IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

NEW YORK STATE RESTAURANT ASSOCIATION,

Plaintiff,

v. Case No. 08-cv-1000 (RJH)

NEW YORK CITY BOARD OF HEALTH, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, and THOMAS R. FRIEDEN, in his official capacity as Commissioner of the New York City Department of Health and Mental Hygiene,

Defendants.

BRIEF OF U.S. REPRESENTATIVE HENRY WAXMAN, PUBLIC CITIZEN, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, AMERICAN DIABETES ASSOCIATION, AMERICAN MEDICAL ASSOCIATION, AMERICAN PUBLIC HEALTH ASSOCIATION, CALIFORNIA CENTER FOR PUBLIC HEALTH ADVOCACY, THE MEDICAL SOCIETY OF THE STATE OF NEW YORK, TRUST FOR AMERICA'S HEALTH, AND PROFESSORS OF MEDICINE, NUTRITION, AND PUBLIC HEALTH AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS

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INTRODUCTION

This is the second time this controversy is before the Court. In December 2006, New York City adopted its first version of Health Code Regulation 81.50, which required restaurants that were already making the calorie content of their food publicly available to post that information on their menus. The New York State Restaurant Association (NYSRA) challenged the regulation, contending that it was preempted by the Nutrition Labeling and Education Act of 1990 (NLEA) and violated the First Amendment. *New York State Rest. Ass'n v. New York City Bd. of Health*, 509 F. Supp. 2d 351 (S.D.N.Y. 2007) ("*NYSRA I*").

In its previous lawsuit, NYSRA complained that the prior version of the regulation "applie[d] only to the small group of restaurants in New York City that ha[d] *voluntarily* decided to communicate nutrition information to their customers and the public."[1] NYSRA argued that this triggering mechanism rendered the regulation preempted because it covered voluntary nutritional claims, a subject also covered by section 343(r) of the NLEA: "Under [FDA] regulations, restaurants are not required to convey nutrition information to their customers. However, *if they voluntarily choose to do so*, they must comply with the regulatory regime promulgated by the FDA under the NLEA." Pl's Mem. in *NYSRA I* at 2 (emphasis added). NYSRA acknowledged that "[r]estaurants are wholly exempt from the food labeling requirements of [21 U.S.C. § 343(q)]," but contended that, "[u]nder subsection (r), any nutrient content claim—*if it is voluntarily made by the*

[1] Plaintiff's Memorandum of Law in *NYSRA I*, Case No. 07-Civ-5710 (Docket # 4) ("Pl's Mem. in *NYSRA I*") at 1 (emphasis added).

restaurant—must be made in accordance with regulations promulgated by the FDA." *Id.* at 9-10 (emphasis added).[2]

In reaching its previous decision, this Court observed that New York City is "not alone" in its judgment that requiring nutrition labeling on menus is an effective way to combat the obesity epidemic; other cities and states are actively considering similar legislation and "[w]hile some of these bills make the disclosure contingent on the restaurant having already provided voluntary nutrition information," as New York's original regulation did, "most simply mandate chain restaurants (variously defined) to post nutrition information on their menu boards." *NYSRA I*, 509 F. Supp. 2d at 354. That "distinction is critical," the Court explained, "to an analysis of whether such state and local regulations are preempted by existing federal law." *Id.* at 354. "Because the City ha[d] chosen a regulatory approach that impose[d] different obligations from federal regulation of voluntary nutritional claims made by restaurants," the Court concluded that the prior regulation "as drafted" was preempted by federal law. *Id.*

Following this Court's decision, in January 2008 the City promulgated a new version of Regulation 81.50 that mandates all chain restaurants with fifteen or more locations nationally to post calorie-content information on their menu boards. NYSRA has sued again, and again contends that Regulation 81.50 is preempted and violates the First Amendment. NYSRA makes three main arguments in support of its renewed preemption claim. *First*, it attacks (at 22-25) as erroneous "dicta" the mandatory-voluntary distinc-

[2] *See also id.* at 10 ("Under the applicable regulations, restaurants *choose whether to opt into* the general nutrition claims and labeling scheme promulgated under subsection (r).") (emphasis added); *id.* at 10 ("Restaurants that *voluntarily disclose* nutrient information about menu items (including the caloric value of food) through food labeling, such as billboards, brochures in restaurants, and restaurant internet websites, are subject to the NLEA's food labeling regime.") (emphasis added).

tion critical to the Court's holding in *NYSRA I*. *Second*, it argues (at 26-28) its position is not in tension with Congress's decision to save state-law nutritional-labeling requirements for restaurants from preemption. *Third*, it argues (at 14-18) that straightforward factual disclosures of calorie content, even when they are mandated by law, are "nutrient content claims" covered by section 343(r).

NYSRA is wrong on all three counts. New York's revised regulation falls squarely within the sphere that Congress intentionally left open to state and local governments when it enacted the NLEA. An important FDA-commissioned report, issued in 2006, acknowledged as much. Echoing the consensus view of the U.S. Surgeon General, the National Academies' Institute of Medicine, and the American Medical Association, among others, the report concluded that, to reduce obesity, "restaurants should provide consumers with calorie information in a standard format that is easily accessible and easy to use," allowing consumers to view the information "when standing at a counter, while reviewing a menu board, in a car when reading a drive-through menu, or when sitting down at a table reviewing a menu.[3] The report concluded that "the FDA *does not have regulatory authority* to require nutrition information in restaurants," but stated that "state legislatures *do have the authority* to require the provision of nutrition information, and a number of these elected bodies have considered nutrition labeling bills [that] would require calories and/or other nutrition information to be listed on menus or menu boards." *FDA Keystone Report* at 74 (emphasis added). That is just the opposite of NYSRA's theory in this lawsuit, which in effect asks this Court to create a

[3] *The Keystone Forum on Away-from-Home Foods: Opportunities for Preventing Weight Gain and Obesity* (2006), at 76, 77-78, *available at* http://www.cfsan.fda.gov/~dms/nutrcal.html ("*FDA Keystone Report*"); *see also FDA Backgrounder*, http://www.cfsan.fda.gov/~lrd/bgowg2.html.

regulatory vacuum in which the federal, state, and local governments are all powerless to act.

This Court has already recognized in two prior decisions that the NLEA leaves states and cities free to enact mandatory nutritional disclosure requirements for restaurants. *See NYSRA I*, 509 F. Supp. 2d at 357-58, 361, 363; *Pelman v. McDonald's Corp.*, 237 F. Supp. 2d 512, 526 (S.D.N.Y 2003). As the NLEA's chief sponsor in the Senate explained just moments before the final vote: "Because food sold in restaurants is exempt from the nutrition labeling requirements of [the NLEA], the bill does not preempt any State nutrition labeling requirements for restaurants." 136 Cong. Rec. S16607-02, S16608 (Oct. 24, 1990) (Sen. Metzenbaum). The FDA takes the same view. *See* FDA, *A Guide for Restaurants and Other Retail Establishments*, *available at* http://www.cfsan.fda.gov/~frf/qatext2.html ("[B]ecause the act exempts restaurant foods that do not bear a claim from mandatory nutrition labeling, State requirements for the nutrition labeling of such foods would not be preempted.").

NYSRA, however, contends that New York's rule is preempted because it is a requirement respecting "claims" of the type regulated by section 343(r) of the NLEA. That contention rests on a fundamental misunderstanding of the NLEA's structure, which is premised on a distinction between requirements governing the mandatory disclosure of straightforward nutritional information (such as a listing of a total number of calories), on the one hand, and requirements concerning descriptive "claims" that industry may choose to make about its food's nutritional content or health effects, on the other hand. The revised New York City rule is the former sort of rule: It does not regulate voluntary statements of any kind and is concerned only with purely factual information, not with descriptive "terms" that restaurants may choose to use to make "claims" that "character-

ize" the nutrients in their food. That conclusion is supported by the Act's text and legislative history, by authoritative FDA interpretations, and by the statute as a whole. A contrary conclusion would lead to absurd results and eviscerate the exception that Congress created for state regulation of restaurant nutrition labeling.

Finally, as before, NYSRA claims that New York's rule violates the First Amendment, but that position is incompatible with settled law, would turn the commercial speech doctrine upside down, and would jeopardize mandatory disclosure requirements that are ubiquitous in the law—including the disclosure requirements imposed by section 343(q) of the NLEA. *See Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 113-16 (2d Cir. 2001).

STATUTORY AND REGULATORY BACKGROUND

The NLEA produced groundbreaking changes in the way food is labeled in the United States. For the first time, it required that nutrition labeling be placed on most packaged food, prohibited the use of terms that characterize the level of nutrients in a food unless they conform to definitions established by FDA, and prohibited claims about the relationship between nutrients and health conditions that are not supported by significant scientific agreement. The Act was introduced in the U.S. House of Representatives by Representative Henry Waxman on July 27, 1989, and signed into law by President George H.W. Bush on November 8, 1990. Although Congress extensively debated a number of issues including preemption of state law and coverage for restaurants, the basic structure of the legislation—which is premised on a distinction between the regulation of mandatory nutrition labeling and the regulation of voluntary claims—remained unchanged over the course of the fifteen months during which it was considered.

