

**SUPREME COURT OF THE STATE OF NEW YORK
APPELLATE DIVISION: FIRST DEPARTMENT**

NATIONAL RESTAURANT ASSOCIATION,

Plaintiff-Petitioner-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 and Mental Hygiene,

Defendants-Respondents-Appellees.

**New York County
Index No. 654024/2015**

**MEMORANDUM OF LAW OF *AMICI CURIAE*
AMERICAN HEART ASSOCIATION,
CENTER FOR SCIENCE IN THE PUBLIC INTEREST, CHANGELAB SOLUTIONS,
COALITION FOR ASIAN AMERICAN CHILDREN AND FAMILIES, THE FOOD TRUST,
NATIONAL ASSOCIATION OF CHRONIC DISEASE DIRECTORS,
NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS,
NATIONAL ASSOCIATION OF LOCAL BOARDS OF HEALTH, NEW YORK STATE
PUBLIC HEALTH ASSOCIATION, NEW YORK STATE ACADEMY OF PEDIATRICS,
PUBLIC HEALTH ASSOCIATION OF NEW YORK CITY, AND
PUBLIC HEALTH LAW CENTER
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PRELIMINARY STATEMENT

Hypertension – high blood pressure – is the second-leading cause of preventable death in the United States; only smoking ends more lives prematurely.¹ Recognizing the urgency of this public health crisis, the Board of Health adopted a rule requiring that larger restaurant chains post icons on their menus warning patrons when any single item exceeds by itself the U.S. government’s recommended *daily* limit for sodium intake.

The response to the Rule has varied. Some restaurant chains immediately complied, taking the opportunity to better inform their customers of the presence of often unexpectedly high levels of sodium in certain menu items.² Unfortunately, the NRA has not taken the advent of the Rule as an opportunity to better inform customers, or to encourage its members to reformulate products so that patrons – knowingly or unknowingly – would *not* be consuming a day’s worth of salt in a turkey sandwich or a bowl of soup. Instead, the NRA has decided that what it needed to do was sue. Now, after waiting – despite ample notice – until after the Rule’s effective date to bring its legal challenge,³ and having had its challenge found unlikely to prevail on the merits, it seeks further delay through the “extraordinary and drastic remedy” of a preliminary injunction. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997).

Plaintiffs have a very steep climb in order to obtain relief on their motion for a preliminary injunction. First, they must overcome “an exceedingly strong presumption of constitutionality,” *Schulz v. State Executive*, 108 A.D.3d 856, 857 (3d Dep’t 2013), with respect to the sodium

¹ Harvard School of Public Health, *Smoking, High Blood Pressure and Being Overweight Top Three Preventable Causes of Death in the U.S.* (2009), <http://www.hsph.harvard.edu/news/press-releases/smoking-high-blood-pressure-overweight-preventable-causes-death-us>

² Daniel Victor, *High-Salt Warnings on New York Menus to Start Tuesday*, N.Y. TIMES (Dec. 1, 2015), <http://www.nytimes.com/2015/12/01/nyregion/salt-warnings-new-york-restaurants.html/> As the CEO of one covered chain observed, “[T]here are a number of items on [our] menu, not a lot, that have high salt levels or that are indulgences and ... that is OK as long as you are clear, you’re making that choice, you’re aware of it and you have the ability to make it on your own.” Reem Nasr, *Panera CEO: I Favor Sodium Warnings on Menus*, CNBC (June 16, 2015), <http://www.cnbc.com/2015/06/16/panera-ceo-i-favor-sodium-warnings-on-menus.html/>

³ See Notice of Adoption, at <http://www.nyc.gov/html/doh/downloads/pdf/notice/2015/noa-section49-article81.pdf> (noting publication date of June 23, 2015 and effective date of December 1, 2015).

warnings rule. N.Y.C. Health Code § 81.49 (the Rule). Second, they must contend with the clarity and strength of the Supreme Court’s denial of their request for a preliminary injunction below; “with the decision to grant or deny a request for a preliminary injunction committed to the sound discretion of the trial court,” this Court’s review is “limited to whether Supreme Court has either exceeded or abused its discretion as a matter of law.” *Matter of Schulz v. State of New York*, 217 A.D.2d 393, 396 (3d Dep’t 1995) (citing *Doe v. Axelrod*, 73 N.Y.2d 748, 750 (1988)).

Far from exceeding or abusing its discretion, the Supreme Court here issued – after full (and supplemental) briefing and oral argument – a carefully considered opinion denying the National Restaurant Association’s request for a preliminary injunction. Sup. Ct. Order at 8. The NRA failed to demonstrate, as it was required to by “clear and convincing evidence,” *Brookhaven Baymen’s Ass’n, Inc. v. Town of Southampton*, 85 A.D.3d 1074, 1078 (2d Dep’t 2011), each of the following: “a probability of success on the merits, danger of irreparable injury in the absence of an injunction and a balance of equities in its favor.” *Schulz*, 108 A.D.3d at 856. The Supreme Court found that because the NRA had failed to establish a likelihood of success on the merits, the inquiry was at an end. Sup. Ct. Order at 8; *see Doe v. Axelrod*, 73 N.Y.2d at 750.

There are no grounds for disturbing that reasoned judgment. Given the likely outcome of the case, and the seriousness of harm to the public if enforcement of the Rule is stayed, the NRA is simply asking this Court for too much. The balance of harms in this case weighs heavily in favor of a City trying to provide vital health information to its citizens. Hypertension shortens the lives of approximately 12,000 New York City residents each year.⁴ Warnings about sodium are crucial for New York residents who are at high risk, including African-Americans, people age 51 and over, and people who have high blood pressure, diabetes, or kidney disease. Underscoring the scale of the crisis, these vulnerable groups who are in particular need of the warnings make up more than half of the City’s adult population. More than 29% of adults in the

⁴ See CDC, Div. for Heart Disease and Stroke Prevention, *Interactive Map - High Blood Pressure Death Rate per 100,000, All Ages, All Race, All Gender, 2011-2013*, <http://tinyurl.com/hbqbeou>

City have been told by a health professional that they already suffer from hypertension,⁵ meaning that there are almost 2 million New Yorkers for whom a reduction in sodium consumption is crucial for improved health and a longer life.

But this Court need not even reach the balance of harms, since the NRA has not established – and cannot establish – a likelihood of prevailing on the merits. Notwithstanding the restaurant association’s attempt to sow scientific doubt and uncertainty about sodium and hypertension, there is a clear and continued scientific consensus regarding the relationship between the two and broad acceptance of the need for a reduction in dietary salt.

Similarly, the NRA’s legal arguments of national import on which this memorandum focuses – that the Rule is arbitrary and capricious, that it violates the First Amendment, and that it is preempted by federal law – do not stand up to serious inspection. First, far from being arbitrary or capricious, the Rule’s lines are in fact drawn with a keen understanding of the boundaries of the Board’s authority. Second, the Rule works in harmony with the First Amendment, which *favors* factual disclosures in the commercial context. Third, the Rule is not preempted by federal law: the explicit savings clause in the federal menu labeling law for “warnings” like this one excepts the Rule from preemption.

The Rule is a necessary, scientifically sound, and legally well-grounded measure, carefully designed to work within the boundaries of New York law and the federal Constitution, as well as to coordinate with the City’s larger effort to reduce hypertension among its residents.⁶ The NRA has no likelihood of success on the merits of its challenge. This Court will of course have ample opportunity to consider the merits of the case in the regular course of appellate proceedings. In the meantime, the request for a preliminary injunction should be denied.

⁵ NYC Dep’t of Health and Mental Health, Community Health Survey (2013), Notice of Adoption at 1.

⁶ See Tom Farley, *SAVING GOTHAM* 113, 161 (2015).

STATEMENT OF INTEREST OF *AMICI CURIAE*

The American Heart Association (AHA) and the other medical and public health organizations that have signed this memorandum⁷ are dedicated to improving the health of their members and the populations they serve. The signatories range from the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke to local groups that comprise thousands of New York City's doctors, biomedical scientists, and public health experts. These organizations come before this Court to share their expertise and experience because in challenging the Rule the NRA has made assertions that run counter to accepted medical science. First, despite the NRA's attempts to muddy the waters, the medical and scientific communities are in broad agreement regarding the need for most New Yorkers, particularly those at greatest risk for hypertension, to reduce their current over-consumption of sodium. Second, there exists no medical or scientific controversy about whether people suffering from or at risk for hypertension should avoid single menu items exceeding 2300 mg of sodium.

Further, the government agencies with which the *amici curiae* work, in New York City and elsewhere, must operate in accordance with statutory and constitutional principles that may be impacted by the decision reached by this Court. This memorandum addresses three legal issues with potential national repercussions – the arbitrary and capricious standard, the First Amendment, and NLEA preemption. *Amici* are keenly interested in having these issues resolved in accord with both current scientific evidence and the current state of the law.

⁷ Statements of Interest for the individual *amici curiae* appear in Appendix A to this memorandum and in the Motion for Leave to File.

ARGUMENT

I. THE SODIUM WARNINGS ARE AN APPROPRIATE RESPONSE TO A PUBLIC HEALTH CRISIS.

The requirement that chain restaurants post a symbol indicating that a single menu item exceeds the recommended total daily sodium limit is a moderate and reasonable response to a severe public health threat. The health benefits of reducing excess sodium consumption continue to be ever more solidly established. Chain restaurants contribute substantially to the problem. The symbols and the accompanying warning statement provide information without limiting consumer choice and can potentially be of significant benefit because most Americans significantly underestimate their sodium consumption, especially when eating restaurant food.

