do not fit clearly into any of the express preemption provisions.[384]

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380. Hillsborough Cnty. Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985) (citing Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977)).

381. *See* Medtronic, Inc., v. Lohr, 518 U.S. 470, 485 (1996) (adhering to *Cipollone*, in which the Court declared a "'presumption against the pre-emption of state police power regulations' to support a narrow interpretation of [a preemption provision]" (quoting Cipollone v. Liggett Group, Inc., 505 U.S. 504, 518 (1992))).

382. 21 U.S.C. § 343-1.

383. *See* N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114, 118–20 (2d Cir. 2009) (analyzing preemption provisions and applying them to New York restaurants); Guerrero v. Target Corp., 889 F. Supp. 2d 1348, 1362 (S.D. Fla. 2010) (applying § 343-1(a)(1) preemption provision to Florida honey labeling law, but finding no conflict).

384. *See, e.g.*, Holk v. Snapple Beverage Corp., 575 F.3d 329, 336 n.3 (3d Cir. 2009) (stating high fructose corn syrup is outside NLEA's express preemption provisions because it is a sweetener and not a flavoring); Lockwood v. Conagra Foods, Inc., 597 F. Supp. 2d 1028, 1029–31 (N.D. Cal. 2009) (holding claims that defendant engaged in "misleading conduct" by advertising pasta sauce as "all natural" were not expressly preempted by NLEA's artificial flavoring provision or imitation food provision); Hitt v. Ariz. Beverage Co., No. 08CV809 WQH (PQR), 2009 WL 449190, at

ii. 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.[385]
- 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.[386]
- State law is not preempted when there is no federal standard of identity with which the state law may conflict.[387]

iii. 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.[388]
- 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.[389]

iv. 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).[390]
- 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.[391]

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*4 (S.D. Cal. Feb. 4, 2009) (ruling defendants did not reference any express preemption provision barring plaintiff's claims).

385. 21 U.S.C. § 343-1.

386. 21 C.F.R. § 130.8 (1981).

387. *See Guerrero*, 889 F. Supp. 2d at 1362 (state law not preempted because no federal standard of identity for honey).

388. 21 U.S.C. § 343-1(a)(4).

389. *Id.* § 343(q)(1); 21 C.F.R. § 101.9(c) (2013).

390. 21 U.S.C. § 343-1(a)(5).

- A nutrient-content claim is a claim that "expressly or implicitly characterizes the level of a nutrient . . . required to be in nutrition labeling."[392]
- An express nutrient-content claim is any direct statement about the level or range of a nutrient in a food (where "nutrient" means those nutrients that are required to be on the label).[393]
- An implied nutrient-content claim "[d]escribes the food or an ingredient therein in a manner that suggests that a nutrient [which is required to be on the label] is absent or present in a certain amount (for example, 'high in oat bran')."[394]
- Health claims characterize the relationship between any of the nutrients in a food product and a disease- or health-related condition.[395]

3. 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"[396] (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.[397] Because a state 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 state labeling law would not be preempted. Under the NLEA, field preemption was not the clear and manifest intention of

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391. *Id.* § 343(r)(1).

392. 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").

393. 21 C.F.R. § 101.13(b)(1).

394. *Id.* § 101.13(b), (b)(2)(i).

395. 21 C.F.R. § 101.14(a)(1); 21 U.S.C. § 343(r)(1)(B).

396. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353 (1990).

397. *See, e.g.*, Cipollone v. Liggett Group, Inc., 505 U.S. 504, 532 (1992) (Blackmun, J., concurring) (citation omitted) (citing English v. General Elec. Co., 496 U.S. 72, 79 (1990)) ("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.").

Congress as evidenced by the fact that the savings clause explicitly leaves some labeling to the states, such as safety warnings.[398] 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.[399] 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.[400] Finally, because the Act does not contain any language pertaining to "genetically engineered" 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 NLEA."[401] Additionally, in *Holk v. Snapple Beverage Corp.*, the Third Circuit determined that even if one looks beyond the language of the NLEA there is still no implied preemption.[402] 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."[403] 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.[404] Other cases have thrown out implied-preemption claims in the food labeling context on similar grounds.[405] As the

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398. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 6(c)(2), 104 Stat. 2353 (1990).

