

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2007

(Argued: June 12, 2008)

Decided: February 17, 2009)

Docket No. 08-1892-cv

NEW YORK STATE RESTAURANT ASSOCIATION,

Plaintiff-Appellant,

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.

Before: POOLER, SOTOMAYOR, Circuit Judges, and RESTANI,* Judge.

New York State Restaurant Association (“NYSRA”) appeals from a Memorandum Opinion and Order of the Southern District of New York (Holwell, J.) dated April 16, 2008, denying NYSRA’s motion for a preliminary injunction, denying NYSRA’s motions for declaratory relief and summary judgment, and granting New York City Board of Health, New York City Department of Health and Mental Hygiene, and Thomas R. Frieden’s cross-motion for summary judgment. Because we conclude that New York Health Code § 81.50: (1) is not

* The Honorable Jane A. Restani, Chief Judge of the United States Court of International Trade, sitting by designation.

expressly preempted by the Nutrition Labeling and Education Act of 1990; and (2) does not infringe on NYSRA's member restaurants' First Amendment rights, we AFFIRM.

KENT A. YALOWITZ and PETER L. ZIMROTH (Nancy G. Milburn, Brandon C. Cowart, Amalia W. Jorns, on the brief), Arnold & Porter LLP, New York, N.Y., for Plaintiff-Appellant.

FAY NG, Assistant Corporation Counsel, City of New York (Michael A. Cardozo, Corporation Counsel, Pamela Seider Dolgow, Mark Muschenheim, Assistant Corporation Counsels, City of New York; Thomas Merrill, General Counsel, N.Y.C. Department of Health and Mental Hygiene, on the brief), for Defendants-Appellees.

DAVID S. JONES, Assistant United States Attorney, Southern District of New York, New York, N.Y. (Michael J. Garcia, United States Attorney, James L. Cott, Assistant United States Attorney, Southern District of New York, New York, N.Y.; Gregory G. Katsas, Acting Assistant Attorney General, Douglas N. Letter, Michael E. Robinson, Attorneys, Appellate Staff, Civil Division, U.S. Department of Justice; Thomas R. Barker, Acting General Counsel, Gerald F. Masoudi, Chief Counsel, Food and Drug Division, Karen E. Schifter, Associate Chief Counsel, Office of the General Counsel, U.S. Department of Health and Human Services, on the brief), for Amicus Curiae U.S. Food and Drug Administration, in support of Defendants-Appellees.

Deepak Gutpa, Brian Wolfman, Public Citizen Litigation Group, for 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, Professors of Medicine, Nutrition, and Public Health, in support of Defendants-Appellees.

Dennis J. Herrera, City Attorney, Danny Chou, Chief of Complex and Special Litigation, Tara Steeley, Francesca Gessner, Deputy City Attorneys, City and County of San Francisco, CA, for Amici Curiae City and County of San Francisco, CA; Cities of Philadelphia, PA and West Hollywood, CA; Los Angeles County, CA; King County, WA; Montgomery County, MD; National League of Cities, National

Association of County and City Health Officials, and International Municipal Lawyers Association; California State Senators Alex Padilla and Carole Migden, California Assembly Member Mark Desaulnier, New York State Assemblyman Felix Ortiz, Chicago Alderman Edward M. Burke, and Washington D.C. Councilmember Phil Mendelson, in support of Defendants-Appellees.

Brian L. Bromberg, New York, N.Y., for Amici Curiae Robert Post, David Boies Professor of Law, Yale Law School; Jennifer L. Pomeranz, Kelly D. Brownell, Rudd Center for Food Policy & Obesity at Yale University, in support of Defendants-Appellees.

POOLER, Circuit Judge:

In this case, the New York State Restaurant Association (“NYSRA”), a not-for-profit business association of over 7,000 restaurants, challenges the constitutionality of New York City Health Code § 81.50, which requires roughly ten percent of restaurants in New York City, including chains such as McDonald’s, Burger King and Kentucky Fried Chicken, to post calorie content information on their menus and menu boards. See New York City, N.Y., Health Code tit. 24, § 81.50 (2008) (“Regulation 81.50”). NYSRA contends that Regulation 81.50 is unconstitutional because it is: (1) preempted by federal laws, specifically the Nutrition Labeling and Education Act of 1990 (“NLEA”), and (2) infringes on its member restaurants’ First Amendment rights. Proceeding pursuant to our jurisdiction under 28 U.S.C. § 1292(a)(1), we conclude that Regulation 81.50 survives both challenges. As we will explain, the federal statutory scheme regulating labeling and branding of food is a labyrinth and interpreting the statute are a series of agency regulations that sometimes appear to conflict and are difficult to harmonize. It is our view, however, that Congress intended to exempt restaurant food from the preemption sections that are necessary to allow food to be sold interstate. In requiring chain

restaurants to post calorie information on their menus, New York City merely stepped into a sphere that Congress intentionally left open to state and local governments. Furthermore, although the restaurants are protected by the Constitution when they engage in commercial speech, the First Amendment is not violated, where as here, the law in question mandates a simple factual disclosure of caloric information and is reasonably related to New York City's goals of combating obesity.

I. Background

A. Federal Statutory Scheme: the Nutrition Labeling and Education Act of 1990

The Federal Food, Drug, and Cosmetic Act (the "FDCA"), enacted in 1938, generally prohibits misbranding of food. Our discussion focuses on two sections of that act -- (q) and (r) -- which were added in 1990 through the passage of the Nutrition Labeling and Education Act (the "NLEA"), Pub. L. No. 101-535, 104 Stat. 2353 (1990). The NLEA sought "to 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, 3337.¹

Sections 343(q) and (r) and their related preemption provisions, Sections 343-1(a)(4) and (a)(5), are the statutory bases from which the preemption questions in this case stem. Section 343(q), entitled "[n]utrition information," addresses mandatory information on nutrients, and requires that basic nutrition facts be disclosed for most foods. The general public is well-

¹ The FDA filed an amicus brief at our request. Numerous cities, counties, government officials, and associations also appear as amici. All ask us to affirm the district court.

acquainted with this provision through the “Nutrition Facts” panel on packaged foods that informs buyers of the “the total number of calories” per serving, along with the quantities of various nutrients contained in the foods. 21 U.S.C. § 343(q).² Restaurants, NYSRA’s membership, are exempt from Section 343(q)’s mandatory nutrition information labeling requirements; they do not have to attach a Nutrition Facts panel to food they serve. *Id.* § 343(q)(5)(A)(i).

Section 343(r), entitled “[n]utrition levels and health-related claims,” addresses voluntary information, that is, those claims that a food purveyor may choose to add to its product label about the nutrient content (for example, “low sodium”) or health benefits (for example, “fiber reduces cholesterol”) of its

Nutrition Facts	
Serving Size 1 cup (228g)	
Servings Per Container 2	
Amount Per Serving	
Calories 260	Calories from Fat 120
% Daily Value*	
Total Fat 13g	20%
Saturated Fat 5g	25%
Trans Fat 2g	
Cholesterol 30mg	10%
Sodium 660mg	28%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	
Vitamin A 4%	• Vitamin C 2%
Calcium 15%	• Iron 4%
*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:	
	Calories: 2,000 2,500
Total Fat	Less than 65g 80g
Sat Fat	Less than 20g 25g
Cholesterol	Less than 300mg 300mg
Sodium	Less than 2,400mg 2,400mg
Total Carbohydrate	300g 375g
Dietary Fiber	25g 30g
Calories per gram:	
Fat 9	• Carbohydrate 4 • Protein 4

² Specifically, Section 343(q)(1) provides in relevant part, that “[a] food shall be deemed to be misbranded”

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 . . . ,
- (B) the number of servings . . . ,
- (C) the total number of calories--
 - (i) derived from any source, and
 - (ii) derived from the total fat,

in each serving size . . . ,

(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 . . . ,

(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.

