08-1892-cv

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

NEW YORK STATE RESTAURANT ASSOCIATION,
Plaintiffs-Appellants,

v.

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-Appellees.

On Appeal from the United States District Court for the Southern District of New York

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Brief of *Amici Curiae* U.S. Congressman Henry Waxman, Former FDA Commissioner David Kessler, Public Citizen, Center for Science in the Public Interest, American College of Preventive Medicine, 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 In Support of Appellees and for Affirmance

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May 15, 2008

DISCLOSURE STATEMENT

The organizational *amici curiae*—Public Citizen, Center for Science in the Public Interest, American College of Preventive Medicine, American Diabetes Association, American Medical Association, American Public Health Association, California Center for Public Health Advocacy, Medical Society of the State of New York, and Trust for America's Health—are non-profit, non-stock corporations. They have no parent corporations, no publicly held corporations have ownership interests in them, and they have not issued shares.

Dated: May 15, 2008

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INTERESTS AND IDENTITY OF *AMICI CURIAE*

In requiring chain restaurants to post calorie information on their menus, New York City stepped into a sphere that Congress intentionally left open to state and local governments when it enacted the Nutrition Labeling and Education Act (NLEA) in 1990. The following *amici curiae*— representing a broad range of expertise in the fields of public health, medicine, epidemiology, nutrition, law, and public policy— support both New York's decision, and its freedom to make that decision.

U.S. Congressman Henry Waxman was the lead sponsor of the NLEA in Congress and is currently Chairman of the House committee with oversight over FDA. David Kessler, M.D., was appointed Commissioner of the FDA by George H.W. Bush in 1990 and was sworn in on the day that President Bush signed the NLEA into law. Dr. Kessler served as Commissioner from 1990 through 1997, the period in which all of the key FDA regulations implementing the NLEA were promulgated. Public Citizen is an advocacy organization with longstanding interests in curtailing exaggerated claims of federal preemption of health regulation and defending consumers' right to know information that affects their health and Center for Science in the Public Interest is a nutrition advocacy organization and

was a leading advocate of both the NLEA and New York's menu labeling legislation.

This brief is joined by the nation's leading medical and public health organizations—the American Medical Association, the American Diabetes Association, the American College of Preventive Medicine, the Medical Society of the State of New York, the American Public Health Association, the California Center for Public Health Advocacy, and Trust for American's Health—as well as distinguished professors and researchers in the fields of medicine, nutrition, and public health. Because of the large number of *amici*, a more detailed listing of their identity and interests is set forth in an appendix to this brief. This brief is filed with the consent of all parties.

INTRODUCTION

Two years ago, an important FDA-commissioned report concluded that "obesity has become a public health crisis of epidemic proportions" and that the consumption of high-calorie meals at fast-food restaurants is a significant cause.[1] Echoing the consensus view of the public-health community—including the Surgeon General, the National Academies' Institute of Medicine, and *amicus* American Medical Association—the

[1] *The Keystone Forum on Away-from-Home Foods: Opportunities for Preventing Weight Gain and Obesity* (2006), at 1, a*vailable at* http://www.cfsan.fda.gov/~dms/nutrcal.html ("*Keystone Report*").

report concluded that "restaurants should provide consumers with calorie information in a standard format that is easily accessible," 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."[2] The report recognized that "the FDA *does not have regulatory authority* to require nutrition information in restaurants," but 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." *Id.* at 74 (emphasis added).

The New York State Restaurant Association (NYSRA) asks this Court to hold that federal law preempts states and local authorities from doing what the federal government itself lacks authority to do—to hold, in other words, that Congress created a regulatory vacuum on the important issue of mandatory nutrition labeling of restaurant food. Congress did no such thing when it passed the NLEA. To the contrary, Congress focused closely on both preemption and coverage for restaurants and enacted carefully limited express-preemption provisions that carved out room for state and local

[2] *Id.* at 76, 77-78.

government to fill the gaps left by the statute. 21 U.S.C. § 343-1(a)(4); *id.* § 343(q)(5)(A)(i). As the legislation'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) (emphasis added).

NYSRA, however, contends that New York's rule is preempted because it is a requirement respecting "claims" of the type regulated by a different section of the NLEA. *See* 21 U.S.C. § 343-1(a)(5); *id.* § 343(r)(1)(A). That contention fundamentally misconstrues the statutory scheme. The NLEA is premised on a distinction between requirements that food sellers disclose straightforward nutritional information (such as a listing of a total number of calories), on the one hand, and the regulation of descriptive "claims" that industry may choose to make about its food's nutritional content or health effects, on the other. New York's is the former sort of rule: It concerns only the mandatory disclosure of purely factual information, not the regulation of descriptive "terms" that restaurants may use to make voluntary "claims" that "characterize" the nutrients in their food.

NYSRA also maintains that the rule violates the First Amendment, but its position would create a conflict with the settled law of this Circuit, *see Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 113-16 (2d Cir. 2001), turn the commercial speech doctrine upside down, and jeopardize mandatory disclosure requirements that are ubiquitous in the law—including the disclosure requirements imposed by section 343(q) of the NLEA.