399. *See* 21 U.S.C. § 343-1 (2006) (addressing national uniform nutritional labeling).

400. *See* N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114, 130 (2d Cir. 2009) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); Hillsborough Cnty. Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 718 (1985); Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005)) (explaining that federal laws typically coexist with state regulation of health and safety matters, rather than preempt that police power).

401. Holk v. Snapple Beverage Corp., 575 F.3d 329, 337–38 (3d Cir. 2009).

402. *Id.* (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 (citing Wyeth v. Levine, 555 U.S. 555, 574–75 (2009))).

403. *Id.* at 339.

404. *Id.* at 342 ("[T]here is no conflict in this case because there is no FDA policy with which state law could conflict.").

405. *See, e.g.*, Lockwood v. Conagra Foods, 597 F. Supp. 2d 1028, 1031–34 (N.D. Cal. 2009) (holding no implied preemption under FDCA for labeling); Hitt v. Ariz. Beverage Co., No 08CV809

Supreme Court explained in *Wyeth v. Levine*: "The case for federal pre-emption 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."[406] These authorities show that a state labeling law should survive any implied preemption challenge.[407]

IV. THE DORMANT COMMERCE CLAUSE

A. Overview of Dormant Commerce Clause

The Constitution grants Congress power "[t]o regulate Commerce with foreign Nations, and among the several States."[408] 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.[409] The Supreme Court has held that this restriction does not require any prior action on the part of Congress: "Although the Commerce Clause is by its text an affirmative grant of power to Congress to regulate interstate and foreign commerce, the Clause has

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WQH (PQR), 2009 WL 449190, at *4 (S.D. Cal. Feb. 4, 2009) (same); Wright v. General Mills, Inc., No. 08cv1532, 2009 WL 3247148 L (NLS), at *2–3 (S.D. Cal. Sept. 30, 2009) (same).

406. *Wyeth*, 555 U.S. at 575 (internal quotation marks omitted) (quoting Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 166–67 (1989)).

407. 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 Co.*, 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. 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) (2006) (addressing mislabeling of fruit beverages that have a standard of identity). As explained above, this would not be the case with state labeling laws.

408. U.S. CONST. art. I, § 8, cl. 3.

409. *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.").

long been recognized as a self-executing limitation on the power of the States to enact laws imposing substantial burdens on such commerce."[410]

The Supreme Court has adopted a two-tiered approach for Dormant-Commerce-Clause analysis.[411] The first tier considers whether a law discriminates against interstate commerce.[412] If a state law "directly regulates or discriminates against interstate commerce" or has an effect that "favor[s] in-state economic interests over out-of-state interests," it will be "generally struck down . . . without further inquiry."[413] The only exception is for laws that are necessary to achieve an important government purpose, and even then the law must be the least restrictive alternative.[414] The burden to prove discrimination "rests on the party challenging the validity of the statute."[415]

The second tier is applied to nondiscriminatory laws.[416] If the "statute has only indirect effects on interstate commerce and regulates evenhandedly,"[417] then courts apply the balancing test described in *Pike v. Bruce Church, Inc.*[418] 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."[419] These regulations enjoy a presumption of constitutionality.[420]

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410. S.–Cent. Timber Dev., Inc. v. Wunnicke, 467 U.S. 82, 87 (1984) (citing Lewis v. BT Inv. Managers, Inc., 447 U.S. 27, 35 (1980); Hughes v. Oklahoma, 441 U.S. 322, 326 (1979); H. P. Hood & Sons, Inc. v. Du Mond, 336 U.S. 525, 534–538 (1949); Cooley v. Bd. of Wardens, 12 How. 299 (1852)).

411. Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 578–79 (1996).

412. *Id.* at 579.

413. *Id.*

414. *See, e.g.*, Fort Gratiot Sanitary Landfill, Inc. v. Mich. Dep't of Natural Res., 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 be met in a less discriminatory manner); Maine v. Taylor, 477 U.S. 131, 133, 151–52 (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).

415. *Hughes*, 441 U.S. at 336.

416. *Brown-Forman*, 476 U.S. at 578–79.

417. *Id.* at 579 (citing Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970)).

418. *Pike*, 397 U.S. at 142.