A. Overconsumption Of Sodium Is A Severe Threat To Public Health.

As noted, high blood pressure is the second-leading cause of preventable death in the United States, behind only smoking. It is responsible for approximately 395,000 premature deaths a year – about one in six deaths of all adults.⁸ Overconsumption of salt is the major factor increasing blood pressure.⁹ Over 100,000 deaths per year in the United States are attributable specifically to high dietary salt, more than any other single dietary factor.¹⁰

Eighty-six percent of adults in the United States consume more than the Tolerable Upper Intake Level (UL) of sodium.¹¹ (The UL is the ceiling recommended by the Institute of Medicine (IOM) for sodium consumption for healthy people not at particular risk for high blood pressure.¹²) Mean daily sodium consumption for adults 20 and over, according to the most recent figures available, is 3592 mg,¹³ almost 1300 mg more than the 2300 mg recommended by the federal government and more than double the 1500 mg recommended for at risk groups.¹⁴

⁸ Harvard School of Public Health, *Smoking, High Blood Pressure and Being Overweight*, *supra* n. 1.

⁹ Feng He & Graham MacGregor, *A Comprehensive Review on Salt and Health and Current Experience of Worldwide Salt Reduction Programmes*, 23 J. HUM. HYPERTENSION 363, 363 (2009).

¹⁰ Amanda Rudelt et al., *Fourteen-Year Trends in Sodium Content of Menu Offerings at Eight Leading Fast-Food Restaurants in the USA*, 17 PUBL. HEALTH NUTR. 1682, 1682 (2014).

¹¹ IOM, *Strategies to Reduce Sodium Intake in the U.S.* 427 (App. F, T. F-5) (2010).

¹² USDA, *DIETARY GUIDELINES FOR AMERICANS 2010*, 21 (2011), <http://health.gov/dietaryguidelines/dga2010/DietaryGuidelines2010.pdf>

¹³ USDA, *What We Eat in America, NHANES 2011-2012*, T1 (2014),

http://www.ars.usda.gov/SP2UserFiles/Place/80400530/pdf/1112/Table_1_NIN_GEN_11.pdf

¹⁴ CDC, *Salt Home*, <http://www.cdc.gov/salt/index.htm>

Studies have demonstrated that reducing sodium consumption would produce tremendous benefits. Reducing daily intake by 1200 mg would avoid between 44,000 and 92,000 deaths annually in the United States, along with 60,000 - 121,000 new cases of heart disease, 32,000 - 66,000 strokes, and 54,000 - 99,000 myocardial infarctions.¹⁵ The decline in cardiovascular events would be at least as large as the decline expected from a 50% reduction in tobacco use.¹⁶ Reducing average population sodium intake to 2300 mg could save \$18 billion in health care expenses and 312,000 quality-adjusted life years, valued at \$32 billion annually.¹⁷

The harms of current levels of sodium consumption result principally from their association with elevated blood pressure, the single most important cause of cardiovascular disease, accounting for 62% of strokes and 49% of coronary heart disease worldwide.¹⁸ An estimated 32.6% of U.S. adults aged twenty and over suffer from hypertension, with considerably higher rates for Black adults, and another 36.3% exhibit pre-hypertension (less elevated, but still higher than normal, blood pressure).¹⁹ Middle-aged and older individuals in the United States have a 90% chance of developing hypertension in their lifetimes.²⁰

Besides its effect on blood pressure, high salt consumption is associated independently with stroke and left ventricular hypertrophy, as well as with stomach cancer, kidney disease, osteoporosis, asthma, and other health problems.²¹

B. The Health Benefits of Reducing Sodium Consumption Are Well Established And Not Scientifically Controversial.

While experts may differ on some details, there is scientific consensus among medical and public health experts concerning the harms of excess sodium consumption and the benefits

¹⁵ Kirsten Bibbins-Domingo et al., *Projected Effect on Dietary Salt Reductions on Future Cardiovascular Disease*, 362 NEW ENG. J. MED. 590, 593 (2010).

¹⁶ *Id.* at 595.

¹⁷ Kartika Palar & Roland Sturm, *Potential Societal Savings From Reduced Sodium Consumption in the U.S. Adult Population*, 24 AM. J. HEALTH PROMOTION 49 (2009).

¹⁸ He & MacGregor, *Comprehensive Review*, *supra* n. 9, at 363.

¹⁹ Dariush Mozaffarian et al., *Heart Disease and Stroke Statistics—2015 Update*, 1331 CIRCULATION e29, e114, e118 (2015).

²⁰ Ramachandran Vasan et al., *Residual Lifetime Risk for Developing Hypertension in Middle-Aged Women and Men*, 287 J. AM. MED. ASS. 1003 (2002).

²¹ He & MacGregor, *Comprehensive Review*, *supra* n. 9, at 370-72.

of reducing sodium consumption below current levels.²² This consensus includes such respected organizations as the National Academy of Medicine / Institute of Medicine (IOM) (“evidence reviewed ... consistently indicates an association in the general population between excessive sodium intakes and increased risk of CVD [cardiovascular disease]”)²³; the World Health Organization (WHO) (“Higher sodium intake [i]s associated with higher risk of incident stroke, fatal stroke and fatal coronary heart disease”)²⁴; and the American Heart Association (AHA) (“There is strong and consistent clinical trial evidence that reducing sodium intake lowers BP [blood pressure].... Observational data also suggest that lower sodium intake is associated with lower risk of cardiovascular events in people with and without hypertension”).²⁵ Researchers recently reviewing the evidence have confirmed this consensus: “[E]vidence from the best-quality cohort analyses and RCTs [randomized controlled trials] are consistent with a direct relationship between Na [sodium] and CVD”²⁶; “High quality evidence in non-acutely ill adults shows that reduced sodium intake reduces blood pressure.... The totality of evidence suggests that most people will likely benefit from reducing sodium intake.”²⁷

Moreover, the federal government recently proposed lowering the daily value for sodium from 2400 mg to 2300 mg. In a rulemaking proceeding about the Nutrition Fact Panels on packaged foods, the Food and Drug Administration noted:

Evidence continues to support the association between increased sodium consumption and increased blood pressure. In 2005, the IOM noted the direct relationship between sodium intake and increased blood pressure. The 2010 [Dietary Guidelines advisory committee] and the 2013 IOM committee on Sodium Intake in Populations concluded that a strong body of evidence has been documented in adults that as sodium intake

²² Dariush Mozaffarian et al., *Global Sodium Consumption and Death from Cardiovascular Causes*, 371 NEW ENG. J. MED. 624, 625, 633 n.7 (2014).

²³ IOM, SODIUM INTAKE IN POPULATIONS: ASSESSMENT OF EVIDENCE 108 (Brian Strom et al. eds., 2013).

²⁴ WHO, *Guideline: Sodium Intake for Adults and Children* 1 (2012, reprinted 2014), http://www.who.int/nutrition/publications/guidelines/sodium_intake_printversion.pdf

²⁵ Robert Eckel et al., *2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk*, 129 (25 Supp. 2) CIRCULATION S76, S89 (2014).

²⁶ Paul Whelton & Lawrence Appel, *Sodium and Cardiovascular Disease: What the Data Show*, 27 AM. J. HYPERTENSION 1143, 1145 (2014).

²⁷ Nancy Aburto et al., *Effect of Lower Sodium Intake on Health: Systematic Review and Meta-Analyses*, 346 BRIT. MED. J. f1326 (2013), at <http://www.bmj.com/content/bmj/346/bmj.f1326.full.pdf>

decreases, so does blood pressure. We agree with the comment that information about sodium content on the food label can help consumers make appropriate food choices.²⁸

The FDA affirmed the scientific consensus for an upper limit for daily sodium no higher than 2300 mg and solicited comments on whether a lower value would be appropriate.

In addition, the Dietary Guidelines Advisory Committee (DGAC) Scientific Report for 2015, submitted after two years of public notice and comment and a thorough review of nutrition science by national experts, reaffirmed the link between sodium overconsumption and hypertension.²⁹ The report noted that “[c]urrent sodium intakes of the U.S. population far exceed the [Upper Level] for all age and sex groups... Due to the critical link of sodium intake to health and [the fact] that intake exceed[s] recommendations, sodium was designated as a nutrient of public health concern for overconsumption across the entire U.S. population.”³⁰

As this summary suggests, the only serious debate about sodium intake levels among health researchers is whether the currently recommended ceiling of 2300 mg is sufficiently *low*. WHO strongly recommends that adult sodium intake be reduced to below 2000 mg, and lower than that for children³¹; “[t]he American Heart Association recommends that Americans should aim to eat no more than 1500 mg of sodium per day”³²; and the United States government recommends reducing sodium intake to 1500 mg for the at risk groups that comprise more than half the adult U.S. population.³³

²⁸ 79 FED. REG. 11879 (Jun. 2, 2014), <https://www.federalregister.gov/articles/2014/03/03/2014-04387/food-labeling-revision-of-the-nutrition-and-supplement-facts-labels#h-57>

²⁹ USDA, SCI. REPORT OF 2015 DGAC, <http://health.gov/dietaryguidelines/2015-scientific-report/pdfs/scientific-report-of-the-2015-dietary-guidelines-advisory-committee.pdf> at Part A, p. 2 (“[S]odium [is] overconsumed by the U.S. population relative to the Tolerable Upper Intake Level set by the IOM or other maximal standard and ... the overconsumption poses health risks”). The DGAC also supported “[i]mplement[ing] policies and programs at local, state and national levels in both the public and private sectors to reduce . . . sodium in foods.” *Id.* at 46.

