08-1892-cv

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

NEW YORK STATE RESTAURANT ASSOCIATION,

Plaintiff-Appellee,

-v.-

NEW YORK CITY BOARD OF HEALTH, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, And THOMAS R. FRIEDEN, In His Official Capacity As Commissioner Of The New York City Department Of Health And Mental Hygiene,

Defendants-Appellees.

_____

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

APPELLEES' BRIEF

MICHAEL A. CARDOZO,
Corporation Counsel of the
City of New York,
Attorney for Defendants-Appellees,
100 Church Street,
New York, New York 10007.
(212) 788-1034 or 1065

PAMELA SEIDER DOLGOW,
MARK MUSCHENHEIM,
FAY NG,

THOMAS MERRILL,
GENERAL COUNSEL,
N.Y.C. DEPT. OF HEALTH
AND MENTAL HYGIENE
of Counsel.

MAY 15, 2008

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases

Pages

Pages

Pages

Statutes

Regulations

Pages

Other Authorities

FDA Publications

Pages

PRELIMINARY STATEMENT

In this action, plaintiff-appellant, the New York State Restaurant Association ("plaintiff"), seeks to declare New York City Health Code §81.50 unconstitutional. Section 81.50 requires restaurants that have 15 restaurants or more nation-wide to post calorie information on their menus and menu boards. Specifically, plaintiff asserts that section 81.50 (1) is preempted by a provision of the federal Nutrition Labeling and Education Act of 1990 ("NLEA"), and (2) violates its First Amendment rights. Before the District Court, plaintiff moved for summary judgment, and in the alternative, for preliminary injunctive relief on its preemption claim. Plaintiff also sought a preliminary injunction on it First Amendment claim. The City cross-moved for summary judgment on plaintiff's preemption claim.

Plaintiff appeals from the Memorandum Opinion and Order of the United States District Court for the Southern District of New York (Holwell, U.S.D.J.), dated April 16, 2008, which granted the City's cross-motion for summary judgment on plaintiff's preemption claim and denied plaintiff's application for a preliminary injunction on its First Amendment claim.

Defendants-Appellees, the New York City Board of Health, the New York City Department of Health and Mental

Hygiene (“DOH”), and Thomas R. Frieden, in his official capacity as Commissioner of DOH (collectively the “City”), submit this brief in support of the affirmance of the District Court's order.

QUESTIONS PRESENTED

1. Whether Health Code §81.50 is preempted by the Nutrition Labeling and Education Act?

2. Whether Health Code §81.50, which requires certain restaurants to post calorie information on restaurant menus and menu boards, violates the First Amendment?

STATEMENT OF THE CASE

(1)

In 2006, in response to the growing obesity epidemic and the associated increase in the health problems related to obesity, DOH adopted the predecessor to the present section 81.50. That predecessor section ("2006 HC 81.50") required restaurants which had already voluntarily published calorie information to the public to post calorie amounts on menus and menu boards. Plaintiff challenged the 2006 HC 81.50 on the grounds that it was preempted by the NLEA and that it violated its members' First Amendment rights.

The United States District Court for the Southern District of New York (Holwell, U.S.D.J.) concluded “that the City has the power to mandate nutritional labeling by

restaurants," but that 2006 HC 81.50 "offends the federal statutory scheme for voluntary nutritional claims" set forth in the NLEA and thus was preempted. New York State Restaurant Ass'n v. New York City Board of Health, 509 F. Supp. 2d 351, 352-53 (S.D.N.Y. 2007) ("NYSRA I"). The District Court held that the restaurants' voluntary act of making this calorie information available meant that these restaurants were making nutrient content claims governed by 21 U.S.C. § 343(r) and its preemption provision, and that 2006 HC 81.50 could thus not regulate how they were made. 509 F. Supp. 2d at 363. See also, 21 U.S.C. § 343-1(a)(5); 21 C.F.R. § 101.10.

In January 2008, the Board of Health repealed 2006 HC 81.50 and reenacted a new Health Code §81.50 (JA550-566).[1] Restaurants which are one of "a group of fifteen or more food service establishments doing business nationally under the same name, and offering for sale substantially the same menu items" are required to post calorie information on their menus and menu boards (JA551).

The City filed a Notice of Appeal from the District Court's order in NYSRA I. The parties, however, stipulated that after former section 81.50 was repealed and the new section

[1] Unless otherwise noted, numbers in parentheses preceded by the letters "JA" refer to the Joint Appendix; numbers preceded by "SPA" refer to pages of the Special Appendix.

81.50 was enacted, the appeal should be dismissed as moot. This Court subsequently so-ordered that stipulation (JA688-689).

(2)

By the filing of a summons and complaint dated January 31, 2008, plaintiff commenced the instant action challenging section 81.50 that was enacted on January 22, 2008 (JA10-21). Plaintiff filed an Order to Show Cause dated February 14, 2008, with supporting declarations, seeking an order preliminarily enjoining the City from enforcing section 81.50 (JA23-597). Plaintiff also sought a judgment under Fed. R. Civ. P. 57 declaring that section 81.50 was preempted by the NLEA (JA24).

The City submitted expert and documentary evidence (1) in opposition to plaintiff's motion for injunctive relief on its First Amendment claim and (2) in support of the City's cross-motion for summary judgment on the plaintiff's preemption claim (JA598-1165).

DECISION BELOW

The District Court held that section 81.50 was not preempted by the NLEA and granted the City summary judgment on this claim (SPA35-38). The District Court reasoned that section 81.50 was not "preempted by NLEA because that statute explicitly leaves to state and local governments the power to impose mandatory nutrition labeling by restaurants" (SPA34). The

District Court conducted a detailed and comprehensive analysis of the relevant statutory and regulatory scheme, as well as the legislative history of the NLEA and recent pronouncements by United States Food and Drug Administration ("FDA") on the issue (SPA35-38).

The District Court also held that plaintiff failed to demonstrate a likelihood of success on its First Amendment claim (SPA38-47). It rejected plaintiff's argument that a heightened standard of scrutiny should be applied to analyze its First Amendment claims, reasoning that the applicable framework was the rational relationship test forth by the Supreme Court in Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985), and applied by this Court in Nat'l Elec. Mfr. Assoc. v. Sorrell, 272 F.3d 104 (2d Cir. 2001), cert. denied, 536 U.S. 905 (2002). The District Court then held that section 81.50 was rationally related to the City's interest in curbing the obesity epidemic and the health risks associated with it (SPA 46-47).

In granting the City summary judgment on plaintiff's preemption claim and denying plaintiff preliminary injunctive relief on its First Amendment claim, the District Court conducted a comprehensive analysis of the relevant law and facts. The District Court's reasoning is discussed in more detail in the argument portion of this brief.

SUMMARY OF ARGUMENT

The plain language of the NLEA demonstrates that it did not preempt state and local governments from requiring restaurants to provide nutrition information to customers. Moreover, because section 81.50 requires the disclosure of purely factual information, under controlling Supreme Court precedent, it does not violate the First Amendment.

(1)

As discussed in Point I, infra, there is no dispute that prior to the enactment of the NLEA, state and local governments could require the inclusion of calorie information on restaurant menus as part of their police power to regulate restaurants. Plaintiff argues that the NLEA took away this power from the states, but at the same time, explicitly denied this power to the FDA. The resulting regulatory gap not only undermines one of the purposes underlying the enactment of the NLEA (providing nutrition information to consumers), it has no support in the NLEA's statutory scheme.

Congress explicitly indicated that the preemption provisions in the NLEA are to be read narrowly. The NLEA specifically provides that it "shall not be construed to preempt any provision of state law, unless such provision is expressly preempted under section 403A [21 U.S.C. §343-1(a)] of the

Federal Food, Drug, and Cosmetic Act." Pub. L. No. 101-535, §6(c), 104 Stat. 2535, 2364. Thus, in order to find preemption, the Court would have to find that the preemption of section 81.50 was expressly required by the statute.

