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SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK

NATIONAL RESTAURANT ASSOCIATION,

Plaintiff-Petitioner,

-against-

THE NEW YORK CITY DEPARTMENT OF HEALTH & MENTAL HYGIENE, THE NEW YORK CITY BOARD OF HEALTH, and DR. MARY TRAVIS BASSETT, in her Official Capacity as Commissioner of the New York City Department of Health & Mental Hygiene,

Index No. 654024/15

Defendants-Respondents.

DEFENDANTS-RESPONDENTS' MEMORANDUM OF LAW
IN OPPOSITION TO THE PETITION

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Defendants-Respondents the New York City Department of Health and Mental Hygiene ("DOH"), the New York City Board of Health ("Board") and Dr. Mary Travis Bassett, the DOH Commissioner (collectively "respondents"), by their attorney, Zachary W. Carter, Corporation Counsel of the City of New York, submit this memorandum of law in opposition to the Petition that seeks to invalidate New York City Health Code § 81.49 ("Section 81.49").

PRELIMINARY STATEMENT

Each year thousands of New Yorkers lose their lives to cardiovascular disease. A major risk factor for cardiovascular disease is high blood pressure, and there is a direct correlation between the consumption of sodium and high blood pressure: typically, the more sodium people consume, the higher their blood pressure. Consequently, the United States government recommends that Americans limit their daily sodium consumption to less than 2300 milligrams. New Yorkers nevertheless consume excessive amounts of sodium, on average more than 900 milligrams above the federal government's recommended daily limit. Food served in chain restaurants — which account for one third of all restaurant traffic in the New York City metropolitan area — contains very high levels of sodium. Customers typically underestimate the sodium content of chain restaurant food, which is not remarkable given that similar menu items (such as sandwiches) can contain a wide range of sodium. To address this epidemic of sodium overconsumption, the Board adopted Section 81.49 which requires chain restaurants to identify menu items that contain more than the federal recommended daily limit, and warn customers about the health risks associated with high sodium intake.

¹ Besides the DOH Commissioner, the Board is comprised of ten public health professionals who serve staggered six year terms; contrary to the NRA's assertion (Pet. ¶ 16), the ten Board members do not serve at the pleasure of the Mayor, but rather can only be removed for cause. New York City Charter ("Charter") ¶¶ 553(a) & 554.

Petitioner, the National Restaurant Association ("NRA"), does not want its chain restaurant members to have to warn their customers about menu items that contain more sodium than a person should consume in an entire day. The NRA starts by relying on an overly broad reading of NY Statewide Coalition of Hispanic Chambers of Commerce v. NYC Dep't of Health & Mental Hygiene, 23 N.Y.3d 681 (2014) ("Statewide Coalition") -- which addressed a different Health Code provision -- to argue that the Board cannot require this warning. This proceeding. however, is not Statewide Coalition. In deciding there that the Board had overstepped its authority by limiting the cup size of sugary drinks, the Court of Appeals went out of its way to note that the Board was still authorized to require posted warnings because they do not infringe on personal autonomy, and thus requiring them does not constitute forbidden policy making. Notably, Section 81.49 did not generate the public outcry that the sugary drink regulation did.² Indeed, the public generally supports it, and even some affected restaurants support it (and have complied with it with apparently no adverse consequences). In an attempt to create a controversy, the NRA submits flawed evidence to try to "debunk" the "great weight of evidence" considered by the federal government when it recommended its daily sodium intake limit and by the Board when it required chain restaurants to warn of food items that exceed it. The NRA's flawed evidence is addressed and rebutted in detail in the affidavits of DOH Commissioner Mary Bassett and Dr. Lawrence Appel attached as Exhibits A and B to the Answer submitted herewith.

The NRA next asserts a CPLR Article 78 claim alleging that the Board's adoption of Section 81.49 was arbitrary and capricious. But the record before the Board conclusively establishes that it had a rational basis to adopt Section 81.49. To start, the evidence before the Board showed that sodium intake was directly linked to high blood pressure, that New Yorkers

² Less than a hundred commented about Section 81.49, and only four of those opposed the regulation. Answer ¶ 93. In stark contrast, more than 38,000 commented about the sugary drink regulation, and tens of thousands signed a petition opposing the regulation. Statewide Coalition, 110 A.D.3d 1, 5 (1st Dep't 2013).

consume sodium in amounts above the federal daily recommended limit, and that individual chain restaurant menu items contain sodium above the daily limit. And the NRA's argument that the sodium warning is under-inclusive because it does not cover all restaurants fails since it is well established that a regulation need not address every facet of a problem.

The NRA also argues that the sodium warning -- which provides factual information -- violates the chain restaurants' First Amendment rights. But well-established precedent, including the Second Circuit's decision rejecting the restaurant industry's similar argument that chain restaurants should not have to post calorie information on menus, hold that such disclosure mandates in purely commercial contexts need only be reasonable. And the sodium warning easily meets the reasonableness standard since it is rationally related to DOH and the Board's interest in protecting public health.

Finally, the NRA argues that the sodium warning is preempted by the federal Nutrition Labeling and Education Act ("NLEA"). That argument fails since the plain language of the NLEA (as well as its legislative history) explicitly provides that state and local governments retain the authority to require warnings such as the sodium warning.

ARGUMENT

I. The NRA's First and Second Causes of Action Fail Because the Board is Authorized to Require Warning Statements.³

The Board did not impermissibly legislate by passing a regulation requiring chain restaurants to identify and warn their customers about "sodium bombs." Rather, the Board properly exercised the broad authority given to it by Charter §§556 and 558 to protect public

³ The NRA argues in its first cause of action that the Board exceeded its delegated rulemaking authority, and in its second that the separation of powers were violated. Pet. ¶¶ 70-85 & 86-91. These arguments overlap and can be considered together. Greater New York Taxi Ass'n v. NYC Taxi & Limousine Comm'n, 25 N.Y.3d 600, 608-09 (2015) ("Greater NY Taxi") (citing Boreali v. Axelrod, 71 N.Y.2d 1, 9 (1987)).

⁴ See http://www.statnews.com/2015/12/24/sodium-diet-high-blood-pressure/.

health, delegations of authority which the Court of Appeal has recognized are valid. See Grossman, 17 N.Y.2d 345, 350 (1966) (upholding delegation of authority in § 558) and Boreali, 71 N.Y.2d at 9 (upholding N.Y. Public Health Law § 225(5) which, similar to Charter § 556, delegated authority to the State Public Health Council to "deal with any matters affecting the ... public health"). Despite the NRA's attempt to argue otherwise, the warning requirement is not equivalent to the sugary drink regulation, which infringed on the public's right to be served large cups of such beverages, and was thus found to be the product of impermissible policy-making. Judge Abdus-Salaam noted, when casting the deciding vote in Statewide Coalition, that "no one should read [that] decision too broadly." 23 N.Y.3d at 702 (Abdus-Salaam concurring). And more recently the Court of Appeals unanimously upheld a regulation based on Charter provisions similar to those at issue here, finding that a City agency, in choosing a particular make and model of car as the "Taxi of Tomorrow," had not "attempted to resolve difficult social problems concerning matters of personal autonomy." Greater NY Taxi, 25 N.Y.3d at 613 (distinguishing Statewide Coalition, 23 N.Y.3d 698-99). Similarly, section 81.49's mandate that chain restaurants warn their customers about menu items containing unhealthy amounts of sodium does not constitute impermissible law-making. Indeed, the Court of Appeals recognized as much in the sugary drink case when it noted that warning requirements fit within the Board's delegated authority because "personal autonomy issues related to the regulation are nonexistent." Statewide Coalition, 23 N.Y.3d at 699.