³⁰ *Id.* at 90.

³¹ WHO, *Guideline*, *supra* n. 24, at 2.

³² AHA, *The Science is Clear: Most Americans Need More Moderate Levels of Sodium* (2015), <http://sodiumbreakup.heart.org/the-science-is-clear-most-americans-need-more-moderate-levels-of-sodium>

³³ USDA, DIETARY GUIDELINES, *supra* n. 12, at 24.

1. The dubious studies favored by the NRA do not upset settled science concerning the benefits of reducing sodium intake.

In an effort to cast doubt on established science demonstrating the health benefits of reducing sodium consumption, the NRA adduces a pair of outlier studies, Ricardo Aff., Exs. 18, 19, that have been widely criticized as containing “severe methodological flaws”³⁴; “weak research methodology”³⁵; “[e]rrors”³⁶; “a variety of ... methodological issues,” including “pooling of biased data”³⁷; “methodological limitations”³⁸; and as otherwise raising “major concerns.”³⁹

Identified methodological flaws of these studies have included: (1) using insufficient urine samples, resulting in unreliable measurements of sodium intake⁴⁰; (2) incorrectly applying the accepted formula for estimating sodium intake from urine samples⁴¹; (3) inadequately accounting for the possibility of ‘reverse causality,’ *i.e.*, the possibility that diagnosed sickness accounts for reduced sodium consumption, rather than vice versa⁴²; (4) drawing data from studies not designed to investigate the relation between sodium intake and cardiovascular disease⁴³; (5) “post hoc choice of nontraditional cut points” for grouping sodium intake levels, which “can dramatically influence findings”⁴⁴; and (6) using data on short-term responses to large changes in salt intake, which are “irrelevant to the current public health recommendations for a modest reduction in salt intake for a long period.”⁴⁵ The meta-analysis that is the NRA’s

³⁴ Feng He & Graham MacGregor, *Salt Intake and Mortality*, 27 AM. J. HYPERTENSION 1424, 1424 (2014).

³⁵ Norm Campbell et al., *Is Reducing Dietary Sodium Controversial? Is It the Conduct of Studies With Flawed Research Methods That Is Controversial? A Perspective From the World Hypertension League Executive Committee*, 17 J. CLINICAL HYPERTENSION 85, 85 (2015).

³⁶ Laura Cobb et al., *Methodological Issues in Cohort Studies That Relate Sodium Intake to Cardiovascular Disease Outcomes*, 129 CIRCULATION 1173, at 8 (2014).

³⁷ Whelton & Appel, *Sodium and Cardiovascular Disease*, *supra* n. 26, at 1143-44.

³⁸ Aburto et al., *Effect of Lower Sodium Intake*, *supra* n. 27, at 2.

³⁹ Nancy Cook et al., *Lower Levels of Sodium Intake and Reduced Cardiovascular Risk*, 129 CIRCULATION 981, 981 (2014).

⁴⁰ Whelton & Appel, *Sodium and Cardiovascular Disease*, *supra* n. 26, at 1143; Campbell et al., *Is Reducing Dietary Sodium Controversial?*, *supra* n. 35, at 85.

⁴¹ Christof Majoor & Liffert Vogt, *Can Sodium Excretion From Single Fasting Urine Really Be Used for Estimation of Dietary Sodium Intake?*, 32 J. HYPERTENSION 2500, 2500 (2014).

⁴² *E.g.*, He & MacGregor, *Salt Intake*, *supra* n. 34, at 1424; Campbell et al., *supra* n. 35, at 85.

⁴³ Whelton & Appel, *Sodium and Cardiovascular Disease*, *supra* n. 26, at 1143.

⁴⁴ *Id.* at 1144.

⁴⁵ Feng He et al., *Effect of Longer Term Modest Salt Reduction on Blood Pressure: Cochrane Systematic Review and Meta-Analysis of Randomised Trials*, 346 BRIT. MED. J. f1325 (2013), <http://www.bmj.com/content/bmj/346/bmj.f1325.full.pdf>

principal scientific authority, Ricardo Aff., Ex. 18,⁴⁶ includes data from one study so flawed that it had previously been retracted,⁴⁷ a fact ignored by the authors of the meta-analysis.

The chief additional authority relied on by the NRA for the assertion that the health impacts of sodium consumption have become controversial – the IOM sodium intake report,⁴⁸ (see NRA Appellate Memorandum of Law (NRA App. MOL) at 10; Ricardo Aff., Ex. 15 at 3) – simply does not support the NRA’s claims. The IOM Committee concluded, “[W]hen considered collectively, [the evidence] indicates a positive relationship between higher levels of sodium intake and risk of [cardiovascular disease],”⁴⁹ and “the available evidence . . . is consistent with population-based efforts to lower excessive dietary sodium intakes.” The only question for the IOM was whether intake levels should be reduced even further to as low as 1,500 mg/day.⁵⁰ The report called for further research on that question.⁵¹

The NRA’s procedurally problematic eleventh-hour submissions to the Supreme Court, Ricardo Aff., Ex. 25 (Ricardo Supp. Aff.) (Feb. 24, 2016), do not call into question the benefits of reducing sodium intake. Two of the three submissions are editorial comments on a study of patients with heart failure.⁵² Ricardo Supp. Aff., Exs. B, C. In an affidavit submitted in this proceeding in response to the NRA’s submission, the lead author of one of those pieces, noting that the NRA “misinterpreted” the comments, explained that “[h]eart failure . . . affects a relatively small proportion of the population”; treatment varies individually depending on medications, type and severity, and the patient’s kidney function; and heart failure can affect “how the body handles fluids and salt.” Hummel Affid., Muschenheim Aff., Ex. P at ¶ 3.

⁴⁶ Niels Graudal et al., *Compared with Usual Sodium Intake, Low- and Excessive-Sodium Diets are Associated with Increased Mortality: A Meta-Analysis*, 27 AM. J. HYPERTENSION 1129 (2014).

⁴⁷ He et al., *Effect of Longer Term Modest Salt Reduction*, *supra* n. 45.

⁴⁸ IOM, SODIUM INTAKE IN POPULATIONS, *supra* n. 23, at 108.

⁴⁹ *Id.* at 122.

⁵⁰ *Id.* at 124.

⁵¹ *Id.* at 125.

⁵² Scott Hummel & Matthew Konerman, *Dietary Sodium Restriction in Heart Failure: A Recommendation Worth Its Salt?*, 4 JACC: HEART FAILURE 36 (2016), at <http://heartfailure.onlinejacc.org/article.aspx?articleid=2479147>; Clyde Yancy, *The Uncertainty of Sodium Restriction in Heart Failure: We Can Do Better Than This*, 4 JACC: HEART FAILURE 39 (2016), at <http://heartfailure.onlinejacc.org/article.aspx?articleid=2479152>

Therefore, “observations made in a study of people with heart failure to inform a standard of care for that specific subpopulation cannot and should not be applied to the general population as a whole.” *Id.* Recommended sodium restrictions for those populations, which were misrepresented by the NRA, *id.* at ¶ 2, are in any event “for a specific clinical population,” and do not “detract[] from ... the general population recommended daily limit of 2300 mg.” *Id.* This recommended guideline is based on a “body of scientific evidence [that] establishes that high sodium intake can increase...the risk of heart disease and stroke.” *Id.* at ¶ 5.

The NRA further misrepresents the Hummel Comment when it reproduces the following statement out of context: “patients reporting sodium restriction had a significantly higher risk for ... death or [heart failure] hospitalization.” Ricardo Supp. Aff., ¶ 14. The Hummel Comment went on to point out that the correlation, besides depending on sodium intake data of questionable accuracy, could be attributed to “reverse causality,” whereby “higher risk individuals might consume less sodium either because they have been instructed to do so or because of the severity of the illness itself,” or because low sodium consumption reflected general undernutrition. Ricardo Supp. Aff., Ex. B at 2. The other editorial offered a similar appraisal of the reported correlation between sodium restriction and worse outcomes: “It remains likely that sodium restriction as shown in the present data serves more as a marker for advanced disease. Certainly, there are no data to infer causality.” Ricardo Supp. Aff., Ex. C at 2. In other words, reduced sodium consumption is a *consequence* of advanced disease, not a *cause* of poor health outcomes.

Finally, the meta-analysis by Trinquart et al., Ricardo Supp. Aff., Ex. A,⁵³ is a sociological study finding that scientists tend to collaborate with and cite colleagues who share their views. It does not purport to investigate the strength of evidence for the benefits of sodium reduction. In an affidavit in this proceeding, one of that study’s co-authors explicitly stated that

⁵³ Ludovic Trinquart et al., *Why do we think we know what we know?*, INT’L J. EPIDEMIOLOGY (Feb. 17, 2016) at <http://ije.oxfordjournals.org/content/early/2016/02/17/ije.dyv184.full.pdf+html>

the meta-analysis does *not* support the argument that the required sodium warning is controversial. Galea Affid., Muschenheim Aff. Ex. O, at ¶¶ 1-3. To the contrary, “there is no disputing that there are large groups of people in our population who can lower their risk of hypertension, stroke, or heart disease by reducing their intake of sodium.” *Id.* at ¶ 2.