21 U.S.C. § 343(q)(1).

product. See id. § 343(r). It prohibits the use of terms that “characterize[]” the level of any nutrient in a food unless they conform to definitions established by the FDA, and requires that claims about the relationship between nutrients and health conditions be supported by scientific consensus.³ See id.; 21 C.F.R. § 101.14(c) (“FDA will promulgate regulations authorizing a health claim only when it determines . . . that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.”). Specifically, that section states that:

- A food shall be deemed misbranded [if it]
 - (A) characterizes the level of any nutrient which is of the type required by [Section 343 (q)(1) or (q)(2)] to be in the label or labeling of the food unless the claim is made in accordance with [Section 343 (r)(2)], or
 - (B) characterizes the relationship of any nutrient which is of the type required by [Section 343(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 [Section 343(r)(3) or (5)(D)].

21 U.S.C. § 343(r)(1)(A)-(B). However, Section 343(r) adds that “[a] statement of the type required by [Section 343(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.” Id. § 343 (r)(1).

In contrast to Section 343(q), restaurants are not exempt from Section 343(r)’s regulation of “claims.” Thus, when a restaurant chooses to “characterize[] the level of any nutrient which is of the type required by [Section 343(q)] to be in the label or labeling of the food,” id. §

³ FDA Regulations define nutrient content claims for a range of specific descriptive terms such as “free,” “low” “good source,” “antioxidant,” and “high potency.” 21 C.F.R. §§ 101.13, 101.54, 101.56. For instance, the FDA Regulations provide that the term “high potency” “may be used on the label or in the labeling of foods to describe individual vitamins or minerals that are present at 100 percent or more of the [Reference Daily Intake] per reference amount customarily consumed.” Id. §§ 101.54(f)(1)(i); see also id. § 101.9(c)(8)(iv) (establishing the nomenclature and reference daily intakes for various vitamins and minerals).

343(r)(1)(A), it must conform to Section 343(r)'s requirements.

The NLEA contains two express preemption provisions relating to both Sections 343(q) and (r). Section 343-1(a)(4), which relates to Section 343(q), preempts any state or local “requirement for nutrition labeling of food that is not identical to the requirement of [S]ection 343(q) . . . , except a requirement for nutrition labeling of food which is exempt under [Section 343(q)(5)(A)(i)],” that is, the restaurant exception. Id. § 343-1(a)(4) (emphasis added).⁴ Section 343-1(a)(5), which relates to Section 343(r), expressly preempts state or local governments 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 [S]ection 343(r) . . . , except a requirement respecting a claim made in the label or labeling of food which is exempt under [S]ection 343(r)(5)(B).” Id. § 343-1(a)(5) (emphasis added);⁵ 21 C.F.R. § 101.13(q)(5)(A). Thus, states are not preempted from adopting nutrition information labeling laws as defined by Section 343(q), but are preempted from adopting nutrient claim laws as defined by Section 343(r).

Though appearing complex, this scheme is simple when it comes to restaurant food -- the NLEA does not regulate nutrition information labeling on restaurant food, and states and localities are free to adopt their own rules. The NLEA, however, does generally regulate

⁴ Only the restaurant exception is relevant in this case, but we note that Section 343-1(a)(4) also provides a preemption exception for “food which is exempt under [Section 343(q)(5)(A)(ii)].” That subsection refers to food sold for immediate consumption in retail establishments such as grocery stores.

⁵ Section 343(r)(5)(B) refers to claims relating to (1) cholesterol, (2) saturated fat, (3) dietary fiber, or (4) nutrients that increase the risk of diet-related health conditions, and is, as NYSRA agrees, inapplicable here. See NYSRA Br. 10.

nutrition content claims on restaurant foods, and states and localities may only adopt rules that are identical to those provided in the NLEA.

B. New York City Adopts Regulations Governing Calorie Labeling in Restaurants; NYSRA Challenges those Regulations.

Seeking to combat rising rates of obesity and associated health care problems, in December 2006, the New York City Board of Health adopted the precursor to the current Regulation 81.50, by amending Article 81 of the Health Code and adding a new Section 81.50. The 2006 regulation, which was to become effective on July 1, 2007, mandated that any food service establishment voluntarily publishing calorie information post such information on its menus and menu boards. This regulation was met with vigorous objection from the restaurants and prompted many to stop voluntarily making such information available. On behalf of the restaurants, NYSRA subsequently sued the New York City Board of Health, the New York City Department of Health and Mental Hygiene, and Thomas R. Frieden (also appellees here, together “New York City” or the “City”) in the Southern District of New York. In a decision issued on September 11, 2007, the district court concluded that Regulation 81.50 as adopted was preempted by 21 U.S.C. § 343-1(a)(5) -- the claims preemption provision -- because, to the extent it applied only to restaurants that had voluntarily provided calorie information, it regulated nutrient content claims. N.Y. State Rest. Ass’n v. N.Y. City Bd. of Health (NYSRA I), 509 F. Supp. 2d 351, 361-63 (S.D.N.Y. 2007). However, in so holding, the district court stated that

By making its requirements contingent on a voluntary claim, Regulation 81.50 directly implicates [Section] 343(r) and its corresponding preemption provision. New York City, although free to enact mandatory disclosure requirements of the nature sanctioned by [Section] 343(q) (and proposed or enacted in other jurisdictions), has adopted a regulatory approach that puts it in the heartland of [Section] 343(r) and has subjected its regulation to preemption under [Section]

343-1(a)(5).

Id. at 363 (footnote omitted). Having decided for NYSRA on preemption, the district court did not reach NYSRA's First Amendment claim.

Taking its cue from the district court's opinion, on January 22 2008, the New York City Board of Health repealed and modified the 2006 regulation, producing the current version of Regulation 81.50. See Dep't of Health and Mental Hygiene Bd. of Health, Notice of Adoption of a Resolution to Repeal and Reenact § 81.50 of the New York City Health Code (Jan. 22, 2008) [hereinafter Notice of Adoption].⁶ The revised Regulation 81.50 requires all chain restaurants with fifteen or more establishments nationally to make statements showing calorie content in the precise manner prescribed by the regulation. For those restaurants covered by the regulation, the calorie information must be presented clearly and conspicuously, adjacent or in close proximity to the menu item, and the font and format of calorie information must be as prominent in size and appearance as the name or price of the menu item. See Notice of Adoption at 12-14. Now, every time New Yorkers walk into or use the drive-through of certain chain restaurants, they are informed, for instance, that the taco salad contains 840 calories, the sausage and egg breakfast sandwich contains 450 calories, and the premium hamburger sandwich with mayonnaise contains 670 calories but without mayonnaise contains 510 calories. Regulation 81.50 expressly permits the restaurants to provide "additional nutritional information" and to provid[e] . . . disclaimer[s] stating that there may be variations in calorie content values across servings based on slight

⁶ New York City also filed a notice of appeal to NYSRA I, however, the parties stipulated that the appeal should be dismissed as moot with prejudice in view of the modifications to Regulation 81.50. N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health, No. 07-4378-cv (2d Cir. Feb. 5, 2008) (stipulation and order dismissing appeal).

variations in serving size, quantity of ingredients, or special ordering.” Id. at 14.