The basic nutrition labeling authority is contained in section 343(q), where Congress directed the FDA to impose mandatory nutrition labeling requirements on most food. Nevertheless, in section 343(q)(5)(A)(i) the statute explicitly exempted restaurants from those labeling requirements. In the applicable preemption section of the statute, section 343-1(a)(4), Congress included parallel provisions. Thus in the first portion of section 343-1(a)(4), the statute preempts the states from establishing any requirement "that is not identical" to a requirement under (q), but in the second portion of that same provision, it states that the preemption shall not apply to "a requirement for nutrition labeling of food which is exempt under subclause (i) of section [343](q)(5)(A)." Subclause (i) exempts restaurants from the federal nutrition labeling requirements.

Thus, the statute explicitly states that the preemption provision does not apply to nutrition information regarding restaurants. The FDA, the expert agency charged with

interpreting the NLEA, has adopted this same interpretation of the statute in a guidance publication to the industry.

Nevertheless, plaintiff argues that a disclosure of the numbers of calories in food is not nutrition information but instead is a claim subject to a different preemption provision of the NLEA, §343(r), and to a different preemption provision, §343-1(a)(5). The problem with this argument is that it has no support in the statute. The statute defines claims as statements that "characterize the level of a nutrient" or characterize the relationship between a nutrient and a disease. Moreover, the statute declares that a "statement of the type required by paragraph (q)" (nutrition information) is not a "claim" subject to paragraph (r). Section 343(r)(1). The calorie information that restaurants must disclose under section 81.50 is "of the type required by paragraph (q)": namely, it is factual information about the nutrition content of food. The FDA has also adopted this interpretation.

(2)

As discussed in Point II, infra, the District Court properly denied plaintiff preliminary injunctive relief on its First Amendment Claim because it has not demonstrated "a clear and substantial likelihood of success on the merits." See, County of Nassau v. Leavitt, ___ F.3d __, 2008 U.S. App. LEXIS

8922 (2d Cir. 2008) (where a party seeks to enjoin government action taken in the public interest pursuant to a statutory or regulatory scheme, it must meet the more rigorous likelihood of success standard).

Applying the Supreme Court's decision in Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985), and this Court's decision in Nat'l Elec. Mfr. Assoc. v. Sorrell, 272 F.3d 104 (2d Cir. 2001), cert. denied, 536 U.S. 905 (2002), the District Court properly found that Health Code §81.50 requires the disclosure of factual information and is constitutional because it is rationally related to the City's interest in reducing consumers' inaccurate perceptions and curbing the health consequences associated with obesity.

Essentially conceding that section 81.50 easily meets the rational basis test, plaintiff argues that "[w]hether plaintiff will prevail depends on the selection of the correct level of scrutiny" (App. Br., p.19). It then argues for the application of a strict scrutiny test which is applicable where one is compelled to speak another's point of view. In the alternative, plaintiff argues for the application of the intermediate test set forth in Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York, 447 U.S. 557

(1980),which is generally applied where commercial speech is restricted.

As set forth in Point II, supra, adopting plaintiff's argument would be a complete departure from controlling precedents which have applied a rational basis test where the statute challenged requires the disclosure of factual information in a commercial context.

POINT I

THE NLEA DOES NOT PREEMPT A LOCAL GOVERNMENT REQUIREMENT THAT RESTAURANTS POST CALORIES ON MENUS.

A. CONGRESS INDICATED THAT THE NLEA'S PREEMPTION PROVISION SHOULD BE NARROWLY CONSTRUED.

The regulation of restaurants is a classic exercise of police power traditionally reserved to state and local government by the Tenth Amendment.[2] There is no question that prior to the enactment of the NLEA the City in the exercise of

[2] Sligh v. Kirkwood, 237 U.S. 52, 59 (1915) ("The power of the state to prescribe regulations which shall prevent the production within its borders of impure foods, unfit for use, and such articles as would spread disease and pestilence, is well established."); Grocery Mfrs. of America v. Gerace, 755 F.2d 993, 1003 (2d Cir.), cert. denied, 106 S. Ct. 69 (1985) ("States have traditionally acted to protect consumers by regulating foods produced and/or marketed within their borders"). FDA Draft Voluntary Hazard Analysis and Critical Control Point Manuals, 70 Fed. Reg. 42072 (July 21, 2005) ("the responsibility for regulating retail and foodservice establishments lies primarily with State, local, and tribal jurisdictions …." (emphasis added)).

this police power could have enacted Health Code §81.50 and mandated that restaurants post calories, and plaintiff does not argue otherwise. Thus, the issue in this case is whether Congress, when enacting the NLEA, intended to usurp that power and to preempt such mandates. As we demonstrate below, there is absolutely no evidence that Congress intended to preempt state and local governments in this area, and in fact the language of the NLEA and its legislative history demonstrate exactly the opposite.

Congress explicitly limited the scope of NLEA preemption by providing that there was no implied preemption under the NLEA. Thus section 6(c)(1) of the NLEA, entitled "Construction" provides that the NLEA "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [the NLEA's preemption provision, 21 U.S.C. § 343-1]." 21 U.S.C. § 343-1, note (Pub. L. No. 101-535, 104 Stat. 2353, 2364). Since Congress clearly provided that the NLEA could not be the basis for an implied preemption claim, plaintiff must demonstrate that Congress expressly preempted local governments from mandating the disclosure of calorie information such as Health Code §81.50.

NLEA's section 6(c) language strengthens the ordinary presumption against federal preemption of fields which have

traditionally been the province of the states. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005) ("we assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest" (internal quotations and citations omitted)). Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 666 (2003) ("presumption against federal pre-emption of a state statute designed to foster public health … has special force when it appears … that the two governments are pursuing common purposes" (citations omitted)). Health Code §81.50 addresses the obesity epidemic in New York City; where, as here, a local regulation relates to "matters of health and safety … the presumption against preemption applies, indeed, stands at it strongest." Desiano v. Warner-Lambert & Co., 467 F.3d 85, 94 (2d Cir. 2007), aff'd, 128 S. Ct. 1168 (2008) (equally divided court).

B. THE PLAIN LANGUAGE OF 21 U.S.C. § 343-1(a)(4) DEMONSTRATES THAT CONGRESS DID NOT INTEND THE NLEA TO PREEMPT THE CITY FROM MANDATING THAT RESTAURANTS PROVIDE CALORIE INFORMATION.

The NLEA amended the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq. ("FFDCA") by the enactment of 21 U.S.C. §§ 343(q) & (r). Pub. Law. 101-535 (November 8, 1990). The two purposes of the NLEA legislation were to "give consumers nutrition information about the products they are consuming;

and, second, prohibit misleading [nutrient content claims and] health claims." 136 Cong. Rec. H5843 (July 30, 1990)(Statement of Henry A. Waxman, House lead sponsor of the bill); see also H.R. Rep. No. 101-538, at 7 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3337.

Section 343(q) mandates that certain nutritional information, including calorie information, be disclosed on the label or labeling of food intended for human consumption. 21 U.S.C. § 343(q)(1). This information is contained on the familiar Nutrition Facts panel that appears on packaged food. Restaurants, however, are exempt from this requirement and under the NLEA need not disclose any nutrition information for the foods they serve. 21 U.S.C. §§ 343(q)(1) & (5)(A)(i). Thus, under the NLEA, the FDA has no authority to require that restaurants provide the type of nutrition information that the statute mandates be provided with most other foods. Health Code §81.50 fills in this gap with respect to calories: it mandates that certain restaurants disclose § 343(q)-type information, the amount of calories in a restaurant food item.

The NLEA's express preemption provisions are set forth at 21 U.S.C. § 343-1(a). Its fourth paragraph, § 343-1(a)(4), applies to § 343(q) nutritional labeling requirements. Section 343-1(a)(4) preempts:

> any requirement for nutrition labeling of food … ***except a requirement for nutrition labeling of food which is exempt under subclause (i) … of [21 U.S.C. § 343(q)(5)(A)*** [*i.e.,* the exemption for food served in restaurants]]

(emphasis added). The only plausible interpretation of the exception clause in § 343-1(a)(4) is that Congress specifically intended to not preempt state and local governments from mandating that restaurants provide nutritional information for the food they serve. If Congress had intended to preempt state and local governments from mandating nutrition information in restaurants, as plaintiff argues, then there would have been no reason to include the exception clause in the provision.