In evaluating a separation of powers claim, the Court of Appeals recognizes that the line between permissible rule-making and impermissible legislative policy-making admittedly is "hazy." <u>Greater NY Taxi</u>, 25 N.Y.3d at 610. The <u>Boreali</u> court identified four "coalescing circumstances" described below to consider in determining whether "the difficult-to-

determine line between" permissible administrative rule-making and impermissible legislative policy-making had "been transgressed." 71 N.Y.2d at 11. These circumstances are treated "as overlapping, closely related factors." <u>Statewide Coalition</u>, 23 N.Y.3d at 696-97. An analysis of these four factors establishes that the Board's adoption was proper.

a. In Adopting Section 81.49 The Board Did Not Engage in Impermissible Policy Making.

In <u>Boreali</u>, the Court of Appeals reviewed regulations prohibiting smoking that were enacted by the State Public Health Council. The regulations were "laden with exceptions based solely upon economic and social concerns." 71 N.Y.2d at 11. Addressing the first coalescing factor, the <u>Boreali</u> Court noted that the Public Health Council "delicately balanced" the need to protect the public from secondhand smoke "against the goal of minimizing 'economic dislocations and governmental intrusions.'" <u>Id.</u> at 14 (citations omitted). Specifically, the challenged regulation included provisions that had "no foundations in considerations of public health" and were based "solely upon economic and social concerns." The Court concluded that the state agency "built a regulatory scheme on its own conclusions about the appropriate balance of trade-offs between health and cost to particular industries in the private sector" and was thus "operating outside of its proper sphere of authority." <u>Id.</u> at 12.

The NRA incorrectly claims that <u>Boreali</u> stands for the proposition that the first factor prohibits consideration of social and economic concerns. <u>See Pet'r Br.</u>, at 35 ("the regulation impermissibly entails the legislative function of balancing social and economic concerns"). The NRA is wrong as both <u>Statewide Coalition</u> and <u>Greater NY Taxi</u> recognized that the "promulgation of regulations necessarily involves an analysis of societal costs and

⁵ Judge Abdus-Salaam noted that the <u>Boreali</u> test utilizes "a flexible case-specific analysis" to determine if an agency has exercised power that has been delegated to it. 23 N.Y.3d at 701.

benefits." 23 N.Y.3d at 697; 25 N.Y.3d at 610-11. Consequently, <u>Boreali</u> does not prohibit an agency from attempting to balance costs and benefits." 23 N.Y.3d at 697.

Indeed, the Court ruled in <u>Greater NY Taxi</u> that agencies may consider costs and benefits when adopting regulations without crossing the line into impermissible policy making. There, the Court relied on several broad Charter provisions, including one that authorized TLC to set "standards for equipment safety and design," to find that the "choice of the best possible vehicle for use as a taxi plainly fits within the purposes of the TLC to develop and improve taxi service as part of the City's overall public transportation system." <u>Greater NY Taxi</u>, 25 N.Y.3d at 608-09, 611.

Here, the Board adopted Section 81.49 based on Charter provisions strikingly similar to those at issue in Greater NY Taxi. Specifically, the Board "may embrace in the health code all matters and subjects to which the power and authority of [DOH] extends." Charter § 558(c). In turn, DOH "shall have jurisdiction to regulate all matters affecting health in the city of New York and to perform all those functions and operations performed by the city that relate to the health of the people of the city." Charter § 556. The Charter also provides that DOH specifically has the authority to "control ... chronic diseases and conditions hazardous to life and health," as well as to "regulate the food ... supply of the city and other businesses and activities affecting public health in the city, and ensure that such businesses and activities are conducted in a manner consistent with the public interest." Charter 556 § (c)(2) & (9). Clearly, a regulation

⁶ The NRA also contends the Board engaged in improper legislative policy-making by only making chain restaurants subject to Section 81.49. Pet'r Br., at 36. The NRA claims <u>Statewide Coalition</u> supports this assertion, but the language it cites from the Court of Appeals' decision merely describes the Appellate Division's reasoning below. In fact, the Court of Appeals specifically noted that "the limited scope of the sugary drink rule would not in itself demonstrate that it amounted to policymaking." Id. at 698, fn 3.

⁷ The Court also noted that the City agency had the power to "set standards and criteria for the licensing of [taxi] vehicles" and "to adopt and establish an overall public transportation policy governing taxi ... services." <u>Greater NY Taxi</u>, 25 N.Y.3d at 609 (citing Charter § 2300).

requiring that restaurants alert their customers to items high in sodium fits within the purposes of the Board and DOH.

In Statewide Coalition, the Court held that the Board impermissibly engaged in policy-making largely because it found that the sugary drink regulation impinged on personal autonomy. See, e.g., 23 N.Y.3d at 698-99 (contrasting regulations relating to lead paint and window guards that had "minimal interference with the personal autonomy of those whose health is being protected"). See also id. at 698 (the regulation's indirect means was "a policy choice, relating to the degree of autonomy a government permits its citizens to exercise and the ways in which it might seek to modify their behavior indirectly"). In focusing on the regulation's effect on personal autonomy, the Court went on to note that "such policymaking would likely not be implicated in situations where the Board regulates by means of posted warnings." 23 N.Y.3d at 699. The NRA summarily dismisses this language as dicta (Pet'r Br. at 37), without once referencing the Court of Appeals' focus on autonomy. It makes no attempt to explain how the sodium warning might interfere with the commonplace daily activities of its members' customers because it cannot. Section 81.49 does not limit the size of meals based on their sodium content. Nor does Section 81.49 improperly attempt to interfere "with the personal autonomy of those whose health is being protected" since -- unlike the sugary drink regulation -- it does not seek to make it inconvenient to purchase an item loaded with sodium. Rather, Section 81.49 merely requires that chain restaurants alert their costumers to items whose sodium contents exceed the federal recommended daily limit of sodium. As the Court predicted in Statewide Coalition, "personal autonomy issues related to the regulation [requiring "posted warnings"] are nonexistent and economic costs either minimal or clearly outweighed by the benefits to society, so that no policymaking in the Boreali sense is involved." 23 N.Y.3d at 699.

b. Section 81.49 Was Not Written On A Clean Slate.

The <u>Boreali</u> Court held that the PHC "wrote on a clean slate, creating its own comprehensive set of regulations without benefit of legislative guidance." 71 N.Y.2d at 13. Like the statute reviewed in <u>Boreali</u>, the Charter broadly provides the Board with the authority "to regulate all matters affecting health in the city of New York" Charter § 556. It, however, also specifies that the Board's authority extends to the "control of ... chronic diseases hazardous to life and health," such as the cardiovascular diseases, as well as the authority to "regulate the food ... supply of the city." Charter §§ 556(c)(2) & (9).

Based on this authority, the Board has adopted Health Code amendments that address a broad array of public health concerns. For instance, the Board has adopted amendments that set forth nutrition and physical activity requirements for group day care facilities (Health Code § 47.61) and that required landlords to keep gas refrigerators in good order (People v. Weil, 286 A.D. 753 (1st Dep't 1955)). The Board also enacted a water fluoridation initiative for the public water supply (Health Code § 141.05). And the Board has prohibited the use of lead paint (Health Code § 173.13) and required building owners to put window guards in apartments housing children (Health Code § 131.15).

Moreover, the Board has a long and comprehensive history of regulating restaurants, including restricting the use of artificial trans fats (Health Code § 81.08), requiring that all restaurants post their inspection grades (Health Code § 81.51), and -- crucially -- mandating the posting of calorie information by chain restaurants (Health Code § 81.50). In

⁸ Upheld in Paduano v. City of New York, 45 Misc.2d 718 (Sup. Ct. N.Y. Co.), aff'd on op. below, 24 A.D.2d 437 (1st Dep't 1965), aff'd, 17 N.Y.2d 875 (1966), cert. denied, 385 U.S. 1026 (1967).