NYSRA’s member restaurants, some of which already provided nutrition information to their customers, just not on their menus and menu boards, were not much happier with the City’s latest effort at calorie disclosure on menus and menu boards specifically. They proposed alternatives to menu/menu board posting including signs directing consumers to nutrition information at the restaurants, posters, food wrappers, counter mats, stanchions, flip-charts, and brochures, with such information. Failing to convince the City -- which concluded that customers often did not see the nutrition information already provided by the restaurants, see id. at 7-8 -- of the superiority of these alternatives, NYSRA filed another action in the Southern District of New York, again seeking to declare the revised Regulation 81.50 preempted by federal law and/or unconstitutional, and to enjoin its enforcement; New York cross-moved for summary judgment on the preemption claim. Reasoning that “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,” the district court rejected NYSRA’s preemption challenge and granted the City summary judgment on this claim. N.Y. State Rest. Ass’n v. N.Y. City Bd. of Health (NYSRA II), No. 08cv1000, 2008 WL 1752455, at *1 (S.D.N.Y. Apr. 16, 2008). NYSRA also asked the district court to conclude that Regulation 81.50 impermissibly infringed on its members’ First Amendment rights. But, the district court instead concluded that “the required disclosure of caloric information is reasonably related to the government’s interest in providing consumers with accurate nutritional information and therefore does not unduly infringe on the First Amendment rights of NYSRA members.” Id. NYSRA then appealed. It also sought a stay pending appeal, which we denied without prejudice to

renewal at or after oral argument, based upon the City's representations that the "no fines" period would be extended. We set an expedited briefing schedule, and subsequently denied the renewed motion for a stay. N.Y. State Rest. Assoc. v. N.Y. City Bd. of Health, No. 08-1892-cv (2d Cir. Apr. 29, 2008, June 16, 2008) (orders denying stay). We held oral argument on June 12, 2008, during which we heard from counsel for NYSRA, the City, and the FDA.

II. Discussion

We review the district court's grant of New York City's cross-motion for summary judgment de novo, and the burden is on New York City to establish that it is entitled to judgment as a matter of law. Price v. N.Y. State Bd. of Elections, 540 F.3d 101, 107 (2d Cir. 2008). We review the denial of NYSRA's motion for a preliminary injunction for abuse of discretion. Sunward Elecs., Inc. v. McDonald, 362 F.3d 17, 24 (2d Cir. 2004). A party seeking a preliminary injunction ordinarily must show: (1) a likelihood of irreparable harm in the absence of the injunction; and (2) either a likelihood of success on the merits or sufficiently serious questions going to the merits to make them a fair ground for litigation, with a balance of hardships tipping decidedly in the movant's favor. Id. In deciding this appeal, we will discuss the motions relating to preemption together since on all motions, the question before us is one of law -- whether the NLEA preempts Regulation 81.50. We will then turn to the denial of a preliminary injunction on NYSRA's First Amendment claims, and "review the district court's judgment for abuse of discretion, although our review of its application of the law is de novo." In re Northwest Airlines Corp., 483 F.3d 160, 165 (2d Cir. 2007). As will be discussed, Regulation 81.50 is not preempted nor does it violate the restaurants' First Amendment rights.

A. Preemption

Under the Supremacy Clause of the United States Constitution, “state laws that conflict with federal law are without effect,” Altria Group, Inc. v. Good, 129 S. Ct. 538, 543 (2008) (quotation marks omitted), and are preempted. The “purpose of Congress is the ultimate touchstone in every pre-emption case,” id. (quotation marks omitted), and “we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” United States v. Locke, 529 U.S. 89, 107 (2000) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)). The presumption against preemption is heightened “where federal law is said to bar state action in fields of traditional state regulation.” N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995). Given the traditional “primacy of state regulation of matters of health and safety,” Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996), courts assume “that state and local regulation related to [those] matters . . . can normally coexist with federal regulations.” Hillsborough County v. Automated Med. Labs., Inc. 471 U.S. 707, 718 (1985); see also Desiano v. Warner-Lambert & Co., 467 F.3d 85, 94 (2d Cir. 2007), aff’d by equally divided court sub nom Warner-Lambert & Co. v. Kent, 128 S. Ct. 1168 (2008). As a result, where the text of a preemption clause is ambiguous or open to more than one plausible reading, courts “have a duty to accept the reading that disfavors pre-emption.” Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005).

Helpfully, the NLEA is clear on preemption, stating that it “shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1(a)] of the [FDCA].” Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364 (21

U.S.C. § 343-1 note) (emphasis added). As already noted, as it pertains to restaurants, the NLEA does not preempt New York City from adopting its own requirements for nutrition information labeling, see 21 U.S.C. § 343-1(a)(4), but it does generally preempt it from adopting different rules for nutrient content claims, id. § 343-1(a)(5). In light of the NLEA’s express preemption provisions, therefore, the issue in this case is less whether the NLEA is clear on preemption, but more whether the quantitative calorie disclosures Regulation 81.50 mandates that chain restaurants place on their menus and menu boards are “claims” falling under Section 343(r) and are thus preempted, or are “nutrition information” falling under Section 343(q) and thus are not preempted. Since NYSRA’s argument that Regulation 81.50 pertains to claims turns primarily on the meaning of “claim” as used in the NLEA, some exposition of that term, especially as compared to the meaning of “nutrition information,” is required.

As explained, the NLEA defines nutrition “information,” to include “the total number of calories” in a food product. Id. § 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 . . .”). Nutrition “claims” are statements “made in the label or labeling of the food which expressly or by implication . . . characterize[] the level of any nutrient which is of the type required by [Section 343(q)].” 21 U.S.C. § 343(r)(1)(A) (emphasis added). However, “[a] statement of the type required by [Section 343(q)] that appears as part of the nutrition information required or permitted by such paragraph is not a claim.” Id. § 343(r)(1) (emphasis added).

An initial reading of these sections of the statute suggests a quantitative-qualitative distinction according to which nutrition “information” refers to quantitative statements such as

“100 calories” and nutrition “claims” refers to descriptive or qualitative statements, such as “heart healthy.”⁷ See Webster’s Third Int’l Dictionary 376 (2002) (defining “characterize” as “to describe the essential character or quality of”); id. at 414 (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”). By that view, Regulation 81.50, a regulation which merely requires the disclosure of quantitative information listed in Section 343(q), would not be preempted by the NLEA.

Such a simple path is not to be ours, however, because the FDA, as the agency charged with implementing the FDCA and NLEA, has defined “claims” with more nuance. See United States v. Mead Corp., 533 U.S. 218, 227 (2001) (“When Congress has explicitly left a gap for an agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation” (quotation marks omitted)); see also Pub. L. No. 101-535, § 3(b)(1)(A)(i), 104 Stat. 2353, 2361 (stating that the FDA “shall identify claims described in section [343(r)(1)(A)] . . . which comply with [S]ection [343(r)(2)].”); 21 U.S.C. § 343(r)(2)(A) (listing conditions under which a claim can be made). In several regulations, the FDA embraces the quantitative-qualitative distinction using terms such as “characterizes,” “describes,” and “suggests,” to define claims.⁸ In listing terms that characterize nutrient levels, the regulations

⁷ NYSRA argues that the doctrine of collateral estoppel prevents New York City from relitigating the qualitative-quantitative distinction because it chose to dismiss its appeal from NYSRA I with prejudice. As we do not ground our decision in this distinction, we do not reach this question.