A. The NLEA's Distinction Between Mandatory Nutrition Information and Voluntary Claims

The NLEA and its regulations "encompass two kinds of information—the mandatory information on nutrients which will appear on the nutrition panel of nearly all food labels [under section 343(q)], and the voluntary information [regulated by section 343(r)] that some manufacturers choose to add to their product labels." Guarino, *Nutrient Descriptor and Disease Claims for Foods*, 48 Food & Drug L.J. 665, 671 (1993); *see also* Caswell et al., *The Impact of New Labeling Regulations on the Use of Voluntary Nutrient-Content Claims and Health Claims by Food Manufacturers*, 22 J. Pub. Pol'y & Marketing 147 (2003).

The different treatment of mandatory and voluntary statements flows from Congress's two distinct but complementary purposes in enacting the NLEA. The purposes of the Act were first, "to clarify and to strengthen the Food and Drug Administration's legal authority to *require* nutrition labeling on foods," and second, "to establish the circumstances under which claims *may be made* about nutrients in foods." H.R. Rep. No. 538, 101st Cong., 2d Sess. 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337 ("*House Report*") (emphasis added). To carry out these twin purposes, the NLEA added two subsections to the Federal Food, Drug and Cosmetic Act—section 343(q), which mandates specific, uniform disclosures that must be made on food labels, and section 343(r), which regulates the descriptive claims that manufacturers may decide to make. 21 U.S.C. §§ 343(q), 343(r). The first section governs the mandatory disclosure of factual nutritional information. The second section creates a framework for regulation by the FDA concerning when and how food purveyors may voluntarily make claims using terms that characterize the nutrient levels or health-related effects of their food. Put another way,

the first section (§ 343(q)) tells food manufacturers or vendors what facts they *must* disclose about their food, while the second section (§ 343(r)) regulates the descriptive claims they may *choose* to make about their food.

1. Section 343(q): Mandatory Nutrition Labeling. The nutrition-information labeling provisions of section 343(q) are the heart of the Act. Most American consumers are familiar with the "Nutrition Facts" panel, a uniform chart that most food manufacturers must use to list "the total number of calories" in each serving of food, § 343(q)(1)(C), as well as the amounts of total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein in the food, both as an "amount per serving" and, with the exception of sugars and protein, as a percent of a dietary reference value, called the "percent daily value." § 343(q)(1)(D); *see* 21 C.F.R. § 101.9. As discussed below, restaurant food is not covered by these federal requirements. 21 U.S.C. § 343(q)(5)(A)(i).

2. Section 343(r): Voluntary Nutrient-Content and Health Claims. In addition to requiring the disclosure of nutrition information, Congress also responded to the proliferation of dubious, misleading, and confusing claims made by food manufacturers about the nutrition and health effects of their foods. *House Report* at 3337.[4] That issue is taken up in the second part of the statute, section 343(r), which distinguishes between two kinds of claims: nutrient content claims (*e.g.* "low salt") and health-related claims (*e.g.* "fiber reduces the risk of cancer"). §§ 343(r)(1)(A), 343(r)(1)(B).

[4] *See generally* Hutt, *A Brief History of FDA Regulation Relating to the Nutrient Content of Food*, in R. Shapiro, ed., *Nutrition Labeling Handbook* 1-27 (1995); Cooper, et al., *History of Health Claims Regulation*, 45 Food Drug Cosm. L.J. 655, 657 (1990); *FDA's Continuing Failure to Regulate Health Claims for Food: Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Gov't Relations*, 101st Cong., 2d Sess. (1989).

a. Nutrient Content Claims. "Nutrient content claims are *voluntary statements* that can assist consumers in selecting foods that may lead to a healthier diet." 64 Fed. Reg. 62745-01, 62758 (Nov. 17, 1999) (emphasis added).

Prior to the NLEA's enactment, the FDA had general authority to prohibit false or misleading food advertising or labeling under the original Federal Food, Drug and Cosmetic Act of 1938. § 343(a). That authority was sufficient to address a manufacturer's claims about straightforward factual information, such as information concerning the ingredients or nutrients in a food, that was verifiably true or false. But "an increasing number of food companies had turned to marketing . . . products bearing adjectival descriptors such as 'lite,' 'low,' 'reduced,' or 'fat free' because of their perception that such descriptors would lure consumers who thought such terms meant the products were more healthful." Sims, *The Politics of Fat: Food and Nutrition Policy in America* 202 (1998). In the absence of specific federal standards, these claims were often meaningless or misleading. *Id.* The word "light," or the non-word "lite," might mean light in fat, or light in color, or something else entirely. At the same time, Congress was aware that consumers increasingly wanted, and could benefit, from accurate nutritional information supplied by food purveyors. Congress aimed to address the problem by ensuring that such "content claims (such as 'low salt' or 'light') would have to be consistent with terms defined by the [FDA]." *House Report* at 3337.

Section 343(r) of the NLEA prohibits any "claim" on a food label that expressly or by implication "characterizes" the nutrient level of a food unless "the characterization of the level made in the claim uses terms which are defined in regulations of the [FDA]." § 343(r)(1)(A); § 343(r)(2)(A)(i). "An example of an express claim covered by [§ 343(r)] would be the statement 'low sodium.' An example of an implied claim covered by this

section would be the statement 'lite,' which implies that the product is low in some nutrient (typically calories or fat), but does not say so expressly, or 'high oat bran,' which conveys an implied high fiber message." *House Report* at 3349 (section-by-section analysis). The FDA's regulations define nutrient content claims for a range of specific descriptive terms including *free*, *low*, *high*, *good source*, *contains*, *provides*, *reduced*, *less*, *light* or *lite*, *modified*, and *more*. 21 C.F.R. §§ 101.13, 101.54, 101.56.[5]

b. Health Claims. "Health claims for foods and dietary supplements are *voluntary statements* that characterize the relation between a substance and its ability to reduce the risk of disease or health-related condition in healthy populations." Barbara Schneeman, FDA Office of Nutritional Products, Labeling and Dietary Supplements, *FDA's Review of Scientific Evidence for Health Claims*, J. Nutr. 137:493-494 (2007) (emphasis added). With respect to health claims, section 343(r) uses the word "claim" in much the same way, to refer to voluntary statements manufacturers choose to make that "characterize" the relationship between the nutrients in their foods and diseases or health effects. § 343(r)(1)(B); Health claims, however, are regulated somewhat differently. Instead of providing a list of specific descriptive terms that manufacturers may use, FDA authorizes a health claim only when it determines that there is "significant

[5] Section 343(r)(1) provides that "[a] statement of the type required by paragraph (q) . . . that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph." § 343(r)(1). The intent of this sentence was "to make it clear that the information on the nutrition label is not a claim under that provision and therefore is not subject to the disclosure requirements in section 403(r)(2)," although similar statements made voluntarily outside the nutrition label could be subject to section 343(r) if they otherwise meet the definition of a "claim." 136 Cong. Rec. H5836-01, H5841 (July 30, 1990) (Rep. Waxman); *see also* 58 Fed. Reg. 2302, 2303-04 (Jan. 6, 1993); 21 C.F.R. § 101.13(c). Thus, voluntary statements relating to the amount of nutrients in a food can potentially constitute "nutrient content claims," provided that they use a descriptor term to "characterize" the amount of the nutrient.

scientific agreement" that scientific evidence supports the health claim. 21 C.F.R. § 101.14(c).

B. The NLEA's Exemption of Restaurant Foods from Federal Nutrition Labeling Requirements

The extent to which restaurants should be covered by the NLEA's nutrition labeling requirements was a matter of considerable debate in Congress. Many of the legislation's supporters wanted restaurants foods to fall under section 343(q)'s mandatory nutrition labeling provisions, but such coverage "was vociferously opposed by the National Restaurant Association," Sim*s*, *Politics of Fat*, at 200, and was not included in the final legislation. *See* § 343(q)(5)(A)(i) (exempting food that is "served in restaurants" from the nutrition labeling requirements of section 343(q)).

