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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

CALIFORNIA RESTAURANT ASSOCIATION, *Plaintiff*, v. THE CITY AND COUNTY OF SAN FRANCISCO and THE SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH, *Defendants*.	Case No. Civ-08-3247 CW Date: Sept. 4, 2008 Time: 2:00 p.m. Place: Courtroom 2, 4th Floor

BRIEF OF *AMICI CURIAE* CONGRESSMAN HENRY WAXMAN, FORMER FDA COMMISSIONER DAVID KESSLER, M.D., PUBLIC CITIZEN, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, AMERICAN COLLEGE OF PREVENTIVE MEDICINE, AMERICAN DIABETES ASSOCIATION, CALIFORNIA CENTER FOR PUBLIC HEALTH ADVOCACY, TRUST FOR AMERICA'S HEALTH, AND PROFESSORS OF MEDICINE, NUTRITION, AND PUBLIC HEALTH IN SUPPORT OF DEFENDANTS

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INTEREST AND IDENTITY OF *AMICI CURIAE*

In requiring fast-food restaurants to disclose calorie information on their menus, the City of San Francisco has stepped into a regulatory gap that Congress intentionally left open to state and local governments when it enacted the Nutrition Labeling and Education Act (NLEA) in 1990. The following *amici curiae* support both San Francisco's decision and its right to make that decision. A more detailed listing of *amici* is set forth in an appendix to this brief.

- U.S. Congressman Henry Waxman, the lead congressional sponsor of the NLEA and currently the Chairman of the committee in the House of Representatives with oversight over FDA;
- David Kessler, M.D., Commissioner of the FDA from 1990 through 1997, the period in which all of the key FDA regulations implementing the NLEA were promulgated;
- Public Citizen, an advocacy organization with longstanding interests in curtailing exaggerated claims of federal preemption of health regulation and defending consumers' right to know information that affects their health;
- Center for Science in the Public Interest, a nutrition advocacy organization and a leading advocate of both the NLEA and state and local menu labeling legislation;
- Leading medical and public health organizations, including the American College of Preventive Medicine, American Diabetes Association, the American Public Health Association, the California Center for Public Health Advocacy, and Trust for American's Health; and
- Distinguished professors and researchers in the fields of medicine, nutrition, and public health, whose names and biographical information are compiled in the appendix.

INTRODUCTION

Two years ago, an important FDA-commissioned report declared that "obesity has become a public health crisis of epidemic proportions." *The Keystone Forum on Away-from-Home Foods: Opportunities for Preventing Weight Gain and Obesity* (2006), at 1.[1] Echoing the consensus view of the U.S. Surgeon General, the National Academies' Institute of Medicine, and the American Medical Association, among others, the report concluded that "restaurants should provide consumers with calorie information in a standard format that is easily accessible and easy to use," allowing consumers to view the information "when standing at a counter, while reviewing a menu board, in a car when reading a drive-through menu, or when sitting down at a table reviewing a menu." *Id.* at 76, 77-78. The report recognized that "the FDA *does not have regulatory authority* to require nutrition information in restaurants," but that "state legislatures *do have the authority* to require the provision of nutrition information, and a number of these elected bodies have considered nutrition labeling bills [that] would require calories and/or other nutrition information to be listed on menus or menu boards." *Id.* at 74 (emphasis added).

In this lawsuit, the fast-food industry repeats arguments that were recently rejected in its challenge to an indistinguishable New York City ordinance. *See N.Y. State Rest. Ass'n v. New York City Bd. of Health*, 2008 WL 1752455 (S.D.N.Y. April 16, 2008), *pending on appeal*, Case No. 08-1892-cv (2d Cir.). Here, as it did there, the industry asks the Court to hold that federal law preempts states and local authorities from doing what the federal government

[1] *Available at* http://www.cfsan.fda.gov/~dms/nutrcal.html ("*Keystone Report*"); *see also FDA Backgrounder,* http://www.cfsan.fda.gov/~lrd/bgowg2.html.

itself lacks authority to do—to hold, in other words, that Congress created a permanent regulatory vacuum on the important issue of mandatory nutrition labeling of restaurant food. Congress did no such thing. To the contrary, Congress focused closely on the issues of preemption and coverage for restaurants during its consideration of the NLEA and enacted carefully limited express preemption provisions that carved out room for state and local government to fill the gaps left by the statute. 21 U.S.C. § 343-1(a)(4); *id.* § 343(q)(5)(A)(i). As the legislation's chief sponsor in the Senate explained just moments before the final vote: "Because food sold in restaurants is exempt from the nutrition labeling requirements of [the NLEA], the bill does not preempt any State nutrition labeling requirements for restaurants." 136 Cong. Rec. S16607-02, S16608 (Oct. 24, 1990) (Sen. Metzenbaum).