In sum, the handful of studies favored by the NRA do not call into question the settled science of the health benefits of reducing sodium consumption. IOM’s balanced appraisal of the evidence simply fails to support the NRA’s desired conclusions. And – crucially – nothing has called into question the scientific consensus that individuals should not consume more than 2300 mg of sodium per day. Labeling menu items exceeding that amount is more than warranted.

2. High-quality recent research corroborates the health benefits of reducing sodium intake.

The NRA’s characterization of a few outlier studies as novel developments that call into question well-accepted views about sodium, *see* NRA App. MOL at 10, is entirely misleading. There have always been outlier studies, and studies of higher quality continue to find poor health outcomes associated with increased sodium consumption. A recent study⁵⁴ tracked pre-hypertensive individuals over periods of 18 months to 4 years, with follow-up for 5-10 years, using multiple 24-hour urine samples – the “gold standard”⁵⁵ – to measure sodium intake. The study found a linear association between lower sodium levels and lower incidence of CVD events. Another recent cohort study, tracking participants for ten years, also employing repeated 24-hour urine collection, found higher sodium intake to be associated with increased risk of coronary heart disease in people with hypertension.⁵⁶

Similar conclusions were reached by recent meta-analyses that were more rigorous than the Graudal study relied on by the NRA. Ricardo Aff., Ex. 18. A recent meta-analysis of 36 randomized controlled trials that met rigorous criteria found that reducing sodium consumption

⁵⁴ Nancy Cook et al., *Lower Levels* (2014), *supra* n. 39.

⁵⁵ Cobb et al., *Methodological Issues*, *supra*, n. 36 at 8-9. This detail is crucial. The studies cited by the NRA relied on a single urine sample, or at most a single 24-hour collection, widely deemed insufficient to estimate sodium intake reliably given the high day-to-day variability in sodium consumption and excretion.

⁵⁶ Michel Joosten et al., *Sodium Excretion and Risk of Developing Coronary Heart Disease*, 129 CIRCULATION 1121 (2014).

lowered blood pressure at all levels of sodium consumption.⁵⁷ Another recent meta-analysis, drawing on data extracted by independent reviewers from randomized controlled salt-reduction trials that met strict measures for study quality, found that modest reductions in salt intake over the longer term led to significant lowering of blood pressure in individuals with high and normal blood pressure, without ill effects.⁵⁸ And a rigorous 2009 meta-analysis of 13 longitudinal studies, covering 19 cohorts totaling 177,025 individuals, found “evidence of a highly significant dose-response relation between the difference in sodium intake and the increase in risk of both stroke and cardiovascular disease.”⁵⁹

In sum, methodologically rigorous studies continue to find correlations between sodium intake and the health outcomes that are the focus of the City’s warning notice.

3. Americans are in no danger of insufficient sodium intake.

There is no merit to the suggestion, NRA App. MOL at 10, that public health measures should balance the dangers of excessive sodium consumption against the dangers of insufficient sodium consumption. While it is true that sodium is an essential nutrient, there is little to no danger of under-consumption. “Virtually all Americans consume more sodium than they need.”⁶⁰ The Institute of Medicine defines adequate intake (AI) for American adults as 1200 to 1500 mg/day, depending on age.⁶¹ Calculations based on 2003-2008 data indicate that 0.6% of Americans consume less than 1500 mg/day, in sharp contrast to the 90.7% who consume more than the IOM’s upper level (UL) of 2300 mg/day.⁶² Even a study cited by the NRA noted that

⁵⁷ Aburto et al., *Effect of Lower Sodium Intake* (2013), *supra*, n. 27.

⁵⁸ He et al., *Effect of Longer Term Modest Salt Reduction*, *supra*, n. 45.

⁵⁹ Pasquale Strazzullo et al., *Salt Intake, Stroke, and Cardiovascular Disease: Meta-Analysis of Prospective Studies* 339 BRIT MED. J. b4567 (2009), <http://www.bmj.com/content/bmj/339/bmj.b4567.full.pdf>. The analysis met exemplary standards for rigor: it included all relevant studies that met preset standards for duration and methodology; to protect against bias, studies were selected for inclusion by independent reviewers; duplicate analyses of the same data were eliminated; and extensive statistical analysis accounted for such variables as age and sex of participants, duration of follow-up, differences in sodium level, method of assessing intake, and baseline blood pressure.

⁶⁰ USDA, DIETARY GUIDELINES, *supra* n. 12, at 21.

⁶¹ IOM, DIETARY REFERENCE INTAKES FOR WATER, POTASSIUM, SODIUM, CHLORIDE, AND SULFATE 11 (2005). In fact a mere 180 mg/day is adequate to replace losses when substantial sweating does not occur. *Id.* at 275.

⁶² Mary Cogswell et al., *Sodium and Potassium Intakes Among US Adults: NHANES 2003-2008*, 96 AM. J. CLIN. NUTR. 647, 651 (2012).

almost no participants “had an intake of less than [1500 mg] per day [of sodium]. This suggests that, at present, . . . consumption of extremely low amounts of sodium for prolonged periods is rare.”⁶³

The NRA’s contention that consumption of less than 2800-3000 mg/day of sodium may be as dangerous as excess consumption, NRA App. MOL at 10, is based on unreliable and discredited studies, as explained *supra* in section I.B.1. In particular, the failure to exclude high-risk individuals from those studies suggests that correlations between low salt consumption and illness likely stemmed from “reverse causality whereby sick people eat less salt . . . based on clinical recommendations,” “rather than lower salt consumption causing illness.”⁶⁴ More reliable studies have found no significant harms from reducing sodium intake.⁶⁵

4. Scientific “controversy” about healthy levels of sodium intake is a fiction manufactured by the salt and prepared food industries.

Notwithstanding the NRA’s protestations to the contrary, disputes about appropriate levels of sodium consumption are less a matter of scientific controversy than a concerted public relations effort by businesses whose products are high in sodium. The world’s most respected governmental and non-governmental medical and public health organizations agree on the dangers of current levels of sodium consumption.⁶⁶ The NRA’s proffered authorities may not – but they are principally individuals and organizations with ties to the salt industry and packaged and prepared food companies.

⁶³ Andrew Mente et al., *Association of Urinary Sodium and Potassium Excretion with Blood Pressure*, 371 NEW. ENG. J. MED. 601, 609 (2014) (Ricardo Aff., EX. 19).

⁶⁴ Campbell, *Is Reducing Dietary Sodium Controversial?*, *supra* n. 35, at 85. See also Cook, *Lower Levels*, *supra* n. 39, at 981 (noting potential for bias attributable to reverse causality, among other concerns, in “[a]ll of the studies reporting a paradoxical inverse or J-shaped association between sodium intake and CVD”).

⁶⁵ E.g., Mozaffarian, *Global Sodium*, *supra* n. 22, at 632 (“a meta-analysis of 37 trials showed no significant adverse effects” of reduced sodium intake); Aburto, *Effect of Lower Sodium Intake*, *supra* n. 27, at 6 (randomized controlled trials showed no adverse effects of reducing intake).

⁶⁶ See Whelton & Appel, *Sodium and Cardiovascular Disease*, *supra* n. 26, at 1144 (“the interpretation by Graudal et al. differs from conclusions by authors of previous meta-analyses, the 2013 IOM Committee, American Heart Association Committees, the WHO, and at least 40 national agencies around the world”). See also Campbell, *supra* n. 35, at 86 (noting that the two NEJM articles relied on by the NRA conflict with the recommendations of the World Hypertension League and the International Society of Hypertension).

The Academy of Nutrition and Dietetics (AND), relied on by the NRA, *e.g.* Ricardo Aff., Exs. 20, 21, has been widely criticized for “haul[ing] in large sums of money advocating for the food industry.”⁶⁷ AND’s recommendations, while claiming to be based on science alone, are often at odds with the consensus of scientists and public health organizations. Conversely, AND’s recommendations are frequently in line with the statements of AND’s corporate sponsors, including such manufacturers of high-sodium processed foods as ConAgra (whose brands include Slim Jims, Hebrew National, and Chef Boyardee), General Mills, and Kellogg.⁶⁸

Given petitioner’s affiant Susan Finn’s background as former President of AND, Ricardo Aff., Ex. 14, Finn Aff., ¶ 2,⁶⁹ it is unsurprising that Finn claims that it would be “irresponsible to move forward at this time” on sodium warnings when there is “research on both sides of the issue.” Ex. 14, Finn Aff., ¶ 25. Her statement is reminiscent of a nutrition fact sheet, sponsored by the National Association of Margarine Manufacturers, published by AND in 1995 (when affiant Susan Finn was a Member of its Strategic Planning Committee), proclaiming, “There is little scientific evidence to suggest that current consumption levels of trans-fatty acids need to be changed.”⁷⁰ Trans fats have since, of course, been banned from the nation’s food supply because of the broad expert consensus regarding their adverse health impacts.⁷¹

The NRA’s principal scientific expert, David McCarron, *see* Ricardo Aff., Ex. 16., McCarron Affid., has worked extensively as a paid consultant to the Salt Institute, an industry

⁶⁷ Sheldon Rampton & John Stauber, *Trust Us, We’re Experts!: How Industry Manipulates Science and Gambles with Your Future* (2002). (AND was then known as the American Dietetic Association).