419. *Id.* (citing Huron Cement Co. v. Detroit, 362 U. S. 440, 443 (1960)). 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. Emp'rs, 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

B. Analysis under Dormant Commerce Clause

The threshold issue in any Dormant-Commerce-Clause analysis is whether the state law in question affects interstate commerce.[421] 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."[422] The Court in *Gibbons v. Ogden* described commerce as all phases of business, including the traffic of goods.[423] In this case, a state labeling statute would be aimed at food products, a type of good that is regularly bought and sold across state lines; these products are within the scope of interstate commerce.[424] Furthermore, courts have specifically reviewed food-labeling requirements under the Dormant Commerce Clause, including a case where in-state and out-of-state food producers were required to adhere to labeling requirements in order to sell their products within New York.[425] Similarly, a state labeling scheme would require all genetically engineered food products, including those produced out-of-state, to disclose that information on labels, and would therefore affect interstate commerce.

1. First Tier: Determining Whether State GE Labeling Legislation Would Discriminate Against Interstate Commerce

The first tier of Dormant-Commerce-Clause analysis is primarily concerned with invalidating overt protectionism: "State laws that discriminate against interstate commerce face a 'virtually *per se* rule of invalidity.'"[426] *Brown-Forman Distillers Corp. v. New York State Liquor Authority* identified two basic categories of regulations that discriminate against interstate commerce: (1) regulations that facially discriminate

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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 would apply in a state labeling analysis.

420. *See generally* Erwin Chemerinsky, CONSTITUTIONAL LAW: PRINCIPLES & POLICIES 429–39 (3d ed. 2006).

421. *See Brown–Forman*, 476 U.S. at 578–79.

422. 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).

423. Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 193–96 (1824).

424. *See* Grocery Mfrs. of Am., Inc. v. Gerace, 755 F.2d 993, 997, 1003 (2d Cir. 1985) (analyzing state labeling law "for foods shipped in interstate commerce" under Commerce Clause).

425. *See id.* at 1003–05 (reviewing a state statute requiring substitute cheese products to be labeled as "imitations").

426. Granholm v. Heald, 544 U.S 460, 473–74, 476 (2005) (quoting *Philadelphia*, 437 U.S. at 624) (holding that a Michigan law which prohibited the shipment of wine from out-of-state wineries to Michigan consumers discriminated against interstate commerce).

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.[427] Additionally, courts have consistently struck down laws aimed at "regulat[ing] conduct occurring wholly outside the state."[428]

The first category of regulations that implicate protectionism are those which facially discriminate between in-state and out-of-state interests.[429] A key factor is whether the law draws distinctions between in-state and out-of-state businesses or products.[430] If no such distinctions are found, then the law is likely facially neutral.[431]

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.[432] 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.[433] 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.[434] The same issue was considered in a Second Circuit case regarding a New York law that required the labeling of products resembling or intending to replace traditional cheese products.[435] 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.[436] Similarly, a state GE disclosure requirement 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.

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427. Brown–Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 579 (1986).

428. *See, e.g.*, U. S. Brewers Ass'n v. Healy, 692 F.2d 275, 279, 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 582 (holding that a New York price affirmation statute violated the Dormant Commerce Clause because it regulated entirely out-of-state commercial activity).

429. *Brown-Forman*, 476 U.S. at 579.

430. *See, e.g.*, Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 519, 528 (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).

431. Minnesota v. Clover Leaf Creamery Co., 449 U.S. 456, 456 (1981).

432. *Id.*

433. *See id.* at 472–73.

434. *Id.* at 471–72.

435. Grocery Mfrs. of Am., Inc. v. Gerace, 755 F.2d 993, 996 (2d Cir. 1985).

436. *Id.* at 1003 (analyzing menu, sign, and container provisions of law).

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.[437] The major factor in this analysis is whether there is actual proof of a discriminatory impact.[438]

In *C & A Carbone, Inc. v. Town of Clarkstown*, a town ordinance required all non-recyclable waste to be processed at a local plant before leaving town.[439] 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.[440] The Court also found a discriminatory impact in *Hunt v. Washington State Apple Advertising Commission*, where 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.[441] 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.[442] 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.[443] The law thus had the effect of "leveling" the apple market to the advantage of North Carolina's apple-producers.[444] 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).[445]

In contrast to these cases, state-GE legislation would not have characteristics that could lead to either the complete exclusion of out-of-

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437. *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 Adver. Comm'n, 432 U.S. 333, 351 (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).