Over the nearly two decades since the NLEA's enactment, the FDA has consistently taken the same position—most recently in response to the Second Circuit's request for an *amicus* brief concerning New York's menu labeling ordinance, which is indistinguishable from San Francisco's. *See FDA Amicus Brief* (June 16, 2008) (Declaration of Tara Steeley, Exhibit 2); *accord* FDA, *A Guide for Restaurants and Other Retail Establishments* (August 1995), *available at* http://www.cfsan.fda.gov/~frf/qatext2.html ("[B]ecause the act exempts restaurant foods that do not bear a claim from mandatory nutrition labeling, State requirements for the nutrition labeling of such foods would not be preempted."). Indeed, the restaurant industry lobbied the FDA to oppose New York's menu labeling ordinance as early as April 2007. The FDA, however, concluded that opposition was unwarranted, citing the agency's "limited authority" concerning restaurants, "the increases in the percentage of

food consumed in away-from home foods, and the general lack of easily accessible nutrition information for these foods." Letter from R.E. Brackett to D. Garren, dated July 8, 2007.[2]

The Restaurant Association nonetheless contends that San Francisco's rule is preempted because it is a requirement respecting "claims" of the type regulated in section 343(r) of the NLEA. That contention rests on a fundamental misunderstanding of the NLEA's structure, which is premised on a distinction between requirements that food manufacturers disclose straightforward nutritional information (such as a listing of a total number of calories), on the one hand, and the regulation of descriptive "claims" that industry may choose to make about its food's nutritional content or health effects, on the other. San Francisco's rule is unmistakably the former sort of rule: It concerns the mandatory disclosure of purely factual information, not the regulation of descriptive "terms" that restaurants may choose to make "claims" that "characterize" the nutrients in their food.

The Association also maintains that San Francisco's rule violates the First Amendment. That argument is incompatible with settled law, would turn the commercial speech doctrine upside down, and would jeopardize mandatory disclosure requirements that are ubiquitous in the law—including the very disclosure requirements imposed by section 343(q) of the NLEA. *See Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 113-16 (2d Cir. 2001); *see also Envt'l Def. Ctr. v. E.P.A.*, 344 F.3d 832, 848-51 (9th Cir. 2003).

[2] The restaurant industry never informed the New York district court of this correspondence, which was received while the industry's challenge to the New York rule was still pending before the court. The correspondence was obtained by *amicus* Center for Science in the Public Interest through a Freedom-of-Information-Act request.

BACKGROUND

The NLEA produced groundbreaking changes in the way food is labeled in the United States. It required that basic nutrition facts be disclosed for most foods, prohibited the use of terms that characterize the level of nutrients in a food unless they conform to definitions established by FDA, and required that claims about the relationship between nutrients and health conditions be supported by significant scientific agreement. The Act was introduced in the U.S. House of Representatives by Representative Henry Waxman on July 27, 1989, and signed into law by President George H.W. Bush on November 8, 1990. Although Congress extensively debated a number of issues, including preemption of state law and coverage for restaurants, the basic structure of the legislation—premised on a distinction between the regulation of mandatory nutrition labeling and the regulation of voluntary claims—remained unchanged over the course of the fifteen months during which it was considered.

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

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

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

1. Section 343(q): Mandatory Nutrition Labeling. The nutrition information labeling provisions of section 343(q) are the heart of the Act. Most American consumers are familiar with the "Nutrition Facts" panel, a uniform chart that most food manufacturers must use to list "the total number of calories" in each serving of food, § 343(q)(1)(C), as well as the amounts of total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein in the food, both as an "amount per serving" and, with the

exception of sugars and protein, as a percent of a dietary reference value, called the "percent daily value." § 343(q)(1)(D); *see* 21 C.F.R. § 101.9. As discussed below, restaurant food is not covered by these federal requirements. 21 U.S.C. § 343(q)(5)(A)(i).

2. Section 343(r): Voluntary Nutrient-Content and Health Claims. In addition to requiring the disclosure of nutrition information, Congress also responded to the proliferation of dubious, misleading, and confusing claims made by food manufacturers about the nutrition and health effects of their foods. *House Report* at 3337.[3] That issue is taken up in the second part of the statute, section 343(r), which distinguishes between two kinds of claims: nutrient content claims (*e.g.* "low salt") and health-related claims (*e.g.* "fiber reduces the risk of cancer"). §§ 343(r)(1)(A), 343(r)(1)(B).

Prior to the NLEA's enactment, the FDA had general authority to prohibit false or misleading food advertising or labeling. § 343(a). That authority was sufficient to address a manufacturer's claims about straightforward factual information, such as information concerning the ingredients or nutrients in a food that was either verifiably true or false. But "an increasing number of food companies had turned to marketing . . . products bearing adjectival descriptors such as 'lite,' 'low,' 'reduced,' or 'fat free' because of their perception that such descriptors would lure consumers who thought such terms meant the products were more healthful." Sims, *The Politics of Fat: Food and Nutrition Policy in America* 202 (1998). In the absence of specific federal standards, these claims were often meaningless or

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

misleading. *Id.* The word "light" might mean light in fat, or light in color, or something else entirely. Congress aimed to address this problem by ensuring that such "content claims (such as 'low salt' or 'light') would have to be consistent with terms defined by the [FDA]." *House Report* at 3337.

Section 343(r) prohibits any "claim" on a food label that expressly or by implication "characterizes" the nutrient level of a food unless "the characterization of the level made in the claim uses terms which are defined in regulations of the [FDA]." § 343(r)(1)(A); § 343(r)(2)(A)(i). "An example of an express claim covered by [§ 343(r)] would be the statement 'low sodium.' An example of an implied claim covered by this section would be the statement 'lite,' which implies that the product is low in some nutrient (typically calories or fat), but does not say so expressly, or 'high oat bran,' which conveys an implied high fiber message." *House Report* at 3349 (section-by-section analysis). The FDA's regulations define nutrient content claims for a range of specific descriptive terms including *free*, *low*, *high*, *good source*, *contains*, *provides*, *reduced*, *less*, *light* or *lite*, *modified*, and *more*. 21 C.F.R. §§ 101.13, 101.54, 101.56.[4]

With respect to health claims, section 343(r) uses the word "claim" in much the same way, to refer to statements manufacturers choose to make that "characterize" the

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

relationship between the nutrients in their foods and diseases or health effects. § 343(r)(1)(B). Health claims, however, are regulated somewhat differently. Instead of providing a list of specific descriptive terms that manufacturers may use, FDA authorizes a health claim only when it determines that there is "significant scientific agreement" that scientific evidence supports the health claim. 21 C.F.R. § 101.14(c).