STATUTORY AND REGULATORY BACKGROUND

The NLEA produced groundbreaking changes in the way food is labeled in the United States. It required that basic nutrition facts be disclosed for most foods, prohibited the use of terms that characterize the level of nutrients in a food unless they conform to definitions established by FDA, and required that claims about the relationship between nutrients and health conditions be supported by scientific consensus. The Act was introduced by Representative Henry Waxman on July 27, 1989, and signed by President George H.W. Bush on November 8, 1990. Although Congress extensively debated a number of issues, including preemption of state law and restaurant coverage, the basic structure of the legislation—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 Labeling 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 NLEA's differential treatment of mandatory and voluntary statements flows from Congress's two distinct but complementary purposes—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 make about their foods. 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 FDA regulation concerning when and how food sellers may make voluntary 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) require food sellers to disclose "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. Sellers of food must make these disclosures to consumers directly on the food packaging, using the now-familiar "Nutrition Facts" panel chart. 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 Claims. In addition to requiring disclosure of nutrition facts, Congress 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. 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).

Prior to the NLEA's enactment, FDA had general authority to prohibit false or misleading food advertising or labeling. § 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 either 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" might mean light in fat, or light in color, or something else. Congress aimed to address this 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) 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. 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.

With respect to health claims, section 343(r) uses the word "claim" in much the same way, to refer to 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 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 restaurant 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 "served in restaurants" from nutrition labeling requirements of section 343(q)).

As a result, restaurant-food coverage turns on the Act's mandatory-voluntary distinction: Federal law does *not* require restaurants 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. But restaurants are not exempt from the Act's regulation of "claims." So the NLEA affects restaurants only 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 menu describes an item as "low fat" 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."). 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 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. In the final moments of the floor debate, Representative Waxman explained that carefully limited federal preemption 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).

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) (describing preemption provisions as "limited in scope" and stating that "the 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).

Because the NLEA exempts restaurant food from its 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) (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 expressly covers the same territory.

ARGUMENT

I. The NLEA Leaves New York City 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 the Restaurant Association effectively seeks from this Court is a holding that the NLEA bars *any* government from taking such action. NYRSA, in other words, wants this Court to create a 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). That presumption is "clearly applicable" and "indeed, stands at its strongest" where matters of public health are at stake." *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94 (2d Cir. 2007), *aff'd by equally divided court*, 128 S. Ct. 1168 (2008).

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 purveyors disclose specific facts 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 barred, as a general matter, from adopting "any requirement for nutrition labeling of food" that is not "identical" what federal law requires. § 343-1(a)(4). Thus, New York City may not adopt its own local rules requiring the disclosure of the

amount of calories on the front of boxes of cereal sold in grocery stores because that subject is governed by federal law.

But New York City is not similarly restrained when it comes to regulating local restaurants. As discussed above, Congress avoided creating 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 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." The NLEA, in other words, specifically does *not* preempt state-law requirements that restaurants disclose nutritional facts, such as the calorie content of their food.

The FDA's position is consistent with that straightforward interpretation. Indeed, in April 2008, after the district court's decision was issued, the FDA issued guidance on this very subject, stating that states and local governments may "require restaurant foods to bear nutrition labeling even if the food is exempt under Federal requirements . . . . [B]ecause the [NLEA] 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." FDA, *Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods*.[1] 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

[1] *available at* http://www.cfsan.fda.gov/~dms/labrguid.html

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 30-32) attempts to downplay the obvious tension between its preemption argument, on the one hand, and the savings-clause contained in section 343-1(a)(4), the legislative history, and the FDA's view, on the other hand. NYRSA argues that this is a false tension because the absence of preemption under section 343-1(a)(4) does not indicate an absence of preemption under section 343-1(a)(5). But NYSRA has no answer to the fact that its position would render the savings clause that Congress placed at the end of section 343-1(a)(4) superfluous. "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 requirements for nutrition labeling of food that are preempted and those that are not, and specifically placed restaurant nutrition-labeling in the latter category.

NYSRA offers no principled basis for distinguishing 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 out of the statute as far as restaurants are concerned. Federal courts should not ignore such clear evidence of Congress's intent to preserve the ability of states to impose nutrition labeling requirements for restaurant food, particularly in light of the presumption against preemption. *See Medtronic v. Lohr*, 518 U.S. 470, 485 (1996) (Congress's intent to preempt state law must be "clear and manifest").

II. New York's Rule Does Not Regulate Voluntary "Claims" That Use Descriptive "Terms" to "Characterize" Nutrient Levels.

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 purveyors 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 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).

But New York City's revised rule has nothing to do with such "claims." The New York rule merely requires factual nutrition disclosures. It 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. New York's rule has nothing to do with "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 Part I above, the NLEA and its regulations encompass two kinds of information—factual information that must be disclosed to consumers, and claims that manufacturers may voluntarily make to characterize the nutrient levels or health effects of their food. 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 authorizes descriptive claims that restaurants choose to make about the benefits of their food over that of their competitors.

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; 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.