Since "the plain wording of [a preemption provision] necessarily contains the best evidence of Congress' pre-emptive intent," CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993), the NLEA must be read as preserving the rights of state and local governments to enact regulations like Health Code §81.50 that requires restaurants to disclose how many calories are in the food they serve. The District Court thus properly found that since "food served in restaurants is explicitly exempt from § 343(q), state authority to impose mandatory nutrition labeling on restaurants is necessarily preserved." (SPA37). See also Pelman v. McDonald's Corp., 237 F. Supp. 2d

512, 526 (S.D.N.Y. 2003) ("§ 343-a(a)(4) does not expressly bar [state-mandated] nutrition labeling on restaurant foods either directly or … indirectly").

The conclusion of the District Court is supported by the legislative history, as well as by the FDA's interpretation of the NLEA. Senator Metzenbaum, the NLEA's chief Senate sponsor, stated: "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." See 136 Cong. Rec. S16607 (Oct. 24, 1990). And just last month, in a Guidance for Industry, the FDA reiterated its long-held position that states may mandate that restaurant food bear nutrition labeling:

> *Question*: "Can a State require restaurant foods to bear nutrition labeling even if the food is exempt under Federal requirements?"
>
> *Answer*: "Yes … because the [FFDCA] exempts restaurant foods that do not bear a claim from mandatory nutrition labeling, State requirements for the nutrition labeling of such foods would not be preempted."

FDA, Guidance for Industry, "A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods" (April 2008) (available at

http://www.cfsan.fda.gov/dms/labrguid.htmlat), Question 106. See also FDA, Food Labeling: Questions and Answers, Volume II, "A Guide for Restaurants and Other Retail Establishments" (Aug. 1995) (question 31) (same) (JA543-544); The Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity (2006) (JA1066) (while "the FDA does not have regulatory authority to require nutrition information in restaurants," "state legislatures do have the authority to require the provision of nutrition information").[3]

In multiple rounds of briefing, plaintiff has yet to even attempt to give meaning to the language of § 343-1(a)(4). Instead, it argues that mandates like Health Code §81.50 can only be imposed on a case-by-case basis if approved by the FDA through the petition process of 21 U.S.C. § 343-1(b). See App. Br., p. 29.[4] This argument should be rejected because

[3] Although the interpretations presented in these publications do not have the force of a regulation, they represent the expert agency's interpretation of its own statute and are entitled to considerable deference by the court. See Auer v. Robbins, 519 U.S. 452, 461 (1997) (when agency is interpreting its own regulation, interpretation is "controlling unless plainly erroneous or inconsistent with the regulation").

[4] Citing the McCarren-Ferguson Act, Plaintiff also argues that the language of the NLEA should have been even more specific if Congress had intended to exempt state and local mandates from its preemptive reach. App. Br., p. 31. That Act, however, was enacted specifically in response to the Supreme Court's decision in United States v. South-Eastern Underwriters Ass'n, 322 U.S. 533 (1944) which had found the business of insurance to be

plaintiff's construction of the statute would render the exception clause superfluous, which is contrary to basic rules of statutory construction. Duncan v. Walker, 533 U.S. 167, 174 (2001). If Congress had intended that any local mandate requiring restaurants to provide nutrition information be approved by the FDA, there would have been no reason for it to have added the last clause to § 343-1(a)(4); Plaintiff's argument here, as elsewhere, would render this last clause entirely superfluous.

C. A § 343(q)-TYPE FACTUAL STATEMENT MADE IN RESPONSE TO A LOCAL MANDATE TO PROVIDE NUTRITION INFORMATION IS NOT A § 343(r) CLAIM.

Section 343(r) of the NLEA regulates claims made by purveyors of food on labels or labeling that either "characterizes the level of any nutrient" (known as nutrient content claims such as "low calorie") or "characterizes the relationship of any nutrient … to a disease or health-related condition" (known as health claims such as "heart healthy"). With limited exceptions, when making such nutrient content or health claims, the purveyors must use terms defined by the FDA.

---

interstate commerce subject to the Sherman Act. See Group Life & Health Ins. Co. v. Royal Drug Co., 440 U.S. 205, 217 (1979). Here, where there is no implied preemption under the NLEA and express language excepts local mandates from the preemptive reach of § 343-1(a)(4), such specificity is not warranted. Congress clearly intended to preserve the power of state and local governments to regulate restaurants in this area.

21 U.S.C. § 343(r)(2)(A)(i). This section of the NLEA does apply to restaurants and, consequently, states and local governments are preempted by 21 U.S.C. § 343-1(a)(5) from imposing any requirement respecting a claim being made by a restaurant that is not identical to the requirements of § 343(r). Whether claims are made by food companies or by restaurants, statements under § 343(r) are entirely voluntary.[5]

Recognizing that nutrient content claims under § 343(r) are preempted, plaintiff attempts to characterize the § 343(q)-type calorie information required by Health Code §81.50 as a nutrient content claim. Once again, plaintiff's argument is contrary to cardinal rules of statutory construction. As the Supreme Court said in Gustafson v. Alloyd Co., 513 U.S. 561, 569 (1995), Courts must interpret a statute "as a symmetrical and

[5] Contrary to plaintiff's current argument that there is no basis for the mandatory/voluntary distinction between § 343(r) claims and § 343(q) claims, in its prior lawsuit plaintiff repeatedly trumpeted the voluntary aspect of the prior version of Health Code §81.50. (SPA35,fn5). See also (JA608,609,612,613,616,617). The District Court rejected plaintiff's current argument, holding that "subsection (q) identifies specific information that must appear on food labels while subsection (r) simply does not apply unless a nutritional claim is first made by a food purveyor." (SPA35). The District Court went on to cite numerous examples of the FDA indicating the voluntary nature of § 343(r) claims. (SPA35) (citations omitted). See also Reyes v. McDonald's Corp., 2006 U.S. Dist. Lexis 81684, at * 14-15 (N.D. Ill. 2006) ("in the event a restaurant chooses to make nutrition claims, it subjects itself to the requirements of the NLEA and the penalties for violations").

coherent regulatory scheme." See also County of Nassau v. Leavitt, _ F.3d _, 2008 U.S. App. LEXIS 8922, at *18 (2d Cir 2008). Disregarding this basic rule of statutory construction, plaintiff nevertheless attempts to obviate the clear language of § 343(q) and its preemption provision by arguing for an expansive interpretation of an FDA regulation, 21 C.F.R. 101.13(b)(1), claiming that any and every statement of amount by a restaurant is a nutrient content claim. Plaintiff's argument would render superfluous the express exception pertaining to restaurants in § 343-1(a)(4) and was properly rejected by the District Court: "This reading of the statute … would frustrate the explicit preservation of state power to mandate nutritional disclosure by restaurants found in the statute's preemption provision. See 21 U.S.C. §§ 343-1(a)(4), (5)." (SPA 37).

Plaintiff's argument disregards the intent of Congress to give local governments the authority to decide what disclosure requirements should apply to restaurants See, e.g., 136 Cong. Rec. H5836 (July 30, 1990) (Rep. Waxman) ("[A]ny preemption provision must recognize the important contribution that the State can make in regulation, and it must leave a role for states."). As the District Court found: "NYSRA's position … ignores the mandatory/voluntary architecture of § 343(q) and (r) … as well as the obvious intent of Congress in drafting § 343-

1(a)(4), which explicitly preserves state authority to impose nutrition labeling requirements on restaurants." (SPA 38).

