08-1892-cv

United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 08-1892-cv

NEW YORK STATE RESTAURANT ASSOCIATION,

Plaintiff-Appellant,

(*Caption continued on inside cover*)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION AS *AMICUS CURIAE* IN SUPPORT OF AFFIRMANCE

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—v.—

NEW YORK CITY BOARD OF HEALTH, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, THOMAS R. FRIEDEN, In His Official Capacity as Commissioner of the New York City Department of Health and Mental Hygiene,

Defendants-Appellees.

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—v.—

NEW YORK CITY BOARD OF HEALTH, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, THOMAS R. FRIEDEN, IN HIS OFFICIAL CAPACITY AS COMMISSIONER OF THE NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE ,

Defendants-Appellees.

BRIEF OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION AS *AMICUS CURIAE* IN SUPPORT OF AFFIRMANCE

Preliminary Statement

Pursuant to Rule 29(a) of the Federal Rules of Appellate Procedure and the request of the Court during the April 29, 2008 oral argument on appellant's motion for a stay pending appeal, the United States Food and Drug Administration ("FDA") respectfully submits this *amicus curiae* brief in support of affirmance of the district court's judgment.

For the reasons detailed below, New York City Health Code Regulation 81.50 is not expressly preempted by the Nutrition Labeling and Education Act of 1990, 21 U.S.C. §§ 343-1(a)(4), (5) (the "NLEA"). The NLEA expressly preempts any state "requirement for nutrition labeling of food that is not identical to the requirement of [section 343(q) of the Act], except a requirement for nutrition labeling of food which is exempt under [certain provisions of section 343(q)]." 21 U.S.C. § 343-1(a)(4). Because food served in restaurants is explicitly exempted from a specified provision of section 343(q), state and municipal authority to impose mandatory nutrition labeling on restaurants is necessarily preserved. The requirement in Regulation 81.50(c) that certain restaurants list the "total number of calories . . . for each menu item they list, . . . clearly and conspicuously, adjacent or in close proximity such as to be clearly associated with the menu item," does not require a "nutrient content claim," which would trigger express preemption. Rather, it compels the disclosure of "nutrition information," as that term is used in sections 343(q) and 343(r)(1), and accordingly is not expressly preempted under the NLEA.

In addition, Regulation 81.50 does not violate the First Amendment.* The Regulation implicates purely

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* While the Court specifically requested FDA's views concerning the statutory preemption issue, this brief also addresses the First Amendment issue, which the Court must reach if it finds Regulation 81.50 not preempted by federal law. The issue is of great importance to the FDA and other federal agencies, because, as the Court itself has recognized, there are

commercial speech, and thus is subject to less stringent constitutional requirements than other forms of speech. Because the Regulation compels an accurate, purely factual disclosure of the calorie content of restaurant menu items, and addresses a legitimate state interest in preventing or reducing obesity among its citizens by making accurate calorie information available to consumers, there is a rational connection between the disclosure requirement and the City's purpose in imposing it such that the Regulation survives constitutional analysis.

Issues Presented

1. Whether New York City Regulation 81.50, which requires national chain restaurants to post statements showing the number of calories for each item on their menus and menu boards, is expressly preempted by the Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 343-1(a)(4) or (5).

2. Whether Regulation 81.50's requirement that restaurants provide a purely factual statement of the calorie content of their menu offerings impermissibly infringes on the First Amendment rights of the members of plaintiff-appellant New York State Restaurant Association ("NYSRA").

"[i]nnumerable federal and state regulatory programs" that "require the disclosure of product and other commercial information." *National Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 116 (2d Cir. 2001), *cert. denied*, 536 U.S. 905 (2002).

Statement of the Case

A. Federal Statutory Scheme Governing Food Labeling

The Federal Food, Drug, and Cosmetic Act (the "FDCA"), enacted in 1938, generally prohibits the misbranding of food. In 1990, Congress passed the Nutrition Labeling and Education Act (the "NLEA"), Pub.L. No. 101-535, 104 Stat. 2535 (1990), requiring nutrition labeling on most packaged foods and regulating certain claims concerning food. The House Report accompanying the bill described the dual purposes as follows: "[T]o clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods." H.R.Rep. No. 101-538, at 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337.

