To Be Argued By:
S. PRESTON RICARDO

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New York Supreme Court

APPELLATE DIVISION—FIRST DEPARTMENT

NATIONAL RESTAURANT ASSOCIATION,

Plaintiff-Appellant,

—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,

Defendants-Respondents.

BRIEF FOR PLAINTIFF-APPELLANT

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Plaintiff-Petitioner the National Restaurant Association ("Petitioner") submits this Brief in support of its appeal from the Decision of the Supreme Court, New York County (Rakower, J.), dated February 26, 2016, which denied the Article 78 and declaratory judgment petition that Petitioner filed against the New York City Department of Health & Mental Hygiene ("DOH"), the New York City Board of Health (the "Board"), and DOH Commissioner Dr. Mary Travis Bassett, to invalidate § 81.49 of the New York City Health Code (the "Sodium Mandate").

Preliminary Statement

This appeal arises from Petitioner's constitutional and statutory challenge to a scientifically controversial citywide sodium regulation that is the first of its kind in the nation. The Board adopted this regulation, which forces thousands of restaurants to post an ominous-looking salt shaker icon on their menus next to food items that contain at least 2,300 mg of sodium, along with a "Warning" to patrons that consuming this purportedly "high level" of sodium "can increase blood pressure and risk of heart disease and stroke," without any legislative guidance and in the face of failed legislative efforts to regulate sodium consumption in restaurants.

Unless the law is stricken, the Board will wield unprecedented power to require private establishments to post dietary risk statements (including controversial ones) about essential nutrients in an unconstitutional and arbitrary

manner. The lower court decision upholding this regulation, like the Sodium Mandate itself, is unparalleled, and is wrong for any of four distinct reasons.

First, the Sodium Mandate violates the separation of powers. By adopting the Sodium Mandate without any legislative direction – indeed, despite multiple failed legislative efforts in this area – the Board has stretched the constitutional limits of its administrative function past the breaking point and improperly assumed the role of a lawmaker. The Board's delegated Charter authority, relied upon by the lower court, does not empower the Board to act as it did.[1] The Board wrongly relied on its own ideas of sound public policy for sodium reduction efforts through impermissible legislative-like balancing of competing social and economic considerations against the backdrop of a mainstream scientific debate. The Board's actions constitute policy-making within the legislature's exclusive domain.

The lower court also erred by concluding that the Board did not usurp the legislature simply because the Sodium Mandate is not an outright ban of "high sodium" menu items and purportedly provides useful information to consumers without infringing on their personal autonomy. Neither the Court of Appeals nor any other New York court has ever held that these narrow factors decide a separation of powers analysis. The lower court's conclusion is improper, in all events, because the compelled disclosure is inaccurate, misleading, and

[1] Capitalized terms not defined in this section shall have the meanings ascribed to such terms below.

controversial, and the Board has interfered with consumer autonomy by pressuring Covered Establishments to eliminate the salty foods that consumers desire rather than face the detrimental consequences of complying with the regulation's onerous requirements.

Second, the Sodium Mandate violates the First Amendment. The lower court wrongly applied the most lenient standard of constitutional review, rather than intermediate scrutiny, on the grounds that the regulation allegedly only compels speech that is "purely factual and uncontroversial." However, read as a whole, and/or given the conflicting science concerning any adverse health effects of consuming the level of sodium at issue, the required risk statement is not "factual" and certainly is not "uncontroversial." The lower court ignored recent mainstream science, published in renowned peer-reviewed journals, that directly contradicts the requisite posting's health claims and that is at the heart of a heated nutrition debate. The lower court also ignored the regulation's many loopholes, which render it invalid on First Amendment grounds under any standard of review. Under the proper intermediate scrutiny analysis (which the lower court did not undertake), the Sodium Mandate is unconstitutional because it does not directly and materially advance the Board's asserted interest of helping consumers make better-informed and healthier menu choices, and the regulation is more extensive and burdensome than necessary to advance that interest.

Third, the lower court erred by holding that the Sodium Mandate is not arbitrary and capricious. The court ignored the fact that the regulation's application to only a small minority of food vendors selling the target foods, and/or its illogical application to "menu items," gut the regulation's purpose. Using the salt-shaker symbol and risk statement as directed steers consumers away from one food to another with comparable or more sodium; often provides misinformation to consumers; and drives consumers from regulated to unregulated establishments that sell foods with the same or higher sodium content. Put simply, the Sodium Mandate is so irrational and under-inclusive as to eviscerate the very purpose for which it was passed.

Last, the Sodium Mandate cannot stand because it is both a "health claim" and a "nutrient content claim" and thus preempted by federal law. The regulation does not fall within a narrow exception to preemption for food safety warnings, relied upon by the lower court. The lower court reached this conclusion without any supporting authority or an example of a single instance in which this exception has been used for a non-toxic substance since the rule's enactment over 25 years ago.

Questions Involved

1. Did the lower court err in holding that the Board did not violate the separation of powers doctrine by adopting the Sodium Mandate?

The court held that, under the Board's overall Charter authority and applying the *Boreali* factors, the Board did not exceed its regulatory authority, when in fact it usurped the legislature's role. The Charter alone cannot be so extended; the Sodium Mandate is the subject of legislative inaction and related failed legislation; and in crafting the regulation, the Board balanced social and economic considerations amid scientific debate, and sought to influence food availability to consumers, which are legislative actions.

2. Did the lower court err by (i) applying *Zauderer*'s relaxed standard of First Amendment review and/or (ii) holding that the Sodium Mandate does not compel speech in violation of the First Amendment?

The court did not consider whether the Sodium Mandate would survive intermediate scrutiny, which it would not. Instead, the court held that the Sodium Mandate passed constitutional muster under *Zauderer,* notwithstanding that this lower standard of review is inapplicable in this context, and was not met due to the regulation's gaping loopholes.

3. Did the lower court err in holding that the Sodium Mandate is not arbitrary and capricious under Article 78 of the CPLR?

The court held that the Sodium Mandate had a rational basis, but in doing so, overlooked the fact that the regulation applies only to a small subset of NYC food vendors and to "menu items" (whether combination meals or à la carte, and with respect to variable items) such that the regulation cannot accomplish its stated objective.

4. Did the lower court err in holding that the Sodium Mandate is not preempted?

The court held that the Sodium Mandate falls within an exception to federal preemption for "food safety warnings," notwithstanding that the exception has rarely been invoked, and has only been applied to toxic substances, not essential nutrients like sodium.

Nature of the Case

This appeal arises from the Board's adoption, without any legislative guidance and despite the failure of related legislative proposals, of a first-of-its-kind sodium regulation. The regulation requires certain chain restaurants in New York City to post a black symbol next to menu items that contain 2,300 milligrams or more of sodium, with a stated "Warning" that such "[h]igh sodium intake can increase blood pressure and risk of heart disease and stroke." On appeal, the issue is whether the regulation is unconstitutional, arbitrary and capricious, and/or preempted.

Factual Background

A. The Board Adopts The Unprecedented Sodium Mandate

In recent years, the Board has attempted to impose a series of nutrition-related regulations on private businesses. In 2008, the Board required chain restaurants to post each menu item's calorie count (Health Code § 81.50); but it did not require them to post any claims about the potential health effects of consuming excess calories (the "Calorie Regulation"). In 2012, the Board prohibited the sale of certain sugary beverages in containers over a specified size to battle obesity (the "Soda Regulation"). *See* Health Code § 81.53. That regulation was struck down as a violation of the separation of powers and, at the trial court level, for being arbitrary and capricious. *New York Statewide Coalition of Hispanic Chambers of Commerce v. New York City Dep't of Health & Mental Hygiene* ("*Statewide*"), 2013 WL 1343607, at *19, 20 (Sup. Ct. N.Y. Cty., Mar. 11, 2013), *aff'd*, 110 A.D.3d 1, 7-16 (1st Dep't 2013), *aff'd*, 23 N.Y.3d 681, 696-701 (2014). Through the Sodium Mandate, the Board now seeks to regulate consumption of an essential nutrient by making New York City "the first jurisdiction to use a warning label on menus."[2]

The Sodium Mandate applies only to food service establishments ("FSEs") in New York City that are part of a chain with 15 or more locations ("Covered

[2] Video Recording, Meeting of the New York City Board of Health, September 9, 2015 http://www.nyc.gov/html/doh/html/about/public-meetings-archive.shtml

Establishments"). Over half of these FSEs are members of Petitioner.[3] Covered Establishments must first post the following black symbol (the "Icon") on a menu or menu board next to any "menu item" containing 2,300 milligrams or more of sodium:[4]

Second, they must post the following Risk Statement where customers order food:

> Warning:  indicates that the sodium (salt) content of this item is higher than the total daily recommended limit (2,300 mg). High sodium intake can increase blood pressure and risk of heart disease and stroke.[5]

Respondents' stated objective for the Sodium Mandate is to reduce cardiovascular disease in New York City:

> The proposed consumer warning label will provide consumers with information about food items that contain exceedingly high sodium levels and will empower them to make well-informed decisions when making choices for themselves and their family members in the food retail environment.[6]

[3] R. 86-87.

[4] R. 192.

[5] *Id.*

[6] R. 190.

The Sodium Mandate applies only to approximately 17% of New York City's 24,000 restaurants, and not to other types of food vendors.[7] Among the excluded vendors are independent and small chain restaurants, most delicatessens, grocery stores, and convenience stores.[8]

"Menu items" includes "combination meals" – such as a cheeseburger and fries sold together – and à la carte items, such as a cheeseburger sold alone.[9] For menu items that can be ordered with various options, DOH requires the Icon to be posted if "any option" or "any possible version of the item" results in a menu item containing at least 2,300 mg of sodium.[10]

B. Legislative Efforts To Pass Similar Sodium Laws Have Failed

The Sodium Mandate concerns a matter that has been raised before the New York City Council and the New York State Legislature. The City Council has twice considered, but not yet adopted, the "Healthy Happy Meals" legislation, which would limit the sodium content in certain kids' meals sold at restaurants.[11] The City Council referred these proposals to the Committee on Health, which held

[7] R. 87 ¶¶ 3-4. Respondents claim the regulation applies to one-third of restaurants. R. 621.