As a result, the coverage of restaurants turns on the Act's mandatory-voluntary distinction: As far as federal law is concerned, restaurants are not required to provide the kind of nutritional information disclosures—such as listings of the calories or fat in all food items—that is required of packaged foods.[6] But restaurants are not exempted from the Act's regulation of "claims." So the only circumstance in which the NLEA affects restaurants is when they choose to make "claims," within the meaning of section 343(r), that "characterize" the nutrients or health effects in the foods they serve using certain descriptive terms—for example, when a restaurant's menu describes an item as "low fat"

[6] In 2004, the FDA's Obesity Working Group explained the implications of the regulatory gap left open by section 343(q)'s exemption for restaurant food: "[U]nder the laws administered by FDA, restaurants are not required to provide nutrition information unless a nutrient content or health claim is made for a food or meal. When claims are made, however, the restaurant need only provide information about the amount of the nutrient that is the subject of the claim. Restaurants may, and many do, provide nutrition information on a voluntary basis. Nevertheless, this nutrition information is often in the form of posters, placemats or menu icons, or on the Internet, rather than at the point-of-sale. Such information is not always readily available or observable at the point-of-sale." FDA, *Calories Count: Report of the Working Group on Obesity* (2004), at Part V.B., *available at* http://www.cfsan.fda.gov/~dms/owg-toc.html ("*FDA Calories Count Report*").

or "heart healthy." 21 C.F.R. § 101.10; *see FDA Talk Paper* T96-52 (July 30, 1996), *available at* http://www.cfsan.fda.gov/~lrd/tpmenus.html ("This final rule affects only those restaurateurs who place claims such as 'low fat' or 'heart healthy' on their menus.").[7] A restaurant that decides to make such a descriptive claim about its food's nutritional content is obligated only to disclose "the nutrient amounts that are the basis for the claim." 21 C.F.R. § 101.10. Such mandatory quantitative disclosures are considered the "functional equivalent" of the type of nutritional labeling required of packaged foods by section 343(q). *Id.*

C. The NLEA's Preemption Provisions

The Act's mandatory-voluntary distinction is carried over into its preemption provisions as well. As with restaurant coverage, Congress devoted careful attention to preemption during its consideration of the NLEA. *See* Sims, *Politics of Fat*, at 199 ("The preemption issue remained a key area of dispute throughout consideration of the food labeling bill, with the basic issue being how far the legislation should go in setting uniform food labeling regulations that preempt state laws.").[8] In the final moments of the floor debate before the NLEA was formally adopted by the House after its passage in both chambers, Representative Waxman explained that carefully limited federal preemp-

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[7] FDA originally decided to exempt restaurant menus—but not restaurant signs, placards or posters—from its regulations implementing section 343(r). 58 Fed. Reg. 2066 (Jan. 6, 1993). In response to a lawsuit, FDA reversed course just six months later and issued proposed regulations to remove the menu exemption, 58 Fed. Reg. 33055 (June 15, 1993), but the regulations were rejected by the White House Office of Management and Budget under pressure from the restaurant industry. *See* Sims, *Politics of Fat*, at 201. The court in that lawsuit ultimately held that the menu exemption was contrary to the NLEA, *Public Citizen v. Shalala*, 932 F. Supp. 13 (D.D.C. 1996), and, about one month later, the agency issued a final rule that adopted its June 1993 proposal. *See* 61 Fed. Reg. 40320 (Aug. 2, 1996) (adopting final rule).

[8] *See generally* Bradley, *The States' Role in Regulating Food Labeling and Advertising: The Effect of the Nutrition Labeling and Education Act of 1990*, 49 Food & Drug L.J. 649, 659 (1994); Jordan, *Preemption and Uniform Enforcement of Food Marketing Regulations*, 49 Food & Drug L.J. 401, 401 (1994).

tion had been added to the bill to induce industry to support the legislation. 136 Cong. Rec. H12951-02, H12954 (Oct. 26, 1990) ("[I]t was decided that the fairest way to expect the food industry to support a nutrition labeling bill, was to give them *some types of preemption* of *some* burdensome State laws that interfered with their ability to do business in all 50 States.") (emphasis added). Even Senator Orrin Hatch, who was the leading proponent of stronger federal preemption, conceded that "the carefully crafted uniformity section of this legislation is limited in scope." 136 Cong. Rec. S16607-02, S16611 (Oct. 24, 1990).

In an effort to satisfy industry concerns while remaining "sensitive to the regulatory roles played by the States," the Senate reached a compromise that was "refined to provide national uniformity where it is most necessary, while otherwise preserving State regulatory authority where it is appropriate." 136 Cong. Rec. S16607-02, S16609 (Oct. 24, 1990) (Sen. Mitchell); *see also* 136 Cong. Rec. S16607-02, S16611 (Oct. 24, 1990). (Sen Hatch) ("[T]he compromise makes clear that the national uniformity in food labeling that is set forth in the legislation has absolutely no effect on preemption of State or local requirements that relate to such things as warnings about foods or components of food."). That default position—of "otherwise preserving State regulatory authority"—is reflected in a special rule of construction limiting the preemptive effect of the NLEA to only state laws that fall within the NLEA's express preemption provisions:

> 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 [21 U.S.C. § 343-1(a)] of the Federal Food, Drug, and Cosmetic Act.

Pub. L. No. 101-535, § 6(c), 104 Stat. 2535, 2364 (21 U.S.C. § 343-1, note).

Given its exemption of restaurant food from NLEA's nutrition labeling regime, Congress specifically considered the question of state and local authority to regulate nutrition labeling in restaurants. The final legislation contained a preemption provision that was carefully drafted to preempt any "requirement for nutrition labeling of food that is not identical to" section 343(q), "*except* a requirement for nutrition labeling of food which is exempt" from section 343(q)—that is, *except* a requirement for nutrition labeling of restaurant food. § 343-1(a)(4) (emphasis added). On the day that the NLEA passed the Senate by a voice vote, the Act's chief Senate sponsor, Senator Howard Metzenbaum of Ohio, explained the meaning of this exception:

> Because food sold in restaurants is exempt from the nutrition labeling requirements of section 403(q)(1)-(4), *the bill does not preempt any state nutrition labeling requirements for restaurants.*

136 Cong. Rec. S16607-02, S16608 (Oct. 24, 1990) (Sen. Metzenbaum) (emphasis added). The result is an Act that carefully avoids creating a regulatory vacuum: State law is preempted only to the limited extent that federal law specifically covers the same territory.

ARGUMENT

I. THE NLEA LEAVES LOCAL GOVERNMENTS FREE TO ENACT MANDATORY NUTRITION-DISCLOSURE REQUIREMENTS FOR RESTAURANT FOOD.

Because "[t]he FDA does not have regulatory authority to require nutrition information in restaurants," *FDA Keystone Report* at 74; *accord FDA Calories Count Report* at V.B., what NYSRA's lawsuit effectively seeks is a holding that federal law preempts states and cities from doing what the federal government itself lacks authority to do. NYSRA, in other words, asks this Court to create a permanent regulatory vacuum—a zone in which the federal, state, and local governments are all powerless to act in the face of what is widely acknowledged to be a public-health epidemic. Given the presumption against preemption, this Court should be especially wary of taking such a radical step. "[B]ecause the States are independent sovereigns in our federal system," federal courts presume "that the historic police powers of the States were not to be superseded by [statute] unless that was the clear and manifest purpose of Congress." *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996). As this Court has already recognized, that presumption is "clearly applicable" in this controversy, and "indeed, stands at its strongest" where matters of public health are at stake. *NYSRA I*, 509 F. Supp. 2d at 355 (quoting *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94 (2d Cir. 2007)).[9]

[9] Although NYRSA has properly abandoned the implied-preemption claim it raised in its first lawsuit, it again suggests (at 19-20) that New York City has somehow interfered with an FDA policy of "flexibility" concerning how restaurants may present nutrition information. But, as we pointed out last time, because "the FDA has no statutory authority under the NLEA to mandate nutritional disclosure by the fast food industry," "its reluctance may be explained simply by its lack of authority." Michael A. McCann, *Economic Efficiency and Consumer Choice Theory in Nutritional Labeling*, 2004 Wis. L. Rev. 1161, 1191 n.164 (2004).

In any event, "[t]here is no federal pre-emption *in vacuo*." *Puerto Rico Dep't of Consumer Affairs*, 485 U.S. 495, 503 (1988); *see Pelman*, 237 F. Supp. 2d at 525-26 (rejecting McDonald's argument that Congress's decision not to impose mandatory nutrition labeling requirements on restaurants preempts state law nutrition labeling requirements for restaurants); *see also*

In fact, Congress focused closely on the nutrition labeling of restaurant food and preemption during its consideration of the NLEA and intentionally carved out room for state and local governments to fill the gaps left by the statute. Section 343(q) of the NLEA requires that food sellers disclose specific nutrition information about most food products sold in the United States, including "nutrition information that provides . . . the total number of calories . . . derived from any source . . . in each serving size or other unit of measure of the food." § 343(q)(1)(C)(i). Under NLEA's preemption provision, states and local governments are *not* free, as a general matter, to adopt "any requirement for nutrition labeling of food" that is not "identical" to what federal law requires. § 343-1(a)(4). Thus, New York City clearly could not adopt a rule requiring the disclosure of the amount of calories in boxes of cereal sold in New York grocery stores.

