

# 08-1892-CV

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IN THE  
**United States Court of Appeals**  
FOR THE SECOND CIRCUIT

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NEW YORK STATE RESTAURANT ASSOCIATION,

*Plaintiff-Appellant,*

—against—

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

*Defendants-Appellees.*

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

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## REPLY BRIEF FOR PLAINTIFF-APPELLANT

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## **I. REGULATION 81.50 IS PREEMPTED**

### **A. The Board May Not Re-litigate the Central Issue Litigated and Decided in *NYSRA I***

In our opening brief, we showed that the “voluntary/mandatory” distinction would turn the doctrine of preemption upside down by allowing a state government to opt out of preemption; that the “voluntary/mandatory” distinction cannot be reconciled with the FDA regulations’ definition of a “claim,” which includes “any direct statement” of the amount of calories; that the distinction ignores critical portions of the statute; and that it would lead to the anomalous result that the state would not be precluded from mandating “claims” such as “low sodium” which the district court characterized as the “heartland” of subsection (r) of the NLEA.

In response, the Board largely ignores the “voluntary/mandatory” distinction, correctly recognizing that it is effectively indefensible. Instead, the Board argues that a quantitative statement of the amount of calories on a menu is not a “claim” at all and that only “qualitative” statements are claims. This, of course, was the central, dispositive issue in *New York State Restaurant Ass’n v. New York City Board of Health*, 509 F. Supp. 2d 351 (S.D.N.Y. 2007) (“*NYSRA I*”). After full briefing and argument, the district court ruled against the Board and held that a statement of the amount of calories *is* a “claim.” SPA-56. The Board is not allowed to re-litigate that issue, which was necessary to the judgment in *NYSRA I*.

Following the entry of a final judgment on the merits in *NYSRA I*, the Board filed a notice of appeal. But it did not prosecute that appeal. Instead, it issued a

notice of intention to repeal the regulation and promulgate a new regulation, expressly invoking the “voluntary/mandatory” distinction. *See* JA-551 (quoting *NYSRA I*). It then stipulated that if it adopted the new regulation, it would dismiss the appeal “as moot with prejudice.”<sup>1</sup> After it adopted the new regulation, the Board dismissed the appeal. JA-688-89. In *New York State Restaurant Ass’n v. New York City Board of Health*, No. 08 Civ. 1000, 2008 WL 1752455 (S.D.N.Y. Apr. 16, 2008) (“*NYSRA II*”), the Board did not ask the district court to revisit the holding in *NYSRA I*, although it purposed to “preserve” the issue for appellate review in a footnote. Def. Mem. in Opp. p. 12 n.9 (2/8/2008).

The Board now contends that it “never had a full and fair opportunity to litigate the issue [decided in *NYSRA I*] and should not be precluded from doing so now.” Br. 23-24 n.8. This assertion is incorrect. Not only did the Board have the *opportunity* to litigate the issue; in fact, it did litigate the issue. That fact is not changed because the Board made a unilateral decision to promulgate a new regulation rather than defend the old one on appeal.

To be sure, when “review [is] prevented by happenstance,” the losing party in the district court may move in the court of appeals to vacate the judgment to preserve its ability in a potential future case to re-litigate the issues it lost in the now-moot case. *See United States v. Munsingwear, Inc.*, 340 U.S. 36, 40 (1950). In *Munsingwear*, the United States “slept on its rights” by failing to make a motion to vacate the judgment; it thereby “acquiesced in the dismissal” of the appeal and

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<sup>1</sup> Stipulation filed November 14, 2007 in No. 07-4378-cv (Second Circuit).

could not avoid the preclusive effects of the district court’s judgment. *Id.*

Here, as in *Munsingwear*, the Board did not seek a vacatur. Indeed, this procedure would not have been available to the Board because the mootness was foreseeably caused by the Board’s own voluntary action. *See United States Bancorp Mortgage Co. v. Bonner Mall P’ship*, 513 U.S. 18, 24-25 (1994) (denying vacatur in case where mootness resulted from settlement); *Karcher v. May*, 484 U.S. 72, 82-83 (1987) (judgment binding when losing party’s failure to appeal caused mootness); *Doe v. Gonzales*, 449 F.3d 415, 420-21 (2d Cir. 2006) (rejecting government’s request to vacate judgment where government’s voluntary actions rendered appeal moot).

The only case cited by the Board—*Gelb v. Royal Globe Insurance Co.*, 798 F.2d 38 (2d Cir. 1986)—did not involve a party whose voluntary actions rendered its appeal moot. In *Russman v. Bd. of Education of Watervliet*, 260 F.3d 114 (2d Cir. 2001), this Court explained the distinction between mootness by happenstance and mootness by voluntary act. “If we were to vacate where the party that lost in the district court has taken action to moot the controversy, the result would be to allow that party to eliminate its loss without an appeal and to deprive the winning party of the judicial protection it has fairly won.” *Id.* at 122. That is precisely what revisiting the issue decided in *NYSRA I* would do.

**B. A Statement in Labeling Such as “100 Calories” Is a “Claim” Within the Meaning of Section 343(r)**

The central issue in *NYSRA I* was whether a statement of the amount of calories—e.g., “100 calories” or “contains 100 calories”—is a “claim” within the

meaning of the NLEA. The regulations answer that question definitively, and the Board’s attempt to re-litigate the issue can be rejected on the merits, as well as on grounds of issue preclusion.

**1. The Regulations Define “Any Direct Statement” of the Amount of Calories as a “Claim”**

The Board argues that the statement “100 calories” is not a “claim” within the meaning of the NLEA because it is a “quantitative” statement rather than a “qualitative” statement. Br. 23 n.8, 25 (“There is a world of difference between the qualitative statement ‘low in fat’ and the quantitative statement ‘100 calories.’”) (quoting *NYSRA II*, SPA-38). In making this argument, the Board ignores the FDA’s controlling regulations. The FDA defines an “expressed nutrient content claim” as “***any direct statement*** about the level (or range) of a nutrient in the food, e.g., ‘low sodium’ or ‘***contains 100 calories.***” 21 C.F.R. § 101.13(b)(1) (emphasis supplied). “Any direct statement” is different from “any qualitative statement.”

The FDA did not merely define “claim” to include “any direct statement” such as “contains 100 calories.” It also went on to add regulations governing what are permissible and what are impermissible express and implied claims. Subsection 101.13(i) thus provides that a label “may contain a ***statement*** about the ***amount*** or percentage of a nutrient,” so long as “[t]he statement does not in any way implicitly characterize the level of the nutrient in the food [such implicit characterizations being subject to other subparagraphs] and it is not false or misleading in any respect (e.g., ‘***100 calories***’ or ‘5 grams of fat’)....” 21 C.F.R.