[8] *Id.* ¶ 4.

[9] R. 190.

[10] R. 272 (emphasis in original).

[11] R. 255-260.

public hearings and received testimony from the public this year, but has not made a decision.[12]

Other legislative initiatives aimed at limiting and/or warning consumers about sodium intake have also been introduced in the New York State Legislature:

- 2011 N.Y.S. Bill No. S02608 (Senator Kruger), calling for a label and warning on certain packaged foods, including one or both of the following based on the level of sodium content: "high in sodium" or "highly salted". The Bill also would have required the following additional "warning statement" on foods with a higher sodium content: "[i]n some people a high salt (sodium) diet may contribute to high blood pressure." R. 263-265.

- 2013 N.Y.S. Bill No. S02971 (Senator Adams), prohibiting the use of sodium by restaurants in the preparation of food. R. 266-267.

- 2015 N.Y.A. Bill No. A08266 (Assembly Member Ortiz), requiring certain "chain restaurants to place a salt-shaker-like symbol on menus with food items that contain more than two thousand three hundred milligrams of sodium" and the following statement on any menus which include a salt-shaker icon next to any food item: "such menu item contains more than 2,300 mg of sodium." R. 268-270.

- 2009 N.Y.S. Bill No. S02824 (Senator Hannon), requiring restaurants to post the sodium content by milligrams per serving on menus and/or menu boards. R. 261-262.

None of these proposed Bills were adopted. R. 261-270.

[12] *See* Int. 0442-2014 Legislative Details, *available at*, http://legistar.council.nyc.gov/LegislationDetail.aspx?ID=1890991&GUID=6F1A4577-176B-425A-B8AF-954369AB46F5

C. The Risk Statement Reflects A Controversial View Among Mainstream Scientists About The Effects Of Consuming 2,300 mg/day Of Sodium

This case is not about a toxic substance, such as lead paint; it is about an essential nutrient.[13] The Risk Statement is a complicated and disputed assertion: It requires Covered Establishments to convey Respondents' highly-debated view about the medical risks, for the general population, associated with consuming more than 2,300 mg/day of sodium.

Respondents purport to rely on the 2,300 mg figure from the federal Dietary Guidelines (the "Guidelines"), but Respondents distort the meaning of that figure.[14] The 2,300 mg figure is a "tolerable upper intake level," or "UL," for sodium. UL means that intake of 2,300 mg/day will *not* cause an adverse health risk for most people.[15] ULs are designed to address the amount of a nutrient consumed over long periods of time, not the amount consumed in any particular day.[16] Even when consumed at that level on a chronic basis, whether and to what extent daily sodium consumption above 2,300 mg puts someone at risk depends, among other things, on his/her overall eating habits over time and his/her individual health conditions.[17] Thus, a UL is not a recommended "limit" above which the general population is in

[13] R. 100 ¶ 7.

[14] R. 516-519. The new Guidelines published in January 2016 reflect the same 2,300 mg UL.

[15] R. 198; R. 121 ¶ 10; R. 103 ¶ 16.

[16] R. 103 ¶ 17.

[17] R. 103-104 ¶¶ 15-20.

danger of adverse health effects – certainly not for a single day, and even over time.[18] With the Risk Statement, however, Respondents are using the UL as a threshold above which there *is* likely to be increased adverse health risks to consumers.

To make matters worse, Respondents have ventured into a scientific area that is "among the most contentious in the field of nutrition. . . ."[19] Several studies reported by the NEJM, the Institute of Medicine, and other esteemed journals in 2013, 2014 and 2016 challenge and undermine the view that consumption above 2,300 mg, even on a long term basis, has *any* adverse consequences for the general population.[20] In fact, they show that consumption over time at far higher levels is not associated with adverse cardiovascular effects.[21] In addition, these studies have concluded that *too little* salt – defined as *less than 2,800-3,000 mg/day* – is as dangerous as "too much," which they define as nearly *three times* Respondents' maximum "limit" of 2,300 mg/day.[22]

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[18] R. 103-106 ¶¶ 15-25.

[19] R. 274.

[20] R. 196, *citing* Institute of Medicine, Sodium Intake in Populations: Assessment of Evidence, May 2013, *available at*, http://iom.nationalacademies.org/Reports/2013/Sodium-Intake-in-Populations-Assessment-of-Evidence.aspx; R. 285-304, 315-336; R. 121-136 ¶¶ 10-34; R. 106 ¶ 24; R. 955-970; McMaster University, *Low-Salt Diets May Not be Beneficial For All Study Suggests: Salt Reduction Only Important in Some People with High Blood Pressure*, Science Daily, May 21, 2016, *available at*, https://www.sciencedaily.com/releases/2016/05/160521071410.htm.

[21] *Supra* note 20.

[22] *Supra* note 20.

These studies have led to tremendous on-going debate about the reliability of the very Guidelines that Respondents use for the Sodium Mandate.[23] Indeed, a February 2016 metaknowledge analysis observed: "the divide between the uncertainty in the scientific literature about the potential benefits of salt reduction in populations and the certitude expressed by decision makers involved in developing public health policies in this area is jarring." R. 956.

D. The Convoluted Construction And Application Of The Sodium Mandate Resulted From Respondents' Desire To Circumvent The FDA's Requirements For Uniform Labeling Of Nutrients At Restaurants

The Board considered a more direct route to informing consumers about sodium via numerical values of milligrams for menu items. But recent federal law precludes that approach, so they concocted the misguided Sodium Mandate.[24]

[23] R. 274-284 (summarizing recent published studies and quoting commentators from both sides of the debate); R. 305 (noting that "[f]or years, there have been contentious debates over reducing the amount of salt in the American diet," and that new "warring studies in The New England Journal of Medicine" have added to the debate and unresolved questions); R. 308 ("We were told the science was settled. Yet new research suggests that salt is not nearly as dangerous as the government medical establishment has been proclaiming for many decades – and a low-salt diet may itself be risky."); R. 310 ("A long-running debate over the merits of eating less salt escalated Wednesday when one of the most comprehensive studies yet suggested cutting back on sodium too much actually poses health hazards."); R. 955-970.

[24] Video Recording, Meeting of the New York City Board of Health, June 10, 2015, http://www1.nyc.gov/site/doh/about/hearings-and-notices/public-meetings-archive.page

Specifically, on December 1, 2014, the FDA published a final rule[25] that implemented the national menu labeling provisions of the 2010 Patient Protection and Affordable Care Act (the "Federal Menu Law").[26] The Federal Menu Law, which now becomes effective in May 2017, requires restaurants with 20 or more locations to make nutritional information (including sodium content in mg)[27] available in writing to customers. This law (passed by legislators, not regulators) does not require representations about potential health effects of consuming particular amounts of any nutrients. These requirements provide accurate, objective, and uniform information to enable customers to make informed dietary choices.

Because the myriad state and local requirements concerning nutritional information on menus was confusing to consumers, inefficient, and costly to industry, Congress adopted an express preemption provision. That provision prohibits state and local governments from enacting menu labeling requirements that are not identical to those contained in the Federal Menu Law. [28]

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[25] *See* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Calorie Labeling of Articles in Food Vending Machines; Final Rule, 79 Fed. Reg. 71,156 (Dec. 1, 2014); 21 C.F.R. 101.11.

[26] Pub. L. No. 111-148 § 4205 (2010).

[27] The information includes: calories from fat, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, fiber, sugars, and protein.

[28] *See, e.g.*, 155 Cong. Rec. E597 (daily ed. March 9, 2009) (statement of Representative Jim Matheson); Pub. L. No. 111-148 § 4205.

Procedural History

On December 3, 2015, Petitioner filed a hybrid Article 78 Petition with request for declaratory relief, and a preliminary injunction motion.[29] On February 24, 2016, the Supreme Court orally denied the requested relief. R. 19-53. On February 26, 2016, the Supreme Court issued a written decision and order supplementing that record (the "Decision").[30]

The Decision Below

Separation of Powers. The lower court evaluated this argument under the *Boreali* factors. *See Boreali v. Axelrod*, 71 N.Y.2d 1, 1-14 (1987). Under the first factor – whether the agency engaged in impermissible policy-making – the lower court relied on *dicta* from *Statewide* (23 N.Y.3d at 699) relating to a hypothetical potentially permissible "warning." R. 27-28.

The lower court distinguished the Soda Regulation struck down in *Statewide* from the Sodium Mandate, because the latter "does not prohibit the sale of food containing high levels of sodium" but instead "simply requires covered establishments to post a warning label. . . ." The court further explained that "personal autonomy is not hindered" but, rather, is "promoted" by "providing information so consumers can make informed decisions…." R. 28.

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[29] *See* R. 40-85, 352-354.

[30] *See* R. 11-32.

Under the next factor – whether the agency adopted the regulation on a "clean slate" – the lower court found that the Sodium Mandate fell within the general powers granted under City Charter § 558(c) and § 556. R. 26-29. The lower court distinguished the Soda Regulation by contending that with the Sodium Mandate, "the Board did not devise a new rule that 'significantly changes' the manner in which menu items containing sodium are provided to customers at eating establishments." R. 28. The court concluded, "[I]t is within the Board's regulatory authority to require the posting of information and warning labels concerning health risks." R. 29.

As to the third factor – whether the agency acted in an area of legislative debate – the lower court ignored two City Council bills, opined that the four legislative bills cited by Petitioner did not receive adequate consideration, and erroneously stated that "none of the bills addressed sodium warning labels in restaurants." *Id*. Under the fourth factor – whether the agency relied on its special expertise – the lower court found that the Board relied on its public health expertise in regulating restaurants. *Id.*

Arbitrary and Capricious. The lower court stated that the Sodium Mandate "simply warns consumers about menu items that contain more sodium than the daily recommended upper limit" and that "such information empowers consumers by making them aware of health risk." R. 30. Applying the regulation only to

chains with 15 or more locations, the court reasoned, "parallels the application of the calorie disclosure rule" and "is rational based on the Board's determination that the requirement is not unduly burdensome for chain restaurants because they have uniformity in their menu items and food preparation." *Id*. The lower court noted that the Board "considered evidence that restaurant food plays a significant role" in sodium intake. *Id.*

The lower court did not address Petitioner's argument that use of the Icon with combination plates and to meals with options results in misinformation to consumers.