But New York City is not similarly constrained when it comes to regulating local restaurants. As discussed above, Congress sought to avoid a regulatory vacuum by intentionally excepting state requirements for nutrition labeling of restaurant food from NLEA preemption at the same time that it exempted restaurant food from the new federal labeling requirements. The NLEA preempts "any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) . . . *except a requirement for nutrition labeling of food which is exempt*" under that section—i.e., a requirement for nutrition labeling of restaurant food. § 343-1(a)(4) (emphasis added); s*ee* § 343(q)(5)(A)(i) (providing that section 343(q)'s nutrition labeling requirements "shall

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Sprietsma v. Mercury Marine, 537 U.S. 51, 65 (2002) (holding that it is "quite wrong" to view the Coast Guard's decision not to require propeller guards on motor boats as the "functional equivalent" of a prohibition against state regulation of the subject matter; the decision was "fully consistent with an intent to preserve state regulatory authority"); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 289 (1995) (where agency had no standard either requiring or prohibiting anti-lock brakes, state claim regarding anti-lock brakes was not preempted). Thus, that FDA has not required nutrition labeling by restaurants in no way precludes cities and states from doing so.

not apply to food . . . which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments").

Taken together, these three provisions—sections 343-1(a)(4), 343(q)(5)(A)(i) and 343(q)(1)(C)(i)—demonstrate that Congress intended that the NLEA would not preempt state requirements "for nutrition labeling"—including labeling "that provides . . . the total number of calories"—for "food . . . which is served in restaurants." Accordingly, this Court has twice rejected the proposition that the NLEA preempts a state-law requirement that restaurants disclose nutritional information about their food. *See NYSRA I*, 509 F. Supp. 2d at 363 (concluding that New York City is "free to enact mandatory disclosure requirements of the nature sanctioned by § 343(q)"); *Pelman*, 237 F. Supp. 2d at 526 ("A finding that a lack of nutritional labeling on McDonalds' products violates [New York law] therefore is explicitly not pre-empted by the NLEA.").

The legislative history fully supports that common-sense interpretation of the statute's text. Senator Howard Metzenbaum's statement—"the bill does not preempt *any* State nutrition labeling requirements for restaurants"—could hardly have been clearer on this point. 136 Cong.Rec. S16607-02, S16608 (Oct. 24, 1990) (Sen. Metzenbaum) (emphasis added).

The FDA is of the same view. *See* FDA, *A Guide for Restaurants and Other Retail Establishments*, *available at* http://www.cfsan.fda.gov/~frf/qatext2.html ("*Question:* Can a State require restaurant foods to bear nutrition labeling even if the food is exempt under Federal requirements? *Answer:* Yes . . . [B]ecause the act exempts restaurant foods that do not bear a claim from mandatory nutrition labeling, State requirements for the nutrition labeling of such foods would not be preempted."). Notably, this FDA

statement specifically distinguishes between "mandatory nutrition labeling" of the type required under section 343(q)—from which restaurant food is exempt—and "foods that bear a claim" under section 343(r), and follows the common-sense reading of the statute discussed above. Moreover, subsequent FDA and FDA-sponsored publications are fully consistent with the 1995 statement, s*ee, e.g.*, *Keystone Report* at 74; *FDA Calories Count Report* at V.B, and NYSRA does not contend otherwise.

NYSRA (at 26-27) attempts to downplay the obvious tension between its preemption argument, on the one hand, and the NLEA's savings-clause contained in § 343-1(a)(4), the legislative history, the FDA's view, and the holdings of this Court, on the other hand. Ignoring the fact that its reading of the statute opens up a gaping regulatory vacuum, NYRSA argues that this is a "false tension" because the "absence of preemption" under section 343-1(a)(4) is "irrelevant" to the question whether there is preemption under section 343-1(a)(5). But the savings-clause that Congress placed at the end of § 343-1(a)(4) is not irrelevant. "That Congress added the remainder of the provision is evidence of its intent to draw a distinction between state labeling requirements that are pre-empted and those that are not." *Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005). Section 343-1(a)(4) distinguishes between "requirement[s]" for nutrition labeling of food" that are preempted and those that are not, and specifically placed mandatory restaurant nutrition-content labeling in the latter category.

NYSRA's reading of the statute fails to distinguish between the sphere of regulation of nutritional information in restaurants that Congress expressly left open to state and local regulation in section 343-1(a)(4) (the companion preemption provision to section 343(q)), and the types of regulations respecting "claims" within the meaning of sections 343-1(a)(5) (the companion preemption provision to section 343(r)). NYRSA's

position would thus effectively read the savings-clause for restaurants out of the statute. Evidence of Congress's intent to preserve the ability of states to impose nutrition-labeling requirements for restaurant food should not be so lightly cast aside, particularly in light of the presumption against preemption. Not only is there no "clear and manifest" evidence of Congressional intent to preempt restaurant labeling regulations like New York's, *Lohr*, 518 U.S. at 485, but the clearest evidence of Congressional intent—the statutory language, legislative history, and agency interpretation, all addressing precisely the question of preemption of state nutrition labeling requirements for restaurant food—points decisively away from preemption.

II. THE REVISED RULE DOES NOT REGULATE VOLUNTARY "CLAIMS" THAT USE DESCRIPTIVE "TERMS" TO "CHARACTERIZE" NUTRIENT LEVELS.

As it did in its previous lawsuit, NYSRA attempts to sidestep Congress's decision to save local restaurant nutrition-labeling requirements from preemption by arguing that the New York rule covers the same ground as section 343(r)'s prohibition of unauthorized or unsubstantiated descriptive "claims" that food sellers choose to make about their food. *See* § 343(r) (prohibiting any "claim" that "characterizes" the nutrient content of food unless the "characterization" employs specific "terms" defined by the FDA); § 343-1(a)(5) (preempting state law "respecting any claim of the type described in section 343(r)"). For this express preemption argument to succeed, the Restaurant Association must demonstrate that New York Health Code Regulation § 81.50 is a "requirement respecting any claim of the type described in section 343(r)." § 343-1(a)(5). NYSRA's argument depends on a reading of the NLEA under which the carefully-calibrated differences between the Act's two main sections disappear: Any statement that a restaurant makes about the nutritional content of its food—voluntary or mandated by

law, descriptive or factual—would be a "claim," and so a state or local law mandating the nutrition labeling of restaurant food would be a requirement respecting "claims."

But New York City's revised rule has nothing to do with "claims" within the meaning of section 343(r). The New York rule merely requires restaurants to make factual nutrition disclosures, just as section 343(q) requires manufacturers of packaged food to make factual nutrition disclosures. The rule neither prevents restaurants from making, nor limits the circumstances under which they may make, voluntary, descriptive claims characterizing the nutrient content or health effects of their food. Restaurants in New York remain just as free as they were in the past to make such descriptive claims, so long as they comply with federal law.

A. The revised rule has nothing to do with voluntary "claims."

Any construction of the word "claim" in section 343(r) must be informed by the distinction between mandatory factual disclosures and voluntary descriptive statements on which the entire structure of the NLEA is premised. As discussed in the statutory and regulatory background section above, the NLEA and its regulations "encompass two kinds of information—the mandatory information on nutrients which will appear on the nutrition panel of nearly all food labels, and the voluntary information that some manufacturers choose to add to their product labels." Guarino, *Nutrient Descriptor and Disease Claims for Foods*, 48 Food & Drug L.J. 665, 671 (1993); *accord NYSRA I*, 509 F. Supp. 2d at 363 (discussing significance of NLEA's mandatory-voluntary distinction); *Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 223 (2d Cir. 1998) (describing section 343(r) as giving FDA authority to "limit the health claims that may be made" by "persons desiring to make health claims on labeling"); *Reyes v. Mcdonald's Corp.*, 2006 WL 3253579, at *4 (N.D.Ill. 2006) (discussing purely voluntary nature of regulation under

section 343(r); "in the event a restaurant chooses to make nutrition claims, it subjects itself to the requirements of the NLEA"). Both Section 343(q) and New York's rule address the former sort of information, while section 343(r) addresses the latter.

"The difference between requiring certain information on a food label and merely allowing truthful and non-misleading information to appear on the label cannot be understated. Mandatory labels bind all manufacturers of a given product to provide standardized information about their product so that consumers can make essential choices . . . Voluntary labels, on the other hand, are typically utilized when a manufacturer wishes to distinguish his product from a competing product." Keane, *The Case of Food Labeling*, 16 Transnat'l L. & Contemp. Probs. 291, 295 (2006). The New York rule, similarly, binds all covered restaurants to provide standardized factual information about their products to allow consumers to make informed choices, but neither prohibits nor permits descriptive claims that restaurants choose to make about the benefits of their food over that of their competitors.