⁹ Health Code § 81.50 was upheld by the Second Circuit. NYS Rest. Ass'n v. NYC Bd. of Health, 556 F.3d 114 (2^d Cir. 2009) ("NYSRA II").

fact, DOH has regulated the City's restaurants for decades (Ex. A, at 2), and the DOH Commissioner is designated as the permit-issuing official for the City's restaurants (formally known as food service establishments). 10 N.Y.C.R.R. § 14-1.190. The extensive involvement of the Board in a wide array of public health matters is analogous to the situation in <u>Greater NY Taxi</u>, where the Court of Appeals held that the "TLC was not writing on a clean slate in the sense that it has always regulated the taxi industry as to almost every detail of operation." 25 N.Y.3d at 611.

Enabling "legislation need not be detailed or precise as to the agency's role. See Greater NY Taxi, 25 N.Y.3d at 609 Legislation that broadly grants rulemaking authority has repeatedly been upheld by the Courts. See id. at 608-09 (upholding regulation based on Charter's broad grant of authority to agency). See also NYS Health Facilities Ass'n v. Axelrod, 77 N.Y.2d 340, 348 (1991) (upholding regulation based on Medicaid statutory provisions that declared that medical assistance for needy persons was a public concern and a goal); Pet Professionals v. City of New York, 215 A.D.2d 742, 743 (2nd Dep't 1995) (Health Code provisions upheld since the Board "was merely filling in the details of broad legislation describing the over-all policy to be implemented").

The NRA claims that <u>Statewide Coalition</u> precludes the Board's from relying on Charter §§ 556 and 558. To support its argument, the NRA relies on the trial court and Appellate Division decisions in <u>Statewide Coalition</u> (which limited their analysis to the issue in dispute). Pet'r Br., at 29. While it cites once to the Court of Appeal's decision, that cite is to the first part of the decision, holding that the Board is not a legislative body, ¹⁰ and not to the Court's <u>Boreali</u> analysis, where the Court of Appeals did not adopt the reasoning of the lower courts. Rather, the

¹⁰ The Board unsuccessfully argued that it could legislate. 23 N.Y.3d at 694. It is not making that argument here.

Court of Appeals analyzed this prong in a similar fashion to its analysis of the first prong, ruling that "[d]evising an entirely new rule that significantly changes the manner in which sugary beverages are provided to customers at eating establishments is not an auxiliary selection of means to an end," and thus the Board went beyond its statutory authority. 23 N.Y.3d at 700.

In stark contrast to <u>Statewide Coalition</u>, Section 81.49 does not significantly alter the way that high sodium menu items are provided to customers. It merely requires that chain restaurants warn their customers of the fact that a particular menu item is higher than the federal daily recommended limit, and the risks associated with high sodium intake.

c. Proposed Legislation Does Not Preclude The Adoption Of Section 81.49.

In <u>Boreali</u>, the Legislature repeatedly failed to amend its anti-smoking law (more than 40 bills were introduced), prompting the state agency to attempt to do so on its own. 71 N.Y.2d at 7, 13. As the First Department has noted, the <u>Boreali</u> Court "had in mind [this] type of extensive and repeated [legislative] considerations" and that it could "not have intended to invalidate a regulation merely because the Legislature had ... considered the same subject matter." <u>Festa v. Leshen</u>, 145 A.D.2d 49, 63 (1st Dep't 1989).

In stark contrast, here the NRA cites to only four bills, three of which are substantively distinct from Section 81.49. Each of the cited bills was merely introduced in one house of the State Legislature by one legislator, and received no further consideration. Moreover, the one bill that was substantively similar to Section 81.49, Assembly bill number 8266 for the year 2015, would specifically not apply to restaurants

¹¹ See, e.g., NYC C.L.A.S.H., Inc. v. NYS Office of Parks, Recreation & Historic Preservation, 125 A.D.3d 105, 111-12 (3rd Dep't 2014), leave to appeal denied, 25 N.Y.3d 963 (2015) (while several bills relating to the same subject as the challenged regulation had been introduced "most died in committee;" Court was 'not persuaded that these failed bills are enough to warrant the conclusion that [the agency] has exceeded its authority"); Agencies for Children's Therapy Services, Inc. v. NYS Dep't of Health, 2015 N.Y. App. Div. Lexis 9650, *14-15 (2nd Dep't Dec. 30, 2015) (three unsuccessful bills "does not ... warrant conclusion that DOH exceeded its authority in promulgating" regulation).

covered by the Board's regulation, in explicit recognition of the Board's authority to enact Section 81.49.¹²

Legislative inaction is not indicative of legislative intent. Thus, the fact of later legislative action or inaction after the "original enabling statute" should be "irrelevant" since the "City either did or did not have the authority to" enact the challenged regulation. Expedia, Inc. v. City of New York Dep't of Fin., 22 N.Y.3d 121, 128 (2013). The authority of the Board of Health as established by the Charter similarly should not turn upon the vagaries of legislative disputes that post-date the enactment of the pertinent Charter provisions.

d. The Board Relied On Its Specialized Expertise In Public Health In Determining The Scope of Section 81.49.

The fourth consideration cited by the <u>Boreali</u> Court concerned the lack of "special expertise or technical competence" required in drafting the antismoking regulations enacted by the PHC. 71 N.Y.2d at 13-14. The Board, however, used its public health expertise when it adopted Section 81.49. It considered the evidence that showed that chain restaurants accounted for a significant percentage of all restaurant meals, and that a percentage of those meals (as well as individual menu items) contained levels of sodium that exceeded the federal daily recommended limit of 2,300 milligrams of sodium. Ex. L, at 2 (Notice of Adoption). ¹⁴ Moreover, both during the public comment period and now, the NRA has questioned the body of

¹² The three other bills were each introduced once during previous legislative sessions; as noted, these bills never received further legislative action nor were any of these bills reintroduced in subsequent legislative sessions. In 2009, Senate bill 2824 proposed to prohibit chain restaurants across the State from using trans fats in preparing foods and required the posting of nutritional information including, calories, fat and sodium content. In 2011, Senate bill 2608 proposed to require sodium content information and warnings on pre-packaged food sold in retail stores, specifically not applying to restaurants and food sold for consumption on premises. In 2013, Senate bill 2971 proposed to prohibit any restaurant in the State from using salt in preparing any foods.

¹³ See, e.g., Rent Stabilization Ass'n v. Higgins, 83 N.Y.2d 156, 170 (1993), cert. denied, 512 U.S. 1213 (1994) (Court rejected the argument that 27 "failed bills alone warrant the conclusion that the agency has exceeded its mandate").

¹⁴ All Exhibits referenced herein are annexed to Respondents' Verified Answer.

science upon which the federal government based its recommended daily limit as well as that establishing the risks associated with excess sodium consumption. See Pet'r Br., at 18-21 & Ex. J, at 4-5 (Board memorandum). While the NRA may not agree with the result, the Board clearly exercised its expertise in rejecting the scientific arguments they raised.

In sum, the <u>Boreali</u> circumstances, considered as a whole, strongly demonstrate that Section 81.49 is an appropriate exercise of the Board's authority.