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

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

As a result, the coverage of restaurants turns on the Act's mandatory-voluntary distinction: As far as federal law is concerned, restaurants are *not* required to provide the kind of nutritional information disclosures—such as listings of the calories or fat in all food items—that is required of packaged foods.[5] But restaurants are not exempted from the Act's

[5] In 2004, the FDA's Obesity Working Group explained the implications of the regulatory gap left open by section 343(q)'s exemption for restaurant food: "[U]nder the laws administered by FDA, restaurants are not required to provide nutrition information unless a nutrient content or health claim is made for a food or meal. When claims are made, however, the restaurant need only provide information about the amount of the nutrient that is the subject of the claim. Restaurants may, and many do, provide nutrition information on a voluntary basis. Nevertheless, this nutrition information is often in the form of posters, placemats or menu icons, or on the Internet, rather than (continued on next page)

regulation of "claims." So the only circumstance in which the NLEA affects restaurants is when they choose to make "claims," within the meaning of section 343(r), that "characterize" the nutrients or health effects in the foods they serve using certain descriptive terms—for example, when a restaurant's menu describes an item as "low fat" or "heart healthy." 21 C.F.R. § 101.10; *see* FDA Talk Paper T96-52 (July 30, 1996), *available at* http://www.cfsan.fda.gov/~lrd/tpmenus.html ("This final rule affects only those restauranteurs who place claims such as 'low fat' or 'heart healthy' on their menus.").[6] A restaurant that decides to make such a descriptive claim about its food's nutritional content is obligated only to disclose "the nutrient amounts that are the basis for the claim." 21 C.F.R. § 101.10. Such mandatory quantitative disclosures are considered the "functional equivalent" of the type of nutritional labeling required of packaged foods by section 343(q). *Id.*

(footnote continued from previous page)
at the point-of-sale. Such information is not always readily available or observable at the point-of-sale." FDA, *Calories Count: Report of the Working Group on Obesity* (2004), at Part V.B., *available at* http://www.cfsan.fda.gov/~dms/owg-toc.html ("*FDA Calories Count Report*").

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

C. The NLEA's Preemption Provisions

The Act's mandatory-voluntary distinction is carried over into its preemption provisions as well. As with restaurant coverage, Congress devoted careful attention to preemption during its consideration of the NLEA. *See* Sims, *Politics of Fat*, at 199 ("The preemption issue remained a key area of dispute throughout consideration of the food labeling bill, with the basic issue being how far the legislation should go in setting uniform food labeling regulations that preempt state laws.").[7] In the final moments of the floor debate before the NLEA was formally adopted by the House after its passage in both chambers, Representative Waxman explained that carefully limited federal preemption had been added to the bill to induce industry to support the legislation. 136 Cong. Rec. H12951-02, H12954 (Oct. 26, 1990) ("[I]t was decided that the fairest way to expect the food industry to support a nutrition labeling bill, was to give them *some types of preemption* of *some* burdensome State laws that interfered with their ability to do business in all 50 States.") (emphasis added). Even Senator Orrin Hatch, who was the leading proponent of stronger federal preemption, conceded that "the carefully crafted uniformity section of this legislation is limited in scope." 136 Cong. Rec. S16607-02, S16611 (Oct. 24, 1990).

In an effort to satisfy industry concerns while remaining "sensitive to the regulatory roles played by the States," the Senate reached a compromise that was "refined to provide national uniformity where it is most necessary, while otherwise preserving State regulatory

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

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

> The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A [21 U.S.C. § 343-1(a)] of the Federal Food, Drug, and Cosmetic Act.

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

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

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

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

ARGUMENT

I. The Restaurant Association bears an especially heavy burden to demonstrate "clear and manifest" congressional intent to preempt state and local nutrition disclosure requirements for restaurants.

In its briefing, the California Restaurant Association (CRA) attacks what it describes as three competing "theories" for why menu-labeling ordinances are not preempted by the NLEA, and suggests that the City bears the burden of proving one or more of those "theories." That is exactly backwards. In fact, the burden is on CRA, and it is an especially heavy one: "Preemption analysis starts with the presumption that the traditional police powers of states are not displaced by federal law unless displacement was the 'clear and manifest purpose of Congress.'" *Chem. Specialties Mfrs. Ass'n, Inc. v. Allenby*, 958 F.2d 941, 943 (9th Cir. 1992) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). The Ninth Circuit has explained that there are two "practical reasons" for that presumption—first, "Congress has the power to make preemption clear in the first instance," and second, "if the court erroneously finds preemption, the State can do nothing about it, while if the court errs in the other direction, Congress can correct the problem." *Id.*

The presumption against preemption is also rooted in an imperative of federalism implicit in the constitutional plan and embodied, among other places, in the Tenth Amendment. An insistence on "clear and manifest" Congressional intent "provides assurance that the 'federal-state balance' will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (quoting

United States v. Bass, 404 U.S. 336, 349 (1971)); *see generally* Grey, *Make Congress Speak Clearly*, 77 B.U. L. Rev. 559 (1997); Hoke, *Preemption Pathologies and Civic Republican Values*, 71 B.U. L. Rev. 685 (1991).[8]

San Francisco's regulation "falls squarely within its prerogative to regulate matters of health and safety, which is a sphere in which the presumption against preemption applies, indeed, stands at its strongest." *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94 (2d Cir. 2007), *aff'd by an equally divided Court*, 128 S.Ct. 1168 (2008) (discussing preemption in context of food and drug law); *see Medtronic v. Lohr*, 518 U.S. 470, 485 (1996). Federal courts presume "that state and local regulation of health and safety matters can constitutionally coexist with federal regulation" because "the regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985). "[T]here is indeed no subject of legislation more firmly identified with local affairs than the regulation of restaurants." *District of Columbia v. John R. Thompson Co.*, 346 U.S. 100, 113 (1953).