The NLEA added two new sections to the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. §§ 343(q), (r). The first, 21 U.S.C. § 343(q), mandates specific, uniform disclosures that must be made on food labels, giving rise to the familiar "Nutrition Facts" panel on packaged foods that sets forth calories per serving, as well as the quantities of various nutrients, including fat, cholesterol, sodium, carbohydrates, protein, and select vitamins and minerals. The second provision, 21 U.S.C. § 343(r), gives the FDA broad authority to regulate when and how a food purveyor may make claims about the nutrient content or certain health benefits of its product.

The NLEA expressly exempts food "served in restaurants" from mandatory nutrition labeling. *See* 21 U.S.C.

§ 343(q)(5)(A)(i). By contrast, restaurants are not generally exempt from subsection (r) and are subject to FDA regulation if they make a nutrient content claim. *See* 21 C.F.R. § 101.13(q)(5) ("A nutrient content claim used on food that is served in restaurants . . . shall comply with the requirements of this section"). The difference between these two provisions is critical for this case. Subsection (r) applies to "a claim . . . made in the label or labeling of . . . food" that "expressly or by implication . . . characterizes the level of any nutrient." 21 U.S.C. § 343(r)(1)(A). Examples of such claims include "low sodium," "lite," or "high in oat bran." H.R. Rep. 101-538, at 19, 1990 U.S.C.C.A.N. at 3349. However, the statute provides that 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." 21 U.S.C. § 343(r)(1).

B. Preemption Provisions in the NLEA

In enacting the NLEA, Congress added two express preemption provisions, 21 U.S.C. § 343-1(a)(4) and (a)(5), which address the scope of preemption for mandatory nutrition labeling requirements under § 343(q) and for nutrient content claim regulations under § 343(r).

Section 343-1(a)(4) expressly preempts any state or municipal "requirement for nutrition labeling of food that is not identical to the requirement of [§ 343(q)], except a requirement for nutrition labeling of food which is exempt under [certain provisions of § 343(q)]."

21 U.S.C. § 343-1(a)(4).* Because food served in restaurants is explicitly exempt from § 343(q) under a referenced provision, state or municipal authority to impose nutrition labeling requirements on restaurants is undisturbed by the NLEA.

Section 343-1(a)(5), on the other hand, expressly preempts states (or municipalities) from imposing any requirement on nutrient content claims made by a food purveyor "in the label or labeling of food that is not identical to the requirement of § 343(r)," "except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B)." 21 U.S.C. § 343-1(a)(5). Although § 343(r)(5)(B) exempts from express preemption some claims regarding "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," 21 U.S.C. § 343(r)(5)(B), this provision does not exempt claims regarding calories.

C. NLEA's Preservation of Other Statutes' Potentially Preclusive Effect

When enacting the NLEA, Congress provided that the statute "shall not be construed to preempt any provision of State law, unless such provision is ex-

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* Specifically, § 343-1(a)(4) exempts "food which is exempt under subclause (i) or (ii) of section 343(q)(5)(A) . . . ." Section 343(q)(5)(A)(i) applies 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."

pressly preempted under [§ 343-1] of the Federal Food, Drug, and Cosmetic Act." Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2535, 2364. However, Congress further provided that the NLEA should not be construed to affect express or implied preemption under other provisions of the Federal Food, Drug, and Cosmetic Act. *Id*. § 6(c)(3) ("The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act not amended by subsection (a), any other Federal law, or any Federal regulation . . . ."). Thus, any state or local food labeling regulation, even if expressly exempted from preemption under the NLEA, that renders food labeling false or misleading would be impliedly preempted under 21 U.S.C. § 343(a) of the FDCA.

D. New York City's Initial Calorie Disclosure Regulation and Prior Litigation

In December 2006, the New York City Board of Health adopted a resolution amending Article 81 of the Health Code by adding a new § 81.50. The regulation was to become effective on July 1, 2007, and mandated that any food service establishment making calorie information publicly available on or after March 1, 2007, must post such information on its menus and menu boards. The New York State Restaurant Association ("NYSRA") brought suit in federal district court for the Southern District of New York challenging the regulation on preemption and First Amendment grounds. The district court held that Health Code

§ 81.50 as adopted was preempted by 21 U.S.C § 343-1(a)(5) because, to the extent it applied only to restaurants that had voluntarily provided calorie information, it regulated nutrient content claims and was therefore preempted by § 343-1(a)(5). *New York State Restaurant Ass'n v. New York City Board of Health*, 509 F. Supp. 2d 351, 361-63 (S.D.N.Y. 2007) (*NYSRA I*).