First Amendment. By adopting the conclusion – without any explanation – that the "warning statement is factual and uncontroversial," the lower court avoided applying intermediate scrutiny and instead applied the less restrictive *Zauderer* standard of review. *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985); R. 31. The court determined that the Sodium Mandate met this standard because the Board "demonstrated a reasonable relationship between the purpose of Section 81.49 – to increase consumer awareness of the health risks of sodium consumption and reduce cardiovascular disease – and the means employed to achieve that purpose – a warning label that alerts consumers when a menu item exceeds the federal daily recommended limit of sodium." R. 30-31.

Preemption. The lower court concluded that the Sodium Mandate falls within the "warning exception" to express preemption under the Nutrition Labeling and Education Act ("NLEA") – *i.e.*, an exception for "any 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." R. 31 (emphasis omitted). The court did not cite authority for its interpretation or application of this exception.

The Appellate Division Grants An Interim Stay, Then Denies Preliminary Injunction

Petitioner filed a motion for a temporary restraining order and preliminary injunction with this Court to enjoin the Sodium Mandate's March 1, 2016, enforcement date. On February 29, 2016, the Appellate Division granted an interim stay. On May 26, 2016, the Appellate Division denied the motion for preliminary injunction and vacated the interim relief. This appeal does not involve a request for injunctive relief.

Argument

I. THE SODIUM MANDATE VIOLATES THE SEPARATION OF POWERS

The Board violated the separation of powers by exceeding the scope of its regulatory authority and usurping the legislative branch's powers.

A regulation violates the separation of powers when an agency crosses the line from administrative rule-making to legislative-like "policy-making". The latter task is expressly reserved for the legislature. *See Boreali*, 71 N.Y.2d at 11.

New York courts have repeatedly struck down executive agency actions that have usurped powers reserved for the legislature. *See Statewide*, 23 N.Y.3d at 694-700 (invalidating Board's Soda Regulation); *Boreali*, 71 N.Y.2d at 9-14 (striking regulation concerning smoking).

The *Boreali* court identified four factors that "when viewed in combination, paint a portrait of an agency that has improperly assumed for itself, the open-ended discretion to choose ends": (1) whether the regulations were issued on a "clean slate" without legislative guidance; (2) whether they concern issues on which the legislature has tried – and failed – to reach agreement in the face of substantial public debate; (3) whether the agency operated outside of its proper sphere of authority by balancing competing social concerns in reliance on its own ideas of sound public policy; and (4) whether the regulations were not a product of "special expertise or technical competence." 71 N.Y.2d at 11-14.

"[T]he *Boreali* factors do not constitute rigid conditions, all of which must be met" in order for an agency to have exceeded its limited rule-making function. *Statewide*, 23 N.Y.3d at 700. Rather, the court shall treat "the circumstances as overlapping, closely related factors that, [when] taken together, support the conclusion that the agency has crossed that line." *Id.* at 696-97.

The Decision effectively eliminates the separation of powers as a means of ensuring that the Board's actions are properly confined to regulatory rulemaking – as distinguished from legislative policy-making – in the dietary realm.

A. The Board Adopted The Sodium Mandate On A "Clean Slate"

Enacting a policy on a "clean slate" is often the "most significant[]" evidence that an agency has impermissibly exercised legislative power. *Rent Stabilization Ass'n of N.Y.C. v. Higgins*, 83 N.Y.2d 156, 170 (1993). The issue is whether the agency "creat[ed] its own comprehensive set of rules without benefit of legislative guidance," rather than "merely fill[ing] in the details of broad legislation describing the over-all policies to be implemented." *Boreali*, 71 N.Y.2d at 13.

This is not the first time the Board has attempted to circumvent the legislative process. In nullifying the Soda Regulation, the Court of Appeals held that the Board acted on a "clean slate" because "there was no articulation [by the State Legislature or City Council] associated with consumption of sugary beverages upon which to ground the [Soda Ban]." 23 N.Y.3d at 700; *Jewish Home & Infirmary of Rochester v. Comm'r of N.Y. State Dep't of Health*, 84 N.Y.S.2d 252, 265 (1994) ("it remains the task of the [Council]" to make the primary decisions about policy). Similarly, there is no legislation concerning the consumption of sodium that the Sodium Mandate is designed to supplement.

Instead, the lower court relied solely on the Board's general delegated authority in Charter §§ 558(c) and 556, which provide for the authority to "supervise the reporting and control of communicable and chronic diseases and conditions hazardous to life and health[,]" supervise "the abatement of nuisances affecting or likely to affect the public health[,]" and "regulate the food and drug supply of the city and other businesses and activities affecting public health in the city." R. 27. But even actions taken pursuant to general Charter authority may violate the separation of powers if the agency's action amounts to impermissible policy–making, as it does here. *Statewide*, 23 N.Y.3d at 696-701. If the court's expansive interpretation of the Board's powers were correct, there would be virtually no limit to its authority, for practically everything can be said to "affect public health." The statutory authority of executive agencies cannot be read to grant them such broad power. *See Boreali*, 71 N.Y.2d at 9, 17 (broad authority to deal with any "matters affecting the security of life or health or the preservation and improvement of public health" did not provide agency with authority to go "beyond its constitutionally valid reach when it used the statute as a basis for drafting a code embodying its own assessment of what public policy ought to be.").

In all events, however, the Sodium Mandate does not fit within the cited Charter provisions, and it is unlike any prior action by the Board. *See Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 505 (2010) ("'Perhaps

the most telling indication of [a] severe constitutional problem…is the lack of historical precedent'" for the action).

The Sodium Mandate does not regulate "chronic diseases" under §556(c)(2). Rather, Respondents' position is that, when chronically consumed in excess, sodium becomes a "risk factor" for another "risk factor" (hypertension) for a chronic disease (cardiovascular disease). Thus, the Board is *not* supervising the reporting or control of the chronic disease itself, and it is *not* regulating hypertension. Countless dietary and lifestyle choices are known to enhance one's risk of a chronic disease or a risk factor for a chronic disease. The lower court's far-reaching interpretation amounts to essentially unfettered legislative power, which Respondents indisputably do not have.

The lower court's reliance on § 556(c)(9) is equally unavailing. Respondents' authority to "regulat[e the] food … supply of the city and other businesses" has traditionally extended only to protecting people from infectious agents and other contaminants. *See*, *e.g.*, R.C.N.Y. tit. 24, § 81.07 ("sanitary preparation" and "protection against contamination"); *id.* § 81.09 (temperature control for safety); *id.* § 81.13 (hygienic practices). The Board's authority under § 558 has always been limited to contamination, sanitation, food-borne illnesses, poisons, medical and nursing facilities, and infectious diseases, none of which are

implicated here. *See, e.g.*, Health Code § 173.13 (banning lead paint because poison).[31]

The examples used by the lower court actually undermine the Decision because in each instance, the Board's authority derived from or was supported by other legislation, and was not based solely on the Charter's general language. R. 28. The authority for Health Code § 47.61 (concerning "group day care facilities") fell within the Board's legislatively supported and long exercised authority to regulate hygiene, feeding, and other aspects of the City's day care facilities. *See, e.g.*, *N.Y. Soc. Serv. Law* § 390 (1942). The Board's trans-fat rule (Health Code § 81.08) is different from the Sodium Mandate in two respects. First, given doubts about the Board's authority to enact that rule, the City Council enacted ratifying legislation "incorporat[ing] the Ban on artificial trans-fat into the Administrative Code," to (in the sponsor's words) "put the trans-fat Ban on stronger legal footing."[32] By contrast, repeated legislative efforts in the sodium realm have failed. *Supra* pp. 9-10. Second, unlike sodium, the regulation reflects the Board's conclusion that "[t]here is *no safe level* of artificial trans-fat consumption."[33]

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[31] S*ee People ex rel. Knoblauch v. Warden of Jail of the Fourth Dist. Magistrates' Court*, 216 N.Y. 154, 158-59 (1915) (power to "abate…or otherwise improve…any building…dangerous to life or health").

[32] Toscano, John, *Vallone's Trans Fat ban Signed By Mayor*, The Queens Gazette, Apr. 4, 2007, *available at*, http://www.qgazette.com/news/2007-04-04/features/019.html

[33] Frieden, et al., Public Health in New York City, 2002-2007: Confronting Epidemics of the Modern Era, 37(5) Int. J. of Epidemiology 966 (2008) (emphasis added).

The lower court also pointed to the Calorie Regulation. But that regulation fell within the Board's food-*labeling* authority, now preempted (s*upra* pp. 13-14), and did not require any risk statement linking calorie intake to potential health effects. Further, although the Calorie Regulation was upheld in *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 556 F.3d 114 (2d Cir. 2009) ("*NYSRA*"), it was not subject to a separation of powers challenge.[34]

The lower court's assertion that, unlike the Soda Regulation, the Sodium Mandate "did not devise a new rule that 'significantly changes' the manner in which menu items containing sodium are provided to customers" is not accurate. The Board has promoted the fact that restaurants can avoid the regulation by reformulating their menu items to reduce sodium content, which will reduce the availability of salty foods that, like soda, consumers want and enjoy. R. 396 ("[R]estaurants are at liberty to discontinue or reformulate menu items"); R. 380 (a warning requirement may cause some to offer their customers healthier

[34] The lower court cites *Greater New York Taxi Ass'n v. N.Y.C. Taxi & Limousine Comm'n*, 25 N.Y.3d 600 (2015), which also applied the *Boreali* factors, but is distinguishable. At issue was whether a TLC regulation requiring taxi owners to replace vehicles with a particular model rather than providing specifications for new vehicles as done in the past violated the separation of powers doctrine. *Id.* at 607. First, the Charter provisions authorizing the TLC's activities were far more specific than the authority relied on here: TLC had express authority "to establish . . . standards for equipment safety and design" of taxis, and for "innovation and experimentation in relation to type and design of equipment." *Id.* at 609. Second, the choice between establishing specs and identifying a particular vehicle was a "distinction without a difference" given that the specs used historically had resulted in one option. *Id.* at 610 n. 6. Thus, the regulation did "not involve difficult social problems of any nature." *Id.* at 613.

choices.").[35] Thus, the Sodium Mandate – like the Soda Regulation before it – will, and is intended to, "significantly change" the availability of the impacted menu items for consumers. *Statewide*, 23 N.Y.3d at 700 ("…significantly chang[ing] the manner in which sugary beverages are provided to customers at eating establishments is not an auxiliary selection of means to and end; it reflects a new policy choice.").