[8]CRA urges this Court to strike down San Francisco's rule because it regards it as a novel social science experiment aimed at solving a problem (the obesity epidemic) for which nobody has found a magic bullet. But, as Justice Brandeis famously observed, one of the chief virtues of our system of federalism is that "a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932). It is precisely when "disagreement exists about how best to accomplish [a] goal" that "the theory and utility of our federalism are revealed, for the States may perform their role as laboratories for experimentation to devise various solutions where the best solution is far from clear." *United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring); *see generally* Hills, *Against Preemption: How Federalism Can Improve the National Legislative Process*, 82 N.Y.U. L. Rev. 1 (2007). The solution San Francisco is pursuing here, moreover, is one that is supported by an growing scientific and public policy consensus. *See generally* Wootan Decl.

Any analysis of the scope of federal preemption must be guided by the principle that "the purpose of Congress is the ultimate touchstone in every preemption case." *Lohr*, 518 U.S. at 485 (internal quotation marks omitted). That purpose, of course, is discerned primarily "from the language of the pre-emption statute and the statutory framework surrounding it." *Id.* at 486 (internal quotation marks omitted). In addition, the Court must examine the "structure and purpose of the statute as a whole, as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Id.* (internal citations and quotation marks omitted).

Here, the analysis must begin and end with the carefully limited language of the NLEA's express preemption clause because Congress made clear that "the Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted" by that language. Pub. L. No. 101-535, § 6(c), 104 Stat. 2535, 2364 (21 U.S.C. § 343-1 note); *see AT&T Communications of Ill., Inc. v. Ill. Bell Tel. Co.*, 349 F.3d 402, 410 (7th Cir. 2003). Thus, the Court's only task is to determine whether San Francisco City's rule falls within "'the domain expressly pre-empted' by that language." *Lohr*, 518 U.S. at 484 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)). To the extent that there is any ambiguity—and, as explained below, there is none—this Court has a "duty" to adopt a plausible reading of the statute that preserves local autonomy. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) ("[I]ndeed, even if its alternative were just as plausible as our reading of that text . . . we would nevertheless have a duty to accept the reading that disfavors pre-emption.").

II. The NLEA leaves San Francisco free to enact mandatory nutrition information disclosure requirements for restaurant food.

Section 343(q) of the NLEA requires that food purveyors disclose specific nutrition information about most food products sold in the United States, including "nutrition information that provides . . . the total number of calories . . . derived from any source . . . in each serving size or other unit of measure of the food." § 343(q)(1)(C)(i). Under NLEA's preemption provision, states and local governments are *not* free, as a general matter, to adopt "any requirement for nutrition labeling of food" that is not "identical" to what federal law requires. § 343-1(a)(4). Thus, San Francisco could not adopt a rule requiring the disclosure of the amount of calories on the front of cereal boxes sold in San Francisco grocery stores.

But San Francisco is not similarly restrained when it comes to regulating local restaurants. As discussed above, Congress sought to avoid a regulatory vacuum by intentionally excepting state requirements for nutrition labeling of restaurant food from NLEA preemption at the same time that it exempted restaurant food from the new federal labeling requirements. The NLEA preempts "any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) . . . *except a requirement for nutrition labeling of food which is exempt*" under that section—i.e., a requirement for nutrition labeling of restaurant food. § 343-1(a)(4) (emphasis added); s*ee* § 343(q)(5)(A)(i) (providing that section 343(q)'s nutrition labeling requirements "shall not apply to food . . . which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments").

Taken together, these three provisions—sections 343-1(a)(4), 343(q)(5)(A)(i), and 343(q)(1)(C)(i)—demonstrate that Congress intended that the NLEA would not preempt state requirements "for nutrition labeling"—including labeling "that provides . . . the total number of calories"—for "food . . . which is served in restaurants." The NLEA, in other words, specifically does *not* preempt state-law requirements that restaurants disclose nutritional facts, such as the calorie content of their food.

The FDA has consistently taken a position in keeping with that straightforward interpretation. In April 2008, the FDA reissued guidelines, reaffirming its view that states and local governments may "require restaurant foods to bear nutrition labeling even if the food is exempt under Federal requirements . . . . [B]ecause the [NLEA] exempts restaurant foods that do not bear a claim from mandatory nutrition labeling, State requirements for the nutrition labeling of such foods would not be preempted." FDA, *Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods*.[9] Notably, this FDA statement specifically distinguishes between "mandatory nutrition labeling" of the type required under section 343(q)—from which restaurant food is exempt—and "foods that bear a claim" under section 343(r), and follows the common-sense reading of the statute discussed above. Moreover, prior and subsequent FDA statements, including its most recent amicus brief in the Second Circuit, are fully consistent with that analysis. *See, e.g., Keystone Report* at 74; *FDA Calories Count Report* at V.B.