Although it found § 81.50 preempted because of the specific way this provision had been written, the district court affirmed the authority of local governments to mandate that restaurants disclose nutritional information: "By making its requirements contingent on a *voluntary* claim, Regulation 81.50 directly implicates § 343(r) and its corresponding preemption provision[, § 343-1(a)(5)]. New York City, although free to enact mandatory disclosure requirements of the nature sanctioned by § 343(q) (and proposed or enacted in other jurisdictions), has adopted a regulatory approach that puts it in the heartland of § 343(r) and has subjected its regulation to preemption under § 343-1(a)(5)." 509 F. Supp. 2d at 363 (emphasis in original; footnote omitted).

E. New York City's Modified Calorie Disclosure Regulation and This Action

The City modified the regulation in accordance with the district court's opinion and did not thereafter pursue an appeal of the judgment in *NYSRA I*. Thus, the current version of Regulation 81.50 requires chain restaurants with 15 or more establishments nationally that sell standardized meals to post calorie content information in their menus and on their menu boards:

> 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 . . . .

Reg. 81.50(c).

NYSRA again filed an action to declare the new Regulation 81.50 preempted by federal law and/or unconstitutional, and to enjoin its enforcement. *New York State Restaurant Ass'n v. New York City Board of Health*, No. 08 Civ. 1000 (RJH), 2008 WL 1752455, at *1 (S.D.N.Y. April 16, 2008) (*NYSRA II*). The district court concluded that the new Regulation 81.50 is not preempted by the NLEA because that statute explicitly leaves to state and local governments the power to impose mandatory nutrition labeling by restaurants. *Id.* at *4-*5. Section 343-1(a)(4), the court noted, preempts any state "requirement for nutrition labeling of food that is not identical to the requirement of [§ 343(q)], except a requirement for nutrition labeling of food which is exempt [from § 343(q)]." Since food served in restaurants is explicitly exempt from § 343(q), the district court determined that "state authority to impose mandatory nutrition labeling on restaurants is necessarily preserved." 2008 WL 1752455, at *4 (citing 136 Cong. Rec. S16607 (Oct. 24, 1990) (Sen. Metzenbaum) ("Because food sold in restaurants is exempt from the nutrition labeling requirements of [§ 343(q)],

the bill does not preempt any State nutrition labeling requirements for restaurants.")).

The district court rejected the argument that mandatory state disclosures are nevertheless preempted by 21 U.S.C. § 343-1(a)(5). As explained above, this section preempts states from regulating nutrient content claims made by a food purveyor, which claims are subject to FDA regulation under § 343(r). *See supra* at 6. The court determined that because the calorie disclosure was mandated by Regulation 81.50, it was not "a claim" made in the label or labeling of food that "expressly or by implication characterizes the level of any nutrient." 2008 WL 1752455, at *4. According to the district court, the term "claim" "carries the connotation of an assertion by a speaker that is voluntary in nature." *Id.* Therefore, the court determined that the mandated disclosure necessarily fell outside the scope of subsection (r), and that states retain the power to require restaurants to disclose nutrition information to consumers. *See id.* A contrary reading of the statute, the court held, "would also create a regulatory vacuum in which neither federal nor state authorities have the power to require restaurants to disclose nutrition information to consumers." A far more persuasive reading, the court found, was that "Congress chose not to exercise this power and explicitly left it to the states to do so." *Id.* at *5.

The district court also found that the required disclosure of calorie information is reasonably related to the City's interest in reducing obesity and providing consumers with accurate nutritional information. Therefore, the court held, Regulation 81.50 does not

unduly infringe the First Amendment rights of NYSRA members. *Id.* at *6-*12.

F. Prior Proceedings in This Court

NYSRA appealed to this Court and sought a stay pending appeal. On April 29, 2008, the Court heard oral argument on the stay application, and during the argument directed counsel for NYSRA to request FDA to submit an *amicus* brief within thirty days, *i.e.*, by May 29, 2008. *See* Letter from Kent A. Yalowitz, Counsel for NYSRA, to Gerald F. Masoudi, Chief Counsel, Food and Drug Division, United States Department of Health and Human Services (April 30, 2008), at 1 (copy docketed in this proceeding). Following the argument, the Court denied NYSRA's stay application, but set an expedited briefing schedule.