§ 101.13(i)(3) (emphasis supplied). In short, the FDA regulations promulgated under authority of subsection (r) define a “claim” to include “contains 100 calories” and expressly permit a claim of “100 calories.”

The NLEA not only delegates authority to promulgate the regulations that include the definition of “claim,” it all but requires a definition that includes simple statements of nutrient amounts. Section 3(b)(1)(A)(iv) of the NLEA specifically instructs the FDA to promulgate regulations that would “permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in [§ 343(r)].”<sup>2</sup> This provision also instructs the agency that its regulations “shall identify claims described in section [343(r)(1)(A)] which comply with section [343(r)(2)].” *Id.* § 3(b)(1)(A)(i). Thus, Congress specifically instructed the FDA to promulgate the regulations quoted above—permitting “statements describing the amount” of calories and other nutrients. If a statement of the amount of a nutrient such as calories were not covered as a “claim” under subdivision (r), there would have been no point in Congress’ directing the FDA to promulgate regulations permitting such statements.

**2. 21 U.S.C. § 343(r)(1) and 21 C.F.R. § 101.13(c) Compel the Conclusion that Statements of the Amount of Calories Are “Claims”**

The Board’s theory for why the statement “100 calories” is not a claim is

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<sup>2</sup> NLEA, Pub. L. No. 101-535, § 3(b)(1)(A)(iv), 106 Stat. 4501 (set out in Historical and Statutory Notes after 21 U.S.C.A. § 343(r)) (emphasis supplied).

based on an incomplete reading of section 343(r)(1). According to the Board, because such a statement is “of the type” required by subsection (q), it is therefore excluded from being a “claim” by section 343(r)(1). It is true that the statement “100 calories” is “of the type” required by subsection (q). However, being a statement “of the type” permitted by subsection (q) is not sufficient for a statement to be excluded from the definition of “claim.” As we demonstrated in our opening brief (pp. 32-33), the statement also has to “appear as part of the nutrition information” required “by such paragraph [subsection (q)]” to fall outside the definition of a “claim.” We explained that an FDA regulation promulgated to implement this portion of the statute makes this requirement explicit:

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

21 C.F.R. § 101.13(c) (emphasis supplied). The statute and regulation thus provide that a simple factual statement is a claim unless it “appears as part of the nutrition label.” The Board does not cite this regulation or otherwise respond to it.

The statement “100 calories” on a menu does not “appear as part of the nutrition label.” The regulations use the term “nutrition label” to mean a printed fact panel in conformity with the substantive requirements of 21 C.F.R. § 101.9(c) and the formatting requirements of 21 C.F.R. § 101.9(d) or § 101.10. *See* 21 C.F.R. § 101.9(d)(1) (describing requirements for presenting “information within

the *nutrition label*”), § 101.9(d)(12) (setting out a “sample label” that “illustrates the provisions” of paragraph (d)). The Board does not and cannot deny that a statement of calories prominently posted next to the food description is not a “nutrition label” as that term is used in the regulations and indeed is not a “label” at all as defined under the statute. 21 U.S.C. § 321(k) (defining “label” as “a display of written, printed, or graphic matter upon the immediate container of any article”).<sup>3</sup> Because the statement mandated by Regulation 81.50 appears “elsewhere...in labeling,” it is a “claim” by operation of section 343(r)(1) [unnumbered portion] and 21 C.F.R. § 101.13(c).

### **3. The Board’s Reliance on Materials Other than FDA Regulations Is Unavailing**

By ignoring the FDA’s regulations, and instead focusing on things like informal industry guidance and FDA-commissioned study group reports, the Board defies basic principles of *Chevron* deference. *See Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). We demonstrated in our opening brief that agency regulations promulgated after formal notice and comment pursuant to a delegation of authority from Congress are entitled to “controlling weight.” Br. 26 (quoting *United States v. Haggard Apparel Co.*, 526 U.S. 380, 390, 392 (1999)). The Board makes no argument against *Chevron* deference for these regulations.

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<sup>3</sup> A menu is “labeling,” *see* 21 U.S.C. § 321(m), and the regulations promulgated by the FDA govern all “nutritional claims or other nutrition information in any context” in restaurants. 21 C.F.R. §§ 101.9(j)(2), 101.13(n); *see Public Citizen, Inc. v. Shalala*, 932 F. Supp. 13, 15 (D.D.C. 1996) (regulations apply to *all* nutrient content claims made by restaurants, including claims on menus).

The snippets of an industry guidance manual and an agency-commissioned report by the Keystone Forum relied on by the Board (Br. 15-16) are *not* entitled to *Chevron* deference: “interpretations contained in policy statements, agency manuals, and enforcement guidelines—all of which lack the force of law—do not warrant *Chevron*-style deference.” *Christensen v. Harris County*, 529 U.S. 576, 587 (2000). Indeed, the documents cited by the Board contain no reasoning or other evidence of deliberation that would make them persuasive. For example, Q/A #106 states that menus are exempt from FDA regulation—which has not been true for more than ten years.<sup>4</sup> *See supra* p. 7 n.3. The remainder of Q/A #106 contains no analysis. The *Keystone* report likewise contains no analysis, does not cite the statute, and is not a product of the agency itself.

In contrast to the informal materials the Board cites, the FDA’s formal notice of rulemaking reflects the agency’s considered judgment and analysis. In promulgating the regulations discussed above, the FDA expressly rejected the theory advanced by the Board here. During the notice and comment period, the FDA was asked to exclude statements about “simple factual information” from the definition of “nutrient content claim” on the theory that such a statement is not “a claim that ‘characterizes’ the level of any nutrient” within the meaning of the statute. 58 Fed. Reg. 2302, 2303 (1993). The comment argued that “a statement of the type contained in nutrition labeling—for example, that a food contains 25

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<sup>4</sup> A Labeling Guide for Restaurants & Other Retail Establishments Selling Away-From-Home Foods (Apr. 2008), *available at* <http://www.cfsan.fda.gov/~dms/labrguid.html>.

calories per serving...—is not a claim characterizing the level of the nutrient.” *Id.* Based on the statutes discussed above, the FDA rejected that contention, embraced the view that a quantitative factual statement about the amount of a nutrient is a “claim” that “characterizes the level” of the nutrient within the meaning of the statute, and promulgated final and binding regulations to that effect. We reprint the relevant portion of the rulemaking below. The FDA’s comments are dispositive.