⁶⁸ Michele Simon, *And Now a Word From Our Sponsors: Are America’s Nutrition Professionals in the Pocket of Big Food?* 6 (2013) (noting AND’s “industry-friendly research and messaging”), http://www.eatdrinkpolitics.com/wp-content/uploads/AND_Corporate_Sponsorship_Report.pdf.

⁶⁹ She also served as President and CEO of the American Council for Fitness & Nutrition (ACFN), *id.*, whose members include the NRA itself, as well as such producers of high sodium foods as McDonald’s, Kraft Foods, and ConAgra, and such trade groups as the National Council of Chain Restaurants, the Snack Food Association, and the Biscuit & Cracker Manufacturers Association. Center for Science in the Public Interest, *Non-Profit Organizations Receiving Corporate Funding* (2003), http://www.cspinet.org/integrity/nonprofits/american_council_for_fitness_and_nutrition_acfn.html.

⁷⁰ Marian Burros, *Group’s Pursuit of Cash Draws Fire*, MILWAUKEE J. SENTINEL (Dec. 6, 1995), http://www.cspinet.org/new/industryties_salt.html

⁷¹ Brady Dennis, *FDA Moves to Ban Trans Fat From US Food Supply*, WASH. POST (June 16, 2015) https://www.washingtonpost.com/national/health-science/fda-moves-to-ban-trans-fat-from-us-food-supply/2015/06/16/f8fc8f18-1084-11e5-9726-49d6fa26a8c6_story.html

trade group “dedicated to advancing the many benefits of salt.”⁷² The McCarron Group’s own website includes a testimonial from the president of the trade group noting that “[t]he Salt Institute has valued Dr. McCarron’s consulting expertise for a quarter century.”⁷³

The academic publications on which the NRA relies are also tainted by the authors’ industry ties. The Graudal meta-analysis, Ricardo Aff., Ex. 18, for example, was co-authored by Michael Alderman, who has also served as a consultant to the Salt Institute.⁷⁴ Industry connections are material and must be disclosed, because industry-sponsored nutrition-related scientific articles disproportionately reach conclusions favorable to the financial interests of the sponsors, as compared with articles without industry funding.⁷⁵ Alderman failed to disclose his clear conflict of interest as Salt Institute consultant.⁷⁶

Scientists’ comments on the publicity received by the PURE study relied on by the NRA, Ricardo Aff., Ex. 19, published at the same time as the methodologically superior study of Mozaffarian et al.,⁷⁷ depict the dispute over sodium as something other than a scientific debate:

[Prominent medical researcher Professor Norman] Campbell insisted . . . that most of the disagreement over the link between sodium and CVD is manufactured by the food industry. In fact, he said, all of the major national and international health organizations have agreed that the bulk of high-quality research supports a link between sodium consumption and cardiovascular death and disability.

“We will always have dissident scientists, regardless of the strength of the evidence, it doesn’t matter what field—you will never have 100% of people agreeing. But in this case, we have the consensus of every national and international organization that has reviewed the topic.”

On the other side, he said, “we have the world’s largest industry, the food industry, a \$3-trillion/year industry that takes those dissident scientists and creates public controversy.”⁷⁸

⁷² John Tierney, *Salt Wars*, N.Y. Times (Feb. 22, 2010), <http://tierneylab.blogs.nytimes.com/2010/02/22/salt-wars>; see Salt Institute, *About Salt Institute* (undated), <http://www.saltinstitute.org/about-salt-institute>

⁷³ McCarron Group, http://www.mccarrongroup.com/?page_id=22

⁷⁴ Gina Kolata, *Low-Salt Diet Ineffective, Study Finds. Disagreement Abounds*, N.Y. TIMES (May 3, 2011), <http://www.nytimes.com/2011/05/04/health/research/04salt.html>

⁷⁵ Lenard Lesser et al., *Relationship Between Funding Source and Conclusion Among Nutrition-Related Scientific Articles*, 4 PLOS MED. 41, 44 (2007) (“Articles sponsored exclusively by food/drinks companies were four to eight times more likely to have conclusions favorable to the financial interests of the sponsoring company than articles which were not sponsored by food or drinks companies.”).

⁷⁶ He & MacGregor, *Salt Intake*, *supra* n. 34, at 1424.

⁷⁷ Mozaffarian, *Global Sodium*, *supra* n. 22.

⁷⁸ Shelley Wood, *Standards Needed for Salt Studies As ‘Big Food’ Takes Sides*, MEDSCAPE MULTISPECIALTY 3 (Aug. 18, 2014), http://www.medscape.com/viewarticle/830079#vp_3

Other medical scientists concur:

The issue is no longer whether reducing sodium (salt) intake is of public benefit; it is how best to reduce population salt intake to save the most lives. Therefore, why has the food and beverage industry mounted yet another campaign to try to resist beneficial changes, either directly or indirectly through their academic voices? ... As early as 1982, the snack industry was systematically distracting attention from the salt–blood pressure issue by encouraging complacent scientists to divert the focus of research elsewhere. Their intent was to delay public health measures. However, since then the weight of scientific evidence has accumulated beyond any reasonable doubt.... It is therefore a sad but familiar story when articles like those of McCarron and colleagues appear (and then reappear) in the scientific literature. They reflect the huge amount of financial resources still committed to try and deny the harmful effects of salt.⁷⁹

The former New York City Health Commissioner, Tom Farley, reflected: “The claims of the salt doubters reminded me of the decades-long arguments that some prominent, industry-funded scientists made about lead in paint and gasoline. The risks aren’t clear, they said; the studies are flawed. Meanwhile, hundreds of thousands of children were getting brain damage from lead poisoning.”⁸⁰

C. Fast Food And Other Chain Restaurants Contribute Significantly To Sodium Overconsumption.

The food service establishments covered by the sodium warning regulation play an outsize role in contributing to sodium overconsumption. About a quarter of the sodium consumed in the United States comes from restaurants, with a majority from fast food outlets.⁸¹

According to USDA data from 2005-2008, meals from full-service and fast food restaurants average respectively 2151 mg and 1864 mg of sodium per 1000 calories, compared with 1369 mg for home-cooked food prepared at home.⁸² That statistic, alarming as it is, actually understates how much restaurants increase sodium consumption, because restaurant meals also average significantly more calories.⁸³ Full-service and fast food restaurants increase daily

⁷⁹ Francesco Cappuccio et al., *Salt: The Dying Echoes of the Food Industry*, 27 AM. J. HYPERTENSION 279, 279 (2014); see also Michael Moss, SALT SUGAR FAT (2013) at 282, 305, 313 (detailing industry efforts).

⁸⁰ Farley, *Saving Gotham*, *supra* n. 6, at 124 (2015).

⁸¹ CDC, *Vital Signs: Food Categories Contributing the Most to Sodium Consumption—United States, 2007-2008*, 61 (5) MORBIDITY & MORTALITY WKLY RPT. 92, 93 (2012).

⁸² USDA Economic Research Service, *Nutritional Quality of Food Prepared at Home and Away From Home, 1977-2008*, 11 (2012), <http://www.ers.usda.gov/media/977761/eib-105.pdf>

⁸³ Ruopeng An, *Fast-Food and Full-Service Restaurant Consumption and Daily Energy and Nutrient Intakes in US Adults*, EUR. J. CLINICAL NUTRITION (advance online publ. 2015), at 5.

sodium intake by almost 300 mg and over 400 mg respectively.⁸⁴ A study of full-service restaurant chains in the Philadelphia area found that one quarter of a la carte entrées exceed the upper limit of 2300 mg by themselves; over half exceed 1500 mg.⁸⁵ A number of popular restaurant and fast food menu items contain well over 3000 mg of sodium, with a single order of cheese fries with ranch dressing containing almost 5000 mg.⁸⁶ The mean sodium content of menu offerings at eight leading fast food chains increased 23.4% from 1997-2010.⁸⁷

The health burdens of fast food restaurants' high sodium offerings fall disproportionately on vulnerable communities. The economic deprivation of a neighborhood often correlates with the density of fast-food restaurants.⁸⁸ Among adults aged 20-39, the percentage of calories consumed from fast food significantly increases as income decreases.⁸⁹ A 2009 study found that New York City fast-food chain restaurants were concentrated disproportionately in predominantly African American neighborhoods, and that "unhealthy foods were more heavily promoted in African American communities."⁹⁰ Nationally, non-Hispanic Blacks consume a significantly greater proportion of their calories from fast food than do other racial groups.⁹¹

These disparities are of particular concern with respect to African American communities, given that non-Hispanic Blacks have higher rates of hypertension and consequent cardiovascular disease than other racial groups in the United States, possibly reflecting "a greater sensitivity to the deleterious effects of diet."⁹² Blood pressure has been found to fall more sharply in response to decreases in dietary sodium among African Americans, both with and

⁸⁴ *Id.*

⁸⁵ Amy Auchincloss et al., *Nutritional Value of Meals at Full-Service Restaurant Chains*, 46 J. NUTR. ED. & BEHAV. 75, 78 T2 (2014).