Summary of Argument

The district court correctly held that Regulation 81.50 is not preempted under the NLEA. *See infra* Point I. However, the district court's reasoning—in essence, that *mandatory* disclosure by restaurants of the nutrient content of the foods they serve *could not* constitute a "claim" under section 343(r) and therefore is not expressly preempted—fails to recognize that some state or local regulations mandating disclosure of information about the nutrient content of restaurant foods would be preempted under the NLEA as a nutrient content claim. The reason Regulation 81.50 is not expressly preempted is that the listing of "total calories" is the type of information that is a component of *nutrition information* regulated under section 343(q) (rather than a nutrient content claim regulated under

section 343(r)), and the NLEA expressly exempts from preemption state or local requirements for restaurants to provide nutrition information of this type in the labeling of their foods. 21 U.S.C. § 343-1(a)(4). *See infra* Points I.A, I.B.

There are, however, circumstances when a locally mandated statement regarding calorie content, or the amount of another nutrient, may fall within the definition of a *nutrient content claim* under section 343(r), and would therefore be expressly preempted notwithstanding its mandatory nature. *See infra* Point I.C. For example, a statement such as "low in fat" would be a nutrient content claim whether the statement was voluntary or mandatory. Indeed, FDA regulations provide that even quantitative statements of nutrient amounts such as "contains 100 calories" may be nutrient content claims. *See* 21 C.F.R. § 101.13(b)(1). However, the NLEA carves out of the scope of nutrient content claims information that is properly included in required nutrition labeling. Because New York City is requiring the number of calories in foods sold at chain restaurants to be disclosed as mandatory nutrition labeling, and because the fact to be disclosed (quantitative calorie content) is properly included in nutrition labeling, the information to be provided under Regulation 81.50 is not a nutrient content claim and there is no express preemption under 21 U.S.C. § 343-1(a)(5). *See infra* Point I.B. The FDA's reasonable interpretation of the statute and regulations that it administers is entitled to deference. *See infra* Point I.D.

The district court also correctly rejected NYSRA's First Amendment challenge to Regulation 81.50. *See infra* Point II. Because the regulation requires disclo-

sure of accurate, purely factual information to consumers in the context of commercial speech, it need only be reasonably related to the governmental interest in protecting consumers. The regulation meets that test. *See id.*

ARGUMENT

POINT I

NEW YORK CITY'S HEALTH CODE REGULATION 81.50 IS NOT EXPRESSLY PREEMPTED BY THE NLEA

A. Subject to Limitations That Are Not Applicable Here, the NLEA Preserves State and Municipal Power to Mandate Labeling of Restaurant Foods

As explained *supra* at 5-6, the NLEA expressly preempts any state, or political subdivision of a state, "requirement for nutrition labeling of food that is not identical to the requirement of [§ 343(q)], except a requirement for nutrition labeling of food which is exempt under [certain provisions of § 343(q)]." 21 U.S.C. § 343-1(a)(4). Because food served in restaurants is explicitly exempt from § 343(q) under a referenced provision, state and local authority to impose mandatory nutrition labeling on restaurants is necessarily preserved. The NLEA, however, does not exempt from preemption *nutrient content claims* made by restaurants. See 21 U.S.C. § 343-1(a)(5). The key question, then, is whether the requirement in Regulation 81.50(c) that certain restaurants list the "total number of calories . . . for each menu item they list, . . . clearly and

conspicuously, adjacent or in close proximity such as to be clearly associated with the menu item" constitutes "*nutrition information*," as to which New York City is exempted from express preemption under the NLEA, or instead a "*nutrient content claim*" that, under section 343-1(a)(5), is not exempted from preemption.

NYSRA argues in its brief that Regulation 81.50 requires nutrient content claims and so is preempted under 21 U.S.C. § 343-1(a)(5); and it argues that the district court's "voluntary/mandatory" distinction is unworkable. *See* NYSRA Br. at 23-35.* Although the district court was incorrect to view the "voluntary/mandatory" dichotomy as dispositive, NYSRA's preemption analysis itself is incorrect because Regulation 81.50 constitutes a requirement for labeling of nutrition information and, accordingly, is not expressly preempted by the NLEA.