⁸ For instance, Regulation 101.13(b) defines a “nutrient content claim” as “[a] claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under [the regulations implementing Section 343(q)].” 21 C.F.R. § 101.13(b) (emphasis added). Regulation 101.13(b)(2) defines “an implied nutrient content claim” as “any claim that:”

point to terms and phrases such as “rich in,” “excellent source of,” “enriched,” “fortified.” See 21 C.F.R. §§ 101.54-101.69. As is particularly pertinent here, the regulations describe “calorie content claims” to include “‘calorie free,’ ‘free of calories,’ . . . ‘without calories,’ ‘trivial source of calories,’ ‘negligible source of calories,’ [and] ‘dietarily insignificant source of calories.’” Id. § 101.60(b)(1). Further, the regulations that discuss the labeling requirements for restaurants making nutrient content claims differentiate between “nutrient amounts” (a phrase indicative of a quantitative statement), and “claims,” by permitting restaurants to provide “the nutrient amounts that are the basis for the claim.” Id. § 101.10.

But, other FDA regulations provide for a definition of claims that includes quantitative statements of the sort listed in Section 343(q). First, Regulation 101.13(b)(1) defines an “expressed nutrient content claim” as “any direct statement about the level (or range) of a nutrient in [a] food” including “contains 100 calories.” 21 C.F.R. § 101.13(b)(1). As the district court pointed out in NYSRA I, the FDA treats “contains” as either a nutrient content claim or a “simple verb” depending on how it is used. 509 F. Supp. 2d at 359 n.9; see also FDA, Guidance for Indus.: A Labeling Guide for Rests. and Other Retail Establishments Selling Away-From-Home Foods ¶ 30 (Apr. 2008), available at <http://www.cfsan.fda.gov/~dms/labrguid.html> (last visited Jan. 13, 2009) [hereinafter FDA,

(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”).
Id. § 101.13(b)(2) (emphases added).

Guidance for Indus.].⁹ In the phrase “contains fiber,” “contains” is a nutrient content claim meaning “good source” of fiber. See 21 C.F.R. § 101.54(c) (defining “contains”); see also FDA, Guidance for Indus., at ¶ 30. In the phrase “contains 2 grams of fiber,” by contrast, “contains” is a “simple verb” and the FDA considers the quantitative declaration “2 grams” to be a nutrient content claim whether or not the word “contains” is employed. FDA, Guidance for Indus., at ¶ 30. And, at other points, by emphasizing that quantitative statements such as “100 calories” are not “implicit characterizations,” the regulations seem to suggest that they can be express characterizations. For instance, 21 C.F.R. § 101.13(i) states that

Except as provided in § 101.9 or § 101.36, as applicable, or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if . . . [t]he 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) (emphases added).¹⁰

If we were merely faced with such ambiguous regulations, we might adhere to the

⁹ In their briefs, the parties cite to a version of this document that has since been superseded. See FDA, Food Labeling: Questions and Answers, Volume II, A Guide for Rests. and Other Retail Establishments (Aug. 1995), <http://vm.cfsan.fda.gov/~frf/qaintro.html> (last visited Jan. 13, 2009).

¹⁰ Confusing matters even more, the FDA suggests that quantitative caloric statements can neither be express or implied characterizations, but simultaneously seems to allow that they can be express characterizations. It states:

[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) (emphases added).

quantitative-qualitative distinction. However, Regulation 101.13(c) unequivocally provides that quantitative statements can be claims:

Information 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 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. 101.13(c) (emphases added). This regulation reflects the FDA’s view that a quantitative statement as to a nutrient amount, 100 calories for example, is not a claim when such a statement appears in the nutrient panel required by Section 343(q), but is one when it does not. And asked, during the notice and comment period, to exclude statements about “simple factual information” from the definition of “nutrient content claim” on the theory that such a statement is not “a claim that ‘characterizes’ the level of any nutrient” within the meaning of the NLEA, the FDA refused, stating that the regulations pertaining to claims “apply to statements of the amount of a nutrient in food as well as to statements of the level of a nutrient in food.” 58 Fed. Reg. 2302-01, 2303-04 (1993).¹¹

¹¹ The full context of this statement is below:
The agency advises that while it can agree that the terms “nutrient descriptor” and “nutrient descriptor claim[.]” may be used to describe the claims subject to section 403(r)(1)(A) of the act and these regulations, it does not agree that the scope of the statute and the regulations excludes statements of the amount of a nutrient in a food. The distribution the comment draws between “nutrient descriptors” and “nutrient content” claims is unpersuasive. In fact, one of the sponsors of the 1990 amendments in the Senate specifically used the term “nutrition content claim” to refer to claims covered under section 403(r)(1) (A) (136 Cong. Rec. S16608 (October 24, 1990)). Moreover, the statement in section 403(r)(1) of the act referred to by the comment as excluding from coverage statements of the type contained in nutrition labeling, in fact excludes “a statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph * * *.” FDA stated in the general principles proposal (56 FR 60421 at 60424), that the legislative history of this provision specifically

Though we might have interpreted the NLEA differently, we owe deference to the FDA’s reading, as it has some support in the statute. See 21 U.S.C. § 343(r)(1) (“[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 . . .”) (emphasis added); Pub. L. No. 101-535, § 3(b)(1)(A)(iv), 104 Stat. 2353, 2361 (instructing FDA to promulgate regulations to implement Section 343(r), to define terms that characterize the level of any nutrient in food “unless the Secretary finds that the use of any such term would be misleading,” and “[to] permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in section [343(r)].”); see also Mead, 533 U.S. at 227 (“[A]ny ensuing regulation [ensuing from authority delegated by Congress to agencies] is binding in the courts unless procedurally defective, arbitrary or capricious in substance, or manifestly contrary

states that the identical information will be subject to the descriptor requirements if it is included in a statement in another portion of the label (136 Congressional Record H5841 (July 30, 1990)). In addition, section 403(r)(2)(E) of the act specifically exempts from the limitations on claims established in section 403(r)(2)(A)(i) through (r)(2)(A)(v), “a statement in the label or labeling of food which describes the percentage of vitamins and minerals in the food which describes the percentage of such vitamins and minerals recommended for daily consumption by the Secretary.” If such declarations as “10 percent of the U.S. RDA for vitamin C” were not within the scope of section 403(r)(1)(A) of the act, there would have been no need for Congress to provide a specific exemption for such claims. Furthermore, section 3(b)(1)(A)(iv) of the 1990 amendments provides that the mandated regulations “shall permit statements describing the amount and percentage of nutrients in food which * * * are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act.” Again, if statements of the amount and percentage of nutrients were not subject to section 403(r)(1)(A) of the act, there presumably would have been no need for Congress to express its desire that such claims be permitted by the regulations. Accordingly, FDA concludes that section 403(r)(1)(A) of the act and therefore these final regulations apply to statements of the amount of a nutrient in food as well as to statements of the level of a nutrient in food.

58 Fed. Reg. 2302-01, 2303-04 (1993) (emphases added).

to the statute.”). Thus, like the district court, we conclude that “under the FDA regulations, statements as to nutrient amount, including calorie content, may be a ‘claim’ subject to the requirements of [Section] 343(r) and its implementing regulations.” NYSRA I, 509 F. Supp. 2d at 360.