II. The NRA's Third Cause of Action Fails Because Section 81.49 is Reasonable and Not Arbitrary or Capricious.

Administrative agencies enjoy broad discretionary power when making determinations on matters they are empowered to decide. CPLR § 7803 provides for very limited judicial review of administrative actions and states, in pertinent part: "The only questions that may be raised in a proceeding under this article are ... (3) whether a determination ... was arbitrary and capricious or an abuse of discretion." The arbitrary and capricious standard is not a demanding one. It requires only that the administrative agency determination be reasonable and supported by the record taken as a whole. Pell v. Bd. of Educ., 34 N.Y.2d 222, 231 (1974). A court "may not substitute its own judgment of the evidence for that of the administrative agency, but should review the whole record to determine whether there exists a rational basis to support the findings upon which the agency's determination is predicated." Purdy v. Kreisberg, 47 N.Y.2d 354, 358 (1979). If the record supports the acts of the administrative agency, then its determination is conclusive. Cohen v. State of New York, 2 A.D.3d 522, 525 (2nd Dep't 2003).

Moreover, agencies are presumed to have developed an expertise and judgment that requires the courts to accept the agency judgment if not unreasonable. <u>Lynbrook v. N.Y.</u>

<u>State Pub. Employment Relations Bd.</u>, 48 N.Y.2d 398, 404 (1979). When matters of specialized knowledge or judgment are entrusted to an agency – such as the Board of Health – the Court may

not substitute its own judgment. Antell v. Bd. of Educ., 21 Misc. 2d 119, 125, (Sup. Ct. N.Y. Co. 1959), aff'd, 10 A.D.2d 699 (1st Dep't 1960). A "presumption of regularity attends to the action of the [agency], and it is incumbent upon the petitioner to overcome that presumption and establish the action to have been without reasonable foundation." Kayfield Constr. Corp. v. Morris, 15 A.D.2d 373, 379 (1st Dep't 1962).

The record considered by the Board – including the original proposal, the comments both made at the public hearing and submitted to the DOH, DOH's summary and response to these comments, and the notice of adoption – establishes that the Board's adoption of Section 81.49 had a rational basis, and was not unreasonable, arbitrary or capricious.

Section 81.49 addresses the leading cause of death in New York City, cardiovascular disease, which claimed nearly 17,000 lives in 2013. Ex. L, at 1. It is well established that high blood pressure is a major risk factor for cardiovascular disease, and according to a 2013 survey, nearly 30 percent of adults in the City had been diagnosed by a healthcare professional with high blood pressure. Id. High blood pressure, however, is a modifiable risk than can be addressed to prolong and improve thousands of lives. See Ex. A, at ¶ 8, 11; Ex. B, at ¶ 14.

It is also well established that there is direct link between sodium intake and high blood pressure: typically, the more sodium people consume, the higher their blood pressure. As such, 2,300 milligrams of sodium is the daily limit recommended by the federal government in the 2010 Dietary Guidelines for Americans. Ex. C, at 21, 24. However, the evidence before the Board established that New Yorkers consume excessive amounts of sodium. A 2010 study found that the average daily sodium intake among New Yorkers was more than 3,200 milligrams, well above the daily recommended limit. Ex. L, at 1.

Restaurant food plays a significant role in sodium overconsumption. Today, nearly one-third of the sodium consumed by Americans comes from restaurant food, and the sodium content in food offered at fast food chains has been on the rise. Ex. L, at 2. Additionally, a 2014 study "analyzing the nutritional profile of more than 2,500 items from chain restaurants ... found that adult meals contained an average of 3,512 milligrams of sodium." Id.

Another factor contributing to this overconsumption of sodium is consumer unawareness of the health risks posed by excess sodium intake. Consumers generally underestimate the amount of sodium that is present in restaurant food. In particular, consumers may be unaware that even menu items that appear or are touted as "healthy" options may actually contain high levels of sodium, or that similar food items may contain disparate levels of sodium due to differences in formulation. <u>Id.</u>

The NRA argues that Section 81.49 is invalid because it is under-inclusive. Pet. ¶ 101. However, it is well established that regulations do not have to address every facet of a problem. See, e.g., NYS Health Facilities Ass'n, 77 N.Y.2d 340, 350 (1991) (regulations not irrational even though they only required new nursing homes to admit a certain percentage of Medicaid patients). The record before the Board sets forth the rationale for applying Section 81.49 to chain restaurants. As noted in DOH's September 2, 2015 memorandum to the Board summarizing the comments received about the proposed regulation, chain restaurants serve a significant share of meals in the City, and these meals contain high levels of sodium. Ex. J, at 3-4. Evidence indicates that in 2007, "major chain restaurants in the New York City metropolitan area accounted for more than one-third of all restaurant traffic." Id. Other evidence indicates that an estimated ten percent of menu items at chain restaurants contain at least 2,300 milligrams

¹⁵ See also NYC C.L.A.S.H., 125 A.D.3d at 111-12 (arbitrary and capricious claim rejected where state agency had a rational basis in adopting regulation prohibiting smoking in state parks within New York City while permitting smoking in certain areas of state parks outside of the City).

of sodium, and that chain restaurant meals¹⁶ contain sodium well in excess of the daily recommended limit. Id.

The record before the Board establishes a reasonable basis to adopt Section 81.49: excessive sodium consumption is associated with high blood pressure, a major risk factor for cardiovascular disease, which is why the federal government recommends that Americans consume no more than 2,300 milligrams of sodium per day. See Ex. C, at 21, 24. Section 81.49 simply informs and warns consumers about menu items that contain more than this amount.

- III. The NRA's Fourth Cause of Action Fails Because Section 81.49 Reasonably Requires Chain Restaurants to Inform and Warn Customers about Menu Items Containing More Sodium that the Daily Recommended Limit and Thus Does Not Violate the First Amendment.
 - a. The Proper Analytical Framework Applicable to Section 81.49 is the Zauderer "Reasonableness" Standard.

The sodium warning merely provides consumers with factual information. It is a matter of fact that the federal government recommends 2,300 milligrams as the daily limit of sodium consumption. Ex. C, at 21, 24. Whether a specific food item contains at least this amount of sodium is also a matter of fact. And it is well established that high sodium intake can increase blood pressure and the risk of cardiovascular disease. The requirement to post such information is no different from numerous other disclosure requirements mandated by federal or state law, including warnings on tobacco and alcohol products.¹⁷

Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985), and its progeny

¹⁶ The NRA argues that Section 81.49's applicability to combination meals is arbitrary. The Board memorandum addressed this argument, noting that combination meals "are intended to be eaten together," and thus a warning label on a meal "with high cumulative sodium content is appropriate." Ex. J, at 3-4.

¹⁷ The U.S. Supreme Court recognizes that "[n]umerous examples could be cited of communications that are regulated without offending the First Amendment, such as the exchange of information about securities, corporate proxy statements, the exchange of price and product information among competitors" <u>Tennessee Secondary Sch. Athletic Ass'n v. Brentwood Acad.</u>, 551 U.S. 291 (2007) (internal citations omitted).

mandate the application of the "reasonableness" standard when reviewing Section 81.49, as it requires the disclosure of factual information in a purely commercial context. In Zauderer, the Supreme Court developed an analytical framework to be used when a governmental regulation "compels" truthful disclosure of factual, non-opinion, non-political, non-ideological information to the consumer. In holding that a state attorney disciplinary regulation did not violate the First Amendment, the Court specifically drew a distinction between regulations that compelled disclosure and those that restricted speech. 471 U.S. at 650. Commercial speech can be compelled "as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." Id. (emphasis added).¹⁸

Following Zauderer, the Second Circuit in Nat'l Elec. Mfr. Ass'n v. Sorrell, 272 F.3d 104 (2^d Cir. 2001), cert. denied, 536 U.S. 905 (2002), applied the reasonableness standard to uphold a regulation requiring warnings on products containing mercury. The First Amendment is satisfied "by a rational connection between the purpose of a commercial disclosure requirement and the means employed to realize that purpose." 272 F.3d at 114-15. In NYSRA II, the Second Circuit again applied the reasonableness standard to uphold a Health Code amendment requiring chain restaurants to disclose calorie content information next to food items on their menus or menu boards. The Court held that the form of speech affected by this regulation is "clearly commercial speech" as it "requires disclosure of calorie information in connection with ... the sale of a restaurant meal[.]" 556 F.3d at 131 (citations omitted).