B. Criteria for Exemption of Nutrition Information from Express Preemption Under the NLEA

A statement is nutrition information exempt from the NLEA's preemption provisions if two criteria are met. First, the statement must be "of the type required by [§ 343(q)] that appears as part of the nutrition information required or permitted by . . . paragraph

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* NYSRA argues in its brief that "[b]ecause the [New York City Health] Board elected not to appeal *NYSRA I*, it is bound by the holding in that case that a quantitative statement about the amount of calories is a 'claim.' " NYSRA Br. at 24. FDA expresses no view on that contention.

[(q)]." 21 U.S.C. § 343(r)(1). Second, a state or local regulatory authority must require the statement to be disclosed with regard to restaurant food as part of nutrition labeling (and the information must be disclosed pursuant to that authority). *Id.* §§ 343-1(a)(4) (excepting from express preemption of specified state and local labeling requirements any "requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 343(q)(5)(A)"), 343(q)(5)(A)(i) (exempting from NLEA's labeling requirements food "which is served in restaurants . . . for immediate human consumption"); *see also id.* § 343(r)(1) (a statement that is part of nutrition information of the type required or permitted by § 343(q) to be in food labeling "is not a claim"); 21 C.F.R. § 101.13(c) ("[i]nformation that is required or permitted . . . to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim . . ."). The statement required by Regulation 81.50 satisfies these criteria.

First, section 343(q) explicitly requires as part of the nutrition information required or permitted by that paragraph "the total number of calories . . . in each serving size or other unit of measure of the food." *See* 21 U.S.C. § 343(q)(1)(C); *see also* 21 C.F.R. § 101.9(c)(1) ("The declaration of nutrition information on the label and in labeling of a food shall contain . . . [a] statement of the caloric content per serving."). The quantitative statement of the total number of calories for each menu item prescribed by Regulation 81.50 accordingly satisfies the first prong of the test for exemption from the express preemption provisions of the NLEA.

A statement of the number of calories in a food may in certain circumstances, however, constitute a nutrient content claim. For example, under FDA regulations, the statement "100 calories" on the front of a package next to the product name would be a nutrient content claim, even though the same information as part of nutrition labeling would not be. *See* 21 C.F.R. § 101.13(c) ("Information that is required by or permitted . . . to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim . . . [but] [i]f such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirement of nutrient content claims."). Therefore, it next must be determined whether Regulation 81.50(c) satisfies the second prong of the test for preemption exemption—*i.e.*, whether a state or local regulatory authority is requiring the statement to be disclosed as part of nutrition labeling.

As to the second criterion, Regulation 81.50 was issued by a local regulatory authority and it requires the calorie information to be "listed adjacent or in close proximity such as to be clearly associated with the menu item." Reg. 81.50(c). This placement is consistent with FDA regulations regarding the placement of nutrition labeling information for foods without labels. *See* 21 C.F.R. § 101.45 (nutrition information "should be displayed at the point of purchase by an appropriate means such as by a label affixed to the food or through labeling including shelf labels, signs, posters, brochures, notebooks, or leaflets that are readily available and in close proximity to the foods"); *see also* 21 C.F.R. § 101.10 (Nutrition labeling of restaurant foods) ("Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other

reasonable means."). Thus, both criteria for the nutrition information exemption are satisfied, and there is no express preemption under 21 U.S.C. § 343-1(a)(5).

NYSRA quotes from FDA regulations and a preamble discussion for the proposition that quantitative statements of nutrient content may constitute nutrient content claims. *See* NYSRA Reply Br. at 9-10. FDA agrees with that assertion. However, nothing in any of the authorities cited requires that *any* quantitative statement of nutrient content will *always* be a nutrient content claim, even when part of mandated nutrition labeling. Such an assertion would be contrary to the express language of section 343(r)(1). In addition, NYSRA's objection that its members may be subject to multiple, inconsistent local regulations in the absence of federal preemption, *see* NYSRA Reply Br. at 15-17, simply states a natural consequence of the choice that Congress has made to permit localities to mandate restaurants to disclose nutrition information about the food they serve. The possible difficulties restaurants may have in complying with multiple localities' requirements, however, is not a permissible basis for this Court to reject that legislative determination.

Moreover, the conclusion that a statement is nutrition information exempt from preemption is not altered by the fact that, whereas the relevant statutory provision refers to disclosures that "appear[] as part of the nutrition information," 21 U.S.C. § 343(r)(1), the corresponding regulation refers to statements that "appear[] as part of the nutrition label." 21 C.F.R.