Since quantitative statements of the type listed in Section 343(q) can be claims, we are brought back, almost full circle, to the question of when such statements are claims and state and local regulations are thus preempted, and when they are simply labeling requirements and state and local regulations are not preempted. The district court concluded that such statements, that is, of the type listed in Section 343(q), are claims when voluntary, but not so when mandatory. NYSRA II, 2008 WL 1752455, at *3. In contending that the district court erred, NYSRA states that the statute and FDA regulations compel the conclusion that while New York City is free to require restaurants to disclose nutrition information under Section 343-1(a)(4), it may do so only if its regulations are identical to federal regulation of such information under Section 343(q); otherwise the “nutrition information” becomes a “claim,” subject to Section 343(r), and preempted by Section 343-1(a)(5). Thus, NYSRA goes one step further than the district court -- to avoid preemption, it is not sufficient for Regulation 81.50 to be mandatory, it must also be identical to Section 343(q).

We do not agree. In urging this interpretation of the statute, NYSRA points to Section 343(r)(1), which, as we have noted, states that “[a] statement of the type required by [Section 343(q)] 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) (emphasis added), and reads these words to mean that: (1) in order for a Section 343(q)-type statement not to be a claim, (2) it must appear with all the

other information listed in Section 343(q)'s complete Nutrition Fact panel. However, in promoting this view, NYSRA renders meaningless Sections 343(q)(5)(A)(i) and 343-1(a)(4). We are not at liberty to do likewise. Together, these sections provide that states are not preempted from establishing, or put differently, are permitted to establish "any requirement [for restaurants] for nutrition labeling of food that is not identical to the requirement of [S]ection 343(q)." *Id.* § 343-1(a)(4) (emphasis added). Since those sections permit states to adopt non-identical labeling rules for restaurants, Section 343(r)(1)'s reference to nutrition labeling "required or permitted" by Section 343(q), does not necessarily pertain to the complete list of nutrient information noted in Section 343(q), but rather to whatever (identical or non-identical) requirements that states or localities choose to adopt as it relates to restaurant food. Thus, we read Section 343(r)(1) to provide that: (1) in order for a Section 343(q)-type statement not to be a claim, (2) it must appear with the other information required or permitted by the NLEA for packaged food, or applicable state or local law for restaurant food, which here, would be that required by Regulation 81.50 -- the total number of calories. As NYSRA notes, therefore, isolated quantitative statements of the type listed in Section 343(q) can be claims, but only if Section 343(q), or the state law addressing restaurant food, requires it to appear along with other nutrient information such as those required by Section 343(q).¹²

¹² One of the sponsors of the Act expressed the view that the NLEA recognizes the authority of states to require restaurants to disclose nutrition content to their customers through rules that are not identical to Section 343(q). *See* 136 Cong. Rec. S16607 (Oct. 24, 1990) (Statement of Sen. Metzenbaum) ("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." (emphasis added)). Further, this conclusion makes sense because Congress chose to exempt restaurants from Section 343(q) in part because it was of the view that full nutrition labeling of restaurant food would be "impractical," H.R. Rep. No. 101-538, at 7. Labeling requirements were met with "vociferous opposition" by restaurants.

But NYSRA further contends that the FDA Regulations do not read the statute as we have. Placing particular emphasis on Regulation 101.13(c), it states that the FDA regulations provide that in order not to be a claim, the nutrition information must meet three criteria. Thus,

Information that [1] is required or permitted by § 101.9 or § 101.36, as applicable, to be declared in nutrition labeling, and that [2] 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 [3] 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.

NYSRA Supp. Br. 5 (quoting 21 C.F.R. § 101.13(c) (alterations in NYSRA Supp. Br.).

However, this regulation, even as parsed by NYSRA, does not change our reading of the statute, because we conclude that it does not address nutrition “information” on restaurant food, but rather on non-restaurant food. This conclusion is based both on the understanding, as explained by the FDA to us, that Regulation 101.13 was adopted with packaged food in mind, see FDA

Laura S. Sims, The Politics of Fat: Food and Nutrition Policy in America 200 (1998). Further, 21 C.F.R. § 101.10, which describes what happens when restaurants make a claim and allows that when a claim is made, a statement of the quantified specific caloric content may qualify as the “functional equivalent” of information required in nutrition labeling under Section 343(q), indicates that the FDA Regulations recognized that restaurants can make single statements as to nutrient information without providing a complete Nutrition Fact panel. See also FDA, Guidance for Indus., at ¶ 106 (“States would be free to apply nutrition labeling and claims requirements to claims on menus. Furthermore, because the [FDCA] 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 State requirements of the type required by [Section 343(q)] and [Section 343(r)] would not be preempted for foods that are exempt from the Federal requirements.”); Keystone Ctr., The Keystone Forum on Away-from-Home Foods: Opportunities for Preventing Weight Gain and Obesity 74 (2006), available at <http://www.cfsan.fda.gov/~dms/nutrcal.html> (last visited Jan. 13, 2009) [hereinafter Keystone Report] (“[T]he FDA does not have regulatory authority to require nutrition information in restaurants. The U.S. Congress and 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.”).

Amicus Br. 19, and the language of the regulation itself. As an initial matter, the “first prong” provides that for Regulation 101.13(c) to transform a Section 343(q) statement into a claim, the information at issue must first be “required or permitted” by either FDA Regulation 101.9, which pertains to the federal requirements for “nutrition labeling of food” or FDA Regulation 101.36, which addresses federal requirements for “nutrition labeling of dietary supplements,” and is inapplicable here. The regulation counterpart to Section 343(q)(5)(A) is Regulation 101.9(j)(2)(i), which exempts restaurant food from Regulation 101.9’s labeling requirements.¹³ Thus, since the regulations noted in Regulation 101.13 -- 101.9 and 101.36 -- do not apply to nutrition information mandated by state or local law to be placed on restaurant food, the “third prong’s” reference to “such information” does not speak to “information” relating to restaurant food.¹⁴ Finally, the “second prong” which references information that appears “as part of the nutrition label,” confirms this reading. The FDCA defines “label” as any “display of written, printed, or graphic matter upon the immediate container of any article,” 21 U.S.C. § 321(k) (emphasis added), and “labeling” as “all labels and other written, printed, or graphic matter (1)

¹³ Regulation 101.9(j)(2)(i) provides: “The following foods are exempt from this section or are subject to special labeling requirements: . . . Food products which are: . . . Served in restaurants, Provided, That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section” 21 C.F.R. § 101.9(j)(2)(i). Because NYSRA appears to suggest otherwise, we note that this provision simply recognizes that food served in restaurants is exempt from Regulation 101.9(j)(2)(i)’s requirements, but then notes an exception for claims. It does not transform quantitative statements of the type covered by Section 343(q) and Regulation 101.9(j) and mandated by state or local law, into claims.

¹⁴ The reference in Regulation 101.13(c) to information “permitted” does not refer to the restaurant exception. Pursuant to Section 343(q)(2)(A), in addition to listing information that must be provided on a Nutrition Fact panel, Regulation 101.9 also lists information that may voluntarily be included. It is to that voluntary information that the term “permitted” refers.

upon any article or any of its containers or wrappers, or (2) accompanying such article,” id. § 321(m). Therefore, although restaurant food might have labeling, most would not have labels. Stated differently, an order of pasta at Olive Garden Italian Restaurant does not come with a label printed on the bowl.