438. *See Carbone*, 511 U.S. at 390–91 (discussing discriminatory effects of state law).

439. *Id.* at 387–88.

440. *Id.* at 392.

441. *Hunt*, 432 U.S. at 339.

442. *Id.* at 353.

443. *Id.* at 336.

444. *Id.* at 351.

445. *Id.*

state business from the local market, nor an advantage specifically for state businesses. It would not create barriers against interstate food producers entering a state, 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 (all GE-free products would share the same benefit, if any).

Finally, the Supreme Court has also consistently struck down state laws that are entirely extraterritorial in effect.[446] 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.[447] The Court reasoned that this requirement had "the 'practical effect' of . . . control[ling] liquor prices in other states."[448] 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.[449] 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."[450]

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.[451] 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.[452] The court disagreed, and concluded 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

446. *See* Healy v. Beer Inst., 491 U.S. 324, 336 (1989) (citing Brown–Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 579 (1986)) (holding that a Connecticut beer-price-affirmation statute violated the commerce clause); Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 528 (1945) (striking down law that established price scale to be imposed across state lines).

447. *Brown-Forman*, 476 U.S. at 575.

448. *Id.* at 583 (citing S. Pac. Co. v. Ariz. *ex rel.* Sullivan, 325 U.S. 761, 775 (1945)).

449. *Id.*

450. *Id.* at 582 (citing Edgar v. MITE Corp., 457 U.S. 624, 642 (1982)).

451. Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 632, 646 (6th Cir. 2010).

452. *Id.* at 647.

requirements of any other state.[453] The law did not purport to "'regulate conduct occurring wholly outside the state.'"[454]

Similarly, years before, the Second Circuit had rejected an industry challenge to Vermont's mercury labeling law on extraterritoriality grounds.[455] The court concluded that Vermont's law did not have "extraterritorial" effect because it did not require lamps in other states to be labeled (only those in Vermont); any withdrawal of mercury lamps from the Vermont market would be made by the manufacturer—not the State; and lamp manufacturers within Vermont, just as those outside the State, would also face any decreases in sales and profits.[456] In the same vein, a state GE labeling law would not regulate conduct wholly outside the state. Food producers would remain free to implement other labeling systems outside the state, and both in-state and out-of-state producers would be subject to any loss in profits flowing from their withdrawals from the state market. Therefore, a state labeling bill would be non-discriminatory and would be subject to the *Pike* balancing test.

2. 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."[457] Courts have consistently used their discretion to uphold laws that reach this second tier of analysis.[458] There is no standard formula for comparing the burden to the benefits; courts are, after all, comparing two very different things.[459] However, reviewing courts' treatment of several common

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453. *Id.*

454. *Id.* (quoting *Brown–Forman*, 476 U.S. at 582).

455. Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 109–12 (2001) (analyzing extraterritoriality question under *Pike* test and applying some of the factors discussed in *Pike*, below).

456. *Id.* at 110–11.

457. Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970) (citing Huron Cement Co. v. Detroit, 362 U.S. 440, 443 (1960)).

458. *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, 368 (1943) (holding that a state law that regulated California's in-state raisin marketing program was not an impermissible burden on interstate commerce).

459. *See, e.g.*, *Pike*, 397 U.S. at 142 (explaining that "the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved").

categories of burdens and benefits shows that a state's legitimate local interests in GE labeling would likely outweigh any incidental effects on interstate commerce.

i. First Prong: Burden

One component of the balancing test focuses on the burdens a law places upon interstate commerce.[460] 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.[461] 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.[462] 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."[463] A similar situation was considered in *Minnesota v. Clover Leaf Creamery Co.*; 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.[464] 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.[465]

A state labeling 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 its products are genetically engineered. Furthermore, the labeling system would be upheld even if it somehow discouraged some food producers from doing business in a state, as business would be able to shift to other out-of-state companies—for example, those not dealing with genetically engineered foods. In fact, the labeling requirement would potentially provide an opportunity for all out-of-state organic and non-GE

460. *Id.*
461. *Exxon*, 437 U.S. at 119–21.
462. *Id.* at 127.
463. *Id.*
464. Minnesota v. Clover Leaf Creamery Co., 449 U.S. 456, 472–73 (1981).
465. *Id.*

food businesses. Finally, any food producer would also be free to bypass the labeling requirement entirely simply by sourcing GE-free ingredients.