B. The Sodium Mandate Intrudes On An Area Of Legislative Debate

The Board cannot use its circumscribed authority to impose its own solution to the sodium debate when this policy area has already been – and continues to be – the subject of legislative debate. Legislative inaction in this context is "evidence that the Legislature has so far been unable to reach agreement on the goals and methods that should govern in resolving a society-wide health problem." *Boreali*, 71 N.Y.2d at 13.[36]

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[35] *Citing* Dolmetsch C, Leslie P., Bloomberg Business, "New York City Sued over New Salt Rules in Fast-Food Fight," *available at,* http://www.bloomberg.com/news/articles/2015-12-03/new-york-city-sued-over-new-salt-rules-in-fast-food-fight ("Burger King and Panera Bread reportedly have changed items on their menus to lower their sodium contents and avoid having to post warnings."); *see also* DOH Guidance Regarding Sodium Mandate, *available at,* https://www1.nyc.gov/site/doh/health/health-topics/national-salt-reduction-initiative.page ("[Restaurants] can let the [DOH] know that a menu item has been reformulated and no longer requires the warning icon ….")

[36] The lower court cites *NYC C.L.A.S.H., Inc. v. N.Y. State Office of Parks, Recreation & Historic Pres.*, 125 A.D.3d 105, 111 (3rd Dep't 2014), *leave to appeal denied*, 25 N.Y.3d 963 (2015), but there, the Legislature explicitly approved the challenged administrative action, whereas here there has been no such approval.

The lower court overlooked the fact that, in the last few years, the City Council has twice-considered adopting the Healthy Happy Meals legislation that would limit the sodium content in certain kids' meals at restaurants. A public hearing on the proposal was conducted earlier this year, and the Council has failed to enact the legislation.[37] By enacting the Sodium Mandate, the Board usurped the City's legislators' role in determining the most effective means to reduce sodium in restaurants.

The State Legislature's failure to pass the bills directed at sodium reduction, including in restaurants, demonstrates the legislature's inability to agree on "the goals and methods that should govern" sodium regulation. *Boreali*, 71 N.Y.2d at 13. The lower court also mischaracterized these legislative efforts in dismissing them. Although it claimed that "none of the bills addressed sodium warning labels in restaurants," in fact three of the four bills did.[38] One of them sought to prohibit restaurants from using sodium in preparing food, which is the real objective of the Sodium Mandate.[39] Moreover, the lower court ignored the fact that legislation need not be identical to preclude agency action under this factor. In *Statewide*, the five state Assembly bills and three City Council resolutions targeting sugar involved the same "area," even though none involved a "portion cap" similar to the

[37] *Supra* pp. 9-10 and notes 11-12.

[38] R. 266-270.

[39] R. 266-268.

one at issue, 110 A.D.3d at 15, and the Court of Appeals held that this *Boreali* factor went against the Board. 23 N.Y.3d at 700. Accordingly, although the Sodium Mandate employs different means of targeting sodium than the legislation at issue here, it pursues the same end of reducing sodium consumption, and thus unquestionably addresses the same policy "area." *Boreali*, 71 N.Y.2d at 13.

The lower court's contention that the bills did not receive sufficient consideration because each "was introduced by one legislator and received no further consideration" is simply not correct. Each of the four bills was introduced by a different legislator, demonstrating broader interest in the topic. Each was also referred to committee for further consideration. In *Statewide*, all of the legislative efforts either "died in committee" or were adjourned *sine die*. The Court explained that such "inaction on the part of the State Legislature and City Council, in the face of plentiful opportunity to act if so desired …" constituted "additional evidence" that the Board engaged in policy-making. 23 N.Y.3d at 700.

C. The Board Has Engaged In Legislative Action

Policy-making is uniquely within the legislature's realm. "[I]t is the province of the people's elected representatives, rather than appointed administrators, to resolve difficult social problems by making choices among competing ends." *Boreali*, 71 N.Y.2d at 13.

Here, the Board improperly balanced health with social, economic and political considerations to improperly devise a policy concerning the difficult social problem of whether and how to regulate sodium consumption. The Board did so by deciding to cover only a small subset of FSEs based on the alleged ease of compliance by them, without health rationales for line drawing, and/or by taking it upon itself to make decisions about sodium regulation amidst scientific controversy.[40] While an agency may at times balance costs and benefits, it is still limited to interstitial rulemaking; the Board "exceed[ed] its authority when it [made] difficult choices between public policy ends, rather than find[ing] means to an end chosen by the legislature. . . ." *Statewide*, 23 N.Y.3d at 700.

1. Respondents Engaged in Legislative Policy-Making By Wading Into The Controversial Sodium Health Arena

The Board has wrongly acted as a legislative body by launching into a highly controversial area. The Board improperly diminished the "long running debate over the merits of eating less salt,"[41] and recent scientific research controverting its desired message that consuming food containing 2,300 mg of sodium is so dangerous that a "Warning" is required.

[40] Even if the relevant state of sodium science were not considered controversial (which it is, *supra* pp. 11-13), the Sodium Mandate would still constitute legislative policy-making because of the way in which the Board weighed its asserted goal of promoting health against economic, social, and political concerns. *Infra* pp. 27-35.

[41] R. 310-314.

A clear schism exits in the scientific community about the Risk Statement's message.[42] The contrary voices are not vocal outliers, but a significant mainstream group of physicians and scientists reporting their scientific results in reputable peer-reviewed journals, and on an increasing basis. A February 2016 metaknowledge analysis of hundreds of sodium studies reveals that only half support the Board's position. R. 955. A worldwide study reported on May 21, 2016, confirmed the finding of prior studies that low salt diets may not be beneficial, and may actually increase the risk of cardiovascular disease.[43]

Further, the Board relies on the Guidelines' UL, but the Risk Statement misinterprets it: a UL does not act as a threshold of daily consumption above which consumers are in danger; yet that is the Risk Statement's erroneous and alarmist message.[44]

The Sodium Mandate will lead consumers to believe that eating the flagged menu items puts them at a health risk, when in fact it distorts the meaning of the 2,300 mg number from the Guidelines, and there is substantial debate about that

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[42] *Supra* pp. 11-13.

[43] McMaster, *supra* note 20; *see also supra* pp. 11-13. The *Wall Street Journal* reported that the NEJM study, "one of the most comprehensive studies yet suggested cutting back on sodium too much actually poses health hazards." R. 310. The Winslow Article reports that the study "found that those who consumed fewer than 3,000 milligrams of sodium a day had a 27% higher risk of death or a serious event such as a heart attack or stroke in that period than those whose intake was estimated at 3,000 to 6,000 milligrams. Risk of death or other major events increased with intake above 6,000 milligrams." *Id*.

[44] *See supra* pp. 11-13; R. 103-106 ¶¶ 15-24.

message. By diving into this debate, combined with the other identified factors, the Board has engaged in unauthorized legislative action.

2. The Board Impermissibly Balanced Non-Health Concerns In Devising The Sodium Mandate

The Board's weighing of competing social, political, and economic interests in an overtly legislative way is improper. *See Boreali*, 71 N.Y.2d at 12 ("Striking the proper balance among health concerns, cost and privacy interests … is a uniquely legislative function").

An example of the Board's improper balancing of non-health related concerns is its determination to apply the Sodium Mandate only to FSEs with 15 or more locations. The lower court found this limitation justified because the Board cited evidence or claimed that "restaurants" are "a primary source of sodium," "sodium content of fast food . . . appears to be on the rise," and such chains "can easily make sodium information available."[45] But for separation of powers purposes, this line drawing itself renders the Sodium Mandate invalid. There is no health-based reason for these distinctions.

This line drawing has serious implications because New York City has a tremendous number of independent and small chain restaurants that compete with Covered Establishments. Petitioner estimates that only 17% of NYC restaurants are Covered Establishments. R. 87 ¶ 4.

[45] R. 16.

The lower court also ignored evidence that undermines its conclusions. It pointed to evidence concerning sodium in fast food, but failed to consider evidence showing that the sodium content at non-covered vendors is comparable or higher. Respondents' evidence shows that restaurant food provides only a small percentage of dietary sodium, and Covered Establishments provide even less. Nearly two–thirds (58.1% to 65.2%) of sodium comes from food and beverages purchased in grocery stores, not restaurants.[46] And of the 18.9% to 31.8% of dietary sodium that comes from "restaurant" food,[47] the Sodium Mandate applies only to a small portion. At most, only 11% of food vendors are impacted.[48]

Moreover, Respondents' evidence shows that the sodium content is comparable (or even higher) in non-covered restaurants. Only between 10.1% and 19.9% of sodium consumed from restaurants by Americans comes from a category of food establishments called "quick service restaurant/pizza."[49] And even that small group includes innumerable non-covered NYC independent pizza establishments.

[46] R. 190, note 12, R. 336-351.

[47] R. 336-351.

[48] This figure is derived from: (i) 19-32% of sodium intake comes from all restaurants combined and (ii) according to the Respondents, chain restaurants represent 1/3 of restaurants (R. 621). If Petitioner's estimate is used (R. 87 ¶ 4), Covered Establishments comprise at most 5.5% of food vendors.

[49] *Id.*

The lower court also ignored the fact that applying the Sodium Mandate to only this small subset of FSEs arbitrarily punishes or benefits essentially identical competitors. The Risk Statement expressly and impliedly states that the food item is unhealthy or may put the consumer at risk, and thus may drive customers not only away from that one item, but to a neighboring establishment that seemingly sells "healthy" or "safe" foods without such warnings.