⁸⁶ Frank Sacks et al., *High Sodium Restaurant Foods*, <http://www.cspinet.org/salt/hsrestaurant.html>

⁸⁷ Rudelt et al., *Fourteen-Year Trends*, *supra* n. 10, at 1684. This was during a time of initiatives to reduce sodium intake.

⁸⁸ Angela Hilmers et al., *Neighborhood Disparities in Access to Healthy Foods and Their Effects on Environmental Justice*, 102 AM. J. PUB. HEALTH 1644, 1649 (2012).

⁸⁹ CDC, *Caloric Intake from Fast Food Among Adults: United States, 2007-2010*, 2 (NCHS Data Brief No. 114, Feb. 2013), <http://www.cdc.gov/nchs/data/databriefs/db114.htm>

⁹⁰ Hilmers et al., *Neighborhood Disparities*, *supra* n. 88, at 1650.

⁹¹ CDC, *Caloric Intake*, *supra* n. 89, at 2.

⁹² Frank Sacks et al., *Effects on Blood Pressure of Reduced Dietary Sodium and the Dietary Approaches to Stop Hypertension (DASH) Diet*, 344 NEW ENG. J. MED. 3, 8 (2001).

without hypertension, than among other racial groups.⁹³ For these reasons, federal guidelines recommend that African Americans reduce their daily sodium intake to 1500 mg,⁹⁴ a level likely to be exceeded with a single snack from a neighborhood chain restaurant.

D. Warnings Are Needed, Because Consumers Lack Awareness Of Their Own Sodium Consumption.

The need for sodium warnings is underscored by findings that, even when generally aware that sodium consumption should be limited, “consumers seem unable to accurately estimate their own sodium intake.”⁹⁵ Most consumers significantly underestimate their sodium consumption, especially when eating food from fast food restaurants. A USDA survey found that 71% of respondents who thought that their sodium intake was “about right” in fact exceeded recommended levels.⁹⁶ In a study of consumers of fast food meals from several national fast food chains, participants on average estimated that their meals contained 820 mg of sodium, when in fact the meals contained an average of 1831 mg – more than ¾ of the IOM’s recommended daily upper limit, and more by itself than the recommended daily limit for at-risk populations.⁹⁷ And nearly half of Americans do not know how much sodium a healthy individual should consume.⁹⁸

Sodium warnings in chain restaurants are amply merited.

II. THE SODIUM RULE IS NOT ARBITRARY AND CAPRICIOUS; IT IS A REASONABLE RESPONSE TO A PUBLIC HEALTH CRISIS.

The Board adopted the Sodium Rule in response to the crisis of hypertension in New York City. It exercised its regulatory authority and expert judgment to protect the health of the City’s residents, especially the millions of those residents who are particularly vulnerable to high blood pressure and its attendant health effects. In writing the Rule, the Board did what agencies do: it drew lines necessary to administer a policy within its jurisdiction. The Board required

⁹³ *Id.* at 6.

⁹⁴ USDA, DIETARY GUIDELINES, *supra* n. 12, at 24.

⁹⁵ IOM, STRATEGIES, *supra* n. 11, at 42.

⁹⁶ *Id.* at 41.

⁹⁷ Scott Burton et al., *Food for Thought: How Will the Nutrition Labeling of Quick Service Restaurant Menu Items Influence Consumers’ Product Evaluations, Purchase Intentions, and Choices?*, 85 J. RETAILING 258, 261 T1 (2009).

⁹⁸ International Food Information Council, *Consumer Sodium Research: Concern, Perceptions and Action* 15 (2009), <http://www.foodinsight.org/Content/6/FINAL-IFIC-Sodium-Consumer-Research-Report-8-14-09.pdf>

warnings in restaurants, rather than in all food service establishments, because its inspectors visit only restaurants⁹⁹; it required warnings only in restaurant chains with 15 or more outlets, because these larger chains are already subject to the City’s menu labeling rule,¹⁰⁰ and because chain restaurants’ standardized operations “mak[e] compliance both feasible and reliable”¹⁰¹; it required that any item (including meals) containing more than 2300 milligrams of sodium be identified with a warning icon, because that is a straightforward symbol easily understood by restaurant patrons.¹⁰² The Board was not obligated to conduct empirical studies proving that each of these choices was the most effective possible option. All that is required under Article 78, which prohibits agency action that is “arbitrary and capricious or an abuse of discretion,” C.P.L.R. § 7803(3), is that the Board make rational choices. The Board did just that: the Rule is a measured, evidence-based approach that easily satisfies Article 78’s requirements. The NRA has not carried its heavy burden of proving otherwise.

A. The Arbitrary And Capricious Standard Is Easily Met.

The role of a court in reviewing an agency regulation, particularly a public health measure, is limited. “Whether the enactment is wise or unwise, whether it is based on sound economic theory, whether it is the best means to achieve the desired result” are questions beyond the scope of the court’s conscribed review. *Montgomery v. Daniels*, 38 N.Y.2d 41, 53 (1975). “The judicial function is exhausted with the discovery that the relation between means and end is not wholly ... an illusory pretense.” *Grossman v. Baumgartner*, 17 N.Y.2d 345, 350 (1966); *see also Matsen v. New York State Dep’t of Motor Vehicles*, 134 A.D.3d 1283, 1286 (3d Dep’t 2015) (“[A c]ourt’s role in reviewing an agency action is not ... to substitute its judgment for that of the agency, but rather to determine if the action taken by the agency was reasonable”).

⁹⁹ Notice of Adoption at 1 (“The Department issues permits to and inspects FSEs [food service establishments] in New York City to ensure safe and healthy dining options”).

¹⁰⁰ *Id.* at 2 (“The definition of a covered establishment in paragraph (2) of subdivision (a) has been made consistent with the definition in [the menu labeling rule]”).

¹⁰¹ Memorandum from Sonia Angell & Daniel Kass to the Members of the Board of Health (Sept. 2, 2015) at 3 (summarizing and responding to comments received regarding the proposed Rule).

¹⁰² *Id.* (“It is imperative that consumers are readily able to identify menu items containing the recommended daily limit of 2,300 mg or more of sodium”).

The NRA asks this court to substitute its judgment for the considered judgment of a Board of expert public health practitioners. But “[a]n administrative agency’s exercise of its rule-making powers is accorded a high degree of judicial deference, especially when,” as here, “the agency acts in the area of its particular expertise.” *Consolation Nursing Home v. Comm’r, NY State Dep’t of Health*, 85 N.Y.2d 326, 331 (1995). The party challenging the regulation bears “the heavy burden of showing that the regulation is unreasonable and unsupported by *any* evidence.” *Id.* at 331-32 (emphasis added); *accord N.Y. State Health Facilities Ass’n, Inc. v. Axelrod*, 77 N.Y.2d 340, 349-50 (1991). That is a burden the NRA cannot meet.

In the field of public health, the courts’ inquiry is a particularly limited one. “The police power is exceedingly broad, and the courts will not substitute their judgment of a public health problem for that of eminently qualified physicians” – like the Board¹⁰³ – “in the field of public health.” *Grossman*, 17 N.Y.2d at 350. Any dispute about the evidence justifying the Rule or its efficacy is something to be resolved not by a court, but by the Board. *See Chiropractic Ass’n v. Hilleboe*, 12 N.Y.2d 109, 114 (1962) (in the public health context, “[i]t is not for the courts to determine which scientific view is correct in ruling upon whether the police power has been properly exercised”).

In sum, the Board need only have a rational basis for its chosen action. The Rule plainly satisfies that minimal standard. Given the alarming toll that hypertension takes on public health, the evidence showing that consumers are unaware of sodium levels in restaurant food, and the fact that the warnings are well within the ambit of mainstream science on sodium and hypertension, *see supra* § I, the Board had more than sufficient reason to enact the measure.

B. The Rule Incorporates Reasonable Line Drawing And The Boundaries Of The Board’s Authority.

Rather than try to establish that no evidence supports the Rule – a standard the NRA cannot meet – the restaurant association criticizes the measure’s scope, (1) deeming it

¹⁰³ There is no dispute that the physicians and scientists who compose the Board of Health are “eminently qualified.” N.Y. City Charter § 553.

underinclusive and (2) questioning the Board’s line-drawing. These attacks are unavailing in the context of the rational basis review called for under Article 78.

1. Incremental regulation is not only permissible but often necessary.

The Board has leeway, under Article 78’s deferential standard of review, to approach a complex health problem like hypertension incrementally. *See N.Y. State Health Facilities Ass’n*, 77 N.Y.2d at 350 (“Merely because respondent has attempted to address part of a perceived concern ... provides no basis for invalidating the regulations”); *E. Fougera & Co. v. City of New York*, 224 N.Y. 269, 278 (1918) (“It is not important that the ordinance fails to compel disclosure to all the world. Laws are not invalid because they fall short of the maximum of attainable efficiency”). A contrary “all-or-nothing” rule would make it impossible for boards of health to function. Thus there is no basis for the NRA’s argument that the Rule is arbitrary because it does not require the sodium warnings to appear in all restaurants or all food service establishments. *See* NRA App. MOL at 38-39. The scope of the Rule reflects the limits of the Board’s jurisdiction, as well as its reasoned judgment of a practicable method to address a pressing health issue. This judgment is owed considerable deference.