Our above analysis perhaps simply comes down to this: accepting NYSRA’s position -- that states or municipalities choosing to regulate nutrition information labeling by restaurants may do so only by adopting labeling requirements that are identical to those listed in Section 343(q) and Regulation 101.9 -- would render Section 343-1(a)(4)’s exception for preemption meaningless.¹⁵ See FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) (“It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.” (quotation marks omitted)). It is well settled that in view of the “primacy of state regulation of matters of health and safety,” Medtronic, Inc., 518 U.S. at 485, “state and local regulation related to [those] matters . . . can normally coexist with federal regulations,” Hillsborough County, 471 U.S. at 718. Therefore, if there is any ambiguity in the NLEA and FDA regulations, we are bound to “accept the reading that disfavors pre-emption.” Bates, 544 U.S. at 449; see also 136 Cong. Rec. H5836 (July 30, 1990) (Statement of Rep. Waxman) (“[A]ny preemption provision must

¹⁵ NYSRA’s contention that Section 343-1(b) resolves this issue is unpersuasive. That section allows the FDA to, if certain conditions are met, grant a case-by-case waiver to proposed state and local regulations that are preempted by the NLEA. See 21 U.S.C. § 343-1(b); see also 21 C.F.R. § 100.1(d) (listing requirements to obtain waiver). This uncertain prospect of securing an individual waiver does not give life to those sections of the NLEA that provide for an unconditional exception to preemption. Thus, as to nutrition information on restaurant food, the statute itself already provides the requisite waiver, and Section 343-1(b) addresses regulations that are actually preempted.

recognize the important contribution that the State can make in regulation, and it must leave a role for the states.”). That our decision might result in NYSRA’s members being subject to multiple, inconsistent local regulations is the result of the choice that Congress made to permit localities to mandate restaurants to disclose nutrition information about the food they serve. It is not a permissible basis to conclude that the NLEA preempts Regulation 81.50.¹⁶

As previously noted, prior to oral argument in this appeal, we invited the FDA to submit an amicus brief to enlighten us as to its views on preemption. It did so and we may consider the views expressed therein for persuasive value. See Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) (stating that agency interpretations “constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of [an agency’s] judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”); Schneider v. Feinberg, 345 F.3d 135, 143 (2d Cir. 2003) (explaining Skidmore deference).¹⁷ The FDA

¹⁶ We have not been asked to conclude that Regulation 81.50 is impliedly preempted by the FDCA and thus do not reach that question. Pub. L. No. 101-535, § 6(c)(3), 104 Stat. 2353, 2364. See Sprietsma v. Mercury Marine, 537 U.S. 51, 65 (2002) (stating that inclusion of express preemption provision does not bar ordinary working of “conflict” or “implied” preemption principles).

¹⁷ NYSRA urges us not to give the FDA’s views even Skidmore deference because “[a]bsent a showing that the regulation leads to absurd results, the ‘plain meaning of language in a regulation governs’” NYSRA Supp. Br. 13 (quoting Lin v. U. S. Dep’t of Justice, 459 F.3d 255, 262 (2d Cir. 2006)). As explained previously, we think NYSRA’s alternative approach, which would permit states to adopt nutrition labeling requirements for restaurants only if those labeling requirements are identical to those provided in the NLEA, renders Section 343-1(a)(4)’s exception for preemption meaningless, an unacceptable and absurd result. See APWU v. Potter, 343 F.3d 619, 626 (2d Cir. 2003) (“A basic tenet of statutory construction, equally applicable to regulatory construction, is that a text should be construed so that effect is given to all its

advances the view that a statement is nutrition information exempt from the NLEA’s preemption provisions if two criteria are met.

First, the statement must be “[1] of the type required by [Section 343(q)] [2] that appears as part of the nutrition information required or permitted by . . . [Section 343(q)].” 21 U.S.C. § 343(r)(1). Second, a state or municipal 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) [(noting exceptions that are inapplicable here)].

FDA Amicus Br. 14-15. The first criterion tracks our above analysis, and thus we find it persuasive.¹⁸ The second criterion, plainly stated as above, is also unobjectionable since Section 343-1(a)(4)’s exception to preemption concerns “nutrition labeling.” 21 U.S.C. § 343-1(a)(4). In defending the second criterion, the FDA attempts to reconcile Regulation 101.13(c) to restaurant food by asking us to conclude that labeling requirements are met when a nutrition information statement appears, “for packaged food, 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 food in a place appropriate for such information at the point of purchase.” FDA Amicus Br. 19. That is, that “the term ‘nutrition label’ as used in [Regulation] 101.13(c)” should be interpreted “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’

provisions, so that no part will be inoperative or superfluous, void or insignificant, and so that one section will not destroy another unless the provision is the result of obvious mistake or error.”) (alterations and quotation marks omitted).

¹⁸ Briefly, first: (1) Section 343(q) lists types of information that fall under the rubric of “nutrition information” to include “total number of calories” and thus the nutrient information regulated by Regulation 81.50 is “of the type” required by Section 343(q). Second, because Section 343(q) permits states to adopt non-identical nutrition information requirements for restaurants, the information required by Regulation 81.50 appears as part of the nutrition information permitted by Section 343(q).

advanced by NYSRA, or whether it instead is placed, as [under Regulation 81.50], in appropriate labeling.” *Id.* at 19-20; *see* 21 C.F.R § 101.45(a)(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.”); *id.* § 101.10 (stating as to “Nutrition labeling of restaurant foods” that “Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.”). Put simply, the FDA asks us to read “label” as stated in Regulation 101.13’s reference to “nutrition label,” as “appropriate labeling.” Accordingly, for restaurants, a menu or menu board would fall within Section 101.13’s definition of “label.” We have concerns about reading the regulation as the FDA proposes, but might be required to do so if it were the only way to keep the structure and meaning of the NLEA intact. However, we think a better approach is to conclude, as we have, that Regulation 101.13(c) does not pertain to restaurant food, but we adopt the FDA’s test, quoted above, ***see supra*, at 25**, as our own.

B. First Amendment

NYSRA’s other objection to Regulation 81.50 is that it impermissibly infringes on NYSRA’s member restaurants’ First Amendment rights. It is undisputed that commercial speech is entitled to the protection of the First Amendment. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 637 (1985). As commercial speech is speech that proposes a commercial transaction, *id.*, and Regulation 81.50 “requires disclosure of calorie information in connection with a proposed commercial transaction -- the sale of a restaurant meal,” *NYSRA II*, 2008 WL 1752455, at *6, the form of speech affected by Regulation 81.50 is clearly commercial speech.

However, the protection afforded commercial speech is “somewhat less extensive than that afforded noncommercial speech.” Zauderer, 471 U.S. at 637 (quotation marks omitted). And, within the class of regulations affecting commercial speech, we accord varying levels of protection depending on the type of commercial speech at issue.

This is where NYSRA’s objection to the district court’s decision lies. It argues that Regulation 81.50 should be subjected to heightened scrutiny, and not, as the district court concluded, “rationality.” However, the district court’s conclusion was compelled by this Circuit’s law, which rested on our interpretation of Supreme Court precedent. The Supreme Court has stated that there are “material differences between [purely factual and uncontroversial] disclosure requirements and outright prohibitions on speech,” id. at 650, and that regulations that compel “purely factual and uncontroversial” commercial speech are subject to more lenient review than regulations that restrict accurate commercial speech. Id. at 651. In light of Zauderer, this Circuit thus held that rules “mandating that commercial actors disclose commercial information” are subject to the rational basis test. Nat’l Elec. Mfrs. Ass’n v. Sorrell, 272 F.3d 104, 114-15 (2d Cir. 2001). We explained that:

Commercial 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. Such disclosure furthers, rather than hinders, the First Amendment goal of the discovery of truth and contributes to the efficiency of the “marketplace of ideas.” Protection of the robust and free flow of accurate information is the principal First Amendment justification for protecting commercial speech, and requiring disclosure of truthful information promotes that goal. In such a case, then, less exacting scrutiny is required than where truthful, nonmisleading commercial speech is restricted.