The FDA has consistently taken the view that "[n]utrient content claims are *voluntary statements* that can assist consumers in selecting foods that may lead to a healthier diet." 64 Fed. Reg. 62745-01, 62758 (Nov. 17, 1999) (emphasis added); 62 FR 49868-01, 49878 (Sept. 23, 1997) ("[T]he use of nutrient content claims is *entirely voluntary*."); 72 FR 52783-01, 52787 (Sept. 17, 2007) (regulatory-impact analysis stating that FDA rule implementing section 343(r) is limited to "*voluntary claims*") (emphasis added); 58 FR 33055-01, 33058 (June 15, 1993) ("[H]ealth or nutrient content claims are *voluntary*.") (emphasis added); Schneeman, *FDA's Review*, J. Nutr. 137:493-494 ("Health claims for foods and dietary supplements are *voluntary statements* that characterize the

relation between a substance and its ability to reduce the risk of disease or health-related condition in healthy populations.") (emphasis added).

The FDA's interpretation is entitled to deference from this Court, *Hillsborough County v. Automated Med. Labs, Inc.*, 471 U.S. 707, 714-15 (1985), and is fully supported by the text, structure, history, and purpose of the statute. As used in the NLEA, the word "claim" is a term of art that refers to an express or implied statement about a food product's nutrient content or health effects that is made voluntarily and intentionally by a manufacturer and that may or may not be substantiated; the purpose of the statute is to protect consumers by ensuring that only substantiated, non-confusing statements are made. *See Webster's Third International Dictionary* 414 (2002) (defining "claim" as "an assertion, statement, or implication (as of value, effectiveness, qualification, eligibility) often made or likely to be suspected of being made without adequate justification."). Section 343(r) covers a "claim" made on a food label that "characterizes" the level of a nutrient or the relationship of a nutrient to a disease or health-related condition, providing that such claims "may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the [FDA]." §§ 343(r)(1), 343(r)(2)(A)(i).

The same or similar use of the word "claim" appears in various places in the U.S. Code to denote assertions made by the vendors or manufacturers of food or agricultural products, both within the NLEA, *see* 21 U.S.C.A. § 343(q)(5)(C) ("the requirements of such subparagraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any *claim* with respect to the nutritional value of such food"), and elsewhere, *see, e.g.*, 7 U.S.C. § 2105(a) ("false or unwarranted *claims* in behalf of cotton or its products or false or unwarranted statements with respect to the quality,

value, or use of any competing product."); 7 U.S.C.A. § 2617(f)(2) ("no advertising or sales promotion program shall make any reference to private brand names or use false or unwarranted *claims* in behalf of potatoes or their products"). In these and other instances, the law regulates voluntary advertising claims in contexts where there is some risk that consumers will be deceived by unsubstantiated assertions or confused by the use of ambiguous or misleading terms.

The final sentence of section 343(r)(1) also supports the understanding that "claims" are statements that are made voluntarily rather compelled by law: "A statement of the type required by paragraph (q) . . . that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph." § 343(r)(1) (emphasis added). NYSRA (at 23-25) says this language is "irrelevant" because it "states *only* that disclosures required by subsection (q) are not claims." But it makes sense that Congress would have specifically addressed the interaction between the two sections of the statute, to clarify that the statements *mandated or permitted* by section 343(q) are not also covered by section 343(r), which regulates *purely voluntary* statements. The need for clarification arose with respect to voluntary statements that could be made on the Nutrition Fact Panel. *See* 56 Fed. Reg. 60421-01, 60424 (Nov. 27, 1991) (explaining that "[t]his exclusion was included in the 1990 amendments to make it clear that the information required on the nutrition label, *and the optional statements that are permitted as part of nutrition labeling*, are not claims under section [343(r)] of the act…"); 136 Cong. Rec. H5836-01 at H5841 (Statement of Rep. Waxman) (stating that the intent of this provision was to "make it clear" that information required on the Nutrition Fact Panel "is not a claim," and that the provision "*would extend to optional statements* permitted on the panel containing nutrition information, but the identical

information will be subject to section [343(r)] if it is included in a statement in another portion of the label") (emphasis added). Congress and the FDA, in other words, wanted to make clear that voluntary statements permitted by section 343(q), which one might have through would be considered claims under section 343(r), are not considered claims when made on the mandated nutrition label. NYSRA points to no explanation, nor any support in the statute or regulations, for the notion that Congress might have silently decided to treat some kinds of disclosures compelled by law as claims.

NYSRA suggests (at 25) that reading section 343(r) as limited to voluntary statements leads to the following absurd hypothetical: "[I]f the city mandates that a food purveyor identify food 'low in fat' (under whatever definition the city chooses to apply), then the statement is no longer a 'claim' (because it is mandated by the city), and the city is free to override the federal regime." NYSRA futher posits that "New York City might, under this theory, require disclosure of the amount of calories of a serving of breakfast cereal on the front panel of the box." But, as described above, New York City is already prohibited from taking that step by section 343-1(a)(4)—which prevents states from requiring nutritional-information disclosure requirements on food labels unless they are identical to federal requirements—regardless of how one interprets section 343(r). Moreover, as to all food, both restaurant food and packaged food, any problem posed by NYSRA's hypothetical would be addressed by section 343(a) of the Food, Drug and Cosmetic Act, which prohibits false or misleading statements. A statement that a food is "low in fat," when it in fact is not low in fact under the federal definition of that term, would mislead consumers and would therefore render that food misbranded under section 343(a). Any state law that required a food manufacturer to do something that

makes compliance with federal law impossible would be preempted. *See Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

In fact, it is NYSRA's reading of the statute that leads to absurd results. NYSRA effectively reads "claims" so broadly that virtually *any* statement containing nutritional information on restaurant food constitutes a claim. But it is difficult to sensibly read the language of the NLEA's "claims" provision, section 343(r), or the regulatory scheme that accompanies it, to cover factual nutrition-information disclosures that are mandated by law. The FDA rule on which NYSRA relied most heavily in its previous lawsuit, 21 C.F.R. § 101.10, provides that a restaurant that makes a descriptive claim of the type covered by section 343(r) must disclose "the nutrient amounts that are the basis for the claim," which are considered the "functional equivalent" of the type of nutritional labeling required of packaged foods. 21 C.F.R. § 101.10. But under NYSRA's construction, under which even a compelled nutrition disclosure by a restaurant is a "claim," there would apparently be no difference between the statement that triggers that regulation in the first place (the "claim") and the factual disclosure that must accompany that statement.

B. The revised rule has nothing to do with claims that use descriptive "terms" to "characterize" nutrient levels.

Finally, even if disclosures compelled by law constitute "claims," as NYSRA contends, a straightforward factual disclosure about calorie content is not a claim that uses descriptive "terms" to "characterize" a nutrient level within the meaning of section 343(r), and thus would not be a "claim of the type described in section 343(r)." § 343-1(a)(5). In *NYSRA I*, this Court held that factual statements concerning nutrient amounts "fall at the very periphery of claims regulated by § 343(r), and the FDA has chosen to include them." 509 F. Supp. 2d at 360 n.12. If the Court reverses its prior holding concern-

ing the NLEA's voluntary/mandatory distinction, as NYSRA suggests, then it should reconsider that conclusion, at least insofar as it applies to straightforward factual disclosures mandated by law.

Section 343(r) uses the word "characterize" in the sense of "to describe the character or individual quality of," as in, for example, "He characterized her in a few well-chosen words." *American Heritage Dictionary of the English Language*, 4th ed. (2006); *see also Webster's Third International Dictionary* 376 (2002) (defining "characterize" as "to describe the essential character or quality of," as in "characterize a friend in a few words"). Thus, factual statements that do not implicitly or explicitly use "terms" to "characterize" the nutrient content of food are not "claims" of the type described in section 343(r).

The FDA's regulations—which are entitled to deference to the extent that they do not exceed the authority conferred by the statute, *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984)—are consistent with that interpretation. The regulations define a nutrient content claim as "[a] claim that expressly or implicitly characterizes the level of a nutrient of a type required to be in nutrition labeling under [the regulations implementing 343(q)]." 21 C.F.R. § 101.13(b). The regulations go on to provide an extensive dictionary of "terms" that "characterize" nutrient levels—including *light*, *lite*, *high*, *rich in*, *excellent source of*, *good source of*, *contains*, *provides*, *more*, *fortified*, *enriched*, *added*, *extra*, and *plus*. 21 C.F.R. §§ 101.54-101.69; *see also* FDA, *Definitions of Nutrient Content Claims*, *Food Labeling Guide—Appendix A*, http://www.cfsan.fda.gov/~dms/flg-6a.html; FDA, *Label Claims: Nutrient Content Claims*, http://www.cfsan.fda.gov/~dms/lab-nutr.html. The FDA has limited section 343(r)'s coverage to any "claim that expressly or implicitly *characterizes* the level of a

nutrient," 21 C.F.R. 101.13(b) (emphasis added), and thus confirms that a statement is a "claim" within the meaning of section 343(r) only if it uses descriptive terms—such as "low," "more" or "contains"—to characterize the level of nutrients. *See*, *e.g.*, 21 C.F.R. 101.54(c) (listing "contains" as a descriptive term and limiting its use).