Much like the calorie disclosure regulation in NYSRA II, Section 81.49 requires chain restaurants to disclose facts on their menus and menu boards. Here, the facts are if a food

¹⁸ The Supreme Court explained that this relatively lenient standard was appropriate because of "the value to consumers of the information such speech provides," and the speaker's "constitutionally protected interest in <u>not</u> providing any particular factual information in his advertising is minimal." 471 U.S. at 651 (emphasis in original).

item contains at least 2,300 milligrams of sodium, and the health risks associated with high sodium intake. As Section 81.49 requires the disclosure of factual information in a purely commercial setting, the reasonableness standard applies.¹⁹

b. Section 81.49 Meets the <u>Zauderer</u> Reasonableness Standard as It Is Rationally Related to the City's Legitimate Interest in Protecting Public Health.

As more fully discussed above in Point II as well as in the Notice of Adoption (Ex. L) and Commissioner Bassett's affidavit (Ex. A), the record before the Board establishes a reasonable basis to adopt Section 81.49, and that the regulation is reasonably related to DOH and the Board's legitimate interests in promoting informed consumer decision-making regarding sodium consumption and in reducing consumers' inaccurate perceptions of sodium content in restaurant foods. Sodium warnings readily apparent at the point of sale are an effective way to communicate this information to consumers eating outside their homes. Section 81.49 identifies for the consumer at the point of purchase items that, if purchased, will immediately put that person's sodium consumption above the federally recommended daily limit. Ex. A, at ¶ 32.

Tellingly, the NRA does not argue that Section 81.49 fails the <u>Zauderer</u> test because the requirement is not reasonably related to the City's legitimate interest. Rather, the NRA asserts in conclusory fashion that the mandated sodium warning is unduly burdensome because it imposes "substantial financial burdens" on its members to comply with the requirement. Pet'r Br. at 61-62. It is, of course, expected that compliance with Section 81.49 will entail some financial expense; however, the NRA has not demonstrated that Section 81.49 is <u>unduly</u> burdensome in a way that "might offend the First Amendment by chilling protected . . .

¹⁹ The applicability of <u>Zauderer</u> is not limited only to regulations that are designed to prevent deception, as the NRA contends. <u>See</u> Pet'r Br. at 60. In <u>NYSRA II</u>, the Second Circuit clearly held that "laws mandating factual disclosures are subject to the rational basis test <u>even if they address non-deceptive speech[.]</u>" 556 F.3d at 133, fn. 21 (emphasis added). Nevertheless, as the Board specifically addressed consumer unawareness concerning sodium intake recommendations and misconception about the amount of sodium that may be contained in menu items, especially those items that appear or are advertised as "healthy" options, even if <u>Zauderer</u> was limited to regulations addressing deception, it would nevertheless be controlling in this case.

speech." Zauderer, 471 U.S. at 651.

In fact, several chain restaurants have already implemented Section 81.49. Ex A, at ¶ 36. For example, 40 Applebee's restaurants in New York City implemented the sodium warning requirement even before the effective date, 20 and in a press interview, Applebee's CEO expressed that any "burden" it may have imposed is "not a strong enough issue to be the difference a P (profit) or an L (loss). Furthermore, restaurants are free to discontinue or reformulate menu items that would require the sodium warning, which would obviate the need to post the salt shaker icon next to those food items, as Burger King, Panera and Quizno's have already done. These examples demonstrate that restaurants covered under Section 81.49 can comply with the regulation quickly and without much financial burden.

c. The Text of the Sodium Warning is Factual and Uncontroversial.

The Zauderer standard applies to Section 81.49 because the sodium warning is

²⁰ Jennifer Peltz, *Restaurant group sues over NYC salt warning labels*, AP, Dec. 3, 2015, available at http://bigstory.ap.org/article/c1c3d5d6f3b24558aff62eaad13587bf/restaurant-group-sues-nyc-over-new-salt-warning-labels (last accessed Dec. 21, 2015).

²¹ CBS New York/AP, *NYC's Salt Warning Rule Set To Take Effect At Chain Restaurants*, CBS New York/AP, Nov. 30, 2015, available at http://newyork.cbslocal.com/2015/11/30/nyc-salt-warning-label-chain-restaurants/ (last accessed Dec. 21, 2015).

²² Chris Dolmetsch, et al., *New York City Sued Over New Salt Rules in Fast-Food Fight*, Bloomberg Business, Dec. 3, 2015, available at http://www.bloomberg.com/news/articles/2015-12-03/new-york-city-sued-over-new-salt-rules-in-fast-food-fight (last accessed Dec. 21, 2015).

The NRA's argument that businesses will be harmed by the sodium warning is not only purely speculative, but based entirely on the NRA's own opinion that the sodium warning is "negative messaging" burdensome to consumers. In any event, the NRA's members are free to post additional information. For example, Subway posts additional information to inform consumers that the salt warning applies only to that item's footlong sandwich option. See Ex. A, at 21. See also, Meese v. Keene, 481 U.S. 465, 481 (1987) (those subject to the statute may go beyond the required disclosures "and add any further information they think germane to the public's viewing of the materials"); see also, Tennessee Secondary Sch. Athletic Ass'n, 551 U.S. at 298-99. The NRA also contends that the salt shaker icon will somehow "overwhelm the appearance" of the menu, see Pet'r Br. at 62. However, not only is this untrue, see e.g., Ex. A, at 21-22, the NRA does not even claim that Section 81.49 "effectively rules out" its ability to convey its own message. See Ibanez v. Florida Dep't of Bus. & Prof. Reg., 512 U.S. 136, 146 (1994). In any event, the legitimate governmental interest here is not outweighed simply by the restaurants' dislike of the appearance of their menus, which is a matter of design that can be modified.

factual and uncontroversial. <u>See Zauderer</u>, 471 U.S. at 651. The NRA nonetheless argues that Section 81.49 should be subject to strict, or at least intermediate, scrutiny, alleging that the sodium warning is "a content-based regulation . . . [that] forces" covered restaurants to disseminate "DOH's opinion on the health effects of ingesting certain levels of sodium." <u>See Pet'r Br. at 55</u>. The NRA additionally contends that there is "contentious scientific debate over the appropriate levels of sodium intake and the likely or actual health impacts of varying levels," and whether consuming 2,300 milligrams of sodium regularly puts individuals at heightened cardiovascular risk. Id. at 61.

But whether a food item contains at least 2,300 milligrams of sodium is a fact that is either true or false, not an opinion. Additionally, while the NRA attempts to dispute the science behind the limit, 2,300 milligrams is, in fact, the daily limit recommended by the federal government in the 2010 Dietary Guidelines for Americans. See Ex. A, at ¶ 4; Ex. C, at 21, 24. Furthermore, the sodium warning informs consumers of well accepted factual information, based on decades of sound scientific research and findings, that "high sodium intake" is associated with increased blood pressure and with health risks such as heart disease and stroke. Ex. A, at ¶¶ 8-11; Ex. B. at ¶¶ 11, 14, 17. Contrary to the NRA's characterization of the sodium warning, it does not convey an opinion, nor does it state that 2,300 milligrams of sodium per day is an absolute level above which risks for high blood pressure will be present for every individual or that amounts less than 2,300 milligrams will be beneficial to one's health. See Pet. at ¶ 50; Pet'r Br. at 57.