The Supreme Court has also reviewed another broad set of burdens—those with financial effects such as increased costs of business, compliance costs, or lost profits.[466] 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.[467] This imposed a burden on raisin producers by limiting their ability to compete and limiting their potential profits.[468] 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.[469] 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."[470] Such costs are tolerable when balanced against legitimate local interests.[471] As the Court in *Clover Leaf Creamery* asserted: "the inconvenience of having to conform to different packaging requirements in Minnesota and the surrounding States should be slight."[472]

While a state 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.

ii. 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

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466. *See generally* Parker v. Brown, 317 U.S. 341 (1943) (discussing a California statute that required two-thirds of the yearly raisin crop to be sold through a California agency at a fixed price and the burden this statute imposed on raisin producers by limiting their ability to compete and limiting their potential for profits).

467. *Id.* at 359.

468. *Id.* at 355, 359.

469. *Id.* at 367.

470. *Id.*

471. *See id.* at 368; *see also* Am. 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).

472. Minnesota v. Clover Leaf Creamery Co., 449 U.S. 456, 472 (1981) (citing Pac. States Box & Basket Co. v. White, 296 U.S. 176, 184 (1935)); *see also* Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 112 (2001) (noting that state law *might* create disproportionate burden in regards to other state laws if it were in "substantial conflict with a common regulatory scheme in place in other states," but that there must be an "actual conflict").

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.[473] Minnesota relied on evidence demonstrating that preventing the introduction of plastic products into the local marketplace would address these specific environmental concerns.[474] 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 stated, "We 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."[475] 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, see Part IV.B.i *supra*).[476] In *Maine v. Taylor*, 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."[477] 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.[478]

As stated in *Hughes v. Oklahoma*, public health and safety is another legitimate local-interest that justifies incidental burdens on interstate commerce.[479] Courts may look at specific examples of how a regulation

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473. *Id.* at 473.

474. *Id.* at 465–70, 473 (applying same interest to Dormant-Commerce-Clause analysis as Equal Protection analysis).

475. Hughes v. Oklahoma, 441 U.S. 322, 336–37 (1979) (quoting Philadelphia v. New Jersey, 437 U.S. 617, 624 (1978)) (noting *Pike* test but finding that law in question overtly discriminated against interstate commerce).

476. Maine v. Taylor, 477 U.S. 131, 138, 148 (1986).

477. *Id.* at 148.

478. *Id.* (internal quotation marks omitted) (quoting United States v. Taylor, 585 F. Supp. 393, 397 (D. Me. 1984)).

479. *See id.* at 151 (stating that a state "retains broad regulatory authority to protect the health and safety of its citizens"); *see also* Parker v. Brown, 317 U.S. 341, 362–63 (1943) (noting the "safety, health and well-being of local communicates" as an appropriate interest).

benefits the local community.[480] In *United Haulers Ass'n, Inc. v. Oneida-Herkimer Sold Waste Management Authority*, 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."[481] 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.[482] This court also stated that, where the "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.[483]

Some of the public health and safety cases have examined trucking restrictions designed to protect public safety on highways.[484] 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.[485] In *Raymond*, the Supreme Court ruled that Wisconsin had "failed to make even a colorable showing that its regulations contribute to highway safety."[486] The Wisconsin law appeared to arbitrarily ban certain sizes of trucks on state highways and failed to offer evidence that these bans provided any particular safety benefits.[487] 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.[488]

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480. *See, e.g.*, United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 347 (2007) (finding that the burden to interstate commerce did not exceed the benefit to the local community).

481. *Id.* at 346–47.

482. Grocery Mfrs. of Am., Inc. v. Gerace, 755 F.2d 993, 1003–04 (2d Cir. 1985).

483. *Id.*

484. *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).

485. *See* Raymond Motor Transp., Inc. v. Rice, 434 U.S. 429, 444–48 (1978) (examining State's asserted public safety justifications for regulations governing truck size that burdened interstate commerce).

486. *Id.* at 447–48.

487. *Id.* at 444–48.