2. It is not arbitrary or capricious for an agency to act only to the extent of its own authority.

Several of the NRA’s challenges involve complaints that the Board excluded establishments over which it does not exercise jurisdiction. *See* NRA App. MOL at 6, 8, 39 (contending that it is improper to apply the Rule to restaurants but not other “retail food establishments” such as convenience stores or grocery stores). To claim that it is irrational for an agency to stop at the boundaries of its own authority is not a tenable argument. “Certainly the Legislature cannot be faulted for not extending the requirement of coverage to those over whom the Legislature had no power to act. Rather than representing an arbitrary and capricious exercise of legislative power, this exclusion merely recognizes the realities of the situation.” *Montgomery*, 38 N.Y.2d at 63. The Health Department inspects restaurants, but not convenience stores or grocery stores. *See*

Notice of Adoption at 1. Accordingly, the Board did not include convenience or grocery stores within the scope of the Rule.

The sharp increase in recent years both in the number of meals eaten outside the home and in the portion sizes of those meals provides a more-than-rational basis for a Rule focusing on restaurants and similar food service establishments.¹⁰⁴ The Rule covers establishments where the combined sodium content of the meal is likely to far exceed recommended amounts. *See supra* § I.B.3.

3. The distinctions made by the rule are rational and not arbitrary.

“Whenever the legislature draws . . . a line some must be included, some excluded,” but “[a]s long as the line drawn is reasonable,” it will be upheld. *Hymowitz v. Eli Lilly & Co.*, 136 Misc.2d 482, 489 (Sup. Ct. N.Y. Cty. 1987). The lines need not be drawn with “mathematical nicety.” *Montgomery*, 38 N.Y.2d at 66. As Justice Holmes observed:

When a legal distinction is determined, as no one doubts that it may be, between night and day, childhood and maturity, or any other extremes, a point has to be fixed or a line has to be drawn, or gradually picked out by successive decisions, to mark where the change takes place. Looked at by itself without regard to the necessity behind it the line or point seems arbitrary. It might as well or nearly as well be a little more to one side or the other. But when it is seen that a line or point there must be, and that there is no mathematical or logical way of fixing it precisely, the decision . . . must be accepted unless we can say that it is very wide of any reasonable mark.

Louisville Gas Co. v. Coleman, 277 U.S. 32, 41(1928) (Holmes, J.); *accord Montgomery*, 38 N.Y.2d at 65.

The lines drawn by the Board are eminently reasonable. For example, the Board determined that the Rule was best applied to larger chain restaurants because they account for approximately one-third of all restaurant traffic in New York and their highly standardized operational processes place them in the best position to comply with the warning label

¹⁰⁴ *See* USDA Economic Research Service, *Food and Nutrient Intake Data: Taking a Look at the Nutritional Quality of Foods Eaten at Home and Away From Home* (June 2012), <http://www.ers.usda.gov/amber-waves/2012-june/data-feature-food-and-nutrient-intake-data.aspx>

requirement.¹⁰⁵ In the Supreme Court, the NRA contended that there was no rational basis for applying the Rule to chain restaurants with 15 outlets but not to independently owned establishments or smaller chains. NRA Trial MOL at 43. Confronted by the fact that the division between chains with 15 outlets and other restaurants is precisely the one selected in New York City’s menu labeling rule, *see* Health Code § 81.50, which the NRA did not call arbitrary or capricious, the NRA has now dropped its number-of-outlets argument. NRA App. MOL at 39. In this Court it argues more vaguely that the Rule creates a “patchwork of covered and non-covered establishments.” *Id.* But the NRA still doesn’t address the reasons for that supposed “patchwork”: jurisdictional limitations and differential capacity. The NRA does not come close to meeting the standard of showing that the City’s stated reasons for drawing these lines lack any rational basis – perhaps because those reasons make a lot of sense.

The NRA has pointed to other marginal issues – such as the reasonable requirements that a menu item available with a choice of toppings be labeled with an icon if at least one of those toppings causes it to exceed 2300 milligrams of sodium, or that each item on the menu (whether a la carte or a meal) should be labeled with its total sodium content – but it has not explained why restaurants cannot simply break out the toppings or the dishes separately if they care about fine-grained accuracy. The NRA certainly has not shown that the Rule is “unsupported by *any* evidence.” *Consolation Nursing Home*, 85 N.Y.2d at 332 (emphasis added). And given the vast amount of health data supporting the Rule, *see supra* at §§ I.B, C, D, it cannot make such a showing.

In sum, it is within the Board’s discretion to make reasonable distinctions, whether between venues or among menu items, and whether based on administrative feasibility, a desire to move incrementally, or limitations on regulatory authority. The party contesting a regulation

¹⁰⁵ *See* Memorandum of Angell & Kass, *supra* n. 101, at 3 (“Because chain FSEs [food service establishments] have highly standardized food procurement, preparation, and operational processes, they can comply with this warning label requirement; the menu items that will bear icons always contain at least 2,300 milligrams of sodium. Addressing the food served in chain establishments regulated by DOHMH is rational and an appropriate part of DOHMH’s broad and comprehensive strategy to address the burden of cardiovascular disease in New York City”).

must carry “the heavy burden of showing that the regulation is unreasonable and unsupported by any evidence.” *Consolation Nursing Home*, 85 N.Y.2d. at 331-32. That is a standard that the NRA has not met.

III. THE SODIUM WARNING COMPORTS WITH THE FIRST AMENDMENT.

The salt shaker symbol and warning statement meet all requirements of the First Amendment. The Rule is reasonably related to the City’s legitimate interest in increasing awareness about sodium, and it is not unduly burdensome; the Rule therefore meets the lenient test for factual and uncontroversial disclosures involving commercial speech.

A. Factual Warnings About Well-Known Health Risks Are Reviewed Under A Lenient Standard, And The Sodium Rule Easily Passes That Review.

The First Amendment extends to commercial speech in order to protect and foster the flow of information of value to consumers. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). That is precisely what the sodium rule is designed to do. It is well established that in the context of commercial speech “the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed.” *Id.* at 651 n.14; *see also id.* at 650 (the “constitutionally protected interest in *not* providing any particular factual information ... is minimal”). There is good reason for this departure from the stringency of much First Amendment review: “mandated disclosure of accurate, factual ... information ... furthers, rather than hinders, the First Amendment goal of the discovery of truth and contributes to the efficiency of the ‘marketplace of ideas.’” *Nat. Electrical Manufacturers Ass’n. (NEMA) v. Sorrell*, 272 F.3d 104, 114 (2d Cir. 2001).

Thus, in asserting that the intermediate or strict scrutiny rather than the permissive *Zauderer* standard applies to the sodium warnings, the NRA “overlooks material differences between disclosure requirements and outright prohibitions on speech.” *Anonymous v. Grievance Comm.*, 136 A.D.2d 344, 348 (2d Dep’t 1988) (quoting *Zauderer*, 471 U.S. at 651). All that a law requiring warnings need show is “a rational connection between the purpose of a commercial disclosure requirement and the means employed.” *NEMA*, 272 F.3d. at 115. In other

words, such a law is subject only to “rational basis review.” *Connecticut Bar Ass’n v. United States*, 620 F.3d 81, 96 (2d Cir. 2010).¹⁰⁶

The sodium rule easily meets that standard. It was enacted in order to increase New Yorkers’ knowledge about the high levels of sodium in certain restaurant foods and to make it easier for individuals – especially at-risk individuals – who want to reduce overconsumption. *See* Notice of Adoption at 2. Given the prevalence of hypertension among the City’s residents and the gravity of the health consequences of that condition, *see supra* § I.A, the Board had more than a reasonable basis for enacting the law. In the context of this lenient *Zauderer* review, the government “has no obligation to produce evidence, or empirical data to sustain ... rationality.” *New York State Restaurant Ass’n (NYSRA) v. New York City Bd. of Health*, 556 F.3d 114, 134 n.23 (2d Cir. 2009). But of course the Board provided more than ample evidence anyway.¹⁰⁷

The sole remaining requirement is that the Rule not be “unduly burdensome,” *Zauderer*, 471 U.S. at 651; disclosure requirements are “unduly burdensome” if they “might offend the First Amendment by chilling protected ... speech.” *Id.*; *see also Ibanez v. Florida Dept. of Bus. and Prof. Reg.*, 512 U.S. 136, 146-147 (1994) (length of required disclaimers prevented including legitimate statements of qualifications on business cards and letterheads). Other asserted burdens are irrelevant.

The symbols and the warning statement do not interfere with restaurants’ ability to convey their own message. The Rule readily meets the relevant First Amendment standard.

B. The Warning Conveys Factual And Uncontroversial Information To Consumers.

Deferential rational basis review applies to required disclosures that are “factual and uncontroversial.” *Zauderer*, 471 U.S. at 651. “Factual” contrasts with “personal or political

¹⁰⁶ The cases cited by the NRA to argue that a higher level of scrutiny applies are all inapplicable, either because they involved non-commercial, “fully protected” speech (*Riley v. Nat’l Fed’n of the Blind*, 487 U.S. 781, 796 (1988)); because they involved compelled statements of subjective opinion (*Entm’t Software Ass’n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006)); because they involved *restrictions* on commercial speech (all the cases cited at NRA App. MOL at 32-34); or because they involved mandated disclosures not about the speaker’s own products or services (*Safelite Grp., Inc. v. Jepsen*, 764 F.3d 258, 263-64 (2d Cir. 2014)).