Moreover, plaintiff's argument directly conflicts with a primary goal of the NLEA, which was to increase the nutrition information provided to consumers. Its labeling mandates were intended to be comprehensive. They extend not only to canned and processed foods, but also to fresh fruits and vegetables. See 21 U.S.C. § 343(q)(4). There are only two areas of food not touched by § 343(q): meat and poultry products, because they are regulated by the U.S. Department of Agriculture (Public Law 101-535, §9, 104 Stat. 2353, 2365);[6] and (2) food served in restaurants, because it is regulated by states. The structure of the NLEA demonstrates that Congress intended to expand the provision of nutrition information for all food products. Plaintiff's argument that Congress in the NLEA created a regulatory void where neither the FDA nor local governments can mandate that restaurants provide nutrition information is directly contrary to all indications, as reflected by the statute and its legislative history, of Congress's goals. Yet, as the District Court found, the net effect of plaintiff's

[6] After enactment of the NLEA, the USDA adopted nutrition labeling requirements for meat and poultry. 9 C.F.R. § 317.300, et seq.

argument would be the creation of such "a regulatory vacuum." (SPA 38).

Plaintiff also argues that the flush provision of § 343(r)(1) supports its preemption argument. That provision states:

> 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 . . .

On its face, this provision simply states that information required to be on the nutrition label under § 343(q) is not subject to the requirements of § 343(r). It offers no guidance as to the circumstances under which nutrition information could be considered to be covered by § 343(r) and thus does not support plaintiff's argument. As the district court concluded, § 343(r) "provides that a statement as to nutrient amount is not a claim when it is a mandated disclosure." (SPA 37).

This provision also has no bearing on food sold in restaurants because such food is not subject to the requirements of § 343(q). Moreover, the entire language of the flush provision demonstrates that it was not intended to convert factual statements made in response to local government mandates into nutrient content claims subject to the provisions of § 343(r). The calorie postings mandated by Health Code §81.50 are

"statement[s] of the type required by" § 343(q) since calories are one of the facts that must be provided in a nutrition facts panel. The phrase "of the type" clearly refers to statements beyond those mandated only by § 343(q), as does the phrase "nutrition information required or permitted by such paragraph." The FDA is of the same view. See FDA, Guidance for Industry, "A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods" (April 2008), (available at http://www.cfsan.fda.gov/dms/labrguid.html), at Question 106 (§ 343-1(a)(4) "provide[s] that State requirements of the type required by [§ 343(q)] (nutrition labeling) … would not be preempted for foods that are exempt from the Federal requirements." (emphasis added)).[7]

Plaintiff's argument relies entirely on the FDA's definition of "claim" at 21 C.F.R. §101.13(b)(1). According to plaintiff, by defining "any direct statement about the level (or range) of a nutrient" as a claim, the FDA effectively over rode the language of § 343-1(a)(4). App. Br., p. 26-28. This argument, however, ignores the statutory limits on the FDA's authority to regulate claims. As explained above, Congress

[7] Moreover, Health Code §81.50 is also permitted by another phrase in the § 343(r) floating provision. Since § 343(q)(5)(A)(i) permits local governments to mandate that restaurants disclose nutrition information, such mandated disclosures are also statements "permitted by such paragraph."

plainly provided that states and local authorities would have the power to require that restaurants provide nutrition information.

It is also relevant that in section 3(b)(1)(A)(iv) of the NLEA, Congress specifically stated that in its health claims regulations, FDA "shall permit statements describing the amount and percentage of nutrients in food which are not misleading …" Pub. L. No. 101-535, 104 Stat. 2353, 2361 (emphasis added). By using the word "statements" rather than the word "claims" in this provision, Congress clearly was setting the parameters on the FDA's regulatory authority; FDA cannot in its regulations convert non-misleading factual statements into nutrient content claims that states and local governments would no longer be free to mandate.[8] See Desiano, 467 F.3d at 97, fn 9 ("whatever

[8] The defendants also contend as an alternative argument that an unadorned factual statement is not a § 343(r) claim. Indeed, the District Court noted that a "plain reading of the statutory language could support an interpretation that limits the reach of subsection (r) to qualitative statements such as 'high fiber,' 'low cholesterol,' or 'lite,'" and that "in the preamble to the regulations implementing § 343(r), the FDA noted that factual statements such as '100 calories' cannot be considered to characterize in any way the level of a nutrient in a food … in which case such a statement would be excluded from coverage by the very words of [§343(r)]." (SPA 37). Plaintiff incorrectly asserts that defendants are bound by the holding in NYSRA I, "that a quantitative statement about the amount of calories is a 'claim.'" App. Br., p. 24. Defendants filed a Notice of Appeal from the District Court's order in NYSRA I. Thereafter, the parties entered into a stipulation (with the assistance of the Court's Staff Counsel's office) that once

deference would be owed to an agency's view in contexts where a presumption against federal preemption does apply, an agency cannot supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against preemption").

Moreover, as the District Court correctly observed, one factor that separates claims from nutrition information is whether they are mandated. (SPA 35). Under § 343(q), food cannot be sold unless its label or labeling discloses certain nutrition information. Conversely, whether to make a claim under § 343(r) is optional. A food purveyor can choose whether it wishes to make a claim characterizing the level of a nutrient. If it does make one, however, it must comply with the requirements of § 343(r) and the FDA's implementing regulations. See 21 C.F.R. § 101.13(f).[9]

---

former Health Code §81.50 was repealed and the new Health Code §81.50 was enacted, the appeal was moot; this Court then so-ordered that stipulation (JA688-689). Thus, the defendants never had a full and fair opportunity to litigate the issue and should not be precluded from doing so now. See Gelb v. Royal Globe Insurance Company, 798 F.2d 38, 44 (2d Cir. 1986) ("inability to obtain appellate review, or the lack of such review once an appeal is taken … prevent[s] preclusion."). Ultimately, however, in light of our arguments in the body of this brief, the Court need not reach this issue.

[9] See, e.g., Food Labeling; Nutrient Content Claims and Health Claims, 61 Fed. Reg. 40320, 40323 ("FDA notes that these rules place no affirmative requirements on restaurants that do not make claims").

Finally, plaintiff's argument that the "voluntary/mandatory distinction would turn the concept of preemption upside down" and would permit "anomalous conflicts between state and federal law" is simply wrong. App. Br., p. 25, 34. The preemption provisions discussed above prevent a state or local government from mandating that restaurant include § 343(r) content claims (i.e. "low calorie"). In contrast, it is clear that under the NLEA local governments can mandate § 343(q)-type information such as the number of calories contained in a particular food item. Indeed, the District Court directly addressed this spurious argument:

> There is a world of difference … between the qualitative statement "low in fat" and the quantitative statement "100 calories." The latter is clearly an unadorned statement of fact that is contemplated by § 343(q) to be disclosed on a food label. And in the absence of federal regulation, it is precisely this type of disclosure that states may mandate. On the other hand, the statement "low in fat" characterizes the level of a nutrient and would be subject to regulation under § 343(r) when voluntarily made. Even if mandated, it would not escape the reach of § 343(r) for the added reason that only "statement of the type required by paragraph (q)" is exempt from regulation under subsection (r). 21 U.S.C. §

343(r). "Low in fat is not such a statement.

(SPA38) (emphasis added).[10]

For all the foregoing reasons, the District Court properly granted the City summary judgment on plaintiff's preemption claim.

POINT II

THE DISTRICT COURT PROPERLY DENIED PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTIVE RELIEF ON ITS FIRST AMENDMENT CLAIM. PLAINTIFF FAILED TO DEMONSTRATE A "CLEAR AND SUBSTANTIAL LIKELIHOOD OF SUCCESS" ON ITS CLAIM THAT HEALTH CODE §81.50 VIOLATES ITS FIRST AMENDMENT RIGHTS.

Contrary to plaintiff's argument (App. Br., pp. 35-49), in analyzing its First Amendment claim, the proper inquiry is whether section 81.50 is reasonably related to the City's interest in curbing obesity and the substantial health risks associated with it. See, Zauderer V. Office Of Disciplinary Counsel, 471 U.S. 626 (1985)

The intermediate standard set forth in Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York, 447 U.S. 557 (1980), advocated by plaintiff, is not applicable

[10] Similarly, plaintiff's argument that a local government could dictate that certain information be identified on packaged food is also misplaced in light of the § 343(q) preemption provisions. See 21 U.S.C. § 343-1(a)(4).

because that test is applied where the regulation restricts the expression of commercial speech. Moreover, the heightened standard of review set forth in United States v. United Foods, Inc., 533 U.S. 405 (2001) is not applicable because plaintiff is not being compelled to state a viewpoint with which it disagrees.