CRA's motion for a preliminary injunction makes no attempt to reconcile its preemption argument with the savings clause contained in § 343-1(a)(4). As the Supreme

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

Court has explained, "[t]hat Congress added the remainder of the provision is evidence of its intent to draw a distinction between state labeling requirements that are pre-empted and those that are not." *Bates*, 544 U.S. at 449. Section 343-1(a)(4) distinguishes between "requirement[s] for nutrition labeling of food" that are preempted and those that are not, and specifically places restaurant nutrition-labeling in the latter category. CRA offers no principled basis for distinguishing between the sphere of regulation of nutritional information in restaurants that Congress expressly left open to state and local regulation in section 343-1(a)(4) (the companion preemption provision to section 343(q)), and the types of regulations respecting "claims" within the meaning of sections 343-1(a)(5) (the companion preemption provision to section 343(r)). CRA's position would thus effectively read the savings-clause out of the statute as far as restaurants are concerned.

Not only is there no "clear and manifest" evidence of Congressional intent to preempt restaurant labeling regulations like San Francisco's, *Lohr,* 518 U.S. at 485, but the clearest evidence of Congressional intent—in the form of statutory language, legislative history, and agency interpretation, all addressing precisely the question of preemption of

state nutrition labeling requirements for restaurant food—points decisively away from preemption.[10]

III. San Francisco's ordinance does not regulate voluntary "claims" that use descriptive "terms" to "characterize" nutrient levels or health effects.

CRA attempts to sidestep Congress's decision to save local restaurant nutrition-labeling requirements from preemption by arguing that the San Francisco rule covers the same ground as section 343(r)'s prohibition of unauthorized or unsubstantiated descriptive "claims" that food purveyors choose to make about their food. *See* § 343(r) (prohibiting any "claim" that "characterizes" the nutrient content of food unless the "characterization" employs specific "terms" defined by the FDA); § 343-1(a)(5) (preempting state law "respecting any claim of the type described in section 343(r)"). For this express preemption

[10]CRA obliquely suggests (Mtn. for Prelim. Inj. at 8-9) that San Francisco has somehow interfered with an FDA policy of "flexibility" concerning how restaurants may present nutrition information. But "FDA does not have regulatory authority to require nutrition information in restaurants" in the first place. *Keystone Report* at 74; *see FDA Calories Count Report* at V.B. Because "the FDA has no statutory authority under the NLEA to mandate nutritional disclosure by the fast food industry," "its reluctance may be explained simply by its lack of authority." Michael A. McCann, *Economic Efficiency and Consumer Choice Theory in Nutritional Labeling*, 2004 Wis. L. Rev. 1161, 1191 n.164 (2004).

"There is no federal pre-emption *in vacuo*." *Puerto Rico Dep't of Consumer Affairs*, 485 U.S. 495, 503 (1988); *see Pelman*, 237 F. Supp. 2d at 525-26 (rejecting McDonald's argument that Congress's decision not to impose mandatory nutrition labeling requirements on restaurants preempts state law nutrition labeling requirements for restaurants); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002) (holding that it is "quite wrong" to view the Coast Guard's decision not to require propeller guards on motor boats as the "functional equivalent" of a prohibition against state regulation of the subject matter; the decision was "fully consistent with an intent to preserve state regulatory authority"); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 289 (1995) (where agency had no standard either requiring or prohibiting anti-lock brakes, state claim regarding anti-lock brakes was not preempted). Thus, that FDA has not required nutrition labeling by restaurants in no way precludes cities and states from doing so.

argument to succeed, CRA must demonstrate that San Francisco Ordinance 40-08 is a "requirement respecting any claim of the type described in section 343(r)." § 343-1(a)(5).

But San Francisco's ordinance has nothing to do with such "claims." The San Francisco rule merely requires restaurants to disclose factual nutritional information. It neither prevents nor limits the ability of restaurants to make voluntary, descriptive claims characterizing the nutrient content or health effects of their food. Restaurants in San Francisco remain just as free as they were in the past to make such descriptive claims, so long as they comply with federal law.

A. San Francisco's ordinance has nothing to do with "claims."

Any construction of the word "claim" in section 343(r) must be informed by the distinction between mandatory factual disclosures and voluntary descriptive statements on which the entire structure of the NLEA is premised. As discussed in Part I above, the NLEA and its regulations "encompass two kinds of information—the mandatory information on nutrients which will appear on the nutrition panel of nearly all food labels, and the voluntary information that some manufacturers choose to add to their product labels." Guarino, *Nutrient Descriptor and Disease Claims for Foods*, 48 Food & Drug L.J. 665, 671 (1993). Both Section 343(q) and San Francisco's rule address the former sort of information, while section 343(r) addresses the latter.

"The difference between requiring certain information on a food label and merely allowing truthful and non-misleading information to appear on the label cannot be understated. Mandatory labels bind all manufacturers of a given product to provide standardized information about their product so that consumers can make essential choices

. . . Voluntary labels, on the other hand, are typically utilized when a manufacturer wishes to distinguish his product from a competing product." Keane, *The Case of Food Labeling*, 16 Transnat'l L. & Contemp. Probs. 291, 295 (2006). The San Francisco rule, similarly, binds all covered restaurants to provide standardized factual information about their products to allow consumers to make informed choices, but neither prohibits nor permits descriptive claims that restaurants choose to make about the benefits of their food over that of their competitors.