Moreover, the competitive and economic consequences of the Sodium Mandate do not merely fall on nationwide corporations. Many chain restaurants are independent franchises, owned by small business owners who have no greater means or ease of complying than their counterparts who own independent restaurants. The favored, exempt businesses will continue to market and sell equally high sodium meals without the burdens of complying with the Sodium Mandate while Covered Establishments suffer the loss of customer goodwill and revenue.[50]

Whether the Board is simply ignoring the significant economic harm that the Sodium Mandate's limited applicability imposes on Covered Establishments, or concluded that the harm is justified by a speculative incremental benefit from reducing daily sodium intake, this is the type of balancing and policy-making that

[50] R. 91-94 ¶¶ 20-28; R. 195.

is Court of Appeals has declared impermissible. *See Statewide*, 23 N.Y.3d at 697 (decision to include similar FSE exclusions constituted "policy-making").

The lower court seems to have gleaned from *Statewide* a *per se* rule that the Board could not have engaged in forbidden policy-making because it dubbed the Sodium Mandate a "Warning" and it purportedly does not infringe on consumers' personal autonomy. The court relied upon *dicta* in *Statewide*, which states that regulating through means of a posted "warning" would "likely not" implicate impermissible policy-making because "[i]n such cases it could be argued that personal autonomy issues related to the regulation are nonexistent and the economic costs either minimal or clearly outweighed by the benefits to society, so that no policy-making in the *Boreali* sense is involved." *Id.* at 699.

The lower court misinterpreted this *dicta* and applied it erroneously to this case. First, the Court of Appeals did not give the Board limitless authority to require posted warnings so long as they do not infringe on personal autonomy. The Court's use of qualifying language ("likely not") demonstrates that whether a required posting is permissible remains a case specific inquiry, regardless of whether the Board calls the posting a "warning."

In all events, the Sodium Mandate *does* undermine personal autonomy. With the Soda Regulation, the Board sought to reduce consumption of sugary beverages by making it more difficult for consumers to obtain those drinks in

larger sizes. *Statewide*, 23 N.Y.3d at 698. With the Sodium Mandate, the Board is seeking to reduce consumption of sodium by pressuring restaurants to change the menu items they offer to consumers to avoid the requirement of posting ominous Icons and warnings suggesting their food is unsafe. Thus, although the lower court acknowledged that consumers want the salty foods, the regulation will make the desired foods less available. *See* R. 20:17-25; R. 380, 396 ¶¶ 4, 34.

Second, the *dicta* specifically refers to balancing a "warning" against personal autonomy concerns, not other concerns with respect to policymaking. With the Sodium Mandate, the personal autonomy issues are not triggered in the same manner, and the policy-making is seen in other ways, such as the content of the Risk Statement. *See Boreali*, 71 N.Y.2d at 8 (finding separation of powers violation where no personal autonomy issues raised).

Third, the Court of Appeals' only indication of what might constitute a "warning" was the example offered in a parenthetical, "(e.g., calorie content on menus)." The Risk Statement, which ties a specified sodium intake to the risk of developing serious diseases, is not at all comparable. *Infra* pp. 37-39. None of the parties in *Statewide* briefed what a "warning" was or could mean, and the Court did not consider whether a required posting like the Risk Statement would be an acceptable "warning" rather than policy-making. The Soda Regulation had no such risk statement.

No matter how well intentioned the Sodium Mandate, it is nothing like what the Board has done before, as a "warning" or otherwise, and through it the Board has engaged in impermissible policy-making.

II. THE SODIUM MANDATE COMPELS SPEECH IN VIOLATION OF THE FIRST AMENDMENT

In *Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557 (1980) ("*Central Hudson*"), the Supreme Court established an "intermediate scrutiny" level of review for commercial speech. To survive intermediate scrutiny, the government must show that the regulation (i) serves a substantial governmental interest; (ii) directly and materially advances the asserted interest; and (iii) is no more extensive and burdensome than necessary to further that interest. *Id.* at 566.

The Supreme Court has carved out a narrow area of compelled commercial speech that is subject to a lesser level of review. *Zauderer*, 471 U.S. at 626. In *Zauderer*, the Supreme Court held that a commercial speaker may be compelled to disclose "purely factual and uncontroversial information" about its own products as long as those disclosure requirements "are reasonably related to the State's interest in preventing deception of consumers." *Id*. at 651. Such requirements, however, cannot be "unjustified or unduly burdensome." *Id.*

Courts reviewing challenges to compelled commercial speech that do not fit *Zauderer*'s narrow parameters have applied heightened levels of review. *See, e.g.,*

Safelite Group, Inc. v. Jepsen, 764 F.3d 258, 263-64 (2d Cir. 2014) (regulation requiring insurers and claim administrators communicating with auto glass claimants, and who mention the name of, or schedule an appointment with, an affiliated auto glass company, to also give the name of a competing glass company); *CTIA-The Wireless Ass'n v. City & County of San Francisco*, 494 F. App'x 752, 753-54 (9th Cir. 2012) (given debate in the scientific community about the health effects of cell phones, compelled information disclosure was not both "purely factual" and "uncontroversial"); *Ent. Software Ass'n v. Blagojevich*, 469 F.3d 641, 651-52 (7th Cir. 2006) (declining to apply *Zauderer* review to government's labeling and signage requirements at video game retailers); *see also Evergreen Ass'n, Inc. v. City of New York*, 740 F.3d 233, 245 n.6 (2d Cir. 2014) ("Assuming arguendo that [the information disclosure requirement] regulates commercial speech, we do not believe that the law regulates 'purely factual and uncontroversial information,' such that [*Zauderer*] review would apply.").

A. The Lower Court Erred By Holding That The *Zauderer* Standard Of Review Applies

Zauderer does not apply in this case for either of two reasons: (i) the compelled disclosures in the Sodium Mandate are not "purely factual and uncontroversial;" and (ii) *Zauderer* governs only where the governmental interest is the prevention of consumer deception, which is not the case here.

1. The Risk Statement Is Not "Purely Factual And Uncontroversial"

The Risk Statement consists of two sentences following the exclamation "Warning." To come within *Zauderer*, both sentences must be "purely factual and uncontroversial." The second, in particular, fails to meet this standard.

Read as a whole, as an average consumer would read it, the Sodium Mandate is not purely factual. Rather, the "warning" advises consumers that (i) consumption of more than 2,300/mg day of sodium is "*high* sodium intake," and (ii) consuming more than this amount can increase blood pressure and risk of heart disease or stroke. Based on an accurate understanding of a UL, and/or recent studies cited herein, the assertion that consuming more than 2,300 mg of sodium a day is "high," and that it increases blood pressure and the risk of heart disease and stroke, are not purely factual and not indisputably accurate.[51] By asserting that is it "factual," without any analysis, the lower court overlooked the wording of the Risk Statement read as a whole and/or the heated debate in the scientific community about the medical risks and health consequences associated with the specified level of sodium consumption.[52]

The lower court's conclusion – again, without any analysis – that the Risk Statement is "uncontroversial" is on even shakier ground. Information can be

[51] *Supra* pp. 11-13.

[52] *Supra* pp. 11-13.

factual and still be controversial, thereby removing it from *Zauderer*. *See Evergreen Ass'n, Inc.*, 740 F.3d at 249-50 (requirement for pregnancy-services centers to disclose facts as to whether they provide referrals for abortion, emergency contraception, or prenatal care overly burdens plaintiff's speech where the context is an area of public debate). Given the debate over appropriate levels of sodium intake and the health impacts of consumption, it cannot be seriously disputed that the Risk Statement is controversial. Even if both sides can cite solid scientific evidence in support, that is precisely what makes the issue controversial.[53]

The difference between the Risk Statement and "purely factual and uncontroversial information" is illustrated by comparing *NYSRA*, a readily distinguishable case that applied *Zauderer* and on which the lower court erroneously relied. The Calorie Regulation required the posting of calorie values, and nothing more. *NYSRA*, 556 F.3d at 134. Such straightforward quantitative statements are "purely factual and uncontroversial." *Id.*; *see also Poughkeepsie Supermarket Corp. v. Dutchess County, N.Y.*, No. 15-3321-cv, 2016 WL 2782988, at *1 (2d Cir. May 13, 2016) (applying *Zauderer* review because the challenged law required only the disclosure of "item pricing … about the retailer's own

[53] "Controversial" is defined as "relating to or causing much discussion, disagreement or argument." *Merriam-Webster's Collegiate Dictionary* (11th ed. 2014), *available at,* http://merriam-webster.com/dictionary/controversial

goods"). The compelled disclosure here, however, goes much further. It ascribes a controversial *judgment* to a particular sodium intake threshold and makes a controversial claim, which many covered members object to posting, about the health *consequences* of consuming sodium in excess of a specified level. By doing so, it goes beyond the purely factual and controversial and takes the Risk Statement outside *Zauderer*.

2. *Zauderer* Does Not Apply Because The Sodium Mandate Does Not Correct Misleading Advertising

Zauderer is limited to situations where the disclosure of the factual, uncontroversial information is necessary to prevent misleading advertising. The lower court did not address this argument.

The U.S. Supreme Court has twice limited *Zauderer* to circumstances in which disclosure of factual, uncontroversial information was necessary to prevent misleading or confusing advertising. *See Zauderer*, 474 U.S. at 651-653 (compelled disclosure was warranted to cure an attorney's misleading advertising); *Milavetz, Gallop & Milavetz P.A. v. United States*, 559 U.S. 229, 250 (2010) (requirement that attorney identify himself as a debt relief agency upheld as directed at inherently misleading ads); *see also Dwyer v. Cappell*, 762 F.3d 275, 282 (3d Cir. 2014) (discussing limitation of *Zauderer* and *Milavetz*); *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 966 (9th Cir. 2009) (same).