A. ZAUDERER V. OFFICE OF DISCIPLINARY COUNSEL, 471 U.S. 626 (1985), AND NAT'L ELEC. MFR. ASSOC. V. SORRELL, 272 F.3D 104 (2D CIR. 2001), CERT. DENIED, 536 U.S. 905 (2002), ARE CONTROLLING AND MANDATE THE APPLICATION OF THE "REASONABLENESS" STANDARD IN DETERMINING WHETHER HEALTH CODE §81.50 VIOLATES THE FIRST AMENDMENT.

The number of calories that a food contains is a fact that is either accurate or not. Health Code §81.50 thus merely requires the posting of factual information. This requirement is no different than numerous other disclosure requirements mandated by federal and state law, including the NLEA. Assuming arguendo, that Health Code §81.50 implicates First Amendment concerns, the District Court properly held that the "reasonableness" standard is the proper framework to apply in determining whether Health Code §81.50 violates the First Amendment (SPA40).

In Zauderer, the Supreme Court developed an analytical framework when a governmental regulation "compels" truthful disclosure of purely factual, non-opinion, non-political, non-ideological information to the consumer. At issue in Zauderer

was a state attorney disciplinary rule providing that an attorney who advertised his availability to bring Dalkon Shield personal injury cases on a contingency basis must make a fuller disclosure about litigation costs if the plaintiff did not prevail on her claim. 471 U.S. at 630. The advertisement stated that if the litigant lost the case, “no legal fees,” meaning attorney fees, would be owed. Id. at 631. But the advertisements were deemed deceptive because they omitted the fact that the “significant litigation costs” of bringing the lawsuit would be owed. Id. at 650.

In holding that the disciplinary rule did not violate the First Amendment, the Court specifically drew a distinction between regulations that compelled disclosure and those that restricted speech. The Court stated:

> Ohio has not attempted to prevent attorneys from conveying information to the public; it has only required them to provide somewhat more information than they might otherwise be inclined to present.

Id. at 650. The Court specifically rejected the argument that the disclosure requirement, in order to be constitutional, had to be "the least restrictive means" or "not more extensive than necessary" to serve the governmental interest, the standard of scrutiny set forth in Central Hudson Gas & Electric Corp. v.

Public Service Comm'n of New York, 447 U.S. 557 (1980). The Court in Zauderer held that commercial speech could be compelled so "long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." 471 U.S. at 651 (emphasis added). The Court explained that this relatively lenient standard was appropriate "[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides," and the speaker's "constitutionally protected interest in not providing any particular factual information in his advertising is minimal." Id. (emphasis in original).

Following Zauderer, this Court in Sorrell applied the reasonableness standard to uphold a regulation requiring warnings on products containing mercury. This Court held that "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 interest." 272 F.3d at 114. Further, this Court reasoned that "disclosure furthers, rather than hinders, the First Amendment goal of the discovery of truth and contributes to the efficiency of the 'marketplace of ideas.'" Id.

Thus, this Court concluded:

> In sum, mandating that commercial actors disclose commercial information ordinarily does not offend the important utilitarian and individual liberty interests that lie at the heart of the First Amendment. The Amendment is satisfied, therefore, by a rational connection between the purpose of a commercial disclosure requirement and the means employed to realize that purpose.

Id. at 114-115. Thus, under Zauderer and Sorrell, the reasonableness standard is the applicable test.

Plaintiff argues that "regulations promulgated under the NLEA itself have repeatedly been scrutinized under *Central Hudson*" and cites Whitaker v. Thompson, 353 F.3d 947, 952 (D.C. Cir. 2004), Pearson v. Shalala, 164 F.3d 650, 654-60 (D.C. Cir. 1999), and Nutritional Health Alliance v. Shalala, 144 F.3d 220, 225 (2d Cir. 1998) (App. Br., p. 46). Plaintiff's reliance on these cases is completely misplaced because they all involve restrictions on speech and not disclosure of factual information. At issue in Whitaker, was whether palmetto could be marketed under a label proposed by the vendor therein without the FDA's approval of palmetto as a drug. In Pearson, the FDA denied marketers of a dietary supplement permission to include certain material on their labels. In Nutritional Health Alliance, retailers challenged FDA regulations requiring advance

approval by the agency before health claims could be placed on vitamins labels.

Plaintiff's reliance on International Dairy Foods Association v. Amestoy, 92 F.3d 67 (2d Cir. 1996) (App. Br., pp. 40,42) is also misplaced. There, this Court applied Central Hudson and preliminarily enjoined a law requiring labeling disclosure of growth hormone in milk. In Sorrell, however, this Court explained that the use of the Central Hudson test in Amestoy was "expressly limited to cases in which a state disclosure requirement is supported by no interest other than the gratification of 'consumer curiosity'". 272 F.3d at 115 n.6. This is very different from the present case, where the disclosure of calorie information is supported by the City's interest in addressing the obesity epidemic.

In sum, since section 81.50 requires the posting of purely factual information, the reasonableness standard set forth in Zauderer and Sorrell is the applicable standard to apply in this case.

B. PLAINTIFF'S ATTEMPTS TO DISTINGUISH ZAUDERER AND SORRELL ARE UNAVAILING.

(1)

Wholly without merit is plaintiff's argument that the Supreme Court in United States v. United Foods, Inc., 533 U.S. 405 (2001), limited the Zauderer standard to regulations that

are designed to prevent deception (App. Br., p. 21). There is only one reference to Zauderer in United Foods (533 U.S. at 416). In that reference, the Court noted that in Zauderer, there was a concern regarding misleading consumers, whereas in United Foods, there was no such concern. Plaintiff's expansive reading of this one reference to Zauderer as limiting the application of Zauderer to regulations involving consumer deception is completely unwarranted. United Foods involved a requirement where mushroom growers had to pay for advertising by an agricultural association and the issue was "whether the government may underwrite and sponsor speech with a certain viewpoint using special subsidies exacted from a designated class of persons, some of whom object to the idea being advanced." 533 U.S. at 510. The issue presented in United Foods, involving compelled speech with which one disagrees, was completely different than that presented in Zauderer, which, like section 81.50, involved the required disclosure of factual information. Further, the Court in United Foods noted that the compelled assessments were not part of a broad regulatory scheme and served no government interest. Thus, plaintiff has taken the one reference to Zauderer in United Foods completely out of context.

The deferential standard of review set forth in Zauderer is to be applied whenever a regulation compels the disclosure of uncontroverted facts because, as the Court in Zauderer reasoned, an entity's "constitutionally protected interest in not providing any particular factual information in . . . advertising is minimal." 471 U.S. at 651 (emphasis in original). It is to be applied regardless of the government's purpose in mandating the disclosure of uncontroverted facts. See, 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 501 (1996) ("When a State . . . requires the disclosure of beneficial consumer information, the purpose of its regulation is consistent with the reasons for according constitutional protection to commercial speech and therefore justifies less than strict review.'"); see also, Glickman v. Wileman Brothers, 521 U.S. 457, 474 n. 18 (1997) ("The Court of Appeals fails to explain why the Central Hudson test, which involved a restriction on commercial speech, should govern a case involving the compelled funding of speech.").

After United Foods, this and other courts have applied Zauderer in compelled speech cases which did not involve misleading information. See Sorrell, 272 F.3d at 115 (compelled disclosure valid pursuant to Zauderer even though the issue was not the prevention of consumer confusion or deception per se,

but rather to better inform consumers about the products they were purchasing); see also, Pharmaceutical Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 310 fn 8 (1st Cir. 2005), cert. denied, 547 U.S. 1179 (2006) (Zauderer's applicability is not limited only to speech preventing deception) (both cases decided after United Foods).