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

The same or similar use of the word "claim" appears in various places in the U.S. Code to denote assertions made by the vendors or manufacturers of food or agricultural products, both within the NLEA, *see* 21 U.S.C. § 343(q)(5)(C) ("[T]he requirements of such

subparagraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any *claim* with respect to the nutritional value of such food…"), and elsewhere, *see, e.g.*, 7 U.S.C. § 2105(a) ("false or unwarranted *claims* in behalf of cotton or its products or false or unwarranted statements with respect to the quality, value, or use of any competing product."); 7 U.S.C.A. § 2617(f)(2) ("no advertising or sales promotion program shall make any reference to private brand names or use false or unwarranted *claims* in behalf of potatoes or their products") (emphasis added). In these and other instances, the law regulates voluntary advertising claims in contexts where there is some risk that consumers will be deceived by unsubstantiated assertions or confused by the use of ambiguous or misleading terms.

CRA suggests (Mtn. for Prelim. Inj. at 14) that an interpretation of section 343(r) as limited to voluntary statements leads to an "anomalous conflict between state and federal law" because "states or localities could mandate sellers of packaged foods to 'disclose' on the front label the number of calories (or any other nutrient)." But there is no such anomaly because, as described above, San Francisco is restrained from taking that step by section 343-1(a)(4)—which preempts nutrition-information disclosure requirements as to packaged foods—regardless of how one interprets section 343(r). CRA further posits that a state or city might "'mandate' labeling of 'low sodium' foods," perhaps under circumstances that would conflict with FDA regulation. *Id.* at 14. But as to all food, *both* restaurant food *and* packaged food, any problem arising out of that hypothetical scenario would be addressed by section 343(a) of the Food, Drug and Cosmetic Act, which prohibits false or misleading statements. A statement that a food is "low in fat," when it in fact is not low in fat under the

federal definition of that term, would mislead consumers and would therefore render that food misbranded under section 343(a). Any state law that required a food manufacturer to do something that makes compliance with federal law impossible would be preempted in any event under the doctrine of conflict preemption.

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

B. San Francisco's ordinance has nothing to do with claims that use descriptive "terms" to "characterize" nutrient levels or health effects.

Finally, even if it were true that some disclosures compelled by law constituted "claims" under the NLEA, a simple factual disclosure of the number of calories in a food is not a claim that uses descriptive "terms" to "characterize" a nutrient level within the meaning of section 343(r), and thus would not be a "claim of the type described in section 343(r)." § 343-1(a)(5).

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

The FDA's regulations define a nutrient content claim as "[a] claim that expressly or implicitly characterizes the level of a nutrient of a type required to be in nutrition labeling under [the regulations implementing 343(q)]." 21 C.F.R. § 101.13(b). The regulations go on to provide an extensive dictionary of "terms" that "characterize" nutrient levels—including *light*, *lite*, *high*, *rich in*, *excellent source of*, *good source of*, *contains*, *provides*, *more*, *fortified*, *enriched*, *added*, *extra*, and *plus*. 21 C.F.R. §§ 101.54-101.69; *see also* FDA, *Definitions of Nutrient Content Claims, Food Labeling Guide – Appendix A*, http://www.cfsan.fda.gov/~dms/flg-6a.html; FDA, *Label Claims: Nutrient Content Claims*, http://www.cfsan.fda.gov/~dms/lab-nutr.html. The FDA has limited section 343(r)'s coverage to any "claim that expressly or implicitly *characterizes* the level of a nutrient," 21 C.F.R. 101.13(b) (emphasis added), and thus confirms that a statement is a claim within the meaning of section 343(r) only if it uses descriptive terms—such as "low," "more" or "contains"—to characterize the level of nutrients. *See, e.g.*, 21 C.F.R. 101.54(c) (listing "contains" as a descriptive term and limiting its use).

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

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

21 C.F.R. § 101.13(i)(3).[11] Notably, the regulation uses the bare phrase "100 calories" as an illustration of a statement about the "amount or percentage of a nutrient" that does *not* "characterize" a nutrient level. Again using "100 calories" as an example, the FDA explained the reasoning for the regulation as follows:

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

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

FDA's guidance concerning its regulations expands on the same point: "Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*. An accurate quantitative statement

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

(e.g., 200 mg of sodium) that does not 'characterize' the nutrient level may be used to describe any amount of a nutrient present." FDA, *Claims that Can Be Made for Conventional Foods and Dietary Supplements* (2003) (emphasis added), *available at* http://www.cfsan.fda.gov/~dms/hclaims.html; *see also* Guarino, *Nutrient Descriptor and Disease Claims for Foods*, 48 Food & Drug L.J. at 671 (discussing 21 C.F.R. 101.13(i)(3)).

If further confirmation is needed that straightforward disclosures of quantitative calorie information fall outside the scope of section 343(r), it can be found in FDA enforcement letters, a few of which are attached as an appendix to this brief. In one of the attached letters, FDA responded to a request from *amicus* Center for Science in the Public Interest (CSPI) urging the agency to regulate products bearing the statement "0 *trans* fat." *See* Letter to M. Jacobson from B. Schneeman, dated Apr. 14, 2006. The FDA letter noted that CSPI had "refer[red] to these statements (i.e., '0g *trans* fat') as claims" and acknowledged that "there are no approved nutrient content claims for *trans* fat." *Id*. at 1. Nevertheless, the agency rejected the request on the grounds that such bare factual statements concerning the amount of nutrients are not claims at all:

> [T]he label or labeling may contain a factual statement about the amount or percentage of a nutrient in accordance with 21 C.F.R. 101.13(i)(3). The use of this kind of factual statement should not in any way imply that there is a little or a lot of the nutrient in the food and is not false or misleading under section 403(a) of the Act. . . . . The use of descriptive words, such as 'only' or 'contains,' would implicitly characterize the level of the nutrient for which there is no definition. A claim that expressly or implicitly characterizes the level of a nutrient may not be made on the label or labeling foods unless the claim is made in accordance with the regulations (21 C.F.R. 101.13(b)).
>
> ***The '0g trans fat' statements presented in your letter are considered factual statements, rather than nutrient content claims***, in accordance with § 101.13(i)(3) and the products are not considered misbranded under the Act.