Id. at 113-14 (footnote and citations omitted);¹⁹ cf. Riley v. Nat’l Fed’n of the Blind of N.C., Inc., 487 U.S. 781, 796 n.9 (1988) (stating that “[p]urely commercial speech is more susceptible to compelled disclosure requirements” than is personal or political speech).

In arguing both that Sorrell was incorrectly decided and that it does not govern this case, NYSRA makes the following three arguments. First, United States v. United Foods, Inc., 533 U.S. 405 (2001), issued three months before Sorrell and which Sorrell does not discuss, limited the rational basis test described in Zauderer to those situations in which the law at issue furthers the State’s interest in preventing deception of consumers. Second, International Dairy Foods Association v. Amestoy (IDFA), 92 F.3d 67 (2d Cir. 1996), in which we applied intermediate scrutiny pursuant to Central Hudson Gas & Elec. Corp. v. Pub. Serv. Commission of New York, 447 U.S. 557 (1980), is more akin to this case.²⁰ Third, the parties in Sorrell did not dispute the significance of the facts that they were being asked to disclose. In contrast, NYSRA’s member restaurants, which do not believe that disclosing calorie information would reduce obesity, and would prefer to provide complete nutrition information, are instead forced, as counsel informed us during oral argument, to “cram” calorie information “down the throats” of their customers.

We think NYSRA reads too much into United Foods. The paragraph on which NYSRA

¹⁹ In Sorrell, we also observed that “[t]o the extent commercial speakers have a legally cognizable interest in withholding accurate, factual information, that interest is typically accommodated by the common law of property and its constitutional guarantors.” 272 F.3d at 114.

²⁰ Under the Central Hudson test, a court considers (1) whether the regulated expression concerns lawful activity and is not misleading; (2) whether the asserted governmental interest is substantial; (3) whether the regulation directly advances the governmental interest asserted; and (4) whether the regulation is more extensive than is necessary to advance that interest. 447 U.S. at 566.

relies simply distinguishes Zauderer on the basis that the compelled speech in Zauderer was necessary to prevent deception of consumers; it does not provide that all other disclosure requirements are subject to heightened scrutiny. United Foods, 533 U.S. at 416. Of course, there is no error in this distinction as Zauderer addressed deceptive advertising. Nor was this distinction lost on us in Sorrell, when we held that Zauderer's holding was broad enough to encompass nonmisleading disclosure requirements. Sorrell, 272 F.3d at 115.²¹ We stated:

To be sure, the compelled disclosure at issue here was not intended to prevent “consumer confusion or deception” per se, Zauderer, 471 U.S. at 651 (internal quotation marks omitted), but rather to better inform consumers about the products they purchase. Although the overall goal of the statute is plainly to reduce the amount of mercury released into the environment, it is inextricably intertwined with the goal of increasing consumer awareness of the presence of mercury in a variety of products. Accordingly, we cannot say that the statute’s goal is inconsistent with the policies underlying First Amendment protection of commercial speech, described above, and the reasons supporting the distinction between compelled and restricted commercial speech. We therefore find that it is governed by the reasonable-relationship rule in Zauderer.

Sorrell, 272 F.3d at 115. We have not been alone in accepting this broader reading. See Pharm. Care Mgmt. Ass’n v. Rowe, 429 F.3d 294, 310 n.8 (1st Cir. 2005) (“[W]e have found no cases limiting Zauderer [to ‘potentially deceptive advertising directed at consumers’].”) (decided four years after United Foods). Thus, “Zauderer, not Central Hudson[], describes the relationship between means and ends demanded by the First Amendment in compelled commercial disclosure

²¹ Alternatively, New York City argues that even if United Foods so constrained Zauderer, Regulation 81.50 was adopted to prevent misleading advertising practices and would still be subject to rational basis. Because we conclude that laws mandating factual disclosures are subject to the rational basis test even if they address non-deceptive speech, we do not reach this argument.

cases.” Sorrell, 272 F.3d at 115.²²

With NYRSA’s challenge to Sorrell’s holding disposed of, its claim that this case is more akin to IDFA, clearly fails. In Sorrell, we explained that our decision in IDFA “was expressly limited to cases in which a state disclosure requirement is supported by no interest other than the gratification of ‘consumer curiosity.’” Sorrell, 272 F.3d at 115 n.6. Given New York’s interest in preventing obesity, which is further explained below, see also Mem. of Law in Supp. of Pl.’s Mot. for Declaratory Relief and a Preliminary Injunction, at 34, No. 08cv1000 (S.D.N.Y. filed Feb. 14, 2008) (conceding that New York City has a substantial interest in passing Regulation 81.50), IDFA is inapplicable.

NYSRA’s final objection is also resolved by Sorrell, which clearly held that laws that compel the reporting of “factual and uncontroversial” information by commercial entities are scrutinized for rationality. Sorrell, 272 F.3d at 114-15; see also Zauderer, 471 U.S. at 650-51. Thus, “[t]he question that we must answer is whether [Regulation 81.50’s] labeling . . . requirements are compelled speech in violation of the Constitution or simply requirements of purely factual disclosures.” Entm’t Software Ass’n v. Blagojevich, 469 F.3d 641, 652 (7th Cir.

²² As in Zauderer, we also reject NYRSA’s suggestions that heightened review is appropriate because New York City has alternative means of achieving its goals or because Regulation 81.50 impacts only ten percent of New York City restaurants.

Because the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed, we do not think it appropriate to strike down such requirements merely because other possible means by which the State might achieve its purposes can be hypothesized. Similarly, we are unpersuaded by appellant’s argument that a disclosure requirement is subject to attack if it is “under-inclusive”-- that is, if it does not get at all facets of the problem it is designed to ameliorate. As a general matter, governments are entitled to attack problems piecemeal, save where their policies implicate rights so fundamental that strict scrutiny must be applied. Zauderer, 471 U.S. at 651 n.14.

2006) (applying strict scrutiny to disclosure requirement requiring placement of “18” sticker that met the statute’s definition of “sexually explicit” because it was “more opinion-based than the question of whether a particular chemical is within any given product” unlike in Sorrell). NYSRA does not contend that disclosure of calorie information is not “factual”; it only claims that its member restaurants do not want to communicate to their customers that calorie amounts should be prioritized among other nutrient amounts, such as those listed in Section 343(q)’s Nutrition Fact panel. However, the First Amendment does not bar the City from compelling such “under-inclusive” factual disclosures, see Zauderer, 471 U.S. at 651 n.14, where as discussed below, the City’s decision to focus its attention on calorie amounts is rational.