In any event, in its Statement of Basis and Purpose in the Notice of Adoption for Health Code §81.50, the Board of Health specifically discussed the fact that consumers have distorted perceptions of calorie counts because of the misleading information gap about calories (JA554-555). Diners at chain restaurants underestimate the numbers of calories in the foods they order (JA748, ¶¶ 26-28). Further, calorie increases with larger portions are not obvious from the price differentials between portions. For example, going from a McDonald's $1.79 medium fries with 380 calories to a $1.99 large fries with 570 calories is an 11% price increase, but a 50% calorie increase (JA754, ¶35). Further, major chain restaurants use advertising to promote the appeal and wholesome image of their products, which can be misleading. For example, one advertisement pictures the chicken nugget happy meal as containing nuggets with low-fat milk and apple slices and states that parents "don't have to worry about quality and nutrition."

The advertisement indicates that the happy meal contains 420 calories (JA762-763). When a DOH staff member ordered the standard chicken nugget happy meal, however, no substitutions were offered and it consisted of 6 chicken nuggets, a small order of French fries, and a soda and totaled 610 calories (JA762-763).

Thus, even if Zauderer and Sorrell were limited to regulations addressing misleading information, they would nevertheless be controlling in this case.

(2)

Plaintiff argues that a heightened scrutiny test must be applied because Health Code §81.50 is compelling its members to convey a message. Specifically, plaintiff argues that its members believe that "there are better ways to communicate with their customers about health and nutrition". Also, plaintiff's members disagree that calories are the most significant factor in weight gain (App. Br., pp. 3-4). Further, plaintiff argues that there is "a hotly debated question whether government should ‘force’ its citizens to consider calories information" (App. Br., p. 41).

Plaintiff's argument is completely meritless because plaintiff's members do not disagree with the factual information

which they are required to post (i.e., the calorie content), but only with providing it. As the District Court reasoned (SPA41):

> Of course, it would be possible to recast any disclosure requirement as a compelled "message" in support of the policy views that motivated the enactment of that requirement. However, . . . , the mandatory disclosure of "factual and uncontroversial" information is not the same, for First Amendment purposes, as the compelled endorsement of a viewpoint.

Even the cases relied on by plaintiff support the distinction between requiring disclosure of factual information and compelling one to support another's point of view. In Johanns v. Livestock Marketing Ass'n, 544 U.S. 550, 557 (2005), the Court explained that it has recognized only two kinds of compelled-speech cases: true "compelled-speech cases," in which an individual must personally express an opinion with which he disagrees, and "compelled-subsidy cases." See, e.g., West Virginia State Bd. of Educ. v. Barnette, 319 U.S. 624 (1943) (requiring school children to recite the Pledge to Allegiance); Wooley v. Maynard, 430 U.S. 705, 706 (1977) (requiring cars to bear license plates with state's motto: "Live Free or Die"); Pacific Gas & Electric Co. v. Public Utilities Comm'n of California, 475 U.S. 1 (1986) (a requirement that a utility company include in its billing envelopes messages prepared by a

consumer organization). Plaintiff's claim does not fall under either of these types of cases.

In United Foods, 533 U.S. at 408, relied on by plaintiff, the Court invalidated a statute which established the Mushroom Council and authorized it "to impose mandatory assessments upon handlers of fresh mushrooms" for certain projects. The monies collected were to be spent on generic advertising to promote the sale of mushrooms. One mushroom handler successfully challenged the act on the grounds that he was paying an assessment to promote the point of view that all mushrooms were worth consuming. The handler who challenged the act wanted, instead, to convey the message that his mushrooms were superior to those grown by others. Id.

In United Foods, the mushroom growers objected to an idea being expressed. A more expansive reading of United Foods is not supported by the opinions. The Court in United Foods stated "[t]he question is whether the government may underwrite and sponsor speech with a certain viewpoint using special subsidies exacted from a designated class of persons, some of whom object to the idea being advanced." 533 U.S. at 410 (emphasis added). See also, id. at 417 (Stevens, J., concurring) ("it does not follow, however, that the First Amendment is not implicated when a person is forced to subsidize

speech to which he objects"). The Court in United Foods followed earlier precedents which "'recognized a First Amendment interest in not being compelled to contribute to an organization whose expressive activities conflict with one's freedom of belief.'" 533 U.S. at 447.

Reliance on the above line of cases involving compelled speech is completely misplaced. Here, the inclusion of factual information on the menu conveys no point of view. See, Environmental Defense Center, Inc. v. E.P.A., 344 F.3d 832, 850 (9th Cir. 2003), cert denied, 541 U.S. 1085 (2004) ("Informing the public about safe toxin disposal is non-ideological; it involves no 'compelled recitation of a message' and no 'affirmation of belief'") Entertainment Software Ass'n v. Blagovech, 469 F.3d 641, 651-52 (7th Cir. 2006) (distinguishing between "opinion-based" compelled speech and "purely factual disclosures," such as "whether a particular chemical is within any given product").

Plaintiff's argument that the posting of factual information could be understood by a consumer as an expression of an opinion is far-fetched. In any event, plaintiff's members are free to post additional information. See Meese v. Keene, 481 U.S. 465, 481 (1987) (in upholding an act which required labeling on movies made by foreign governments as

“political propaganda,” the Court noted that "Congress simply required the disseminators of such material to make additional disclosures that would better enable the public to evaluate the import of the propaganda. . . . Disseminators of propaganda may go beyond the disclosures required by statute and add any further information they think germane to the public's viewing of the materials"); see also, Tennessee Secondary Sch. Athletic Ass’n, __ U.S. __, 127 S. Ct. 2489, 2495 (2007) ("Given that TSSAA member schools remain free to send brochures, post billboards, and otherwise advertise their athletic programs, TSSAA's limited regulation of recruiting conduct poses no significant First Amendment concerns").

Thus, plaintiff's argument that strict scrutiny should be applied because section 81.50 forces it to express the City's point of view is completely meritless.

Further, contrary to plaintiff's argument, the application of strict scrutiny review in this case is not supported by Riley v. Nat’l Fed’n of the Blind, 487 U.S. 781, 796 (1988) (App. Br., p. 42). Plaintiff argues that there is no distinction between compelled statements of opinion and fact, and that “‘either form of compulsion’ burdens protected speech.'” In Riley, however, the Court applied strict scrutiny because it involved the regulation of charitable solicitation

and the regulation of such speech must "be undertaken with due regard" because it "is characteristically intertwined with informative and perhaps persuasive speech" Id. at 796.

(3)

In sum, plaintiff's First Amendment argument is completely contrary to settled law. As this Court noted in Sorrell:

> Innumerable federal and state regulatory programs require the disclosure of product and other commercial information. See, e.g., . . . 15 U.S.C.§ 1333 (tobacco labeling); 21 U.S.C. § 343(q)(1) (nutritional labeling); 33 U.S.C. § 1318 (reporting of pollutant concentrations in discharges to water); 42 U.S.C. §11023 (reporting of releases of toxic substances); 21 C.F.R. § 202.1 (disclosures in prescription drug advertisements); 29 C.F.R. § 1910.1200 (posting notification of workplace hazards); Cal. Health & Safety Code § 25249.6 ("Proposition 65"; warning of potential exposure to certain hazardous substances); N.Y. Envtl. Conserv. Law §33-0707 (disclosure of pesticide formulas).

272 F.3d at 116. See also BMW of North America, Inc. v. Gore, 517 U.S. 559, 571 fn 15 (1996) (“disclosure requirements are, of course, a familiar part of our law”); Rubin v. Coors Brewing Co., 514 U.S. 476, 492 (1995) (Stevens, J., concurring) (“In the

commercial context … government … often requires affirmative disclosures that the speaker might not make voluntarily.").

Further, it is well-established that Zauderer and Sorrell set forth the appropriate framework to be applied here, where section 81.50 requires only the disclosure of factual information. See, Pharmaceutical Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 310 fn 8 (1st Cir. 2005), cert. denied, 126 S. Ct. 2360 (2006) (Zauderer's applicability is not limited only to speech preventing deception); European Connection & Tours, Inc. v. Gonzales, 480 F. Supp. 2d 1355, 1371 (N.D. Ga. 2007) (government "disclosure requirements are properly analyzed under Zauderer and must be upheld if there is a reasonable relationship to a legitimate governmental interest"); BellSouth Adver. & Pub. Corp. v. Tenn. Regulatory Authority, 79 S.W.3d 506 (Tenn. 2002), cert. denied, 537 U.S. 1189 (2003) (Zauderer, not United States v. United Foods, Inc., 533 U.S. 405 (2001), supplies the proper standard in cases involving factual commercial disclosure requirements).