Id. at 2 (emphasis added).

In short, San Francisco's rule does not come close to addressing "claims" that restaurants may decide to make about their food, let alone claims that "characterize" nutrient levels using descriptive "terms" of the type regulated by section 343(r) and its implementing regulations. Rather, San Francisco's ordinance compels the disclosure of straightforward factual nutrition information for certain restaurant food, just as section 343(q) mandates similar disclosures for packaged food, and thus falls squarely into the sphere that Congress intentionally left open to the states.

IV. The Restaurant Association's First Amendment theory stands the commercial-speech doctrine on its head.

To explain why CRA's First Amendment theory is misguided, it would be difficult for us to improve upon *National Electrical Manufacturers Association v. Sorrell*, 272 F.3d 104, 113-16 (2d Cir. 2001), which upheld a Vermont law requiring labeling of mercury-containing lightbulbs, or *Evironmental Defense Center v. EPA*, 344 F.3d 832, 848-51 (9th Cir. 2003), which followed *Sorrell* in upholding a federal requirement that storm-sewer providers disclose information concerning environmental hazards. We write only to highlight the breathtaking implications of the Restaurant Association's position.

Adopting CRA's plea for intermediate or heightened scrutiny would not only run afoul of cases like *Sorrell* and *Environmental Defense*, but would turn the commercial-speech doctrine upside down. In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976), the first case to establish First Amendment protection for commercial speech, the consumer plaintiffs wanted information about drugs so they could make informed decisions in the marketplace. The Court struck down a statute barring drug-price advertising because the "consumer's interest in the free flow of commercial

information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Id.* at 763.

The commercial-speech doctrine that grew out of *Virginia Board* has consistently observed a "constitutional presumption favoring disclosure over concealment," *Ibanez v. Fla. Dep't. of Bus. and Prof'l Reg.*, 512 U.S. 136, 145 (1994), because "disclosure furthers, rather than hinders" First Amendment values: "Protection of the robust and free flow of accurate information is the principal First Amendment justification for protecting commercial speech." *Sorrell*, 272 F.3d at 114. It is for this reason that commercial disclosure requirements—including requirements justified by promotion of the public health—are assessed under the reasonable-relationship test of *Zauderer* rather than the intermediate-scrutiny standard of *Central Hudson*. *Id.* at 115 (citing *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985); *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980)); *cf. Rubin v. Coors Brewing Co.*, 514 U.S. 476, 484 (1995) (citing federal nutrition labeling requirements as evidence of a trend "favor[ing] greater disclosure of information, rather than less"). But as *Sorrell* recognized, subjecting purely factual commercial disclosure requirements to heightened scrutiny would upend these settled principles and distort the commercial speech doctrine into a *barrier* to "the free flow of information" critical to promoting public health. *Id.* No existing law requires such a topsy-turvy result.

CRA's attempts to distinguish *Sorrell*, *Environmental Defense*, and *Zauderer* are unpersuasive. First, the City ordinance does not "dictate a specific message," *Envt'l Defense*, 344 F.3d at 849, but requires only the disclosure of factual information to consumers. Fast-food restaurants have every right to disagree with San Francisco about whether disclosing

calorie information helps reduce obesity. The expression of that view—whether in CRA's brief to this Court, or in the public square, or before the City Council—is protected by the First Amendment, and it will continue to be. The City's regulation does not force CRA to express a contrary view any more than the Vermont law in *Sorrell* forced the lightbulb manufacturers to express the view that mercury is dangerous or the EPA's regulation in *Environmental Defense* forced storm-sewer providers to express the view that stormwater discharges are hazardous. Second, the proposition that *Zauderer* applies only to disclosure requirements that prevent deception is one that has been explicitly rejected in similar cases. *See Sorrell*. 272 F.3d at 115; *accord Pharmaceutical Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294 (1st Cir. 2005). Although the overall goal of the San Francisco ordinance is plainly to reduce obesity, it is analyzed under *Zauderer* because "it is inextricably intertwined with the goal of increasing consumer awareness" of high calorie content in a variety of restaurant foods. *Sorrell*, 272 F.3d at 115. In any event, San Francisco's rule *is* in fact designed to prevent consumer deception and confusion concerning calorie content, and so *Sorrell* controls even if one applies the cramped (and incorrect) interpretation that CRA urges.

CRA's theory in this case is even more radical than the position rejected in *Sorrell* and *Environmental Defense* because it asks the Court to apply not just intermediate scrutiny, but *strict scrutiny*, on the theory that the San Francisco rule constitutes "compelled speech" under *United States v. United Foods, Inc.*, 533 U.S. 405 (2001). To appreciate just how much CRA's position would disrupt settled law, consider how it would change the outcome in many cases that have adopted *Sorrell*'s approach in the face of compelled-speech challenges to various disclosure and posting laws. *See*, *e.g.*, *Rowe*, 429 F.3d 294 (1st Cir. 2005)

(upholding Maine law requiring intermediaries between drug companies and pharmacies to disclose conflicts of interest and financial arrangements); *UAW-Labor Employment & Training Corp. v. Chao*, 325 F.3d 360, 365 (D.C. Cir. 2003) (upholding requirement that federal contractors post notices at all of their facilities informing employees of rights under federal labor law that protect employees from being forced to join union or to pay mandatory dues for costs unrelated to representational activities); *United States v. Wenger*, 292 F. Supp. 2d 1296, 1303-04 (D. Utah 2003) (upholding federal securities disclosure requirements); *BellSouth Adver. & Pub. Corp. v. Tenn*, 79 S.W.2d 506, 516-21 (Tenn. 2002) (upholding requirement that "baby Bell" phone company disclose names of its local-phone-company competitors). CRA does not even attempt to grapple with this line of post-*United Foods* cases.