In keeping with the plain meaning of the word "characterize," the same regulation makes clear that section 343(r) does not extend to straightforward listings of calorie amounts that are not accompanied by statements that implicitly "characterize" the calorie content. "The label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:"

> (3) The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required.

21 C.F.R. § 101.13(i)(3).[10] Notably, the regulation uses the bare phrase "100 calories" as an illustration of a statement about the "amount or percentage of a nutrient" that does *not* "characterize" a nutrient level. Again using "100 calories" as an example, the FDA explained the reasoning for the regulation as follows:

> [B]ased on the comments and its review of the 1990 amendments, FDA finds that there are some circumstances in which an amount claim cannot be considered to characterize in any way the level of a nutrient in a food. For example, the statement "100 calories" or "5 grams of fat" on the principal display panel of a food would be a simple statement of amount that, by itself, conveys no implied characterization of the level of the nutrient.

58 Fed. Reg. 2302-01, 2310 (Jan. 6, 1993).

[10]The qualification that a statement may not be "false or misleading in any respect" is a reference to FDA's general authority, under section 343(a), to regulate false or misleading food advertising or labeling. Notably, the NLEA does not list section 343(a) among the provisions of the statute that preempt state law. *See* Jordan, *Preemption and Uniform Enforcement*, 49 Food & Drug L.J. at 402.

FDA's guidance concerning its regulations expands on the same point: "Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*. An accurate quantitative statement (e.g., 200 mg of sodium) that does not 'characterize' the nutrient level may be used to describe any amount of a nutrient present." FDA, *Claims that Can Be Made for Conventional Foods and Dietary Supplements* (2003) (emphasis added), *available at* http://www.cfsan.fda.gov/~dms/hclaims.html; *see also* Guarino, *Nutrient Descriptor and Disease Claims for Foods*, 48 Food & Drug L.J. at 671 (discussing 21 C.F.R. § 101.13(i)(3)).

* * *

In short, New York's revised rule does not address "claims" that restaurants may decide to make about their food, let alone claims that "characterize" nutrient levels using descriptive "terms" of the type regulated by section 343(r) and its implementing regulations. Rather, New York's rule mandates nutrition labeling for certain restaurant food, just as section 343(q) mandates nutrition labeling for packaged food, and thus falls squarely into the sphere that Congress intentionally left open to the states.

III. THE RESTAURANT ASSOCIATION'S FIRST AMENDMENT THEORY STANDS THE COMMERCIAL SPEECH DOCTRINE ON ITS HEAD.

1. To explain why the Restaurant Association's First Amendment theory fares no better than its preemption claim, it would be difficult for us to improve on Judge Walker's opinion in *National Electrical Manufacturers Association v. Sorrell*, 272 F.3d 104, 113-16 (2d Cir. 2001). *Sorrell* upheld a Vermont law that required manufacturers to inform consumers that their products contain mercury and should be recycled or

disposed of as hazardous waste. Applying the reasonable-relationship test of *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), the court held that the First Amendment is satisfied "by a rational connection between the purpose of a commercial disclosure requirement and the means employed to realize that purpose." 272 F.3d at 114-15. By contrast, the more demanding intermediate-scrutiny standard of *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), is reserved for statutes that *restrict* commercial speech. In this case, NYSRA does not deny that there is a reasonable relationship between the means and the ends of New York City's calorie-labeling rule, and that is enough to dispose of its claim.[11]

2. The Restaurant Association's plea for heightened scrutiny would not only run afoul of *Sorrell* but would turn the commercial speech doctrine on its head. In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976), Public Citizen represented the plaintiff consumer council, whose members wanted

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[11] NYSRA's three attempts to distinguish *Sorrell* are unpersuasive. *First*, the suggestion (at 40) that an ordinary commercial disclosure requirement is constitutional only when it is "an adjunct necessary to implement a law that makes a certain activity unlawful" has no support in existing law. Disclosure alone—disclosure of a product's safety risks, or the terms of consumer credit, or the source of campaign contributions—is a legitimate governmental objective in its own right.

Second, NYSRA (at 40-41) confuses the nature of *what* must be disclosed with controversy over *whether* it must be disclosed. NYSRA has every right to "vigorously dispute[] the city's point of view that informed nutritional decisions can be made by considering calories out of the context of other nutritional values." Its expression of that view, whether in its brief to this Court or in the public square, is protected speech. But New York's rule neither prevents restaurants from expressing that view nor forces them to express a contrary view any more than the Vermont law in *Sorrell* forced lightbulb manufacturers to embrace the state's views on mercury, the wisdom of disclosing its presence, or the need to recycle it.

Third, the proposition (at 41-43) that *Zauderer* applies only to disclosure requirements that prevent "misleading speech" is one that both the First and Second Circuits have expressly rejected. *Sorrell*, 272 F.3d at 115; *Pharmaceutical Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 310 n.8 (1st Cir. 2005). Although "the overall goal" of New York's rule is to reduce obesity, it is analyzed under *Zauderer* because "it is inextricably intertwined with the goal of increasing consumer awareness" of high calorie content in a variety of restaurant foods. *Sorrell*, 272 F.3d at 115. In any event, the City's rule *is* designed to combat widespread misperceptions among consumers about the calorie content of restaurant food, and so *Sorrell* controls either way.

information about drug prices so they could make informed decisions in the marketplace. The Court struck down a statute barring drug-price advertising because the "consumer's interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Id.* at 763. The commercial speech doctrine that has developed since *Virginia State Board* has consistently observed a "constitutional presumption favoring disclosure over concealment," *Ibanez v. Fla. Dep't. of Bus. and Prof'l Reg.*, 512 U.S. 136, 145 (1994), because "disclosure furthers, rather than hinders" First Amendment values: "Protection of the robust and free flow of accurate information is the principal First Amendment justification for protecting commercial speech." *Sorrell*, 272 F.3d at 114. It is for this reason that commercial disclosure requirements are assessed under the reasonable-relationship standard. *Id.* at 115; *cf. Rubin v. Coors Brewing Co.*, 514 U.S. 476, 484 (1995) (citing federal nutrition labeling requirements as evidence of a trend "favor[ing] greater disclosure of information, rather than less"). As *Sorrell* recognized, subjecting purely factual commercial disclosure requirements to heightened scrutiny would upend these settled principles and distort the commercial speech doctrine into a *barrier* to the free flow of information that may be critical to promoting public health. 272 F.3d at 115.

NYSRA's theory in this case is even more radical than the challenge rejected in *Sorrell*, because it asks the Court to apply not just intermediate scrutiny but *strict scrutiny*, on the grounds that the New York rule constitutes "compelled speech" under *United States v. United Foods, Inc.*, 533 U.S. 405 (2001)—a decision that struck down a requirement that mushroom growers pay for advertising by a private agricultural association. The question in *United Foods* was "whether the government may underwrite and sponsor speech with a certain viewpoint using special subsidies exacted from a

designated class of persons, some of whom object to the idea being advanced." *Id.* at 410. Although the mushroom growers were "required simply to support speech by others, not to utter the speech itself," the Court held that such "mandated support is contrary to the First Amendment principles set forth in cases involving expression by groups which include persons who object to the speech, but who, nevertheless, must remain members of the group by law or necessity." *Id.* at 413. The Court emphasized that "the mandatory assessments imposed require[d] one group of private persons to pay for speech by others." *Id.* at 416. Here, by contrast, the New York rule does not require restaurants to pay for speech by others, does not require them to support or belong to any private association, and does not require them to fund or express *any* viewpoint, let alone a viewpoint with which they disagree.

To appreciate just how much NYSRA's First Amendment theory would disrupt settled law, it is worth considering how it would change the outcome not only in *Sorrell*, but in many other cases (all decided after *United Foods*) that have adopted *Sorrell*'s approach in the face of similar compelled-speech challenges to various disclosure and posting laws. *See Envt'l Defense Center v. E.P.A.*, 344 F.3d 832, 848-851 (9th Cir. 2003) (upholding a requirement that storm-sewer providers distribute information concerning the environmental hazards of stormwater discharges and steps the public can take to reduce pollutants in stormwater runoff); *UAW-Labor Employment & Training Corp. v. Chao*, 325 F.3d 360, 365 (D.C. Cir. 2003) (upholding requirement that federal contractors post notices at all of their facilities informing employees of rights under federal labor law that protect employees from being forced to join a union or to pay mandatory dues for costs unrelated to representational activities); *Rowe*, 429 F.3d 294, 316 (1st Cir. 2005) (upholding Maine law requiring intermediaries between drug companies and pharmacies

to disclose their conflicts of interest and financial arrangements); *United States v. Wenger*, 292 F. Supp. 2d 1296, 1303-04 (D. Utah 2003) (upholding federal securities disclosure requirements); *BellSouth Adver. & Pub. Corp. v. Tenn.*, 79 S.W.3d 506, 516-21 (Tenn. 2002) (upholding requirement that "baby Bell" phone company disclose to consumers the names of its local-phone-company competitors on the covers of its phonebooks). Notably, the Restaurant Association makes no attempt to grapple with any of these post-*United Foods* cases.