²⁴ The NRA overlooks the fact that the sodium warning is required only for food items that contain at least as much sodium as is the recommended maximum for the entire day, not for just that one meal. The NRA also overlooks the fact that the federal recommendations are even lower than 2,300 milligrams per day for certain vulnerable groups, such as individuals who have high blood pressure, diabetes and chronic kidney disease, and that the sodium warning would help such consumers make better informed decisions about food items that contain significantly more sodium than they should consume in an entire day. See Ex. C, at 21, 24.

Even where the underlying science is, unlike here, actually unsettled, a locality may inform its citizens about potential risk, especially when that risk has been determined by a federal agency. For example, in CTIA— The Wireless Ass'n v. City of Berkeley, 2015 U.S. Dist. LEXIS 126071 (N.D. Ca. 2015), a city ordinance required cell phone retailers to disclose to customers that the federal government requires that cell phones meet radio frequency (RF) exposure guidelines, and that under certain circumstances, RF exposure to customers may exceed those guidelines. The District Court applied Zauderer, and not the intermediate scrutiny standard of Central Hudson Gas & Elec. Comm'n, 447 U.S. 557 (1980) ("Central Hudson"), when reviewing this warning, and further held that the warning contained accurate and uncontroversial information because the Federal Communications Commission had in fact made the determinations referred to in the warning. 2015 U.S. Dist. LEXIS 126071 at *33-34.25"

Here, the NRA similarly mistakenly frames the issue as whether a risk to health in fact exists²⁶ rather than whether the text of the sodium warning itself is factual and accurate. To this end, the NRA attempts to portray the sodium warning as "controversial" policy even though there is no controversy regarding the truth of its content. The Second Circuit in NYSRA II

²⁵ Much like the NRA, the plaintiff in <u>CTIA</u> argued that the mandated notice was "misleading because it suggests a substantial risk to health that does not in fact exist." 2015 U.S. Dist. LEXIS 126071 at * 55. The District Court, however, rejected this argument, recognizing that the government cannot be prevented from issuing safety warnings simply because there may be some disagreement in the scientific community. "The mere fact of scientific uncertainty and/or inexactitude does not render the government's interest in issuing safety warnings to the public irrational or unreasonable. . . . To require the government to prove a particular quantum of danger before issuing safety warnings would jeopardize an immeasurable number of laws, regulations, and directives." <u>Id.</u> at *57-58, fn. 10. The Court continued, "Zauderer cannot be read to establish a 'factual and uncontroversial' requirement that can be so easily manipulated that it would effectively bar any compelled disclosure by the government. . . . One could easily imagine that an overly rigorous "factual and uncontroversial" test would render even the Surgeon General's textual warnings found on cigarette packages a violation of the First Amendment." <u>Id.</u> at *60-61.

²⁶ In Sorrell, the Second Circuit clarified that although it applied the Central Hudson test in Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2^d Cir. 1996), its decision was "expressly limited to cases in which a state disclosure requirement is supported by no interest other than the gratification of 'consumer curiosity.'" 272 F.3d at 115, fn. 6. Here, unlike Int'l Dairy Foods, Section 81.49 is designed to address real and present health risks faced by many New Yorkers as a result of high sodium intake.

rejected a similar argument (also made by the restaurant industry) that disclosing calorie information would not reduce obesity and disputing "the significance of the facts that they were being asked to disclose." 556 F.3d at 133-34.²⁷ The restaurant industry's argument in the instant case is no more relevant or effective than the restaurant industry's argument was in NYSRA II.

d. Even Assuming, <u>Arguendo</u>, That the Standard Set Forth in <u>Central Hudson</u> Applies, The Sodium Warning Meets That Standard.

Finally, even applying the intermediate scrutiny test of <u>Central Hudson</u>, Section 81.49 still survives constitutional review. In <u>Central Hudson</u>, the Supreme Court set forth a four-part analysis for regulation of commercial speech: (1) whether the speech concerns lawful activity and is not misleading; (2) whether the asserted governmental interest is substantial; (3) whether the regulation directly advances the governmental interest asserted; and (4) whether the regulation is not more extensive than is necessary to serve that asserted interest. 447 U.S. at 566. Here, the NRA does not dispute that Section 81.49 meets the first two prongs. Rather, the NRA contends that Section 81.49 fails the third and fourth prongs of the <u>Central Hudson</u> test. <u>Id.</u>

In applying the third prong of <u>Central Hudson</u>, it is well settled that in assessing whether the regulation directly advances the stated governmental interest, respondents can rely on studies, history, consensus, and "simple common sense." <u>See Florida Bar v. Went For It, Inc.</u>, 515 U.S. 618, 628 (1995). Here, the City has clearly met its burden. As set forth above in Point

Pac. Gas & Elec. Co. v. Pub. Util. Comm'n of California, 475 U.S. 1 (1986), the case relied upon by the NRA in support of its argument that strict scrutiny should apply, is wholly inapposite as that case involved noncommercial speech, such as political editorials and other stories on "matters of public concern." Riley v. Nat'l Fed'n of the Blind of N. Carolina, Inc., 487 U.S. 781 (1988) is likewise inapplicable. Unlike the sodium warning, the speech at issue in Riley involved a required disclosure within fully protected non-commercial speech soliciting charitable contributions. Entm't Software Ass'n v. Blagojevich, 469 F.3d 641 (7th Cir. 2006), is also distinguishable. The Seventh Circuit distinguished between "opinion-based" compelled speech, such as whether a video game is "sexually explicit or not, and "purely factual disclosures," such as "whether a particular chemical is within any given product." Id. at 651-52. In stark contrast, Section 81.49 requires the placement of a salt shaker icon next to any food item that contains at least 2,300 milligrams of sodium, which is a purely factual, non-subjective description.

II as well as in the Notice of Adoption (Ex. L) and Commissioner Bassett's affidavit (Ex. A), addressing food served in chain restaurants is especially warranted. While the NRA argues that the sodium warning will not reach "the vast majority of consumers" because Section 81.49 does not apply to restaurants that do not have fifteen or more chain restaurants nationally, see Pet'r Br. at 57, evidence indicates that in 2007, major chain restaurants in the New York City metropolitan area accounted for more than one-third of all restaurant traffic. This percentage is not insignificant. More importantly, the Supreme Court, in applying the Central Hudson test in United States v. Edge Broadcasting Co., 509 U.S. 418, 434 (1993), rejected this type of underinclusiveness argument and stated that the First Amendment does not require that the government "make progress on every front before it can make progress on any front." By requiring the sodium warning at such high-traffic restaurants in New York City where high amounts of sodium are consumed, Section 81.49 directly advances the Board's substantial interest in promoting informed consumer decision-making regarding sodium consumption.