§ 101.13(c).* Much restaurant food does not have a "label" that is "written, printed, or graphic matter upon the immediate container of any article," 21 U.S.C. § 321(k), so that, as NYSRA observes, the regulation's use of the term "label," if construed narrowly, could be read to eliminate most restaurant food from the statutory carve-out of certain "nutrition information" from the scope of nutrient content claims.

Such a narrow reading, however, would be contrary both to the broader statutory and regulatory scheme, and to FDA policy. Indeed, the FDA regulations themselves elsewhere make clear that nutrition information for non-packaged foods, when required, is to appear in other forms of labeling (*e.g.*, a tag attached to the product, or a sign or booklet at point of purchase) in the absence of a label. *See* 21 C.F.R. §§ 101.9(a), 101.10, 101.45. Moreover, as noted above, the corresponding provision in the NLEA uses the unambiguously broad term "nutrition information." *See* 21 U.S.C. § 343(r)(1) ("appears as part of the nutrition information"). Because mandatory nutrition information on restaurant food is excluded from federal regulation under the NLEA, *see* 21 U.S.C. § 343(q)(5)(A)(i), reading the regulation as NYSRA proposes would exclude most restaurant food from state and local regulation of labeling requirements, and therefore from the reach of *all* governmental authority to require nutrition labeling, other than under the procedures by which states

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* Both the statute and the regulation provide that the statements they describe are not "claims," which, as discussed *supra* at 5-6, are subject to exclusive federal regulation.

and their political subdivisions may petition for an exemption from federal preemption. *See* 21 U.S.C. § 343-1(b).

This reading, however, is contrary to the plain text of the statute and its broader purpose, and is not compelled by the regulation's text. There is no indication that the FDA intended or sought to use regulations to narrow the scope of the statute's preservation of local control over restaurant labeling; the preambles to the proposed and final rules that included this regulation contain no discussion of this issue, which strongly suggests a lack of any intent by FDA to so narrow the statutory definition of nutrition information, and thereby to essentially negate the exemption from the preemption provision of 21 U.S.C. § 343-1(a)(4). *See* 56 Fed. Reg. 60421, 60424 (Nov. 27, 1991) (proposed rule); *see also* 58 Fed. Reg. 2302 (Jan. 6, 1993) (final rule). Thus, section 101.13(c) should be read in tandem with the statute and consistent with the overall regulatory scheme to mean that a quantitative statement of the amount of a nutrient in a food is not a nutrient content claim when it is part of nutrition labeling consisting of the types of statements required or permitted under 21 U.S.C. § 343(q), and when it appears, for packaged foods, in the nutrition information section of the food label or, for non-packaged foods that bear no label, as part of the nutrition information for the food in a place appropriate for such information at the point of purchase. In other words, FDA interprets the term "nutrition label" as used in section 101.13(c) to include, in the context of restaurant food, nutrition information whose disclosure is required by a state or local regulatory body, whether it is placed somewhere that meets the narrow definition of 'label' advanced by NYSRA, or

whether it instead is placed, as here, in appropriate labeling. For restaurants, a menu or menu board is an entirely permissible means of such disclosure.

C. Whether a Statement is Mandatory or Voluntary Is Relevant But Not Dispositive

The district court's mandatory/voluntary dichotomy is relevant to the second prong of the analysis (whether a state or local regulatory authority requires the statement to be disclosed as part of nutrition labeling) but is not the sole criterion for distinguishing nutrition information (which cities and states are not expressly preempted from mandating be disclosed) from nutrient claims under section 343(r) (which are expressly preempted from local regulation). For example, if a state were to require qualitative statements regarding nutrient levels (*e.g.*, to describe certain foods as "low fat"), those statements would be nutrient content claims because they expressly "characterize the level of any nutrient," 21 U.S.C. § 343(r)(1), 21 C.F.R. § 101.13(b), and they are not "of the type required by [§ 343(q)]," to be in nutrition labeling, 21 U.S.C. § 343(r)(1), despite being mandated by the state.