As these cases recognize, "the First Amendment's guarantee of freedom from 'compelled speech' is not absolute. Particularly in the commercial arena, the Constitution permits the State to require speakers to express certain messages without their consent, the most prominent examples being warning and *nutritional information labels*." *Entertainment Software Ass'n v. Blagovech*, 469 F.3d 641, 651 (7th Cir. 2006) (emphasis added) (distinguishing between "opinion-based" compelled speech and "purely factual disclosures," such as "whether a particular chemical is within any given product"); *Dutchess/Putnam Rest. & Tavern Ass'n, Inc. v. Putnam County Dep't of Health*, 178 F. Supp. 2d 396, 406 (S.D.N.Y. 2001) (rejecting "argument that a sign stating that there are health risks to children from secondhand smoke is an 'ideological message'"); *BellSouth*, 79 S.W.3d at 516-21 (*Zauderer*, not *United Foods*, supplies proper standard in cases involving factual

commercial disclosure requirements); *see also Johanns v. Livestock Marketing Ass'n*, 544 U.S. 550, 557 (2005) (explaining that the Court has recognized only two kinds of compelled-speech cases: "true compelled-speech cases," in which an individual is forced to personally express an opinion with which he disagrees, and "compelled-subsidy cases," like *United Foods*).

Under CRA's expansive theory of compelled speech, countless federal, state, and local laws mandating disclosure on a wide range of subjects—from tobacco, pesticides, and pollutants, to hand-washing by restaurant employees—would fall, after being exposed to "searching scrutiny by unelected courts." *Sorrell*, 272 F.3d at 116. As *Sorrell* noted, even the mandatory nutrition labeling provisions of the NLEA would be among those laws. *Id.* (citing 21 U.S.C. 343(q)). "Such a result is neither wise nor constitutionally required." *Id.*

CONCLUSION

For the foregoing reasons, the Court should reject the California Restaurant Association's request to invalidate San Francisco Health Ordinance 40-08.

Respectfully submitted,

/s/ Monique Olivier
Monique Olivier
THE STURDEVANT LAW FIRM

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July 31, 2008

APPENDIX LISTING *AMICI CURIAE*

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

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

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

Public Citizen is a non-profit consumer advocacy organization with a longstanding interest in fighting exaggerated claims of federal preemption of state health and safety regulation and defending consumers' rights to know information that affects their health. Public Citizen's lawyers have argued several significant federal preemption cases before the United States Supreme Court and the lower federal courts, and have also argued several of the seminal cases involving the commercial speech doctrine, including *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976), and *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985).

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

The **American College of Preventive Medicine**, established in 1954, is the national professional society for physicians committed to disease prevention and health promotion. To address the lack of nutrition labeling and the rising obesity rates in adults and children, ACPM introduced the menu-labeling resolution that was passed by the AMA's House of Delegates last month.

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

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

California Center for Public Health Advocacy is a non-profit organization established in 1999 by California's two public health associations to raise awareness about critical public health issues and is currently the lead supporter of a bill before the California State Legislature to require nutrition labeling on menus and menu boards in chain restaurants.

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

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

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

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

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

Interdisciplinary Center for Obesity and the Division of Nutrition Epidemiology and studies dynamic changes in diet, physical activity, and body composition, with a focus on rapid changes in obesity.

APPENDIX OF STATUTORY AND REGULATORY PROVISIONS

21 U.S.C. § 343. Misbranded food.

A food shall be deemed to be misbranded--

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

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

* * *

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

* * *

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

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

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

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

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

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

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

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

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

> **(a)** Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—
>
> * * *
>
> **(4)** any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 343(q)(5)(A) of this title, or
>
> **(5)** any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

21 U.S.C. § 343-1, note

> The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A [21 U.S.C. 343-1(a)] of the Federal Food, Drug, and Cosmetic Act.

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

> Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (e.g., "low fat, this meal provides less than 10 grams of fat") may serve as the functional equivalent of complete nutrition information as described in § 101.9. Nutrient levels may be determined by nutrient data bases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

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

> (a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.
>
> (b) A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

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

* * *

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

* * *

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

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

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

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

(2) The terms "low calorie," "few calories," "contains a small amount of calories," "low source of calories," or "low in calories" may be used on the label or in labeling

of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i)(A) The food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and does not provide more than 40 calories per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and does not provide more than 40 calories per reference amount customarily consumed and, except for sugar substitutes, per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the "as prepared" form).

(ii) If a food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the caloric content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "celery, a low calorie food").

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

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

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

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

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

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

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

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

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

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

(i) The food contains at least 25 percent fewer calories per 100 g of food than an appropriate reference food as described in § 101.13(j)(1); and
(ii) As required in § 101.13(j)(2) for relative claims:
(A) The identity of the reference food and the percent (or fraction) that the calories differ between the two foods are declared in immediate proximity to the most prominent such claim (e.g., Larry's Reduced Calorie Lasagna, "25 percent fewer calories per oz (or 3 oz) than our regular Lasagna"); and
(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces (e.g., "Calorie content has been reduced from 108 calories per 3 oz to 83 calories per 3 oz.") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.
(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or labeling of food if the reference food meets the definition for "low calorie."