**The agency** advises that while it can agree that the terms “nutrient descriptor” and “nutrient descriptor claims” may be used to describe the claims subject to section 403(r)(1)(A) of the act and these regulations, it **does not agree that the scope of the statute and the regulations excludes statements of the amount of a nutrient in a food.** The [distinction] the comment draws between “nutrient descriptors” and “nutrient content” claims is unpersuasive. In fact, one of the sponsors of the 1990 amendments in the Senate specifically used the term “nutrition content claim” to refer to claims covered under section 403(r)(1)(A) (136 Cong. Rec. S16608 (October 24, 1990)). Moreover, the statement in section 403(r)(1) of the act referred to by the comment as excluding from coverage statements of the type contained in nutrition labeling, in fact excludes “a statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph \* \* \*.” **FDA stated in the general principles proposal (56 FR 60421 at 60424), that the legislative history of this provision specifically states that the identical information [i.e., the identical information that would be required in the nutrition fact panel required by subsection (q)] will be subject to the descriptor requirements if it is included in a statement in another portion of the label (136 Congressional Record H5841 (July 30, 1990))... Furthermore, section 3(b)(1)(A)(iv) of the 1990 amendments provides that the mandated regulations “shall permit statements describing the amount and percentage of nutrients in food which \* \* \***

**are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act.**” Again, if statements of the amount and percentage of nutrients were not subject to section 403(r)(1)(A) of the act, there presumably would have been no need for Congress to express its desire that such claims be permitted by the regulations. **Accordingly, FDA concludes that section 403(r)(1)(A) of the act and therefore these final regulations apply to statements of the amount of a nutrient in food as well as to statements of the level of a nutrient in food.**

58 Fed. Reg. at 2303-04 (emphasis supplied).<sup>5</sup>

The Board also relies on floor statements by two members of Congress. Br. 15, 19. A floor statement does not trump the statute and regulations. “Floor statements are among the most dangerous and least reliable forms of legislative history.” *Hayden v. Pataki*, 449 F.3d 305, 353 (2d Cir. 2006) (Parker, J., dissenting); see *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 457 (2002) (there is “no reason to give greater weight to the views of two Senators than to the collective votes of both Houses, which are memorialized in the unambiguous statutory text.”).<sup>6</sup>

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<sup>5</sup> *Amici* distort another passage in this notice of final rulemaking to suggest that the FDA was arguing that a quantitative statement of amount does not characterize the level of a nutrient. Waxman Br. 25. That is not a fair reading of the FDA’s final rulemaking statement, which distinguished between “expressed” claims and “implied” claims. The notice explains that the statement “100 calories”—which is plainly an “expressed claim”—“conveys no ***implied*** characterization.” 58 Fed. Reg. at 2310 (emphasis supplied).

<sup>6</sup> Finally, the Board relies (Br. 14-15) on *Pelman v. McDonald’s Corp.*, 237 F. Supp. 2d 512, 526 (S.D.N.Y. 2003), but in that case the defendant made no argument about—and the court did not consider—the preemptive reach of 21 U.S.C. § 343-1(a)(5).

**C. The Relevant Statute—21 U.S.C. § 343-1(a)(5)—Unambiguously Preempts State and Local Laws that Impose “Any Requirement Respecting Any Claim” that Is “Not Identical to” the FDA Regulations**

If a statement “100 calories” on a menu is a “claim” under the NLEA, then the words of the relevant preemption statute—21 U.S.C. § 343-1(a)(5)—make as clear as words can that Regulation 81.50 is preempted.

The statute displaces state laws that are “not identical to” the requirements of the NLEA and the regulations promulgated thereunder. It covers “any requirement respecting any claim of the type described in section 343(r)(1).” 21 U.S.C. § 343-1(a)(5). In these circumstances, the Board’s contention that there is a “presumption” against preemption is irrelevant. “[W]hen Congress has made its [preemptive] intent known through explicit statutory language, the court’s task is an easy one.” *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990); *see Engine Mfrs. Ass’n v. South Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 252, 256-57 (2004) (where an express preemption provision is “categorical,” the Court assumes “that the ordinary meaning of [statutory] language accurately expresses the legislative purpose.”) (internal quotation omitted).<sup>7</sup>

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<sup>7</sup> The Board also contends (Br. 10-11) that states had unbridled police power to adopt requirements like Regulation 81.50 before adoption of the NLEA and that the NLEA produced groundbreaking changes in the FDA’s authority. That assertion is irrelevant, given the express preemption statute here. But it is also wrong. The federal government has been regulating the labeling and manufacture of foods in interstate commerce since Congress enacted the Pure Food and Drug Act of 1906; and since that time there have been state labeling laws that have been impliedly and expressly preempted by federal law. *See, e.g., McDermott v. Wisconsin*, 228 U.S. 115 (1913); *Jones v. Rath Packing Co.*, 430 U.S. 519, 540-43 (1977). The FDA established nutrition information labeling requirements for foods

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**D. The Board Cannot Sustain the “Voluntary/Mandatory” Distinction**

Toward the end of its preemption argument (Br. 24-25), the Board makes a fleeting defense of the district court’s “voluntary/mandatory” distinction. When viewed in light of the regulations themselves—which clearly and unequivocally define “100 calories” on a menu as a “claim”—the “voluntary/mandatory” distinction cannot stand.

If “100 calories” were not a claim on the theory that state law “mandates” the statements, the same would be true of the statement “low sodium.” Even the Board acknowledges that “low sodium” is always a claim, whether a state “mandates” it or not. So, under the Board’s reading, a state or locality can “mandate” statements that something is “low sodium” using whatever definitions it wants to use, and the “mandate” would not be preempted by the NLEA. But that would eviscerate the preemption provision in section 343-1(a)(5).<sup>8</sup>

The Board quotes the district court’s attempt in *NYSRA II* to rebut this logic.

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Footnote continued from previous page  
in interstate commerce in 1973. *See* 38 Fed. Reg. 2125. The FDA has expressly stated since at least 1976 that its nutrition labeling requirements apply to restaurant food. *See* 41 Fed. Reg. 51001 (1976).

<sup>8</sup> *Amici* contend that no harm would come from the evisceration of section 343-1(a)(5) because *other* preemption doctrines, such as implied preemption and conflict preemption, would prevent the state from interfering with the FDA’s regulations. Waxman Br. 21-22. This argument does not respond to the central flaw in the district court’s reasoning, which is that the “voluntary/mandatory” distinction is unsupportable. Moreover, the argument demonstrates something else important, discussed *infra* pp. 13-14: an exemption from preemption in one section of a statute does not necessarily preclude preemption by another section of the statute.

Br. 25. The Board states that there is a “world of difference” between quantitative statements and qualitative statements. The Board does not explain what this “world of difference” might have to do with the issues in this case. The district court correctly held in *NYSRA I* that both kinds of statements—qualitative *and* quantitative—are “claims.” SPA-54-56. So whatever the difference might be, it has no bearing on the dispositive issue in the case—whether the statement “100 calories” on a menu is a “claim” within the meaning of section 343-1(a)(5).