NYSRA suggests (at 34) that the district court's interpretation of section 343(r) as limited to voluntary statements leads to the following absurd hypothetical: If the city mandates that a food seller identify food as "low sodium" (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 further posits that "states or localities could mandate sellers of packaged foods to 'disclose' on the front label the number of calories (or any other nutrient) per serving." NYRSA Br. at 34. But New York City is restrained from taking that step by section 343-1(a)(4), regardless of how one interprets section 343(r). Moreover, as to all food, both restaurant food and packaged food, any perceived problem that might be created by NYSRA's hypothetical could 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 sodium," when it in fact is not low in sodium under the federal definition of

that term, could mislead consumers and 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 in any event under the doctrine of conflict preemption.

In fact, it is NYSRA's reading of the statute that leads to absurd results. NYSRA effectively reads "claims" so broadly that the distinction between sections 343(q) and 343(r) collapses, and virtually *any* factual statement containing nutritional information constitutes a claim. But it is difficult to sensibly read the language of section 343(r), or the regulatory scheme that accompanies it, to cover factual nutrition-information disclosures that are mandated by law. An FDA regulation 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, there would apparently be no difference between the type of claim that triggers that regulation in the first place and the factual disclosure that must accompany the claim as a result.

B. New York's rule has nothing to with claims that use descriptive "terms" to "characterize" a nutrient level.

Finally, even if it were true that some disclosures compelled by law could constitute "claims" under the NLEA, a simple factual disclosure of the number of calories in food 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).

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).

FDA's 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. 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).

More to the point, and 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). 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).

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 come close to addressing "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.

III. The Restaurant Association's First-Amendment Theory Turns the Commercial Speech Doctrine Upside Down.

To explain why the Restaurant Association's First Amendment theory fares no better than its preemption arguments, it would be difficult to improve on this Court's decision in *National Electrical Manufacturers Association v. Sorrell*, 272 F.3d 104, 113-16 (2d Cir. 2001), which, in the face of an indistinguishable First-Amendment challenge, upheld a Vermont law requiring manufacturers to inform consumers that certain products contain mercury and should be recycled or disposed of as hazardous waste.

Adopting the Restaurant Association's plea for heightened scrutiny would not only afoul of *Sorrell*, but would turn the commercial-speech doctrine upside down. In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976), the first case to establish First Amendment protection for commercial speech, the consumer plaintiffs

wanted information about drugs 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 then 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—including requirements justified by promotion of the public health—are assessed under *Zauderer*'s reasonable-relationship test rather than *Central Hudson*'s intermediate-scrutiny standard. *Id.* at 115 (discussing *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), and *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n*, 447 U.S. 557 (1980)). But, as this Court recognized in *Sorrell*, subjecting purely factual commercial disclosure requirements to

heightened scrutiny, as NYSRA proposes, would upend these settled principles and distort the commercial speech doctrine into a *barrier* to "the free flow of accurate information" critical to promoting public health. 272 F.3d at 115. No existing law requires such a topsy-turvy result.

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 theory that the New York rule constitutes "compelled speech" under *United States v. United Foods, Inc.*, 533 U.S. 405 (2001). 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 just in *Sorrell*, but in other cases that have adopted *Sorrell*'s approach in the face of 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 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); *Pharmaceutical Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294 (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 names of its local-phone-company competitors). Notably, the Restaurant Association makes no attempt to grapple with this line of 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." *Ent. Software Ass'n v. Blagovech*, 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 Rest. & 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"); *BellSouth*, 79 S.W.3d at 516-521 (*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, 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. 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 affirm the district court's decision and 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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May 15, 2008

APPENDIX LISTING AMICI CURIAE

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

U.S. Congressman 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.

David A. Kessler, M.D. was appointed Commissioner of the U.S. Food and Drug Administration by President George H.W. Bush in 1990. He was sworn in as Commissioner on the same day that President Bush signed the NLEA into law, oversaw the promulgation of regulations implementing the NLEA, and served as FDA Commissioner through 1997, when he became Dean of the Yale School of Medicine. Dr. Kessler is currently Professor of Pediatrics, Epidemiology, and Biostatistics, at the School of Medicine, University of California, San Francisco. Prior to his tenure at FDA, Dr. Kessler, who is also a lawyer, was a lecturer in food and drug law at Columbia Law School.

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 have argued some of most significant federal preemption cases—including the two most recent cases on preemption in the food and drug context in the U.S. Supreme Court—as well as several seminal cases on the commercial speech doctrine, including *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), and *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.[2]

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.

[2] 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.

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 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, 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.

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.

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)(7)

I hereby certify that the foregoing Brief for *Amici Curiae* complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief is composed in a 14-point proportional typeface, ITC Century Standard Book. As calculated by my word processing software (Microsoft Word), the Brief contains 6,685 words, excluding the parts exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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Deepak Gupta

CERTIFICATE OF SERVICE

I hereby certify that on May 15, 2008, I served all counsel by email and caused two copies of the foregoing Brief for *Amici Curiae* to be sent by regular U.S. Mail to the following counsel of record:

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ANTI-VIRUS CERTIFICATION FORM
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