As this Court recognized in Sorrell, subjecting purely factual commercial disclosure requirements to heightened scrutiny would be contrary to the principles underlying the commercial speech doctrine, which is to foster the free flow of information, here information that is critical to promoting

public health. See Ibanez v. Florida Dep't of Business & Professional Regulation, 512 U.S. 136, 142 (1944) ("'disclosure of truthful, relevant information is likely to make a positive contribution to decision-making than is concealment of such information'").

In sum, if Health Code §81.50 implicates any First Amendment concerns, it should be analyzed under the reasonableness standard set forth in Zauderer and applied in Sorrell because it mandates disclosure of facts in a purely commercial context.

C. HEALTH CODE §81.50 IS RATIONALLY RELATED TO THE CITY'S LEGITIMATE INTEREST IN PROTECTING PUBLIC HEALTH.

As more fully discussed in Dr. Frieden's Declaration and the Notice of Adoption (JA730-1164; JA550-566), New York City is facing an obesity epidemic and the health consequences associated with obesity are significant. Heart disease, stroke, cancer and diabetes are four of the five leading causes of death in New York City in 2006 with 38,337 victims (69.2% of all deaths). These conditions are significantly more prevalent among persons who are obese (JA734, ¶ 8). More than 9 percent, or half a million New York adults have diagnosed diabetes, and another 200,000 have it but do not know it; this number has increased over the past decade. About 23.5%, or 1.3 million New Yorkers, have higher than normal fasting blood sugars that,

while not in the range of diabetes, put them at high risk for developing diabetes. Among New Yorkers who have diabetes, 80% are overweight or obese. Both diabetes and obesity have increased rapidly in New York City, as they have nationally (A737, ¶12).

Health Code §81.50's requirement that calories be posted at the point of sale is reasonably related to the City's substantial interest in curbing the obesity epidemic. First, an estimated one third of daily caloric intake for all Americans comes from foods purchased outside of the home (JA733, ¶ 4; JA551). Moreover, eating out is generally associated with increased calorie intake (JA743-A744; JA552-553; JA708,¶6). Although the NLEA, 21 U.S.C. § 343(q), has made nutrition information available to consumers on packaged foods purchased in retail stores, this requirement does not apply to restaurants.

Calories are recognized as the single most important element fueling the obesity epidemic (A740, ¶¶ 15-17; JA706-713). In a comment submitted after section 81.50 was published, even the National Restaurant Association acknowledged that (JA583):

> [t]he calorie content of . . .[a] 16-ounce beverage can vary from 160 to 260 calories. That 100 calorie difference means a great

> deal to someone who is watching his or her calorie intake. Small, specific changes in food and physical activity behaviors can have a positive effect on health. Research shows that affecting energy balance by 100 calories per day could prevent weight gain in most of the population.

Further, the FDA's Obesity Working Group ("OWG") concluded in its 2005 work with a report entitled "Calories Count" that "weight control is primarily a function of balance of the calories eaten and calories expended on physical and metabolic activity." (JA741,¶ 17; JA888-889).

Additionally, the final report of the FDA-commissioned Keystone Forum on Away-From-Home Foods recommends that food service establishments "provide consumers with calorie information in a standard format that is easily accessible and easy to use" (JA749, ¶ 29; JA1004). Health Code §81.50, which requires prominently posting calorie information near menu items, is consistent with this recommendation.

Plaintiff cites portions of the Keystone Report which discuss the different views on the posting of calories and how consumers will use such information (App. Br., pp. 3-7). The Keystone Forum, however, did recognize that although there may be "cons" to posting on menus and menu boards, as there were to all the other posting options, there were many "pros" to this

approach, including: (1) "Easy to find and linked to an essential information method in the business;" (2) provides information at point of purchase and decision-making; (3) "Can use and compare options at point of purchase;" (4) allows consumers to compare price and nutrition information in one place (JA1121).[11] See also President's Cancer Panel. Promoting Healthy Lifestyles. Policy, Program and Personal and Recommendations for Reducing Cancer Risk. 2006-2007 Annual Report. U.S. Department of Health, National Institutes of Health, National Cancer Institute. Bethesda, Maryland, 2007 (Panel recommendation: "Make nutrition information on restaurant foods readily available on menus and understandable to

[11] In her January 29, 2008 declaration, Debra Demuth, the Global director of Nutrition of McDonald's Corporation quoted the actual recommendation of the Keystone Report as follows (JA-177, ¶12):

> Recommendation 4.1: Away from home food-establishments should provide consumers with calorie information in a standard format that is accessible and easy to use. This recommendation emphasizes accessibility and ease of use – calorie content next to price on menu boards may not be the solution.

Although the Forum discussed "pros" and "cons" with respect to different posting options (JA1121-1125), the language of the last sentence of Demuth's recitation of the Recommendation 4.1 that "menu boards may not be the solution" is not part of Recommendation 4.1 (JA1068).

consumers.”) (JA750, ¶30); See also, Questions and Answers, The Food and Drug Administration's (FDA) Obesity Working Group Report (Recommendation that the "FDA urge the restaurant industry to launch a nation-wide, voluntary and point of sale nutrition information campaign for customers") (JA549).

Plaintiff argues that there is no empirical data or studies that posting calorie counts on menu boards will affect consumer choice and that more research has to be conducted (App. Br. pp. 7, 10). With the posting of calories, however, consumers can compare calorie levels of different menu items and make more informed decisions (JA753, ¶34; JA710, ¶10). This is particularly true because consumers are generally familiar with calories from nutrition labels on foods they purchase for consumption at home. Three-quarters of American adults report using food labels, and about half (48%) report that nutrition information on food labels has caused them to change their food purchasing habits. The calorie section is the most frequently consulted part of the Nutrition Facts panel on packaged foods, with 73% of consumers reporting that they look at it (JA 751, ¶ 31).

A study found that when calorie information is readily available, high-calorie menu items are chosen 24% to 37% less often (JA752, ¶32). National polls indicate that 62% to 87% of

respondents would like calories to be listed on menus or menu boards in chain restaurants (JA752, ¶32).

As discussed in Dr. Frieden's Declaration, not only do consumers underestimate the calorie count of less-healthy items, even experienced nutrition professionals have difficulty accurately estimating calorie count of restaurant food. These professionals generally underestimated calories in restaurant food by 200 to 600 calories. A study indicated that the more calories there are in a meal, the more people underestimate the amount they believe they eat (JA748, ¶¶ 26-28).

Having calorie information readily available to consumers at the time that they are making their dining choices is the most effective way to get this information to consumers eating outside their homes. Currently, restaurants covered under Health Code §81.50 do not effectively transmit calorie information. Current voluntary attempts by some restaurants fail because the information is usually not displayed where consumers are making their choices and purchases, such as when a restaurant's nutrition information is available on the internet. While such information may also be available in brochures, on placemats covered with food items, or on food wrappers, the information is hard to find or difficult to read and only

accessible after the purchase is made. Thus, the information as provided has little impact on choice (JA756-759, ¶¶ 40-46).

In May and June 2007, DOH surveyed 11,865 diners in a random sample of 274 of the restaurants covered by the previous 2006 HC 81.50. With the exception of Subway, less than 8% of customers reported seeing calorie information in the restaurant where they had purchased food. The percentage was particularly low (< 5%) among those restaurants (McDonald's, Dunkin' Donuts, Burger King, and Yum Brands locations) that submitted declarations in support of plaintiff's motion, and whose declarations claim that they provide extensive nutrition information to customers (A757-758). Burger King and McDonald's have put nutrition information on websites. All website hits for McDonald's would represent a rate of one nutrition information hit per 25,000 meals served (JA755-756, ¶¶ 37-38).