With respect to the fourth prong, whether the restriction is not more extensive than necessary to serve the government's interests, the Supreme Court has rejected the "least restrictive" approach to the regulation of commercial speech. Rather, the DOH and the Board must demonstrate "a reasonable fit" between the their interests and the means chosen to accomplish those goals. This means "a fit that is not necessarily perfect, but is <u>reasonable</u>; that represents not necessarily the single best disposition but one whose scope is in proportion to the

²⁸ The NRA also argues that consumers might assume that similar food items offered by restaurants not covered under Section 81.49 contain less sodium. Pet'r Br. at 57-58. However, the sodium warning informs consumers' choice of menu items at a restaurant, not the selection between restaurants. Additionally, Section 81.49 is not the first time that DOH has required the posting of health information in chain restaurants. Consumers in New York City may generally expect to see such health information, e.g., the number of calories in menu items, in chain restaurants, and also expect that non-chain restaurants may not provide these types of health information on their menus. Moreover, the converse of the NRA's assumption may also be true – consumers who are more aware of food items with high sodium content from seeing the sodium warning in chain restaurants may associate similar food items in non-chain restaurants as having similar sodium content.

interest served" <u>Bd. of Tr. v. Fox</u>, 492 U.S. 469, 480 (1989) (emphasis added). While some restaurants may have nutrient information available in brochures, pamphlets or on their websites, making sodium warnings readily apparent at the point of sale is an effective way to communicate this information to consumers, identifying at the point of purchase those items that, if purchased, will immediately put that consumer's sodium consumption above the federally recommended daily limit.²⁹ This provides an eminently reasonable fit with respondents' interests in promoting informed consumer decision-making regarding sodium consumption and in reducing consumers' inaccurate perceptions of sodium content in restaurant foods.

IV. The NRA's Fifth Cause of Action Fails Because Federal Law Specifically Allows State and Local Governments to Require Warning Statements.

a. It is Presumed that Local Provisions Such as Section 81.49 are Not Preempted by Federal Law.

While the NRA argues that Section 81.49 is preempted by the NLEA, it fails to note that there is a presumption against federal preemption in fields traditionally reserved to state and local governments such as the regulation of restaurants. NYSRA_II, 556 F.3d at 123. Indeed, it is assumed that the State and local government's historic police powers are not preempted by federal legislation "unless that was the clear and manifest purpose of Congress." Consequently, given "the traditional primacy of state regulation of matters of health and safety, Courts assume that state and local regulation related to [those] matters . . . can normally coexist with federal regulations." Id. (citations and internal quotations omitted). Moreover, "where the text of a preemption clause is ambiguous or open to more than one plausible reading, Courts

²⁹ The NRA argues that since the sodium warning does not apply to individual food items that separately contain less than 2,300 milligrams of sodium but exceed that amount if purchased and consumed together, this "exemption swallows the Sodium Mandate." Pet'r Br. at 58. However, the point of Section 81.49 is to identify and warn consumers of menu items that alone contain at least as much sodium as is the recommended limit for the entire day. Moreover, as discussed above, Section 81.49 requires the sodium warning on combination meals, acknowledging that restaurants may offer such combination meals consisting of individual menu items that are intended to be eaten together. See Ex. A, at ¶ 33; Ex. J, at 3-4.

'have a duty to accept the reading that disfavors pre-emption.'" <u>Id.</u> (quoting <u>Bates v. Dow</u> Agrosciences LLC, 544 U.S. 431, 449 (2005)).

A local law³⁰ can be preempted in three different ways: express preemption, field preemption or conflict preemption. Hillsborough County, 471 U.S. at 713 (citations omitted). Here only express preemption is at issue.³¹ An uncodified provision³² of the NLEA Amendment provides that nothing "in the amendments made by this section shall be construed (1) to preempt any provision of State or local law, unless such provision ... is expressly preempted." Pub. L. No. 111-148 § 4205(d), 124 Stat. 119, 576. See also NYSRA II, 556 F.3d at 123 (the "NLEA is clear on preemption, stating that it 'shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1(a)]' Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364" (emphasis in original)).

b. The NLEA Provides that Localities Can Require Warnings.

Rather than expressly preempting the sodium warning, federal law expressly allows it. Congress, both when originally enacting the NLEA and later when amending it, provided states and localities with the right to warn their constituents about the safety of food. An uncodified provision of the NLEA Amendment states: "Nothing in the amendments ... shall be construed ... (2) to apply to any ... local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food."

³⁰ For "the purposes of the Supremacy Clause, the constitutionality of local ordinances is analyzed the same way as statewide laws." Hillsborough County v. Automated Medical Labs., Inc., 471 U.S. 707, 713 (1985).

³¹ The NRA appears to acknowledge as much. Pet'r Br., at 62. In any event, the "NLEA makes clear ... that [it] does not occupy the field." Sciortino v. Pepsico, 2015 U.S. Dist. Lexis 73336, *35 (N.D. Cal. June 5, 2015) (citation omitted). Nor is conflict preemption at issue here, since chain restaurants can comply with both the NLEA (posting calorie counts and making nutrition information available) and Section 81.49 (posting the salt shaker icon and sodium warning). Hillsborough County, 471 U.S. at 713 ("conflict [preemption] arises when compliance with both federal and state regulations is a physical impossibility" (citations omitted)).

While not codified, "Congress's enacted note on construction has the 'force of law' and 'works together' with the statute." Sciortino, 2015 U.S. Dist. Lexis 73336, *35-36 fn 5 (citation omitted).

Pub. L. No. 111-148 § 4205(d)(2), 124 Stat. 119, 576 (emphasis added). See also Pub. L. No. 101-535, § 6(c)(2), 104 Stat. 2353, 2364 (same). See Sciortino, 2015 U.S. Dist. Lexis 73336, *48 ("the NLEA carves out an exemption from its express preemption clause where warnings concerning the safety of food or component of food are at issue" (emphasis in original)).

Section 81.49 fits squarely within the NLEA Amendment warning exception. It warns customers that any menu item identified by a salt shaker icon contains more sodium than people are supposed to eat in an entire day. It also warns that high sodium intake can cause certain health problems. The language contains a "warning concerning the safety of [a] component of the food." Broken down, the language contains a warning³³ (the salt shaker icon and the word "Warning") concerning the safety (the statement that "High sodium intake can increase blood pressure and risk of heart disease and stroke")³⁴ about a component of food (the sodium content of the menu item with a salt shaker icon).

c. The Legislative History of the NLEA Supports the Warning Exception.

In addition to the plain language of the NLEA warning exception, the NLEA's legislative history demonstrates a clear rejection of a broad preemptive effect on local warnings. For example, the June 13, 1990 report on the NLEA from the House of Representatives Committee on Energy and Commerce indicated that a proposed amendment was rejected that would have prevented states from requiring warnings regarding substances in food (such as sodium) that pose a nutrition or disease risk (such as cardiovascular disease). See H.R. Rep. No. 101-538, 101st Cong., 2d Sess. (1990) at 10.

³³ A "warning" is defined as "something (such as an action or a statement) that tells someone about possible danger or trouble." Merriam-Webster's Collegiate Dictionary [11th ed 2014].

While the NRA contends that daily sodium intake above 2300 milligrams is not a safety concern, the evidence indicates otherwise. See, e.g., Verified Answer, Exs. A & B (Bassett & Appel Affs.).

Additionally, considerations in both the House of Representatives and the Senate specifically addressed the role of state and local regulations and acknowledged that the NLEA does not preempt state or local health warning requirements. Rather, the NLEA permits states and local governments to adopt warning requirements about the ingredients or components of food. As explained by Congressman Henry Waxman, bill sponsor in the House of Representatives:

Section 403A(b)(1) states that section 403(a) does not apply to any requirement for a statement in food labeling (including statements on the label) that provides a warning concerning the safety of the food or component of the food. This section may be unnecessary because section 403 does not require health warnings and therefore, by the terms of section 403A, state laws requiring health warnings would not be preempted. Nevertheless, section 403A(b)(1) has been included to underscore that State laws requiring warnings pertaining to the safety of foods are not preempted.