Further, both the NLEA and FDA regulations indicate that placement of the statement in the place designated for nutrition information is part of the criteria for distinguishing nutrition information from nutrient content claims. Thus, § 343(r) provides: "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 . . . ." 21 U.S.C. § 343(r)(1) (emphasis added); *see also* 21 U.S.C. § 343(q)(1)(A) (providing that the Secretary may by regulation

establish requirements for presentation of nutrition information). Similarly, FDA regulations provide that "information that is required by or permitted . . . to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim . . . [but] [i]f such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirement of nutrient content claims." 21 C.F.R. § 101.13(c); *see also* 58 Fed. Reg 2302, 2303 (Jan. 6, 1993) (noting that "identical information" could be nutrition information or a nutrient content claim depending on its placement on the label) (citing 136 Cong. Rec. H5841 (July 30, 1990) (statement of Rep. Waxman)).*

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* Although neither the parties nor the district court have addressed the issue, certain local regulations mandating restaurant disclosures or statements could be impliedly preempted under the FDCA even though not expressly preempted by the NLEA. *See supra* at 6-7; *see also Sprietsma v. Mercury Marine, a Div. of Brunswick Corp.,* 537 U.S. 51, 65 (2002) (inclusion of express preemption provision does not bar ordinary working of "conflict" or "implied" preemption principles). The NLEA provides that it should not be construed to preempt state laws, other than by virtue of the NLEA's express preemption provisions. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364. The NLEA further provides, however, that the statute does not affect express or implied preemption under other provisions of the FDCA that were not amended by the NLEA. *Id*. § 6(c)(3). Thus, any state or local food labeling regulation, even if expressly exempted from

D. FDA's Views Are Entitled to Deference

As the foregoing discussion makes clear, determining whether New York's Regulation 81.50 is expressly preempted under the NLEA requires consideration of a complex federal statutory and regulatory scheme whose interpretation and application are vested in the FDA. To the extent the Court finds more than one interpretation permissible under the NLEA's and federal regulations' plain meaning, the FDA's views are entitled to deference under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron*, if the statute is silent or ambiguous on the matter at issue, the courts will uphold the agency's interpretation if it is "based on a permissible construction of the statute." 467 U.S. at 843; *see also Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 739 (1996) ("It is our practice to defer to the reasonable judgments of agencies with regard to the meaning of ambiguous terms in statutes that they are charged with administering."). Courts give weight to the agency's interpretation of a statute it administers because of the "presumption that Congress, when it left ambiguity in a statute meant for implementation by an agency, understood that the ambiguity would be resolved, first and foremost, by the agency, and desired the agency (rather than the courts) to possess whatever degree of discre-

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preemption pursuant to the NLEA, that renders food labeling false or misleading, for example, would be impliedly preempted under the FDCA, 21 U.S.C. § 343(a).

tion the ambiguity allows." *Smiley*, 517 U.S. at 740-41. Courts similarly accord deference to an agency's interpretation of its regulations. *Auer v. Robbins*, 519 U.S. 452, 461-62 (1997); *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512-13 (1994).

As Regulation 81.50 has just taken effect, FDA necessarily has not had prior occasion to assess whether the regulation is consistent with, or preempted by, the NLEA and related FDA regulations. Rather, the FDA's views on these questions are set forth herein in response to the Court's request of April 29, 2008. The recency of the FDA's views on the precise question presented should have no effect on the deference due here, because there "is simply no reason to suspect that the interpretation does not reflect the agency's fair and considered judgment on the matter in question." *Auer*, 519 U.S. at 462 (affording deference to agency interpretation first expressed in *amicus* brief in case before court). Accordingly, *Auer* dictates affording *Chevron* deference to the FDA's views here.

Even if the Court concludes that *Chevron* is not applicable, it should at a minimum defer to the agency's interpretation under the standards set forth in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). *See Schneider v. Feinberg*, 345 F.3d 135, 143 (2d Cir. 2003) ("Interpretive guidelines that lack the force of law but nevertheless 'bring the benefit of [an agency's] specialized experience to bear' on the meaning of a statute, are still entitled to 'some deference.' "). In *Skidmore*, the Supreme Court recognized that agency interpretations "constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance." 323 U.S. at 140. The Supreme Court there-

fore held that such agency interpretations are given "considerable and in some cases decisive weight," depending upon the "thoroughness evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade." *Id.*

POINT II

REGULATION 81.50 DOES NOT VIOLATE THE FIRST AMENDMENT

The district court was correct to hold that Regulation 81.50 does not violate the First Amendment rights of NYSRA or its members. *See* 2008 WL 1752455, at *6-*12. As the district court held, *id.* at *6, Regulation 81.50 implicates commercial speech, and regulations affecting commercial speech are subject to less stringent constitutional requirements than those that affect other forms of speech. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 562-63 (1980); *National Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 113 (2d Cir. 2001), *cert. denied*, 536 U.S. 905 (2002). Furthermore, within the class of regulations affecting commercial speech, there are "material differences between [purely factual and uncontroversial] disclosure requirements and outright prohibitions on speech." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 650 (1985). Regulations that compel "purely factual and uncontroversial" commercial speech are subject to more lenient review than regulations that restrict accurate commercial speech, and will be sustained if they are "reasonably related to the State's interest" in protecting consumers. *Id.* at 651. As this Court has held, "[c]ommercial disclosure requirements

are treated differently from restrictions on commercial speech because mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests . . . ." *Sorrell*, 272 F.3d at 113-14.