The Board also repeats the theory that a statement “of the type” required by subsection (q) is not a claim. But as we have shown, *supra* p. 5-7, the regulations (especially § 101.13(c)) prove that such a statement is excluded from the definition of a “claim” *only* when it “appears as part of the nutrition label.”<sup>9</sup>

#### **E. The Board’s Reliance on Section 343-1(a)(4) Is Unavailing**

Ultimately, the Board seems to hope that the Court will be distracted from section 343-1(a)(5) and instead will focus on section 343-1(a)(4). According to the Board, “there would have been no reason to include the exception clause” for restaurants in section 343-1(a)(4) if Congress had intended to preempt state and local governments from mandating that restaurants provide nutritional information.

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<sup>9</sup> *Amici* cite a law journal article to support the assertion that, in the NLEA, a statement mandated by state law is not a “claim,” saying: “The difference between requiring certain information on a food label and merely allowing truthful and non-misleading information to appear on a label cannot be understated.” Waxman Br. 19-20 (quoting Steve Keane, *The Case of Food Labeling*, 16 *Transnat’l L. & Contemp. Probs.* 291, 295 (2006)). However, the comment in the article is not about the NLEA. It addressed whether proposals in Europe for labeling genetically modified organisms could survive review by the World Trade Organization.

Br. 14. However, as we showed in our opening brief, exempting states from one preemption provision does not mean that state laws are “preserved” for purposes of *all* preemption (Br. 30-32; *see supra* p. 12 n.8), and Congress included two other preemption provisions that the Board simply ignores—sections 343-1(a)(5) and 343-1(b). The text of the entire statute, including the provisions ignored by the Board, leads to the conclusion that Regulation 81.50 is preempted.

**1. The Board Ignores Section 343-1(a)(5)**

Congress delegated to the FDA the power to promulgate regulations defining nutrient content claims and intended that the scope of preemption under section 343-1(a)(5) would follow from the substantive scope of the agency’s regulations. In exercising this delegated power, the FDA promulgated three regulations that control this case. *First*, the FDA defined “claims” to include “any” statement of the amount of nutrients by restaurants, including unadorned statements of the amount of calories. 21 C.F.R. § 101.13(b)(2); *see* 58 Fed. Reg. at 2303 (final rulemaking quoted *supra* pp. 9-10). The FDA’s definition of “claim” (and thus the preemptive scope of preemption under section 343-1(a)(5)) covers the exact statements that the Board purports to regulate. *Second*, the FDA determined, following the statute, that a statement of the amount of calories is a claim unless it “appears as part of the nutrition label.” 21 C.F.R. § 101.13(c); *see supra* pp. 5-7. *Third*, the FDA granted restaurants much broader flexibility in the way they present nutrition information than it granted to the purveyors of packaged foods. 21 C.F.R. § 101.10.

The combined effect of the statute and these three regulations preempts

Regulation 81.50. Regulation 81.50 regulates “claims.” Statements on restaurant menus do not “appear as part of the nutrition label.” And Regulation 81.50 is not identical to the FDA’s regulations— specifically, 21 C.F.R. § 101.10.

## **2. The Board Ignores Section 343-1(b)**

When it passed the NLEA, Congress created a mechanism that would be available to resolve future disputes over whether the broad preemptive effect of section 343-1(a) is undesirable, as the Board now contends. The mechanism was not unilateral state action. Rather, the mechanism was a petition to the FDA for an exemption from the preemptive scope of the statute, available on a finding by the FDA that the proposed state mandate “would not unduly burden interstate commerce” and “is designed to address a particular need for information which need is not met” by current FDA regulations. 21 U.S.C. § 343-1(b). Congress would have had no need to include this provision in the statute if a state could simply opt out of preemption by mandating what otherwise would have been preempted. The Board does not mention this provision of the statute.

The brief of *amici* San Francisco and other cities highlights the importance of this provision and underscores why Congress wanted the FDA to oversee the process. *Amici* represent more than 18,000 individual localities. They state that— so far—two dozen different menu labeling laws have been introduced at the state and local level, and they suggest that the trend is toward more and varied menu labeling requirements.

The three regulations adopted so far illustrate the burden that would be imposed on nationwide businesses attempting to keep track of and comply with the

evolving local requirements. The New York City requirement is limited to calories. The City of San Francisco, in contrast, requires printed menus to include calories, saturated fat, carbohydrates, and sodium, as well as a statement about “recommended limits.” San Francisco also requires a poster near the front door or point of sale. King County, Washington requires menus to include calories, saturated fat, carbohydrates, and sodium, as well as two statements about “recommended limits”—one similar to the San Francisco statement plus an additional statement not required in San Francisco. King County also permits a *different* kind of poster—a sign adjacent to the menu board or at eye level in the queue for buying food. *See* SPA-30-32; City of San Francisco Request For Judicial Notice, Exs. 18, 19.

Regulations that have been proposed but not yet adopted have still more variations. Hawaii’s proposed law would require restaurants to furnish calories, saturated fat, trans fat, carbohydrates, sodium, protein, and sugar. Vermont’s law would require the same nutrition information as King County, Washington; but New Jersey, California and Washington, D.C., for example, would require calories, saturated fat, trans fat, carbohydrates, and sodium. New Mexico would require calories and “the proportion of trans fat per serving.” Legislation introduced in Pennsylvania would require restaurants without menus to display “full nutrition information, readable from 12 feet away from each entrance.” Some localities would require special “recommended limits” language, which varies from locality to locality. For example, in Illinois, restaurants would be required to advise customers on their menu boards that “Daily values are based on a 2,000 calorie

diet.” Some regulations actually mandate the font size of the posting—albeit different sizes in different jurisdictions—9 point in King County, Washington, 11-point in Michigan, 2/3 the size of the other menu information in Maine, a size and font “similar to” the other information in Illinois, and “at least as large” in Tennessee. *See Id.*, Exs. 2, 5, 6, 7, 9, 10, 11, 14, 15, 16, 19, 23.

Complying with the two dozen regulations proposed so far, as well as the three already promulgated, would be a severe burden on a nationwide vendor. Complying with such variation among even a modest percentage of the 18,000 localities that demand the power to regulate restaurant food labeling would be beyond human ability.

### **3. NYSRA’s Reading Gives Meaning to Section 343-1(a)(4)**

The Board accuses NYSRA of not giving “meaning” to section 343-1(a)(4). Br. 16. By this, the Board must mean that under NYSRA’s theory of the case, the state would be preempted from taking any action concerning nutrition labeling in restaurants, and therefore no state role and no state laws are preserved by section 343-1(a)(4). But NYSRA’s theory of section 343-1(a)(5) permits a role for the states with respect to labeling in restaurants.