As these cases recognize, "the First Amendment's guarantee of freedom from 'compelled speech' is not absolute. Particularly in the commercial arena, the Constitution permits the State to require speakers to express certain messages without their consent, the most prominent examples being warning and nutritional information labels." *Entertainment Software Ass'n v. Blagojevich*, 469 F.3d 641, 651 (7th Cir. 2006) (distinguishing between "opinion-based" compelled speech and "purely factual disclosures," such as "whether a particular chemical is within any given product"); *Dutchess/Putnam Restaurant & Tavern Ass'n, Inc. v. Putnam County Dep't of Health*, 178 F.Supp.2d 396, 406 (S.D.N.Y. 2001) (rejecting the "argument that a sign stating that there are health risks to children from secondhand smoke is an 'ideological' message") (McMahon, J.); *BellSouth*, 79 S.W.3d at 516-521 (holding that *Zauderer*, not *United Foods*, supplies the proper standard in cases involving factual commercial disclosure requirements); *Rowe*, 429 F.3d at 316 (applying *Zauderer* and describing a compelled-speech challenge to a commercial disclosure requirement as "completely without merit"); *see also Johanns v. Livestock Marketing Ass'n*, 544 U.S. 550, 557 (2005) (explaining that the Court has recognized only two kinds of compelled-speech cases: "true compelled-speech cases," in which an

individual is forced to personally express an opinion with which he disagrees out of his own mouth, and "compelled-subsidy cases," like *United Foods*.).

Under NYSRA's expansive theory of compelled speech, countless federal, state and local laws mandating disclosure on a wide range of subjects—from tobacco, pesticides, and pollutants, to hand-washing by restaurant employees—would fall, after being exposed to "searching scrutiny by unelected courts." *Sorrell*, 272 F.3d at 116. "There are literally thousands of similar regulations on the books—such as product labeling laws, environmental spill reporting, accident reports by common carriers, [and] SEC reporting as to corporate losses." *Rowe*, 429 F.3d at 316. As Judge Walker noted in *Sorrell*, even the mandatory nutrition labeling provisions of the NLEA would be among those laws placed at risk. 272 F.3d at 116 (citing 21 U.S.C. 343(q)). "Such a result is neither wise nor constitutionally required." *Id.*

CONCLUSION

For the foregoing reasons, the Court should reject the New York State Restaurant Association's request to invalidate New York City Health Code Regulation 81.50.

Respectfully submitted,

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APPENDIX LISTING *AMICI CURIAE*

This brief is submitted on behalf of the following *amici*:

U.S. Representative Henry Waxman was the chief sponsor of the Nutrition Labeling and Education Act (NLEA) in the U.S. House of Representatives and has long been a leader in Congress on nutrition and food policy issues. He has represented California's 30th District since 1974 and is currently the Chairman of the House Committee on Oversight and Government Reform, which has oversight authority over all federal agencies, including the U.S. Food and Drug Administration.

Public Citizen is a non-profit consumer advocacy organization with a long-standing interest in fighting exaggerated claims of federal preemption of state health and safety regulation and defending consumers' rights to know information that affects their health. Public Citizen's lawyers, who have argued many of the most significant federal preemption cases, represent the plaintiffs in all three food-and-drug-law preemption cases currently pending before the U.S. Supreme Court—*Riegel v. Medtronic*, No 06-179, *Warner-Lambert Co. v. Kent*, 06-1498, and *Wyeth v. Levine*, 06-1249; *see also Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005); *Medtronic v. Lohr*, 518 U.S. 470 (1996). Public Citizens's lawyers have also argued several of the seminal cases involving the commercial speech doctrine, *see e.g.*, *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748 (1976); *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985); *Edenfield v. Fane*, 507 U.S. 761 (1993).

Center for Science in the Public Interest (CSPI) is a national, non-profit advocacy organization for nutrition and health, food safety, and sound science. CSPI's advocacy was instrumental in getting Congress to consider nutrition labeling legislation in 1989 and in securing passage of the NLEA in 1990, and CSPI has tirelessly advocated for effective FDA enforcement of the NLEA in the seventeen years since its enactment. In addition, CSPI led the advocacy efforts on behalf of New York City's restaurant calorie labeling rule and is working with other cities and states across the nation on similar measures.

The **American Diabetes Association** is a nationwide non-profit organization founded in 1940 to advance the interests of the now nearly 21 million Americans with diabetes. ADA's mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. It is the nation's leading voluntary health organization supporting diabetes research, information and advocacy. ADA believes that providing calorie information available through postings on menu boards is a critical step in helping people get the information they need to understand how foods they eat impact their weight and overall nutrition goals.

The **American Medical Association**, an Illinois non-profit corporation, is the largest professional association of physicians and medical students in the United States. The AMA was founded in 1847 to promote the science and art of

medicine and the betterment of public health, and these still remain its core purposes. Its members practice in every state, including New York, and in every specialty. In June 2007, the AMA, concerned by the alarming incidence of obesity and of obesity-related medical conditions, specifically resolved that calorie content, in addition to other nutrition information, be displayed on menus and menu boards in fast-food and other chain restaurants.[12]

The **American Public Health Association** is the oldest, largest and most diverse organization of public health professionals in the world and has been working to improve public health since 1872. The Association aims to protect all Americans and their communities from preventable, serious health threats. APHA believes that requiring nutrition labeling at fast-food and other chain restaurants is particularly important given how many of our calories are consumed at restaurants, the large portion sizes and high calorie contents often served at restaurants, and the lack of nutrition information at restaurants.

California Center for Public Health Advocacy is a non-profit organization established in 1999 by California's two public health associations to raise awareness about critical public health issues and has been the lead advocate in California for laws that would require nutrition labeling on menus and menu boards in chain restaurants.

The Medical Society of the State of New York, an organization of approximately 30,000 licensed physicians, medical residents, and medical students in New York State, is committed to representing the medical profession as a whole and advocating on its behalf concerning health-related rights, responsibilities, and issues.

Trust for America's Health is a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority.

Sharon R. Akabas, Ph.D., is Associate Director of the Institute of Human Nutrition, and Director of the M.S. in Nutrition Program at Columbia University's College of Physicians and Surgeons, where her research focuses on childhood obesity prevention.

George L. Blackburn, M.D., Ph.D., holds the S. Daniel Abraham Chair in Nutrition Medicine at Harvard Medical School, where his research focuses on obesity and clinical nutrition. He is also the Chief of the Nutrition Laboratory and

[12] The AMA and Medical Society of the State of New York join this brief both in their own persons and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center was formed in 1995 as a coalition of the AMA and private, voluntary, nonprofit state medical societies to represent the views of organized medicine in the courts.

Director of the Center for the Study of Nutrition Medicine at the Beth Israel Deaconess Medical Center, Boston.

Carlos Camargo, M.D., M.P.H., Dr.P.H., is Associate Professor of Medicine & Epidemiology at Harvard Medical School, as well as past president of the American College of Epidemiology. He works clinically as an emergency physician at Massachusetts General Hospital and serves on several national committees related to asthma/COPD, emergency medicine, nutrition, and public health.

Richard J. Deckelbaum, M.D., is the Robert R. Williams Professor of Nutrition, Chairman of the Institute of Human Nutrition, and Professor of Pediatrics and Epidemiology at Columbia University's Mailman School of Public Health and College of Physicians and Surgeons, where his research focuses on translating basic nutritional questions into lipid and cellular biology.

Penny M. Kris-Etherton, Ph.D., is Distinguished Professor of Nutrition at Pennsylvania State University, where her research focuses on effects of diet on metabolism and platelet function.

Francine R. Kaufman, M.D., is Director of the Comprehensive Childhood Diabetes Center at Children's Hospital Los Angeles and Professor of Pediatrics at the University of Southern California School of Medicine. She is an expert on childhood diabetes-obesity epidemic and the author of *Diabesity* (2005).

David L. Katz, M.D., M.P.H., F.A.C.P.M., F.A.C.P., is Director and Co-Founder of the Yale Prevention Research Center, Founder and Director of the Integrative Medicine Center, and Associate Professor of Public Health at the Yale University School of Medicine. He is a nationally recognized authority on the prevention of chronic disease, nutrition, and weight management and has published nearly 100 scientific articles, as well as nine books.