Regulation 81.50 compels only disclosure of "purely factual and uncontroversial" commercial information—the calorie content of restaurant menu items. The regulation also addresses a state policy interest in attacking obesity among its citizens by making accurate calorie information available to consumers. Because there is a "rational connection" between the disclosure requirement and the City's purpose in imposing it, *see Sorrell*, 272 F.3d at 115, Regulation 81.50 passes constitutional muster.* *Cf. Zauderer*, 471 U.S. at 651 n.14 (rejecting the contention that the Court should subject disclosure requirements to a strict "least restrictive means" analysis under which they must be struck down if there are other means by which the State's purposes may be served, and distinguishing *Central Hudson*, 477 U.S. at 565).

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* This Court's decision in *Sorrell* is on all fours with the instant dispute, and thus controls the outcome here, notwithstanding NYSRA's argument that a different result is compelled by *United States v. United Foods, Inc.*, 533 U.S. 405 (2001), and *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996). *See* NYSRA Reply Br. at 24-27. *International Dairy* preceded *Sorrell* so by definition does not disturb it, and NYSRA has not identified any aspect of *United Foods* that undermines this Court's holding in *Sorrell*.

CONCLUSION

Because Regulation 81.50(c) is not expressly preempted under the NLEA and is consistent with the First Amendment, the Court should affirm the district court's judgment.

Dated: New York, New York
May 29, 2008

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure, the undersigned counsel hereby certifies that this brief complies with the type-volume limitation of Rule 32(a)(7)(B). As measured by the word processing system used to prepare this brief, there are 6185 words in this brief.

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ADDENDUM

21 U.S.C. § 343. Misbranded food

A food shall be deemed to be misbranded—

* * *

(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—

(A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or

(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,

(B) the number of servings or other units of measure per container,

(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,

(D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars,

dietary fiber, and total protein contained in each serving size or other unit of measure,

(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this chapter before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

* * *

(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,

* * *

(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).

* * *

(5)(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do 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.

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 C.F.R. § 101.9. Nutrition labeling of food

(a) Nutrition information relating to food shall be provided for all products intended for human consumption and offered for sale unless an exemption is provided for the product in paragraph (j) of this section.

* * *

(2) When food is not in package form, the required nutrition labeling information shall be displayed clearly at the point of purchase (e.g., on a counter card, sign, tag affixed to the product, or some other appropriate device). Alternatively, the required information may be placed in a booklet, looseleaf binder, or other appropriate format that is available at the point of purchase.

* * *

(c) The declaration of nutrition information on the label and in labeling of a food shall contain . . .

(1) "Calories, total," "Total Calories," or "Calories": A statement of the caloric content per serving. . . .

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. Nutrient 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").

* * *

(c) Information that is required or permitted by § 101.9 or § 101.36, as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

* * *

21 C.F.R. § 101.45. Guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish

(a) Nutrition labeling for raw fruits, vegetables, and fish listed in § 101.44 should be presented to the public in the following manner:

(1) Nutrition labeling information should be displayed at the point of purchase by an appropriate means such as by a label affixed to the food or through labeling including shelf labels, signs, posters, brochures, notebooks, or leaflets that are readily available and in close proximity to the foods. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

* * *

ANTI-VIRUS CERTIFICATION

Case Name: NYS Rest. Assoc. v. NYC Bd. of Health

Docket Number: 08-1892-cv

I, Louis Bracco, hereby certify that the Amicus Brief submitted in PDF form as an e-mail attachment to **civilcases@ca2.uscourts.gov** in the above referenced case, was scanned using CA Software Anti-Virus Release 8.3.02 (with updated virus definition file as of 5/29/2008) and found to be VIRUS FREE.

Louis Bracco
Record Press, Inc.

Dated: May 29, 2008