488. *See id.* at 445 (listing factors contributing to "substantial" burden); *see also* Bibb v. Navajo Freight Lines, 359 U.S. 520, 529–30 (1959), where 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

Finally, addressing local economic concerns has repeatedly been upheld as a legitimate local interest that outweighs any incidental burdens on interstate commerce.[489] As discussed above, the *Parker* Court held that protecting the long-term viability of California's raisin crop was a legitimate local purpose.[490] In the *Gerace* labeling case, the Second Circuit noted that preventing unfair competition and promoting consumer information were legitimate local purposes (among others).[491] Finally, even local revenue generation has been upheld as a legitimate local purpose.[492] 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."[493] 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, state GE labeling legislation would likely be upheld under the *Pike* balancing test. Once a law is found to be non-discriminatory, it enjoys a presumption of constitutionality, with courts balancing the legitimate local interest against the burden on interstate commerce. In this case, a state labeling law would likely 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.

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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 (quoting Navajo Freight Lines, Inc. v. Bibb, 159 F. Supp. 385, 388 (S.D. Ill. 1958)) (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 523, 527–28. The Court noted that it was "one 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.* at 529–30 ("A State [may] insist[] on a design out of line with the requirements of almost all the other States . . . [and] [s]uch a new safety device . . . may be so compelling that the innovating State need not be the one to give way.").

489. *See* Parker v. Brown, 317 U.S. 341, 368 (1943).

490. *Id.*

491. Grocery Mfrs. of Am., Inc. v. Gerace, 755 F.2d 993, 1003–04 (2d Cir. 1985).

492. *See* United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 346 (2007).

493. *Id*. at 346 (upholding law that gave localities means to finance waste disposal services).

C. Readers' Guide to the Dormant-Commerce-Clause Test

This section reviews the various rules for both tiers of Dormant-Commerce-Clause analysis. Labeling requirements for trade goods are a type of regulation that may affect interstate commerce.[494] As explained above, properly drafted state labeling requirements should not violate the Dormant Commerce Clause.

1. First Tier: Laws that Discriminate

- A law is usually *per se* invalid if it discriminates against interstate commerce.[495]
- Laws that facially discriminate against interstate commerce are discriminatory.[496]
  - The key factor is whether the law's language draws distinctions between in-state and out-of-state businesses or products. For example:
    - State law that facially distinguished out-of-state milk and regulated the in-state prices of milk produced out-of-state.[497]
    - State law that, on its face, prevented the importation of out-of-state waste to in-state landfills.[498]
  - Regulations are facially neutral if they treat in-state and out-of-state business alike.
    - Prohibition on plastic milk containers treated in-state and out-of-state business alike.[499]
    - 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.[500]

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494. *See Gerace*, 755 F.2d at 1003–05 (holding that a statute requiring substitute cheese products to be labeled as "imitations" did not violate the Commerce Clause).

495. Granholm v. Heald, 544 U.S 460, 476 (2005) (citing Philadelphia v. New Jersey, 437 U.S. 617, 624 (1978)).

496. Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 579 (1986).

497. Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 519, 528 (1935).

498. *Philadelphia*, 437 U.S. at 621–23, 625.

499. Minnesota v. Clover Leaf Creamery Co., 449 U.S. 456, 471–72 (1981).

500. Grocery Mfrs. of Am., Inc. v. Gerace, 755 F.2d 993, 1003 (2d Cir. 1985).

- Even if facially neutral, laws that have the practical effect of favoring in-state commerce over out-of-state commerce are discriminatory.[501]
  - The key test is whether the regulation denies out-of-state businesses or products access to the local market. For example, 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.[502]
  - Regulations that are protectionist—those that shield local businesses from competition with out-of-state businesses—are also discriminatory. For example, 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.[503]
- The Supreme Court has also consistently struck down laws that attempt to regulate conduct occurring entirely outside the state:
  - 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.[504]
  - Holding that a New York price-affirmation statute violated the Dormant Commerce Clause because it regulated entirely out-of-state commercial activity.[505]
  - Holding that a 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.[506]

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501. *Brown-Forman*, 476 U.S. at 579.

502. C & A Carbone, Inc. v. Town of Clarkstown, 511 U.S. 383, 386, 394–95 (1994).

503. Hunt v. Wash. State Apple Adver. Comm'n, 432 U.S. 333, 351 (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).

504. U.S. Brewers Ass'n v. Healy, 692 F.2d 275, 282 (2d Cir. 1982).

505. *Brown-Forman*, 476 U.S. at 582 (citing *Brewers Ass'n*, 692 F.2d at 279).

506. Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 647 (6th Cir. 2010) (reviewing a milk labeling regulation).

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."[507]
- Non-discriminatory laws enjoy a presumption of constitutionality.[508]
- Burden analysis:
  - Legitimate local interests may outweigh withdrawal of some business from an in-state market. For example:
    - In a case where out-of-state refinery operators were denied access to a portion of the local retail-fuel market, holding that exclusion of some out-of-state businesses from in-state markets did not constitute an impermissible burden on interstate commerce.[509]
    - Where in- and out-of-state plastic manufacturers were excluded from the local milk-packaging market the Court found 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.[510]
  - Financial effects such as compliance costs or lost profits for interstate businesses may be outweighed by legitimate local interests.
    - In particular, the Supreme Court has held that regulating California's in-state raisin-marketing program was not an impermissible burden on interstate commerce.[511]
    - "[T]he inconvenience of having to conform to different packaging requirements in Minnesota and the surrounding States should be slight."[512]

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507. Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).
508. *See generally* Chemerinsky, *supra* note 420, at 429–39.
509. Exxon Corp. v. Governor of Md., 437 U.S. 117, 127 (1978).
510. Minnesota v. Clover Leaf Creamery Co., 449 U.S. 456, 472–73 (1981).
511. Parker v. Brown, 317 U.S. 341, 367–68 (1943).
512. *Clover Leaf Creamery*, 449 U.S. at 472.

- Benefit analysis:
  - Addressing environmental concerns is a legitimate local interest.
    - The Supreme Court has found that there was a "substantial state interest in promoting conservation of energy and other natural resources and easing solid waste disposal problems."[513]
    - Conservation is a legitimate local interest.[514]
  - Public health and safety are legitimate local interests. Various courts have found:
    - "[S]afety, health and well-being of local communities" as an appropriate interest.[515]
    - Incentives for recycling and increasing enforcement of recycling laws "conferr[ed] significant health and environmental benefits upon the [local] citizens."[516]
    - Regulation prohibiting the misleading labeling of imitation-cheese products serves local legitimate interests, where "record shows that health and nutrition professionals strongly disagree about the intrinsic value of the federal nutritional guidelines applied to alternative cheese products"; indeed, the "very existence of [the] controversy" meant that New York's labeling law was not unreasonable.[517]
    - A law restricting truck weight and size based on public-safety concerns was constitutional.[518]
  - Consumer information, preventing deception, and permitting consumers to clearly discern what type of products they purchase are legitimate local interests.[519]
  - Addressing local economic concerns is a legitimate local interest.

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513. *Id.* at 473.
514. Hughes v. Oklahoma, 441 U.S. 322, 336–37 (1979).
515. *Parker*, 317 U.S. at 362–63.
516. United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 346–47 (2007).
517. Grocery Mfrs. of Am., Inc. v. Gerace, 755 F.2d 993, 1003–04 (2d Cir. 1985).
518. S.C. State Highway Dep't v. Barnwell, 303 U.S. 177, 195–96 (1938).
519. *Gerace*, 755 F.2d at 1003–04.

- Protecting the long-term viability of California's raisin crop was a legitimate local purpose.[520]
- Preventing unfair competition and promoting consumer information constitute legitimate local purposes.[521]
- Law that gave localities means to finance waste-disposal services upheld.[522]

- Local benefits may be found illegitimate if it is conclusively shown that the regulation does not further the benefits and the burdens are severe.[523]

CONCLUSION

The public is calling for labels on genetically engineered foods, there is good reason to label, and states have the authority to require it. As set forth in this Article, properly developed state labeling laws for genetically engineered foods should withstand scrutiny under the First Amendment, the Preemption Doctrine, and the Dormant Commerce Clause. The laws would not be passed for mere "consumer curiosity," they would not infringe upon powers left to the federal government, and they would not impose impermissible burdens on interstate commerce.

520. *Parker*, 317 U.S. at 367–68.

521. *Gerace*, 755 F.2d at 1003–04.

522. United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 334 (2007).

523. Bibb v. Navajo Freight Lines, Inc., 359 U.S. 520, 527–30 (1959) (striking down a regulation requiring certain mudguards for trucks).