Alice H. Lichtenstein, D.Sc., is the Stanley N. Gershoff Professor of Nutrition Science and Policy and Professor of Public Health and Family Medicine at Tufts University, as well as Senior Scientist and Director of the Cardiovascular Nutrition Laboratory at the Jean Mayer USDA Human Nutrition Research Center on Aging. Her research examines the effect of diet on disease risk factors.

Marion Nestle, Ph.D., M.P.H., is the Paulette Goddard Professor of Nutrition, Food Studies, and Public Health at New York University, where her research focuses on the role of food marketing as a determinant of dietary choice. Her books include *Food Politics: How the Food Industry Influences Nutrition and Health* (2002, revised 2007); and *What to Eat* (2006).

Barry M. Popkin, Ph.D., is the Carla Steel Chamblee Distinguished Professor of Global Nutrition at the University of North Carolina, Chapel Hill, where he directs the Interdisciplinary Center for Obesity and the Division of Nutrition

Epidemiology and studies dynamic changes in diet, physical activity, and body composition, with a focus on rapid changes in obesity.

Walter Willett, M.D., M.P.H., Dr.P.H., is the Fredrick John Stare Professor of Epidemiology and Nutrition at the Harvard School of Public Health, Professor of Medicine at Harvard Medical School, and the author of *Eat, Drink, and Be Healthy: The Harvard Medical School Guide to Healthy Eating.* He is also one of the principal investigators on the Nurses Health Study, one of the largest, long-term studies to look at the effect of diet on health.

APPENDIX OF STATUTORY AND REGULATORY PROVISIONS

New York City Health Code Regulation 81.50

§81.50 Posting of calorie information.

(a) Definitions and construction of words and terms used in this section.

(1) Covered food service establishment shall mean a food service establishment within the City of New York that is one of a group of 15 or more food service establishments doing business nationally, offering for sale substantially the same menu items, in servings that are standardized for portion size and content, that operate under common ownership or control, or as franchised outlets of a parent business, or do business under the same name.

(2) Menu shall mean a printed list or pictorial display of a food item or items, and their price(s), that are available for sale from a covered food service establishment and shall include menus distributed or provided outside of the establishment.

(3) Menu board shall mean any list or pictorial display of a food item or items and their price(s) posted in and visible within a covered food service establishment or outside of a covered food service establishment for the purpose of ordering from a drive-through window

(4) *Menu item* shall mean any individual food item, or combination of food items, listed or displayed on a menu board or menu that is/are sold by a covered food service establishment.

(5) *Food item tag* shall mean a label or tag that identifies any food item displayed for sale at a covered food service establishment.

(b) *Scope and applicability.* This section shall apply to menu items that are served in portions the size and content of which are standardized at a covered food service establishment. This section shall not apply to menu items that are listed on a menu or menu board for less than 30 days in a calendar year.

(c) *Posting calorie information for menu items.* All menu boards and menus in any covered food service establishment shall bear the total number of calories derived from any source for each menu item they list. Such information shall be listed clearly and conspicuously, adjacent or in close proximity such as to be clearly associated with the menu item, using a font and format that is at least as prominent, in size and appearance, as that used to post either the name or price of the menu item.

(1) *Calculating calories.* Calorie content values (in kcal) required by this section shall be based upon a verifiable analysis of the menu item, which may include the use of nutrient databases, laboratory testing, or other reliable methods of analysis, and shall be rounded to the nearest ten (10) calories for calorie content values above 50 calories and to the nearest five (5) calories for calorie content values 50 calories and below.

(2) *Food item tags.* When a food item is displayed for sale with a food item tag, such food item tag shall include the calorie content value for that food item in a font size and format at least as prominent as the font size of the name of the food item.

(3) *Drive-through windows.* Calorie content values at drive-through windows shall be displayed on either the drive through menu board, or on an adjacent stanchion visible at or prior to the point of ordering, so long as the calorie content values are as clearly and conspicuously posted on the stanchion adjacent to their respective menu item names, as the price or menu item is on the drive through menu board.

(4) *Range of calorie content values for different flavors, varieties and combinations.*

(i) *Different flavors and varieties.* For menu items offered in different flavors and varieties, including, but not limited to, beverages, ice cream, pizza, and doughnuts, the range of calorie content values showing the minimum to maximum numbers of calories for all flavors and varieties of that item shall be listed on menu boards and menus for each size offered for sale, provided however that the range need not be displayed if calorie content information is included on the food item tag identifying each flavor or variety of the food item displayed for sale, in accordance with paragraph (2) of this subdivision.

(ii) *Combinations.* For combinations of different food items listed or pictured as a single menu item, the range of calorie content values showing the minimum to maximum numbers of calories for all combinations of that menu item shall be listed on menu boards and menus. If there is only one possible calorie total for the combination, then that total shall be listed on menu boards and menus.

(d) *Effective date.* This section shall take effect on March 31, 2008.

(e) *Severability.* If any provision of this section, or its application to any person or circumstance, is held invalid by any court of competent jurisdiction, the remaining provisions or the application of the section to other persons or circumstances shall not be affected.

21 U.S.C. § 343. Misbranded food.

A food shall be deemed to be misbranded--

21 U.S.C. § 343(q). Nutrition information

(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides--

* * *

(C) the total number of calories--
(i) derived from any source, and
(ii) derived from the total fat,
in each serving size or other unit of measure of the food,

* * *

(5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food—
(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments[.]

21 U.S.C. § 343(r). Nutrition levels and health-related claims

(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication--

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

A statement of the type required by paragraph (q) of this section that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

(2)(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A)–

(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary[.]

21 U.S.C. §§ 343-1. National uniform nutrition labeling

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

* * *

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 343(q)(5)(A) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

21 U.S.C. § 343-1, note

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 [21 U.S.C. 343-1(a)] of the Federal Food, Drug, and Cosmetic Act.

21 C.F.R. 101.10. Nutrition labeling of restaurant foods.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (e.g., "low fat, this meal provides less than 10 grams of fat") may serve as the functional equivalent of complete nutrition information as described in § 101.9. Nutrient levels may be determined by nutrient data bases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of

nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

21 C.F.R. 101.13. Nutrition content claims—General principles

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.

(b) A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium" or "contains 100 calories."
(2) An implied nutrient content claim is any claim that:
(i) Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or
(ii) Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

* * *

(i) Except as provided in § 101.9 or § 101.36, as applicable, or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

* * *

(3) The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required.

21 C.F.R. 101.60. Nutrient content claims for the calorie content of foods.

(a) *General requirements.* A claim about the calorie or sugar content of a food may only be made on the label or in the labeling of a food if:
(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13;
(3) The food for which the claim is made is labeled in accordance with § 101.9, § 101.10, or § 101.36, as applicable; and
(4) For dietary supplements, claims regarding calories may not be made on products that meet the criteria in § 101.60(b)(1) or (b)(2) for "calorie free" or "low calorie" claims except when an equivalent amount of a similar dietary supplement (e.g., another protein supplement) that the labeled food resembles and for which it substitutes, normally exceeds the definition for "low calorie" in § 101.60(b)(2).

(b) *Calorie content claims.* (1) The terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietarily insignificant source of calories" may be used on the label or in the labeling of foods, provided that:
(i) The food contains less than 5 calories per reference amount customarily consumed and per labeled serving.
(ii) As required in § 101.13(e)(2), if the food meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to disclose that calories are not usually present in the food (e.g., "cider vinegar, a calorie free food").

(2) The terms "low calorie," "few calories," "contains a small amount of calories," "low source of calories," or "low in calories" may be used on the label or in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:
(i)(A) The food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and does not provide more than 40 calories per reference amount customarily consumed; or
(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and does not provide more than 40 calories per reference amount customarily consumed and, except for sugar substitutes, per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the "as prepared" form).
(ii) If a food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the caloric content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "celery, a low calorie food").

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m), provided that:

(i) The product contains 120 calories or less per 100 g; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the calorie content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which it attaches.

(4) The terms "reduced calorie," "reduced in calories," "calorie reduced," "fewer calories," "lower calorie," or "lower in calories" may be used on the label or in the labeling of foods, except as limited by § 101.13(j)(1)(i) and except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the calories differ between the two foods are declared in immediate proximity to the most prominent such claim (e.g., reduced calorie cupcakes "33 1/3 percent fewer calories than regular cupcakes"); and

(B) Quantitative information comparing the level of the nutrient per labeled serving size with that of the reference food that it replaces (e.g., "Calorie content has been reduced from 150 to 100 calories per serving.") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or labeling of foods if the reference food meets the definition for "low calorie."

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent fewer calories per 100 g of food than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the calories differ between the two foods are declared in immediate proximity to the most prominent such claim (e.g., Larry's Reduced Calorie Lasagna, "25 percent fewer calories per oz (or 3 oz) than our regular Lasagna"); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces (e.g., "Calorie content has been reduced from 108 calories per 3 oz to 83 calories per 3 oz.") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or labeling of food if the reference food meets the definition for "low calorie."