Even if, as some federal appellate courts have concluded, *Zauderer* applies to circumstances in addition to correcting deception, that standard comes into play only where, unlike the Sodium Mandate, the compelled disclosure consists entirely of factual, uncontroversial, commercial information about the product or services being offered. *See, e.g.*, *NYSRA*, 556 F.3d at 131-34 (disclosure of caloric amounts for all food items on menu); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001) (regulation requiring manufacturers of light bulbs to label their products to inform consumers that the product contains mercury and should be disposed of as hazardous waste).

B. The Lower Court Erred By Failing To Apply Intermediate Scrutiny

A compelled disclosure that falls outside of *Zauderer*'s parameters is minimally subject to intermediate scrutiny. The Sodium Mandate flunks this test.

Concededly, promoting the health of New Yorkers by reducing hypertension, cardiovascular disease and stroke is a compelling government interest. But the Sodium Mandate does not directly and materially advance that interest. Nor can Respondents show that the Sodium Mandate is no more extensive and burdensome than necessary to further that interest. *Central Hudson*, 447 U.S. at 566.

1. The Sodium Mandate Does Not Directly And Materially Advance The Asserted Interests

To show that the Sodium Mandate directly and materially advances the Board's interests, Respondents "must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) (internal citations and quotation marks omitted). "[T]he regulation may not be sustained if it provides only ineffective or remote support for the government's purpose." *Central Hudson*, 447 U.S. at 564. A law compelling speech will not directly and materially advance the government's interest when the law contains numerous exemptions that undercut the government's purpose. *Expressions Hair Design v. Schneiderman*, 975 F. Supp. 2d 430, 446-47 (S.D.N.Y. 2013) (law violated First Amendment where it was "riddled with numerous 'exemptions and inconsistencies [that] bring into question the purpose' of the statute") (quoting *Rubin*, 514 U.S. at 489)), *vacated on other grounds*, 808 F.3d 118 (2d Cir. 2015).

To satisfy these requirements, Respondents would have to show both that ingesting 2,300 mg or more of sodium in a meal, or daily, is in fact harmful to consumers, and that its purported "warning" would reduce consumers' ingestion of more than 2,300 mg of sodium. They cannot do so.

To begin with, given the substantial scientific debate about sodium consumption, especially in a single meal or day, Respondents cannot demonstrate

that consuming more than 2,300 mg of sodium is harmful or that reducing sodium consumption below that level will reduce consumers' risk of heart disease and stroke. In addition, the "risk" relating to sodium is not direct – as it is, say, with tobacco and alcohol, where the use of even a small amount can be harmful. It is, rather, the risk of a risk that potential harm may occur. This causal relationship is not sufficiently real to pass First Amendment muster.

Further, given the inconsistent application of the Sodium Mandate to food establishments and menu items, and the confusion it is likely to cause consumers (*see infra* pp. 47-55), Respondents cannot demonstrate that the Sodium Mandate directly and materially advances the goals of promoting informed consumer decision-making about sodium consumption and reducing consumers' inaccurate perceptions of sodium content in restaurant foods.

Underinclusivity is also relevant to *Central Hudson's* direct advancement prong because it "may diminish the credibility of the government's rationale" for burdening speech. *City of Ladue v. Gilleo*, 512 U.S. 43, 52 (1994). The numerous exemptions undercut the Board's asserted purpose by exempting the majority of the sources of the supposed harm. One of the regulation's glaring carve-outs is the Sodium Mandate's limited application to chain FSEs with 15 or more locations, which comprises at most 11% of food vendors, and at most one-third of restaurants. *Supra* p.31 and *infra* pp. 49-52. Given that nearly 90% of FSEs in

New York City are not covered, the statements compelled by the Sodium Mandate will not reach the vast majority of consumers. Moreover, the Sodium Mandate may cause customers simply to trade one "high" sodium meal for another, because so few establishments must post the Risk Statement. This directly undermines the objective of enhancing a consumer's ability to make decisions about whether to order a food item based on its sodium content. Any message that Respondents hope to convey through the Sodium Mandate will instead be inconsistent and confusing. *See infra* pp. 47-55.

Another exemption that prevents the Sodium Mandate from directly and materially advancing the Board's asserted interests is that even at Covered Establishments, the Sodium Mandate does not apply to combinations of á la carte food items that separately contain less than 2,300 milligrams each, but exceed that amount in combination. The Sodium Mandate thus, at best, simply directs consumers from one meal to another (bought á la carte) that contains the same sodium content. *See infra* pp. 52-55.

Respondents, thus, cannot show that consuming 2,300 mg of sodium in a meal is in fact harmful, or that the Sodium Mandate will reduce sodium consumption.

2. The Sodium Mandate Is More Extensive And Burdensome Than Necessary To Further The Board's Asserted Interests

The Sodium Mandate is also "more extensive than necessary to further the State's interest." *Central Hudson*, 447 U.S. at 569-70. "[I]f there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech, that is certainly a relevant consideration in determining whether the 'fit' between ends and means is reasonable." *City of Cincinnati v. Discovery Networks, Inc.*, 507 U.S. 410, 417 n.13 (1993).

The Sodium Mandate is not "narrowly tailored" to promote health. Rather, because the Sodium Mandate requires a blanket "warning" to all consumers in a Covered Establishment, the Risk Statement will invariably be broadcast not only to consumers whose health is unaffected by what the Sodium Mandate refers to as "high sodium intake," but also to those whose health requires "high sodium intake," or who could suffer adverse health consequences from heeding the Risk Statement. R. 121-131.

There are also plainly less restrictive alternatives to serve the Board's asserted interests. If Respondents want to make consumers aware of the contents of the Risk Statement, the seriousness of cardiovascular disease, and the sources of "high sodium," they can and should distribute their message using their own resources, including by continuing and expanding the myriad efforts they have long undertaken to deliver their views themselves. R. 401 ¶¶ 41-44. These

alternatives include publishing materials on DOH's own website, conducting public awareness campaigns, publishing its own list of "high sodium" foods, directing consumers to free informational sources, and using a variety of other means to promote their views and recommendations about sodium intake.

DOH can even publicize the very message set forth in the Risk Statement, and such communications can target all New Yorkers, not just those who frequent the 11% of food vendors impacted by the Sodium Mandate. That Respondents could so easily achieve their purported objectives through these alternative means, without conscripting private businesses to speak for them, is sufficient to doom the Sodium Mandate. *See Rubin*, 514 U.S. at 491 ("[T]he availability of these options . . . which could advance the Government's asserted interest in a manner less intrusive to [the plaintiff's] First Amendment rights[ ] indicates that [the Government's preferred approach] is more extensive than necessary"); *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 800 (1988) (alternative means "would communicate the desired information to the public without burdening a speaker with unwanted speech[.]"); *Ent. Software*, 469 F. 3d at 652 (suggesting government publication as an alternative to compelled speech).

C. Even If *Zauderer* Applied, Which It Does Not, The Lower Court Erred By Holding That The Sodium Mandate Satisfies *Zauderer* Review

The lower court erred not only by applying *Zauderer*, but by concluding that *Zauderer*'s "reasonable relationship" test was met. R. 16-17.

First, because the communicated "information" in the Risk Statement is scientifically questionable, the regulation is not reasonably related to its objective. *Supra* pp. 11-13. Second, the Sodium Mandate is riddled with exemptions and exceptions that will confuse customers rather than inform them, and often lead to the dissemination of misinformation. *Infra* pp. 47-55. Third, Respondents' efforts to regulate the risk of a risk that potential harm may occur is too remote to survive First Amendment scrutiny. *Supra* pp. 41-42.

The Sodium Mandate is also unjustified. The FDA has already passed regulations that, beginning in May 2017, will require Covered Establishments to make available nutritional information, including sodium content, for all menu items. *Supra* pp. 13-14. Based on this comprehensive information, consumers will be able to make their food choices accordingly. Imposing the Sodium Mandate – with its burden on the free speech rights of private parties, and its potential for confusion and worse – is not rational, and it is unjustified.

Finally, the Sodium Mandate is unduly burdensome, based on the financial and manpower burdens that it imposes on Covered Establishments,[54] and the associated negative messaging that will injure their goodwill, customer relationships, and competitive position relative to non-covered FSEs. The regime's arbitrary nature will not only create uncertainty for customers, it will also interject an element of unjustified fear, that will discourage consumers from purchasing the Covered Establishments' products and drive people to patronize the more than 80% of restaurants that sell foods containing the same or higher amounts of sodium, but without Respondents' "Warning."

III. THE SODIUM MANDATE SHOULD BE INVALIDATED BECAUSE IT IS ARBITRARY AND CAPRICIOUS

The Sodium Mandate is also unlawful because it is "arbitrary and capricious." CPLR § 7803(3). "[A]n administrative regulation will be upheld only if it has a rational basis, and is not unreasonable, arbitrary or capricious." *N.Y. State Ass'n of Counties v. Axelrod*, 78 N.Y.2d 158, 166 (1991); CPLR § 7803(3). In making this determination, agency rules "are not judicially reviewed pro forma in a vacuum, but are scrutinized for genuine reasonableness and rationality in the specific context." *Axelrod*, 78 N.Y.2d at 166.

The "two-step process" for this claim "requires examination of the reasonableness of the action and, secondly, whether the alleged action is arbitrary

[54] R. 92-94 ¶¶ 24-29.

and capricious." *Statewide*, 2013 WL 1343607 at *20.[55] A regulation is properly invalidated where it has "arbitrary and capricious consequences" or where it contains elements or loopholes that "effectively defeat the stated purpose of the Rule." *Statewide*, 2013 WL 1343607 at *20. *See also Axelrod*, 78 N.Y.2d at 167-168 (regulation arbitrary and capricious where it "clashes with the design and intendment" of the regulation, or where it has a "discriminatory and disparate impact" on the affected parties).

The decision in *Statewide* is particularly relevant here. The Supreme Court found that there was a reasonable basis for the Soda Regulation given the rising obesity rate in New York City. 2013 WL 1343607, at *19. Under the second prong of the test, however, the court struck it down as arbitrary and capricious:

> The Rule is nevertheless fraught with arbitrary and capricious consequences. The simple reading of the Rule leads to the early acknowledged uneven enforcement even within a particular City block, much less the City as a whole. Furthermore, as previously discussed, the loopholes in this Rule effectively defeat the stated purpose of the Rule. It is arbitrary and capricious because it applies to some but not all food establishments in the City, it excludes other beverages that have significantly higher concentrations of sugar sweeteners and/or calories on suspect grounds, and the loopholes inherent in the Rule, including but not limited to no limitations on refills, defeat and/or serve to gut the purpose of the Rule.