*First*, a state law that requires full nutrition labeling in accordance with subsection (q) and sections 101.9 and 101.10 of the FDA’s regulations appears not to be preempted. Complete nutrition labeling appears to fall within the unnumbered portion of section 343(r)(1), which excludes from the definition of a “claim”—and thus from the preemptive scope of section 343-1(a)(5)—a statement that “appears as part of the nutrition information required or permitted by

[paragraph (q)].” 21 U.S.C. § 343(r)(1) [unnumbered portion]. By operation of section 101.10, a restaurant could comply with the formatting and presentation requirements of such a law using “reasonable means.” 21 C.F.R. § 101.10 (“Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.”). Under such a law, restaurants would be required to disclose full nutrition information—something they are not required to disclose by federal law. But they would be afforded the flexibility that the FDA deemed appropriate for restaurants.

Of course, Regulation 81.50 is nothing like the hypothesized law mandating full nutrition labeling under subsection (q) and sections 101.9 and 101.10 of the FDA’s regulations. The Board’s regulation requires a prominent statement of calories alone in a specified location and in a specified manner. The regulation ignores most of section 101.9 and all of section 101.10. The regulation cannot be considered full nutrition labeling under subsection (q) and the relevant FDA regulations. It requires effectively nothing more than a “claim” governed by subsection (r) and by the preemption provision in section 343-1(a)(5).

*Second*, one court has held that a state tort action premised on a claim that the restaurant violated standards of behavior “identical” to federal requirements would not be preempted. *Reyes v. McDonald’s Corp.*, Nos. 06 C 1604, 06 C 2813, 2006 WL 3253579 (N.D. Ill. Nov. 8, 2006) (cited with approval by the Board, Br. 18 n.5). The *Reyes* court added that such a tort action may not impose requirements that are “not identical to” the FDA’s regulations. For example, federal regulations require restaurants to employ the FDA’s methodology for

calculating calories. *See* 21 C.F.R. § 101.10.

*Third*, a state law approved by the FDA under authority of section 343-1(b) would not be preempted. As noted above, Congress delegated to the agency the authority to exempt state laws from the broad preemptive scope of section 343-1(a) following a process in which the agency was expected to weigh the burdens on interstate commerce against the need for information not supplied by the federal regulatory regime. Congress made the sensible decision to require review by the expert federal agency with supervisory power over the labeling of the nation's food supply in cases in which a state or local government seeks to impose labeling requirements on a nationwide industry that plays such a significant role in the national economy.

## **II. REGULATION 81.50 VIOLATES THE FIRST AMENDMENT**

The major premise of the Board's First Amendment argument is that Regulation 81.50 is a "disclosure" law and that such laws can be justified by showing nothing more than a reasonable relationship between the law and some legitimate state interest. Although Regulation 81.50 would violate the First Amendment even if it could fairly be characterized as a disclosure law, it is not a disclosure law. Regulation 81.50 exempts 90% of the restaurants in New York City from its reach. Those restaurants must "disclose" nothing. And almost all the restaurants that *are* subject to the regulation already "disclose" the level of calories in their foods in accordance with regulations promulgated by the FDA. They also "disclose" the level of other nutrients in their foods—fat, saturated fat, cholesterol, sodium, total carbohydrates, sugars, dietary fiber, and total protein. *See* JA-186,

346, 353, 366-71, 395. By making these disclosures, the restaurants are providing nutrition information to their customers in a format consistent with FDA regulations and conveying a health message—although calories are relevant, they should be considered in the context of other nutrition information (as well as in the context of information about exercise).

Regulation 81.50 is thus quite different from an ordinary disclosure law. It requires the targeted restaurants to shout the number of calories at their customers. By design and effect, the regulation discourages customers from buying the food of the targeted restaurants and drowns out the other health messages that some restaurants had been conveying.

**A. The Regulation Is Subject to Traditional Scrutiny for Regulation of Commercial Speech Under the First Amendment**

**1. The First Amendment Protects Commercial Speakers and Not Just Listeners**

According to the Board, the First Amendment’s protection of commercial speech exists only to expand the flow of information to consumers. Br. 29, 41-42. That is not correct. The right to be free of compelled speech—even compelled commercial speech—is a personal freedom, and its loss is irreparable. In *International Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996), this Court recognized the personal nature of the right of companies not to be subject to a labeling law compelling a disclosure with which they disagreed: “The wrong done by the labeling law to the dairy manufacturers’ constitutional right *not* to speak is a serious one that was not given proper weight by the district court.\* \* \* [The

manufacturers’] compelled speech ‘contravene[s] core First Amendment values,’ \* \* \* [T]he [labeling] statute at hand unquestionably implicates the dairy manufacturers’ speech rights....” 92 F.3d at 71, 72.

This Court’s holding in *International Dairy* comports with the rationale of the Supreme Court’s commercial speech cases cited in our opening brief. Br. 45-46 (*United States v. United Foods, Inc.*, 533 U.S. 405, 410 (2001); *Edenfield v. Fane*, 507 U.S. 761, 767 (1993); and *Glickman v. Wileman Bros. & Elliott, Inc.*, 521 U.S. 457, 489-90 (1997) (Souter, J., dissenting)); *see generally* Congressional Research Service, *Constitution of the United States of America: Analysis & Interpretation* 1176-85 (2004) (discussing cases protecting the commercial speech rights of advertisers).

## **2. The Cases Support NYSRA**

The Board’s regulation is designed to intrude directly on speech by forcing a targeted group of vendors to make statements to their customers that are intended to discourage the customers from buying the targeted vendors’ products. It does not seem too much to ask that the Board defend its right to force speech in this way by satisfying the burden of proof required to survive scrutiny under traditional commercial speech doctrine. Because the parties have expressed divergent views of the applicable cases, it is useful to review the cases as they developed.

### **a. *Central Hudson* (1980)**

The seminal commercial speech case is *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of New York*, 447 U.S. 557, 564 (1980). The Board argues that the case only applies when the government has “restricted” commercial

speech. Br. 26-27. But the Court announced a rule covering both “suppression” and “regulation” of commercial speech:

The First Amendment...protects commercial speech from unwarranted governmental regulation. Commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information. In applying the First Amendment to this area, we have rejected the “highly paternalistic” view that government has complete power to suppress or regulate commercial speech.

447 U.S. at 561-62 (citation omitted; emphasis supplied).

When the Court announced the applicable legal standard to govern future cases, it did not limit its standard to laws that “suppress” speech:

In commercial speech cases, then, a four-part analysis has developed. At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask 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 (emphasis supplied).