Plaintiff also submitted a declaration by David B. Allison who asserted that DOH's survey was flawed (App. Br., pp. 8-9) (JA26-159). Dr. Allison's specific assertions are countered in Dr. Frieden's Declaration (JA773-775, ¶¶ 65-68), as well as in the declarations submitted by outside experts (JA692-700; JA719-729). Plaintiff suggests that the DOH survey should not be credited because it was not accepted for publication in a bulletin of the Centers for Disease Control and Prevention

("CDC") (App. Br., pp. 8-9). The concerns raised by the CDC editor as the basis for the decision, however, were first raised by the DOH and discussed in the study (JA1140; JA1360-1361). The fact that a CDC editor agreed with the factors identified by DOH simply validates the fact that DOH was candid about the conclusions in the study.[12]

Moreover, the limitations noted do not in any way alter the conclusions that 1) few chain restaurant patrons saw calorie information, even after they made their purchase, 2) at the one chain which posted calorie information somewhat prominently, a far higher proportion of customers saw calorie information, and 3) a large proportion of chain restaurant customers consumed a large and unhealthy number of calories. Further, the basis for enacting Health Code §81.50 was not based solely on the results of this one study. Rather, as discussed above, there is a wealth of other studies and expert opinion that argues conclusively that if calorie information is posted in restaurants, there is a reasonable expectation that some consumers will use this information to make healthier choices.

[12] The CDC editor also noted that its publication may not be the best format for presenting the study because "[t]here is just not enough space in 1400 words to discuss the possible problems with interpretation"(JA160-1361).

Plaintiff's argument that Health Code §81.50 will have no impact on curbing obesity because it applies to only 10% of the City's restaurants (App. Br., p. 3) is meritless. First, this percentage is not insignificant; when market share is taken into consideration, these restaurants constitute approximately 34.7% of restaurant visits in the NYC metropolitan area. Even using plaintiff's 10% figure in New York City, more than 145 million, and possibly more than 500 million, meals would be affected by this regulation each year (JA757-764). Moreover, the Court in Zauderer rejected this type of "under inclusive" argument and stated: "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." 471 U.S. at 651, fn 14. See also, Mainstream Marketing Services, Inc. v. FTC, 358 F.3d 1228, 1238 (10th Cir.), cert. denied, 543 U.S. 812 (2004) (even under the intermediate standard of Central Hudson, "the First Amendment does not require that government regulate all aspects of a problem before it can make progress on any front").

Finally, the issue is not whether there is uncontroverted evidence supporting the adoption of section 81.50, but whether Health Code §81.50 is rationally related to the City's legitimate and substantial interest in reducing

inaccurate perceptions of consumers and curbing obesity and the health consequences associated with it. Even plaintiff's expert, Dr. Allison, accepted the following propositions: (1) obesity largely results from an imbalance between calories eaten and energy expended, (2) many of the foods served in restaurant are quite high in calories, and (3) consumers underestimate the calories of food served in restaurants (JA35-36). Moreover, Dr. Allison opined that it was "reasonable to conjecture that providing calorie information at the point of purchase might be beneficial in reducing obesity levels" (JA39). Although Dr. Allison also believes that it is equally reasonable to conjecture that posting calories will not have an effect on obesity levels, the fact remains that even plaintiff's "expert" admits that DOH's approach is "reasonable".

In sum, Health Code §81.50 is supported by the wealth of studies set forth in Dr. Frieden's Declaration, the Notice of Adoption, and the Declarations submitted in opposition to plaintiff’s motion. Even if that were not the case, there is no requirement that Health Code §81.50 be supported by empirical data with undisputed scientific proof. In Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 555 (2001), the Court, in applying the third Central Hudson factor, stated:

> We do not, however, require that “empirical data come . . .

> accompanied by a surfeit of background information . . . We have permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and 'simple common sense.'"

Certainly, if such proof is not necessary under Central Hudson, it is not required under the more lenient standard set forth in Zauderer, which is applicable here.

For all the above reasons, there is a rational relationship between Health Code §81.50 and the City's legitimate interest in reducing inaccurate perceptions of consumers and curbing obesity and the health consequences associated with it. Thus, Health Code §81.50 does not violate the First Amendment. See Zauderer & Sorrell.

D. SECTION 81.50 IS CONSTITUTIONAL UNDER CENTRAL HUDSON.

Finally, even applying the intermediate test of Central Hudson, Health Code §81.50 easily survives constitutional scrutiny.[13] Under Central Hudson, the inquiry is

> At the outset, we must determine whether the expression is protected by the First Amendment.

[13] Contrary to plaintiff's argument that the City conceded that section 81.50 could not meet the Central Hudson test (App. Br., p. 19), the City argued before the District Court that section 81.50 was constitutional under Central Hudson.

> For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we must determine whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.

447 U.S. at 566. Plaintiff does not dispute the first two prongs, including the fact that the asserted governmental interest here is substantial.

Plaintiff, relying on Dr. Allison's opinion, argues that section 81.50 does not advance the City's asserted interest in a "direct and material way" (App. Br., p. 37). As stated earlier, in demonstrating the third prong of Central Hudson, whether the regulation directly advances the governmental interest asserted, defendants can rely on "studies," "consensus" and "simple common sense." Clearly, the City has met that burden: increased knowledge about calories is necessary for consumers to choose foods with fewer calories; consumption of fewer calories leads to reduced obesity and reduced diabetes, and customers use calorie information when it is posted. As discussed above, section 81.50 is supported by a wealth of studies. Thus, this case is distinguishable from Edenfield v.

Fane, 507 U.S. 761 (1993), where the Court invalidated a ban on solicitations by Certified Public Accountants because the state board did not submit any studies or anecdotal evidence supporting its interest in imposing the ban.

With respect to the fourth prong, whether the restriction is not more extensive than necessary to serve the government's interests, the Supreme Court has rejected the "least restrictive" approach to the regulation of commercial speech. Rather, the City must demonstrate "a reasonable fit" between the City's interests and the means chosen to accomplish those goals. This means "a fit that is not necessarily perfect, but is reasonable; that represents not necessarily the single best disposition but one whose scope is 'in proportion to the interest served' . . ." Bd. of Trustees v. Fox, 492 U.S. 469, 480 (1969).

Plaintiff argues that its member restaurants already post calorie information on websites, brochures, tray-liners, food packaging, website and a toll-free hotline and that they should be permitted flexibility in how to post the calorie information (A170, ¶7); A320, ¶7; A321-323). As plaintiff acknowledged, however, the menu boards are "their most important tool" for communicating with their customers. (App. Br., p.38). Clearly, posting the calories at the point of purchase would be

the most effective way of getting this information to the consumer, especially, as discussed above, in light of how other methods of communicating fail to reach 95% of customers, even after purchase (JA757, ¶42).

For all the foregoing reasons, the District Court properly denied plaintiff's preliminary injunctive relief on its First Amendment claim since it failed to demonstrate a "clear and substantial" likelihood of success on merits.

CONCLUSION

THE MEMORANDUM OPINION AND ORDER APPEALED FROM SHOULD BE AFFIRMED, WITH COSTS.

Respectfully submitted,

MICHAEL A. CARDOZO
Corporation Counsel of the
City of New York
Attorney for Defendants-Appellees.

By: _____
Fay Ng
Assistant Corporation Counsel

PAMELA SEIDER DOLGOW,
MARK MUSCHENHEIM,
FAY NG,

THOMAS MERRILL,
GENERAL COUNSEL,
N.Y.C. DEPT. OF HEALTH
AND MENTAL HYGIENE

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 11,455 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

Dated: New York, New York
May 15, 2008

MICHAEL A. CARDOZO
Corporation Counsel of the
City of New York
Attorney for Defendants-Appellees.

By: _____
FAY NG
Assistant Corporation Counsel

ANTI-VIRUS CERTIFICATION

I, FAY NG, hereby certify that I scanned this brief with VirusScan Enterprise Version 8.5i anti-virus software and no virus was detected.

Dated: New York, New York
May 15, 2008

FAY NG
Assistant Corporation Counsel