[55] The Court is limited to considering the reasons the Board gave in taking action. "'If those grounds are inadequate or improper, the court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis.'" *Scherbyn v. Wayne-Finger Lakes Bd. of Coop. Educ. Servs.*, 77 N.Y.2d 753, 758 (1991) (quoted source omitted).

Id. at *20.[56]

The Sodium Mandate, too, is so arbitrary as to whom it applies and how it applies that it guts the very purpose it is supposed to serve, and is more likely to confuse consumers than to help them. More specifically, the Sodium Mandate is arbitrary and capricious because it: (1) applies arbitrarily only to a small minority of vendors selling foods containing 2,300 mg of sodium, and/or (2) irrationally requires the Icon and Risk Statement to appear for "menu items" containing 2,300 mg or more of sodium, including combination meals and in a manner that provides misinformation for items offered in varieties.

In short, the Sodium Mandate irrationally steers customers away from certain items to others with comparable or even higher sodium content, and away from regulated vendors to unregulated ones that sell foods with comparable or higher sodium contents. It thus draws irrational lines, and requires Covered Establishments to convey to all customers an alarmist Risk Statement that does not advance the objective of enabling consumers to identify "high sodium" foods.

A. Application Of The Sodium Mandate To Some Food Vendors But Not Others Is Arbitrary And Capricious

Respondents' stated objective for the Sodium Mandate is to "provide consumers with information about food items that contain exceedingly high sodium levels," meaning 2,300 mg or more, and thus "empower them to make

[56] On appeal, the Appellate Division did not address this determination.

well-informed decisions" in the retail food environment.[57] Given this purpose, it is irrational to require only a small segment to post the Icon and Risk Statement, but not thousands of others. The result is an arbitrary patchwork of covered and non-covered establishments that bears no rational relationship to the asserted goal of helping consumers identify high sodium foods.

First, there is no health-based rationale for applying the Sodium Mandate to a small subset of FSEs, and not others, and the lower court erred in ignoring evidence concerning non-covered establishments in its ruling. *Supra* pp. 30-35. The stated objective of the Sodium Mandate and the arbitrary focus on larger chain fast food restaurants, which provide at most 11% of dietary sodium to city residents, renders the Sodium Mandate indefensible. Second, the lower court ignored the devastating consequences of the Sodium Mandate to this small subset of FSEs, as it arbitrarily punishes them while ignoring essentially identical competitors. *Supra* pp. 30-35.

The lower court also accepted the Board's rationale that the regulation "is not unduly burdensome for chain restaurants because they have uniformity in their menu items and food preparation." R. 16. As an initial matter, this justification shows that Respondents weighed competing economic factors in an impermissible

[57] R. 190.

way, which, as set forth above, constitutes legislative policy-making. *Supra* pp. 27-35.

But even if the Board were entitled to consider and balance these competing economic considerations, it would have to undertake that task in a careful, rational fashion. The lower court failed to cite any basis for the assumption that the Sodium Mandate is not unduly burdensome, Respondents offered none, and the assumption is wrong. *See Axelrod*, 78 N.Y.2d at 168 (percentage reduction in regulation based on an assumption, not empirical information, was arbitrary and capricious).

As explained *supra* pp. 30-33, the economic consequences do not merely fall on nationwide corporations, but on many independent franchise owners for whom it is a significant burden. *See Metro. Taxicab Bd. of Trade v. N.Y.C. Taxi & Limousine Comm'n*, 18 N.Y.3d 329, 334 (2011) (regulation that imposed unjustifiable burdens on taxi drivers without any beneficial effect or rational basis was arbitrary and capricious).

The fact, noted by the court below, that the Sodium Mandate is imposed on the same establishments as the Calorie Regulation does not save it from being arbitrary and capricious. That regulation merely requires restaurants to list the calorie content of each menu item; it does not address the purported medical impact as does the Risk Statement, which will provide controversial and

incomplete information to consumers, drive them away from Covered Establishments, and thus arbitrarily and unfairly impact them.

The fact that consumers will avoid the Risk Statement simply by purchasing the same food items at the more than 80% of restaurants, and 90% of food vendors, which are not covered by the regulation eliminates any realistic likelihood of reducing sodium consumption and improving cardiovascular health through this regulation. The arbitrary and limited reach of the regulation, and its irrational loopholes, ensures that consumers will continue unwittingly to consume food items with such sodium levels, which will "defeat and/or serve to gut the purpose of the" Sodium Mandate. *See Statewide*, 2013 WL 1343607, at *20; *see also Law Enforcement Officers Union Dist. Council 82 v. State of N.Y.*, 229 A.D.2d 286, 289-90 (3d Dep't 1997) (affirming annulment of regulation governing square footage requirements in inmate housing units given arbitrary and unjustifiable distinctions between types of units); *Kelly v. Kaladjian*, 155 Misc.2d. 652, 657-58 (Sup. Ct. N.Y. Cty. 1992) (regulation setting guidelines for emergency home relief grants was unreasonable because it drew artificial distinctions between applicants that bore no rational relationship to agency's goal of providing emergency assistance to persons facing eviction).

B. The Sodium Mandate As Applied To "Menu Items" Is Arbitrary And Capricious

Because the Sodium Mandate focuses on "menu items," and not meals, and requires the Icon to appear if any version of an item exceeds 2,300 mg, the Sodium Mandate is arbitrary and capricious. The lower court upheld the Sodium Mandate because it allegedly provides "information" and thus "empowers consumers," but ignored the fact that that it will often provide misleading information, and thus not empower, but confuse, consumers.

The Sodium Mandate requires the Icon to appear next to any "menu item," including "combination meals," that contain 2,300 milligrams or more of sodium. If any version of an item contains the requisite amount, the Icon must be posted. *Supra* p. 9 and notes 9-10.

The focus on "menu items" – which treats á la carte items and combination meals the same – creates the illogical result that foods served as a combination meal are flagged as containing allegedly risky levels of sodium, but the exact same foods sold á la carte do not. The consumer purchasing the items á la carte thus receives no notification that the foods selected allegedly contain risky levels of sodium, but the purchaser of the combination item does. This is as illogical as the Soda Regulation, which prevented a consumer from purchasing a 32 oz. soda, but would not have prohibited a sale of a 16 oz. soda with free refills. *Statewide,* 2013 WL 1343607, at *20. If the Icons drive consumer selections of foods as intended,

it will lead to results that directly contradict the stated purpose of the regulation, because even in the same restaurant, the Risk Statement will steer consumers away from one menu item and to another that has equal, or even higher, sodium levels.

Once varieties of menu items are taken into account, any rationality of the Sodium Mandate entirely breaks down: it results in flagging menu items as having more than 2,300 mg of sodium when they do not. If only one of six available burrito toppings would cause it to exceed the threshold, the Icon must appear next to the burrito. The Icon informs consumers that the burrito has more than 2,300 mg of sodium – and may cause high blood pressure and increased risk of cardiac illness – when most burritos created from the optional toppings do *not* contain that level of sodium. The vast number of options available in many Covered Establishments exponentially increases the misleading information provided by the Sodium Mandate.

The lower court ignored these issues entirely, and Respondents have not provided any credible health-based or scientific rationale for using the Icons in these irrational ways. Respondents appear to have drawn these irrational requirements for reasons of expediency and to try to avoid federal preemption (*supra* pp. 13-14), but at best, they result in a regulation that is completely illogical and arbitrary. There is no rational relationship between what items bear the Icon and the objective of identifying high sodium foods for consumers. *See Statewide*,

2013 WL 1343607 at *20 (soda ban arbitrary and capricious because it excludes beverages with higher concentrations of sweeteners on suspect grounds, and "the loopholes inherent in the Rule, including . . . no limitations on re-fills, defeat and/or serve to gut the purpose of the Rule").

IV. THE SODIUM MANDATE IS PREEMPTED BY FEDERAL LAW

The Risk Statement characterizes (1) the relationship of sodium to a disease or health-related condition and (2) the level of sodium contained in certain menu items. As such, the lower court did not dispute the fact that the Risk Statement is both a "health claim" and "nutrient content claim" regulated by the FDA. The court erred, however, by holding that an exception for "food safety" warnings applies in this case. It does not, and the Risk Statement is preempted.

A. The Sodium Mandate Requires A "Health Claim" and "Nutrient Content Claim" That Are Not Identical To The Labeling Requirements Of The NLEA, And Is Preempted

Congress enacted the NLEA "to establish the circumstances under which claims may be made about the nutrients in foods." *Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 223 (2d Cir. 1998) (quotation omitted). The NLEA amended the Federal Food, Drug, and Cosmetic Act ("FFDCA"), to, among other things, expressly preempt any state or local requirements for food labeling that are "not identical" to certain requirements of the NLEA or the FFDCA. 21 U.S.C. § 343-1.

At issue is Section 343(r) of the NLEA, entitled "Nutrition levels and health-related claims," and the related preemption provision, Section 343-1(a)(5). The NLEA expressly preempts state or local requirements "respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r)." 21 U.S.C. § 343-1(a)(5).

The claims described in section 343(r)(1), which are expressly preempted, include "health claims" and "nutrient content claims." 21 U.S.C. § 343(r)(1)(A) and (B). "Health Claims" are any claim that "characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or health-related condition." 21 U.S.C. § 343(r)(1)(B). "Nutrient content claims" are any claim that "characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food." 21 U.S.C. § 343(r)(1)(A). Paragraphs (q)(1) and (q)(2) refer to nutrition labeling, and sodium is a nutrient required in nutrition labeling. 21 C.F.R. § 101.9(c)(4).