136 Cong. Rec. H5836, Jul. 30, 1990 (emphasis added). Similarly, Senator Orrin Hatch, a proponent of the bill in the Senate, explained: "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." As Senator Hatch explained, an "example of such a warning would be a statement required under a state law regarding the possibility of an allergic reaction from a component of a food." 136 Cong. Rec. S16607, Oct. 24, 1990.

Sciortino made even clearer that state or local warning requirements are not preempted. The Court observed that it was "noteworthy" that after the enactment of the NLEA "food manufacturers … petitioned Congress to enact legislation expressly preempting state warning requirements as to ingredients that the FDA has deemed safe. Such legislation was

reported in 2000, 2004, and 2006, but no such legislation has been passed." 2015 U.S. Dist. LEXIS 73336 at * 55-56 (internal citations omitted).

Case law is in accord with the plain language of the statute and the unambiguous legislative history.³⁵ In Sciortino, 2015 U.S. Dist. Lexis 73336, defendant argued that plaintiffs' claim relating to a failure to warn about a caramel color ingredient in defendant's soft drink based on a violation of a local law was preempted by the NLEA. The Court disagreed, holding that NLEA section 6(c)(2) "saves from express preemption state laws such as [the one at issue] requiring food safety warnings." Id. at * 47-48. The Court based its conclusion on the "plain language, legislative history and purpose of the NLEA as set forth in section 6(c)(2)." Id. at 48. See also Lockwood v. ConAgra Foods, In., 597 F. Supp. 2d 1028, 1033 (N.D. Cal. 2009) ("the NLEA – including the savings clause (no preemption unless the law is expressly preempted) – shall not be construed to affect preemption of food safety laws"). In addition, the Court based its holding on the fact that "preemption is particularly disfavored where state laws in exercise of traditional and historic police powers to protect health and safety are rendered ineffective ... a point underscored by the legislative history of [NLEA] § 6(c)(2)." Sciortino, 2015 U.S. Dist. Lexis 73336, at *55.

d. The NRA's Assertion that the Salt Shaker Icon and Sodium Warning are Claims Fails.

Attempting to sidestep the fact that the NLEA allows localities to require warnings, the NRA incorrectly argues that Section 81.49 mandates nutrient content and health claims preempted by the NLEA. Pet'r Br., at 65. Such claims, which are voluntarily made by

³⁵ The NRA's reliance on Mills v. Giant of Maryland, LLC, 441 F. Supp. 2d 104, 109 (D.D.C. 2006), is misplaced, since there the court merely held that lactose intolerance "did not implicate 'safety' concerns as that term is understood in by FDA." But unlike lactose intolerance, the FDA has specifically outlined the dangers associated with high sodium intake. See 21 C.F.R. § 101.74(b)(1)-(3).

purveyors of food, are regulated by 21 U.S.C. § 343(r) and its implementing regulations. A section 343(r) nutrient content claim "characterizes the level of any nutrient;" for instance, "low sodium," is a nutrient content claim. 21 C.F.R. § 101.61(b)(4). A section 343(r) health claim "characterizes the relationship of any nutrient ... to a disease or health-related condition;" for instance, diets "low in sodium may reduce the risk of high blood pressure," is a health claim. 21 C.F.R. § 101.74(e)(1).³⁶

To start, the NRA fails to recognize that section 343(r) nutrient content and health claims "only apply when a purveyor voluntarily chooses to make a covered claim." NYSRA I, 509 F. Supp. 2d at 363.In NYSRA I, the Court found that the original Health Code calorie disclosure regulation was preempted because the regulation only applied if chain restaurants were already voluntarily providing this information (on, for instance, a restaurant's website). "By making its requirements contingent on a voluntary claim, [Health Code] 81.50 directly implicates § 343(r) and its corresponding preemption provision." 509 F. Supp. 2d at 363. Thereafter the Board adopted a new regulation that mandated that chain restaurants disclose calorie information regardless of whether they were already voluntarily providing that information elsewhere. The restaurant industry challenged the new regulation, arguing that by disclosing "calorie content" the restaurants would "be making a claim that is subject to federal regulation under § 343(r)." That argument was rejected: "a mandatory disclosure is not a [section 343(r)] claim, which term carries the connotation of an assertion by a speaker that is voluntary in nature." The Court held that the restaurant industry's argument that "any statement

³⁶ In contrast to section 343(r), 21 U.S.C. §§ 343(q) mandates that certain nutritional facts be disclosed on the label of food intended for human consumption, such as that sold in supermarkets. NYS Rest. Ass'n v. NYC Bd. of Health, 509 F. Supp. 2d 351, 356 (S.D.N.Y. 2007) ("NYSRA I"). The 2010 amendment to the NLEA ("NLEA Amendment") requires that chain restaurants disclose the calorie count of food items at the point of purchase, and also make available at the restaurant other nutrition information. 21 U.S.C. § 343(q)(5)(H)(ii). While the NLEA Amendment added a provision to section 343(q), it did not touch section 343(r) which regulates nutrient content and health claims, or it preemption provision, 21 U.S.C. § 343-1(a)(5).

regardless of context [is] a claim ... is inconsistent with the language of NLEA," and that the "FDA regulations draw the same distinction." NYSRA II, 2008 U.S. Dist. Lexis 31451, *13-15 (citations omitted). Similarly, here chain restaurants are not voluntarily supplying the sodium warning. Rather, they are mandated to do so by Section 81.49.

Second, the NRA's argument attempts to turn the section 343(r) claims concept on its head, contending that chain restaurants that sell food containing excessive amounts of sodium are making nutrient content and health claims. But claims regulated by section 343(r) are made to tout the positive aspects of a particular food item. For instance, an implied nutrient content claim may suggest "that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices." 21 C.F.R. § 101.13(b)(2)(ii). And 21 C.F.R. § 101.61, titled "Nutrient content claims for the sodium content of foods," sets forth various standards that must be followed if a food purveyor seeks to make such a claim when touting its food as "sodium free," "very low sodium," "low sodium," "reduced sodium" or "unsalted." None of the provisions set forth in 21 C.F.R. § 101.61 proscribe any requirements for those seeking to sell high sodium food, as is the case here.

Health claims also are made to tout the positive aspects of a particular food item. Similar to the provision relating to the sodium nutrient content claims, the section addressing health claims relating to sodium³⁷ -- titled "Health Claims: sodium and hypertension" -- sets forth no requirements for those seeking to sell high sodium food.³⁸ 21 C.F.R. § 101.74. See also 21 C.F.R. § 101.70(f).

³⁷ This provision reiterates what has been established by public health professionals: "The scientific evidence establishes that diets high in sodium are associated with a high prevalence of ... high blood pressure." 21 C.F.R. § 101.74(a)(2). And "High blood pressure is a public health concern primarily because it is a major risk factor for mortality from coronary heart disease and stroke." 21 C.F.R. § 101.74(b)(1).

³⁸ The one negative claim that the NRA cites to is, in fact, not one. Rather, the NRA cherry picks one component of a positive claim relating to artificial sweetener; the other component provides that a claim about an artificial

The explicit NLEA warning exception and the legislative history of the statute clearly indicates that Section 81.49 is not preempted, a conclusion bolstered by the presumption against preemption of local regulation in fields involving public health and welfare. Federal law does not preempt Section 81.49; rather, it expressly allows Section 81.49.

CONCLUSION

WHEREFORE, the Respondents respectfully request that the petition be denied and this proceeding be dismissed.

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sweetener shall state: "'does not promote,' 'may reduce the risk of,' 'useful [or is useful] in not promoting,' or 'expressly [or is expressly] for not promoting' dental caries." 21 C.F.R. § 101.80(c)(2)(i)(B). Tooth decay is another word for dental caries. 21 C.F.R. § 101.80(a)(1).