**b. *Zauderer* (1985)**

The Board relies on *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985). The Board contends that *Zauderer* “developed an analytical framework when a governmental regulation ‘compels’ truthful disclosure of purely factual, non-opinion, non-political, nonideological

information to the consumer.” Br. 27. But *Zauderer* began its analysis by reiterating the *Central Hudson* standard, not departing from it:

The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading.... Commercial speech that is not false or deceptive and does not concern unlawful activities, however, may be restricted only in the service of a substantial governmental interest, and only through means that directly advance that interest.

471 U.S. at 638 (citing *Central Hudson*). Although the Court struck down most of the attorney-advertising regulations at issue in the case, it did uphold a rule forbidding advertisements that promised “no legal fees” without the additional disclosure that “significant litigation costs” of bringing the lawsuit would be owed no matter what. *Id.* at 650. The Court held that the possibility of deception by such advertising was “self-evident.” *Id.* at 652. Therefore, the Court upheld the regulation without requiring actual evidentiary proof of its effectiveness. *Id.* at 652-53.

The Board suggests that this means that *all* “disclosure requirements” are entitled to only minimal First Amendment protections, no matter the reason for the state’s regulation. The Court held no such thing: “We do not suggest that disclosure requirements do not implicate the advertiser’s First Amendment Rights at all.” *Id.* at 651. Rather, “we hold that an advertiser’s rights are adequately protected as long as disclosure requirements are reasonably related to the State’s interest in preventing deception of consumers.” *Id.* (emphasis supplied).

This aspect of *Zauderer* derives directly from the *absence* of First

Amendment protection for misleading and deceptive commercial speech—just as obscenity, fighting words, and statements necessary to commit crimes do not merit constitutional protection. *See R.A.V. v. City of St. Paul*, 505 U.S. 377, 389 (1992). The Court pointed to the absence of First Amendment protection for misleading commercial speech in both *Central Hudson* and in *Zauderer* itself.

The Board offers no response to this point other than to say that its regulation is aimed at correcting “distorted” consumer “perceptions.” Br. 34. In the district court, the Board conceded that menus without calories listed are not misleading speech.<sup>10</sup> That concession was correct. A menu saying “Hamburger, \$1.99” is not misleading or deceptive in any way. Such transactions have been commonplace since the beginning of commercial food establishments without any suggestion that the purchasers of the food were being deceived because they did not know the specific number of calories in the food.

**c. *International Dairy* (1996)**

In *International Dairy*, this Court applied *Central Hudson* to a law that compelled the labeling of dairy products to disclose the use of rBST growth hormone to treat cows that produced the milk. 92 F.3d at 69, 74. In evaluating the labeling law, the court held that:

Under *Central Hudson*, we must determine: (1) whether the expression concerns lawful activity and is not misleading; (2) whether the government’s interest is substantial; (3) whether

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<sup>10</sup> Def. Mem. in Opp., p. 27 (2/8/2008) (“There is no dispute as to the first two prongs [of *Central Hudson*]”).

the labeling law directly serves the asserted interest; and (4) whether the labeling law is no more extensive than necessary. Furthermore, the State of Vermont bears the burden of justifying its labeling law.

92 F.3d at 72 (citing *Central Hudson*). The court struck down the law because it failed the second prong of the *Central Hudson* test. *Id.* at 73.

According to the Board, the rule of *International Dairy* is that *Central Hudson* applies only to laws failing its second prong. Br. 31. Nothing in *International Dairy* itself suggests such a limitation. Nor would such a limitation make sense. Why have a rule that says the four-part test applies only to laws that fail part two of the test?

**d. *United Foods* (2001)**

By the time the Supreme Court decided *United States v. United Foods, Inc.*, 533 U.S. 405 (2001), four members of the Court had expressed the view that “*Zauderer* carries no authority for a mandate unrelated to the interest in avoiding misleading or incomplete commercial messages.”<sup>11</sup> In *United Foods*, a majority of the Court again addressed *Zauderer*, specifically limiting it to laws “preventing deception of consumers” by “misleading” speech. 533 U.S. at 416.

The Board contends that this limitation was really just distinguishing the case on its facts. Br. 31-32. That seems unlikely, as the government (the petitioner

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<sup>11</sup> *Glickman*, 521 U.S. at 491 (Souter, J., dissenting, joined by Rehnquist, C.J., Scalia, and Thomas, J.J.). These Justices noted that the Solicitor General had not relied on *Zauderer*. *Id.* at 490. Similarly, the majority opinion did not rely on (or cite) *Zauderer* in that case.

in that case) did not even cite *Zauderer* or otherwise argue its applicability.<sup>12</sup> As one commentator put it following *United Foods*, “[w]hile the *Zauderer* test could have potentially raised some interesting questions regarding the application of *Central Hudson*, the Court has limited the *Zauderer* test to cases involving misleading advertising.”<sup>13</sup>

e. ***NEMA v. Sorrell* (2001)**

The Board relies on *National Electric Manufacturers Ass’n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001) (“*Sorrell*”). *Sorrell* was principally a Commerce Clause challenge to a regulation that required manufacturers of mercury-containing lamps to etch the symbol “Hg” onto their bulbs. But the manufacturers included a First Amendment challenge to a requirement that the packaging contain the following statement: “‘If Purchased in Vermont—Don’t Put in Trash—Recycle or Dispose of as Hazardous Waste.’” *National Elec. Mfs. Ass’n v. Sorrell*, 72 F. Supp. 2d 449, 453 (D. Vt. 1999), *vacated & remanded*, 272 F.3d 104 (2d Cir. 2001). This Court found that these statements did not pose a “risk that the state is forcing speakers to adopt disagreeable state-sanctioned positions.” 272 F.3d at 114.

On the facts, this case is akin to *International Dairy*, not *Sorrell*. In *International Dairy*, this court struck down a law that the plaintiffs argued “compel[led] them ‘to convey a message regarding the significance of rBST use

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<sup>12</sup> Brief for the United States in No. 00-276.

<sup>13</sup> Emily Buchanan Buckles, *Food Fights in the Courts: The Odd Combination of Agriculture and First Amendment Rights*, 43 Hous. L. Rev. 415, 435 (2006).

that is “expressly contrary” to their views.”” *International Dairy*, 92 F.3d at 71-72. Like *International Dairy*, this case is a food labeling case in which the plaintiff’s members disagree with the significance of the facts they are being forced to feature prominently in their labeling. Here, the regulation turns the commercial speech of plaintiffs’ members into a health message that the restaurants do not want to deliver and that conflicts with their own health messages. *See* Br. 3-4.<sup>14</sup> Here, as in *International Dairy*, the state cannot satisfy *Central Hudson*. In contrast, the plaintiff in *Sorrell* made no assertion that the state had forced its members “to adopt disagreeable state-sanctioned positions,” and the state vigorously argued that it satisfied *Central Hudson*.