The relevant FDA regulations make clear that the preemptive effect of section 343-1(a)(5) extends to health claims and nutrient content claims regarding food nutrients. These regulations define "health claims" broadly as "any claim made on the label or in the labeling of a food . . . that expressly or by implication, . . . characterizes the relationship of any substance to a disease or

health-related condition." 21 C.F.R. § 101.14(a)(1). Sodium qualifies as a "substance" because it is a component of a food. *Id.* at 101.14(a)(2).[58] A "nutrient content claim" is any "claim on a food product that directly or by implication characterizes the level of a nutrient in the food (*e.g.*, "low fat," "high in oat bran," or "contains 100 calories"). 21 C.F.R. 101.13. In a case involving a nutrient content claim, the Second Circuit made clear that "states are . . . preempted from adopting nutrition claim laws as defined by Section 343(r)," and that as to restaurant food "this scheme is simple:" "the NLEA . . . *does* generally regulate nutrition content claims on restaurant foods, and states may only adopt rules that are identical to those provided in the NLEA." *NYSRA*, 556 F.3d at 120 (emphasis in original).

The Sodium Mandate violates the NLEA by impermissibly requiring an unauthorized health claim linking the substance sodium with the health-related conditions high blood pressure, heart disease, and stroke. The Icon is part of this health claim: symbols are included within the definition of health claim, and the salt shaker symbol links the food to the statement about blood pressure, heart

[58] Examples of "health claims" include "fiber helps to prevent cancer" (*Pub. Citizen, Inc. v Shalala*, 932 F. Supp. 13, 15 (D.D.C. 1996)); "frequent between-meal consumption of foods high in sugars and starches can promote tooth decay" (21 C.F.R. 101.80(c)(2)(A)); and "[d]iets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may reduce the risk of heart disease and some cancers" (*see* FDA Modernization Act Health Claim, Docket No. 1999P-2209.)

disease, and stroke.[59] The statutory definition of a "health claim" matches precisely the elements of the Icon and Risk Statement.

The FDA has not authorized any health claims regarding "high sodium intake" and blood pressure, heart disease, or stroke, either under its regulations or through the notification process. It has authorized claims about low sodium intake and the risk of hypertension or high blood pressure, *see* 21 C.F.R. § 101.74, but the Risk Statement – linking *high* sodium intake with the subject health-related conditions – is not "identical to" this authorized health claim, and the statutory and regulatory framework requires that the exact claim language be pre-authorized by the FDA. *Turek v. General Mills*, 662 F.3d 423, 427 (7th Cir. 2011) ("Even if the disclaimers that the plaintiff wants added would be consistent with the requirements imposed by the [FFDCA], consistency is not the test; identity is.")

The preemption of the Risk Statement is clear. In *Turek*, for example, plaintiffs alleged that defendant misrepresented the fiber in its granola bars because defendant failed to disclose to consumers that the bars contained "non-natural" fiber which had not been shown to possess the health benefits of natural fibers. Plaintiffs sought injunctive relief, including a requirement that defendant implement a corrective advertising campaign. The court held that plaintiff's claims were preempted, because they would require the defendant to make claims

[59] By way of comparison, FDA treats a heart symbol as a health claim, regardless of whether it is linked to a statement about the risk of a disease. 21 C.F.R. § 101.14(a)(1).

about fiber that were not identical to federal regulations. *Id*. at 427. Similarly, in *Mills v. Giant of Maryland, LLC*, 441 F.Supp.2d 104 (D.D.C. 2006), *aff'd* 508 F.3d 11 (D.C. Cir. 2007), plaintiffs sought an injunction requiring milk sellers to adopt a warning label that alerted consumers about the possible risks of lactose intolerance. The court held that plaintiff's claims were preempted because the desired statement was inconsistent with federal milk regulations. *Id.* at 108.

In addition, the Sodium Mandate requires restaurants to make an unauthorized nutrient content claim because the Icon and first sentence of the Risk Statement categorize the level of sodium (*i.e.*, at or above 2,300 mg) as "high sodium intake." Such statements made in the label or labeling of food that categorizes the level of a nutrient in a food may only be made if specifically authorized by the FDA. 21 U.S.C. § 343(r)(1)(A). While the FDA has authorized nutrient content claims concerning the level of sodium in foods, *see* 21 C.F.R. § 101.61, the FDA has not authorized the nutrient content claim made in the Icon and Risk Statement.

B. The NLEA's Exception For Safety Warnings Does Not Apply To The Sodium Mandate

In finding no preemption, the lower court relied on an exception to express preemption for "a warning concerning the safety of the food or component of the food." Pub. L. No. 101-535 § 6(c), 104 Stat. 2353, 2364 (1990).

Although the food safety exception has existed for more than 25 years, it has rarely been invoked, and is not properly relied upon here. We are unaware of any state or locality nationwide that has utilized this exception to allow warning statements about non-toxic substances or, more specifically, about an essential nutrient, as Respondents do here. If local governments could avoid federal preemption simply by placing the word "Warning" in front of health or nutrient content claims, they would routinely do so, and the notion of federal preemption of such claims would be rendered meaningless. Whether the Risk Statement is a preempted "health claim" or "nutrient content claim" is determined by the definitions of those terms, and not by DOH's addition of the word "Warning" in front of the claim.

Moreover, the exception has applied only to warnings about inherently dangerous substances, not to statements about the consumption of essential nutrients, even when consumed in allegedly excessive amounts. An example is the carcinogens at issue in California's Prop 65, a statute aimed at products "known to cause cancer, birth defects or other reproductive harm," and one of the few statutes found to fall within this exception. *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 4 (Cal. 2004) ("The Modernization Act, however, contained a savings clause designed specifically to preserve Proposition 65. . . . Proposition 65 is the only state enactment that falls within the savings clause."). *See also*

Mills, 441 F. Supp. at 109 (symptoms of lactose intolerance did not raise safety concerns to invoke the exception for warnings).

Many hundreds of nutrients pose potential adverse health effects in certain circumstances, whether related to amount ingested or the particular sensitivities of the consumer. The statute's "safety" exception has never before been used to reach such circumstances, and should not be so extended here.

CONCLUSION

For any or all of the foregoing reasons, the Decision of the lower court should be reversed.

Dated: New York, New York
August 8, 2016

Respectfully submitted,

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SUPREME COURT OF THE STATE OF NEW YORK
APPELLATE DIVISION, FIRST DEPARTMENT

NATIONAL RESTAURANT ASSOCIATION,

Plaintiff-Appellant,

-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,

Defendants-Respondents.

Index No. 654024/2015

PRE-ARGUMENT STATEMENT

Pursuant to 22 NYCRR § 600.17, Plaintiff-Petitioner, National Restaurant Association, in connection with its appeal, states as follows:

1. Title of the Action.

The title of the action is set forth in the caption above.

2. Full names of original parties and any change in the parties.

The full names of the original parties to this action are set forth in the caption above. There have been no changes to the parties.

3. Name, address and telephone number of counsel for appellant or petitioner.

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5. Court and county from which the appeal is taken.

This appeal is being taken from the Supreme Court of the State of New York, New York County (Rakower, J.).

6. Nature and object of the cause of action.

On December 3, 2015, Plaintiff-Appellant filed a Verified Article 78 and Declaratory Judgment Petition (the "Petition"). The Petition sought a decision and declaration that § 81.49 of the New York City Health Code (the "Sodium Mandate") was unlawful on the following grounds: (i) its adoption by the New York City Board of Health (the "Board") violated the separation of powers doctrine; (ii) the Sodium Mandate is arbitrary and capricious in violation of CPLR § 7803(3); (iii) the Sodium Mandate violated the First Amendment rights of the chain restaurants to which it applied; and (iv) the Sodium Mandate is preempted by the federal Nutrition Labeling and Education Act.

On December 4, 2015, Plaintiff-Appellant filed a motion for a preliminary injunction seeking to enjoin implementation and enforcement of the Sodium Mandate pending a final decision on the merits of its claims (the "Motion").

7. Result reached in the court below.

On February 24, 2016, the Court heard oral argument. At the conclusion of oral argument, the Court issued an oral decision from the bench denying both the Petition and the Motion. By Decisions and Orders dated February 24, and 26, 2016, and entered on February 26, 2016, the Court incorporated its remarks from the bench and supplemented them with further analysis.

8. Grounds for seeking reversal, annulment or modification.

The lower court erred in dismissing the Petition. The lower court misapplied the law and erroneously concluded that Plaintiff-Appellant did not establish its claims. First, the lower court erred in finding that the Board acted within its regulatory authority in enacting the Sodium Mandate, and did not violate the separation of powers doctrine. Among other things, the Board engaged in impermissible policy making with this regulation, and violated the separation of powers doctrine. Second, the lower court erred in finding that the Sodium Mandate does not violate the First Amendment rights of covered chains, and that a *Zauderer* standard of review applied. Among other things, the Sodium Mandate forces the covered restaurants to promote the Respondents' views in the form of a scientifically controversial health claim, and despite the existence of numerous less restrictive means that the government can use and has used to promote its message about sodium. Third, the lower court erred in finding that the Sodium Mandate is not arbitrary and capricious. The regulation is arbitrary as to which food establishments it applies to and how it applies within a restaurant. The result is to defeat the very purpose it is supposed to serve, and to more likely confuse consumers than help them. Fourth, the lower court erred in determining that the Sodium Mandate is not preempted. The Sodium Mandate is preempted by because it is a health claim and/or nutrient content claim that is not identical to federal law, and it does not fall within an exception for food safety warnings under

the Nutrition Labeling and Education Act.

The lower court also erred in denying the Motion. The court erred in finding that Plaintiff-Appellant did not demonstrate a likelihood of success on the merits of its respective claims. The court did not address irreparable harm or balance of the equities, but both were established by Appellant. Irreparable harm included violations of constitutional rights, harm from Defendants-Respondents' other constitutional violations, damage to members' good will and reputations, and unrecoverable economic harm from compliance with the regulation. Against the above irreparable harm, Defendants-Respondents would suffer minimal or no harm in refraining from enforcing the regulation pending judicial review.

9. Other actions/appeals

There are no actions or proceedings related to this action presently pending in any other court. There are no additional appeals pending in this action.

Dated: New York, New York
February 26, 2016

Respectfully submitted,

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