A. Rational Basis Review

Accordingly, rational basis applies and NYSRA concedes that it will not prevail if we apply that test. Our review reveals the concession to be warranted; New York City has plainly demonstrated a reasonable relationship between the purpose of Regulation 81.50’s disclosure requirements and the means employed to achieve that purpose. Citing what it termed an “obesity epidemic,” New York City enacted Regulation 81.50 to: (1) reduce consumer confusion and deception; and (2) to promote informed consumer decision-making so as to reduce obesity and the diseases associated with it. See Notice of Adoption. Identifying numerous studies, the Notice of Adoption made the following relevant findings.²³ First, that obesity is epidemic and is a serious and increasing cause of disease; in New York City, 54% of adults, and 43% of elementary school children are overweight or obese and obesity is a contributing factor for heart

²³ Though it has, we note that to survive rational basis review, New York “has no obligation to produce evidence, or empirical data to sustain . . . rationality.” Lewis v. Thompson, 252 F.3d 567, 582 (2d Cir. 2001) (quotation marks omitted).

disease, diabetes, stroke, and cancer, which caused 70% of deaths in New York City in 2005. Id. at 3. Second, that the obesity epidemic is mainly due to excess calorie consumption, often resulting from meals eaten away from the home. Americans, including New Yorkers, are eating out more than in the past and when doing so, typically eat more than they do at home, and in just one meal ordered in a fast food restaurant, might consume more than the advised daily caloric intake. Id. at 3-4. Third, that chain restaurants serve food that is associated with excess calorie consumption and weight gain. Id. at 5. Fourth, that consumers' distorted perceptions about how many calories food contained led to unhealthy food choices. Id. Fifth, that providing calorie information, similar to that provided in the NLEA's Nutrition Fact panel, at the point-of-decision would help consumers make informed, healthier food choices. Id. at 6. Finally, it noted that voluntary activities by restaurants were "woefully inadequate" and failed to inform the vast majority of customers, only 3.1% of whom in a study, reported noticing calorie information, id. at 7-8, and that leading health authorities recommend posting calorie information at the point of purchase, id. at 8.

New York City was not alone in making these observations. A 2006 FDA-commissioned report concluded that "obesity has become a public health crisis of epidemic proportions." Keystone Report at 4. In addition, a 2005 study by the Centers for Disease Control and Prevention (the "CDC") estimated that approximately 112,000 deaths in 2000 were associated with obesity in the United States. Katherine M. Flegal et al., Excess Deaths Associated with Underweight, Overweight, and Obesity, 293 J. AM. MED. ASS'N 1861, 1863-64 (2005). Another study concluded that rising obesity rates led to increasing diabetes rates, finding that as of 2005, 15.8 million Americans had diabetes, almost triple the number from 1980. Ctr. for Disease

Control, Nat'l Ctr. For Health Statistics, Nat'l Diabetes Surveillance Sys., Prevalence of Diabetes (1980-2005), available at <http://www.cdc.gov/diabetes/statistics/prev/national/tablepersons.htm> (last visited Jan. 13, 2009). Yet another study concluded that with these increased rates of obesity and associated health problems, have come increased health-care costs. See Eric A. Finkelstein et al., State-Level Estimates of Annual Medical Expenditures Attributable to Obesity, 12 OBESITY RESEARCH 18, 22-23 (2004) (listing increased annual medical expenditures of states attributable to obesity in several states including New York).

Further, studies have linked obesity to eating out. The Keystone Report also concluded that the consumption of high-calorie meals at fast-food restaurants is a significant cause of obesity, stating that “[e]ating out more frequently is associated with obesity, higher body fatness, and higher body mass index.” Keystone Report at 27. And, it found, among other things that, whereas in 1970 American spent just 26% of their food budget on food prepared away from home, they now spend 46% of their food dollars on such items; and that away-from-home foods provided 34% of American’s daily total caloric intake in 1995, nearly double the 18% intake in 1977-78. Id. at 30, 122. The United States Department of Agriculture has observed that away-from-home foods have lower nutritional quality than home foods and found a correlation between increased caloric intake and eating out. See Biing-Hwan Lin, et al., U.S. Dep’t of Agric., Econ. Research serv., Agric. Info. Bull. No. 749, Away-From-Home Foods Increasingly Important to Quality of American Diet (1999), available at <http://www.ers.usda.gov/Publications/AIB749/> (last visited Jan. 13, 2009). Yet another study found that between 50% and 80% of diabetes cases are associated with obesity, unhealthy eating and physical inactivity. F.B. Hu, et al., Diet, Lifestyle, and the Risk of Type 2 Diabetes Mellitus

in Women, 345 NEW ENG. J. MED. 790, 790-97 (2001).

Stating that “calorie information is most relevant to obesity prevention,” Keystone Report at 80, the Keystone Report concluded that “restaurants should provide consumers with calorie information in a standard format that is easily accessible and easy to use,” id. at 76, 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,” id. at 77.²⁴ In arriving at this conclusion the Keystone Report stated that “[w]ithout nutrition information, consumers typically are unable to assess the caloric content of foods,” id. at 68, a statement which we do not doubt upon being informed, counter-intuitively, that a smoked turkey sandwich at Chili’s contains 930 calories, more than a sirloin steak, which contains 540, or that 2 jelly-filled doughnuts at Dunkin’ Donuts have fewer calories than a sesame bagel with cream cheese. City and County of San Francisco, CA et al. Amicus Br. 13-14; see also Scot Burton et al., Attacking the Obesity Epidemic: The Potential Health Benefits of Providing Nutrition Information in Restaurants, 96 AM. J. PUB. HEALTH 1669, 1669-75 (2006) (finding that calories

²⁴ The American Medical Association, the American Heart Association, the American Association of Retired Persons (AARP), and the American Public Health Association (APHA), have all endorsed nutrition labeling at fast food and chain restaurants as well. See Am. Med. Ass’n, Press Release, AMA Adopts Policies to Promote Healthier Food Options to Fight Obesity in America (June 27, 2007), available at <http://www.ama-assn.org/ama/pub/category/print/17768.html> (last visited Jan. 13, 2009); Am. Heart Ass’n, Position Statement on Menu Labeling (Mar. 4, 2008), available at <http://www.americanheart.org/downloadable/heart/I204661406112Policy%20Position%20Statement%20n%20Menu%20Labeling.pdf>; AARP, Nutrition Labeling At Fast-Food And Other Chain Restaurants (July 2004), available at <http://www.aarp.org/research/health/healthquality/aresearch-import-882-IB71.html> (last visited Jan. 13, 2009); Am. Public Health Ass’n, Support for Nutrition Labeling in Fast-Food and Other Chain Restaurants (Nov. 9, 2004), available at <http://www.apha.org/advocacy/policy/policysearch/default.htm?id=1300> (last visited Jan. 13, 2009).

in restaurant items were almost two times more than what consumers expected). Indeed, NYSRA's expert does not assert that provision of information about the calorie content of food at the point of purchase in restaurants will not be beneficial in reducing obesity levels, and only states that it might not.

In view of all the above findings, Regulation 81.50's calorie disclosure rules are clearly reasonably related to its goal of reducing obesity.²⁵ We thus conclude that NYSRA has not demonstrated a likelihood of success on its First Amendment claims and affirm the district court's denial of an injunction.

III. Conclusion

For the reasons stated above, we reject NYSRA's challenge to Regulation 81.50 because we conclude that it is not preempted by the NLEA and does not violate NYSRA's member restaurants' First Amendment rights. Because this panel did not grant a stay of enforcement of the district court's order and NYSRA and its member restaurants are complying with Regulation 81.50, or facing fines for non-compliance, no further action is required by this Court.

²⁵ As requested in *City and County of San Francisco, CA et al. Amici Curiae's Request for Judicial Notice*, we take judicial notice of the fact that numerous other states and or localities have passed or introduced similar nutrition disclosure legislation. See *County of Suffolk v. First Am. Real Estate Solutions*, 261 F.3d 179, 190 n.5 (2d Cir. 2001) (“[W]e take judicial notice of the introduction of a similar bill seeking to amend [New York State's Freedom of Information Law] now before the 224th Legislature.”).