Of course, it is not the facts of *Sorrell* that interest the Board; it is the language used by the court when it discussed *Zauderer*. But *Sorrell* does not discuss the limitation of *Zauderer* by the Supreme Court in *United Foods*. This is understandable. Although this court decided *Sorrell* three months after the Supreme Court decided *United Foods*, the parties had briefed and argued *Sorrell*

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<sup>14</sup> Plaintiffs’ members are not alone in believing that calories should be viewed in context. When the FDA promulgated labeling requirements in 1973, it stated: “when...a claim or information with respect to nutritional properties of a food is included in labeling or advertising, e.g.,...the caloric or fat content of a food,...the full nutrition labeling established in this regulation must be utilized. Only by having available the full nutrition labeling for a food...can such a claim or information be evaluated and understood and the food properly used in the diet. Without full nutrition labeling such claims or information would be confusing and misleading for lack of completeness and could deceive consumers about the true nutritional value of the food, its overall nutritional contribution to the daily diet, and its nutritional weaknesses as well as strengths.” 38 Fed. Reg. at 2125 (1973).

many months before *United Foods* came out. Our investigation indicates that the parties did not bring *United Foods* to the attention of this court. In these circumstances, this court does not appear to have addressed whether *United Foods* limited *Zauderer*.<sup>15</sup>

**B. The Board Cannot Prevail Under *Central Hudson* or *United Foods***

The Board virtually concedes that it cannot meet the standard set out in *Central Hudson*, devoting the vast majority of its First Amendment argument to the proposition that it need not meet this traditional level of scrutiny.

**1. The Board Makes No Effort to Demonstrate that Regulation 81.50 Is “Narrowly Tailored to Achieve the Desired Objective”**

*Central Hudson* requires the Board to prove that Regulation 81.50 is

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<sup>15</sup> Cases from other jurisdictions do not support departing from *Central Hudson*. In *Entertainment Software Ass’n v. Blagojevich*, 469 F.3d 641, 653 (7th Cir. 2006), the court struck down the “disclosure” law because it compelled speech. *Pharmaceutical Care Management Ass’n v. Rowe*, 429 F.3d 294, 310 (1st Cir. 2005), involved misleading speech: the court held that the regulation was “‘reasonably related’ to Maine’s interest in preventing deception of consumers.” *Environmental Defense Center, Inc. v. EPA*, 344 F.3d 832, 848-51 (9th Cir. 2003), did not involve commercial speech at all—it concerned EPA regulations that required municipalities to educate the public about safe disposal of toxins. Finally, in *European Connections & Tours, Inc. v. Gonzalez*, 480 F. Supp. 2d 1355 (N.D. Ga. 2007), the court upheld a federal statute that imposes reporting requirements on men convicted of human trafficking and child abuse, to protect women from being lured to the United States as sex slaves. The court held that this reporting requirement does not regulate commercial speech at all, and then went on to hold that the statute passed muster under every form of First Amendment scrutiny. *Id.* at 1370-71 & n.7.

narrowly tailored to achieve a reasonable fit between the regulation and its stated purpose in reducing obesity in New York City. The Board does not attempt to make such a showing. Instead, it argues that “posting calories at the point of purchase would be the most effective way of getting this information to the consumer.” Br. 54-55 (emphasis supplied). The Board does not explain why “posting” “at the point of purchase” is narrowly tailored to achieve its objective. But even taking the Board at its word, the Board simply ignores alternatives “at the point of purchase” that would be less burdensome to restaurants’ speech. NYSRA members specifically proposed several “point of purchase” options to the Board, such as counter mats, table tents, stanchions, brochures, and posters, all of which the Board rejected. JA-347-48, 376-77, 402-03.

**2. The Board Fails to Demonstrate that Regulation 81.50 Will Reduce Obesity in a “Direct and Material Way”**

*Central Hudson* requires the Board to prove that Regulation 81.50 advances its interest in combating obesity among New Yorkers in a “direct and material way.” *Edenfield*, 507 U.S. at 767. In our opening brief, we showed that there is a complete absence of scientific evidence of any kind supporting the conclusion that requiring restaurants to make statements of the amount of calories on their menus would reduce obesity in New York City, or even that it would decrease caloric intake.

In response, the Board contends that it need not come up with “undisputed” scientific evidence (Br. 51) and offers a series of assertions that admittedly do not prove that Regulation 81.50 will be effective—that obesity is an important public

health issue, that obese people eat out often, and that people generally do not know off the tops of their heads the number of calories in a given plate of food. The Board also submitted declarations expressing the opinion that Regulation 81.50 “might” or “could” be helpful.<sup>16</sup> These assertions are no substitute for evidence that Regulation 81.50 will, in fact, contribute in the slightest way to reducing obesity in New York City or even reducing the number of calories eaten in a year, a month, a week, or even a single day.

Principally, the Board relies on a survey it conducted in anticipation of Regulation 81.50. Dr. Allison’s critique of that “study” (JA-1185) was echoed by the editor of a respected public health journal published by the Centers for Disease Control: “In my mind, it is not possible to conclude that looking at the caloric info is causally related to reduced calorie purchase.” JA-1360.<sup>17</sup>

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<sup>16</sup>JA-717 (“could be helpful”); JA-720 (“might contribute”); JA-715 (“may help”); JA-1131 (“might contribute”). These statements are consistent with Dr. Allison’s conclusion that the evidence makes it reasonable to “conjecture” that the regulation might or might not have the desired effect. The Board’s claim (Br. 51) that Dr. Allison admits that Regulation 81.50 is “reasonable” is simply incorrect. *See* Allison Decl. at 4-5 (JA 29-30).

<sup>17</sup> The published studies on calorie labeling cited by San Francisco (Br. 17-18) and the Rudd Center (Br. 23) do not even purport to show weight loss due to calorie posting, as Dr. Allison pointed out in his declaration. JA-41-47. These *amici* now offer new “studies,” each of which is *dehors* the record, and each of which has been “published” recently on the internet rather than in peer-reviewed journals.

The “study” cited by San Francisco (Br. 18) refers to “*potential*” effects of the mandatory labeling, and states that its findings suggest that labeling “*could* have a sizable salutary impact.” Dated May 2008, it states that “no studies to our knowledge have sought to quantify the potential impact of this strategy on the [obesity] epidemic.” That is just what Dr. Allison pointed out. The internet study

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The Board also relies on selective quotations from the Keystone Report, attempting to create the misimpression that the Keystone Report provides scientific support for requiring calories to be listed on menus. It does not. The Keystone Report states that there are “pros” and “cons” to providing information on menus. According to the Keystone Report, there is no consensus whatsoever on what format is best (JA-1073), and available scientific information is “limited” (JA-1061), with “a clear need for more research” (JA-1075).

Finally, the Board invokes “common sense” and “consensus.” For the proposition that “common sense” and “consensus” might be enough, the Board cites *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001). But the *Lorillard*

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then purports to “address this gap” with a “health impact assessment” of its own. But that assessment suffers from obvious flaws of the kind Dr. Allison discussed in his declaration. For example, it is premised on the assumption that a significant percentage of patrons will reduce their orders by an average of 100 calories per meal—a figure not supported in any published study. In addition, the authors “assumed in the calculations that restaurant patrons who ordered reduced calorie meals would not increase their food and beverage intake at other times of the day.” That is another key, unfounded assumption. As Dr. Allison discussed, the promise offered by strategies to decrease consumption in one setting has often proved illusory as a result of compensation in other settings.

The Rudd Center discusses (Br. 22-23) an internet-posted “working paper” on the impact that the NLEA has had on obesity since its regulations took effect in 1994. *Amici* say that the authors estimate that the law had a positive effect, but fail to note that the finding was limited to one subgroup— non-Hispanic white women, with no positive impact in the population as a whole and some indications of a possible negative effect in other subgroups. The paper notes the evidence that the overall trend toward obesity “accelerated” in the decade following implementation of the law. *See* JA-886.

Court did not look to “common sense” or “consensus.” It looked to evidence. *Id.* at 555-61 (relying on the “numerous studies” conducted and evidence gathered by the government that “demonstrated a link” between “tobacco advertising and trends in the use of various tobacco products”); *accord 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 505 (1996) (“We can agree that common sense supports the conclusion that a prohibition against price advertising...will tend to mitigate competition and maintain prices at a higher level than would prevail in a completely free market.... However, without any findings of fact, or indeed any evidentiary support whatsoever, we cannot agree with the assertion that the price advertising ban will significantly advance the State’s interest in promoting temperance.”); *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 626-27 (1995) (relying on the “breadth and detail” of studies with statistical data in support of the government’s regulation); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487-88 (1995) (rejecting government’s arguments based on “common sense” and history, and finding that the statute “cannot directly and materially advance [the government’s] asserted interest”); *Edenfield*, 507 U.S. at 771 (the state “present[ed] no studies that suggest personal solicitation of prospective business clients by CPAs creates the dangers of fraud, overreaching, or compromised independence that the Board claims to fear”).

### **3. Regulation 81.50 Unconstitutionally Compels Speech**

The Board does not deny that if this case is treated under *United Foods*, the regulation cannot survive. The Board argues that this is not a compelled speech case “because plaintiff is not being compelled to state a viewpoint with which it

disagrees.” Br. 27. That is incorrect. Not only are the restaurants being required to change their commercial message into a health message, they are being required to do so in a way that drowns out and contradicts the health messages these restaurants already communicate.

#### **4. This Case Does Not Threaten Consumer Protection Laws**

The Board and its *amici* contend that “literally thousands” of disclosure statutes and regulations will be jeopardized if this Court continues to apply the law of the land embodied in *Central Hudson*. The Court should not credit this alarmism. For example, when the FDA promulgated its recent regulation requiring disclosure of trans-fatty acids in nutrition labeling, it concluded that the regulation would survive First Amendment scrutiny under any applicable standard of review, including *Central Hudson*. 68 Fed. Reg. 41434, 41439-40 (2003).

The Board and its *amici* cite laws that (a) are directed toward preventing deceptive speech in commercial transactions,<sup>18</sup> (b) do not concern commercial speech at all,<sup>19</sup> or (c) survive review under *Central Hudson*.<sup>20</sup>

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<sup>18</sup> See, e.g., 15 U.S.C. § 78l (registration requirements for securities, including anti-fraud disclosures); 21 C.F.R. § 202.1 (regulating drug advertisements to protect consumers from confusing or misleading advertisements); 15 U.S.C. §§ 68-68j (requiring labeling of wool products’ actual content, so as to “protect consumers against the concealment of substitutes for wool in products claimed to be made wholly or partially of wool” (*Marcus v. FTC*, 354 F.2d 85, 87 (2d Cir. 1965))).

<sup>19</sup> See, e.g., 33 U.S.C. § 1318 (preparation and filing of point source pollution discharge reports); 42 U.S.C. § 11023 (preparation and filing toxic chemical release reports); 29 C.F.R. § 1910.1200 (employer notifications of workplace chemical hazards); N.Y. E.C.L. § 33-0707 (submission of pesticide formulas to state commissioner).

Regulation 81.50 is easily distinguishable from these examples. *First*, the commercial speech at issue here is not misleading. *Second*, the Board confuses commercial “disclosure” requirements with “reporting” requirements (*e.g.*, accident reports by common carriers and environmental spill reporting). Reporting requirements do not propose a commercial transaction, and thus are not subject to First Amendment scrutiny applicable to commercial speech. *Third*, there is no reason to suspect that *Central Hudson* would be the death knell for state and federal laws requiring warnings about products that the government has determined, after extensive study, to be inherently dangerous, such as cigarettes, pesticides, pollutants, prescription medications, power tools, heavy metals, undercooked meats, and alcohol. Such laws have proven robust in the three decades that *Central Hudson* has been the law of the land.

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<sup>20</sup> 15 U.S.C. § 1333 (cigarette labeling) (*cf. Lorillard*, 533 U.S. 525); Cal. Health & Safety Code § 25249.6 (warnings to persons who will be intentionally exposed to carcinogens).

## CONCLUSION

The district court's order should be reversed. This Court should enjoin Regulation 81.50.

May 23, 2008

Respectfully submitted,

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

I hereby certify that the foregoing Brief for the Appellants, excluding the corporate disclosure statement, table of contents, table of authorities, signature block, and this certificate, contains 9,472 words, according to the Word Count feature in Microsoft Word.

/s/ Kent A. Yalowitz

Kent A. Yalowitz

## ANTI-VIRUS CERTIFICATION

Case Name: NYS Restaurant v. NYC Board of Health

Docket Number: 08-1892-cv

I, Jacqueline Gordon, hereby certify that the Reply Brief submitted in PDF form as an e-mail attachment to **briefs@ca2.uscourts.gov** in the above referenced case, was scanned using CA Software Anti-Virus Release 8.3.02 (with updated virus definition file as of 5/23/2008) and found to be VIRUS FREE.

/s/ Jacqueline Gordon

Jacqueline Gordon  
*Record Press, Inc.*

Dated: May 23, 2008