¹⁰⁷ *See* Notice of Adoption and citations therein; Memorandum of Angell & Kass, *supra* n. 101.

opinion,” *Discount Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d 509, 556 (6th Cir. 2012); “uncontroversial” should generally be equated with “accurate” in this context. *CTIA-The Wireless Ass’n v. City of Berkeley*, — F. Supp. 3d —, 2015 WL 5569072, at *17 (N.D. Cal. Sept. 21, 2015); see also *NEMA*, 272 F.3d at 114 (“mandated disclosure of accurate, factual, commercial information” is reviewed under *Zauderer*). The Rule readily meets both conditions.

The required warning statement contains neither opinion nor questionable facts. It states simply, “Warning: [Salt shaker symbol] 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.” Each aspect of this statement is uncontroversially true. The sodium content of any labeled item is greater than 2300 milligrams. 2300 milligrams of sodium is in fact the daily limit recommended by the U.S. government.¹⁰⁸ And not even the NRA’s authorities dispute that high sodium intake can heighten blood pressure and the risk of coronary heart disease. Similarly, a salt shaker symbol is a factual disclosure about the amount of sodium content (2300 mgs).

Even if the benefits of the Rule were controversial, as argued by the NRA, this would not subject it to a more stringent standard of review. Factual statements are “uncontroversial” within the meaning of *Zauderer* when there is no reasonable controversy about their truth, regardless of disputes over policy. See *NYSRA*, 556 F.3d at 133-34 (applying *Zauderer* to NYC menu labeling rule, and rejecting restaurants’ argument that more rigorous scrutiny should apply because “the *significance* of the facts” to be disclosed was disputed) (emphasis added); *Disc. Tobacco*, 674 F.3d at 569 (“[W]hether a disclosure is scrutinized under *Zauderer* turns on whether the disclosure conveys factual information . . . , not on whether the disclosure . . . incites controversy”).

Nor is there anything misleading about the warnings. Even if one were to accept the NRA’s contention that the warnings would be misleading if they were based on controversial science, the outcome of the case would not be changed, because in reality the underlying science is *not* controversial.

¹⁰⁸ USDA, DIETARY GUIDELINES, *supra* n.12, at 21.

See supra § I. Even if the proper treatment protocols for patients with extreme heart failure are not settled, and even if there is some disagreement as to just how much sodium consumption should be reduced, the Dietary Guidelines’ recommendation that daily sodium consumption of less than 2300 mg is generally safer is *not* controversial. A statement may be “factual and uncontroversial” even if some scientists may disagree with some aspect of it. If scientific unanimity were required for *Zauderer* review to apply, any imaginable science-based disclosure – about health risks, environmental hazards, or other vital information – would be subject to heightened review under the First Amendment.

A “controversy” cannot be created any time there is a disagreement between the parties because *Zauderer* would never apply, especially where there are health and safety risks, which invariably are dependent in some degree on the current state of science and research. ... [S]cience is almost always debatable at some level (*e.g.*, even if there is agreement that there is a safety issue, there is likely disagreement about at what point a safety concern is fairly implicated). Under [the plaintiff’s] position, any science-based warning required by a governmental agency would automatically be subject to heightened scrutiny under the First Amendment.

CTIA-The Wireless Ass’n v. City of Berkeley, No. 15-CV-02529-EMC, 2016 WL 324283, at *6 (N.D. Cal. Jan. 27, 2016). Reasonable (and noncoercive) public health measures cannot wait for unanimity or certainty. “All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action it appears to demand at a given time.”¹⁰⁹ The point is echoed in the very study proffered by the NRA to demonstrate the existence of scientific controversy: “The mandates of public health require decision makers to act in the absence of certitude in many, if not most, cases.” *Ricardo Aff.*, Ex. A at 7.

There is nothing new about an affected industry or trade group ginning up scientific “controversy” when it opposes the government’s response to a public health threat. The best-known example comes of course from the tobacco industry:

From at least 1953 until at least 2000, [the tobacco companies] ... mounted a coordinated, well-financed, sophisticated public relations campaign to attack and distort the scientific evidence demonstrating the relationship between smoking and disease, claiming that the link between the two was still an “open question.”

¹⁰⁹ Frank Hu, *Resolved: There Is Sufficient Scientific Evidence That Decreasing Sugar-Sweetened Beverage Consumption Will Reduce the Prevalence of Obesity and Obesity-Related Diseases*, 14 *OBESITY REVIEWS* 606 (2013), at 7, at <https://www.sfdph.org/dph/files/hc/HCCommPublHlth/Agendas/2013/2013/December/review%20of%20evidence%20ssb.pdf>

United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, 208 (D.D.C. 2006), *aff'd in relevant part*, 556 F.3d 1095 (D.C. Cir. 2009); *see also Philip Morris*, 556 F.3d at 1108 (describing secret initiatives to “generate ‘marketable science’ to use for public relations purposes”). Similar efforts have been mounted by the oil and gas industry in response to evidence of climate change, *see* Naomi Oreskes and Erik Conway, *MERCHANTS OF DOUBT 186-90* (2010) (detailing workings of industry-funded “institute” designed to sow doubt in the media despite consensus among scientists); by parts of the chemical industry in addressing evidence of the carcinogenic effect of fire retardants in furniture, *see* Patricia Callahan & Sam Roe, *Playing With Fire*, CHICAGO TRIB. (2012) (explaining manipulation of research results and passing off of “biased, industry-funded reports as rigorous science”)¹¹⁰; and, most recently, by the beverage industry, *see* Anahad O’Connor, *Research Group Funded by Coca-Cola to Disband*, N.Y. TIMES (Dec. 1, 2015)¹¹¹ (noting demise of the allegedly independent Global Energy Balance Network, after revelations of industry influence on the group’s scientific claims).

Following a similar playbook, the NRA here attempts to manufacture scientific discord, relying heavily on methodologically unsound studies authored by industry-approved and industry-supported scientists. *See supra* at § I.B.4; Farley, *SAVING GOTHAM* at 219-26 (detailing industry ties and retracted research underlying the purported “controversy” over sodium levels). But even if one were to accept the NRA’s proffered studies as tenable, they would still be outliers: the vast majority of medical and scientific research, and the consensus of authoritative government agencies, support the claim that overconsumption of sodium is a significant health risk to American fast food restaurant consumers. *See supra* § I.

C. Application Of The Lenient *Zauderer* Standard Is Not Limited To Instances Where The Law Seeks To Prevent Consumer Deception.

The NRA’s claim in the Supreme Court that *Zauderer* applies only when the government’s interest is in preventing consumer deception or confusion, NRA Trial MOL at 60-61, has been rejected by every U.S. Court of Appeals to have addressed the issue, along with the

¹¹⁰ *At* <http://media.apps.chicagotribune.com/flames/index.html>

¹¹¹ *At* <http://well.blogs.nytimes.com/2015/12/01/research-group-funded-by-coca-cola-to-disband>

California Supreme Court.¹¹² It appears that the NRA has now dropped this argument.

Still, it would not matter if *Zauderer* were so limited, since the sodium rule reveals high levels of sodium in many menu items – like breads and muffins¹¹³ – where consumers might not expect it. It is precisely because restaurant meals may be deceptively high in sodium that the warnings are necessary.

In sum, the sodium rule does not violate the First Amendment.

IV. THE SODIUM RULE IS NOT PREEMPTED BY FEDERAL LAW.

Federal law does not prohibit the sodium warnings required by the Board of Health. The directly relevant statute, the menu labeling provision of the Patient Protection and Affordable Care Act (ACA),¹¹⁴ contains an explicit exemption from preemption for “warnings” of this type. ACA § 4205(d)(2). That specific exception is all that is necessary to remove the sodium rule from the threat of federal preemption.

The existence of the warning exception is not, however, the only reason that federal preemption does not apply to the sodium rule. Indeed, the preemption provision of the Nutrition Labeling and Education Act,¹¹⁵ the larger statute which contains the menu labeling law, doesn't even apply to the Rule in the first place. The provisions of the NLEA relating to “health claims” and “nutrient claims,” NRA App. MOL at 41-43, are irrelevant to the sodium rule. The “claims” that the NLEA prohibits local governments from regulating are *positive* statements intended to induce consumers to purchase a product, not warnings required by the government itself. In

¹¹² See, e.g., *NEMA*, 272 F.3d 104, 115 (2d Cir. 2001); *Amer. Meat Inst. v. USDA*, 760 F.3d 218 (D.C. Cir. 2014) (en banc) (reversing contrary holdings in the circuit); *Disc. Tobacco*, 674 F.3d 509, 556 (6th Cir. 2012); *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 316 (Boudin, C.J. & Dyk, J.) (1st Cir. 2005); *Env'tl. Def. Ctr., Inc. v. EPA*, 344 F.3d 832, 849 (9th Cir. 2003); *Beeman v. Anthem Prescription Mgmt.*, 58 Cal.4th 329 (2013).

¹¹³ See CDC, *Vital Signs*, *supra* n. 81, at 94 T. F-8 (bread and rolls are the number one sodium-contributing food category for all age groups in the United States).

¹¹⁴ Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119. It is not clear from its Memorandum of Law whether the NRA means to argue that the sodium warning is preempted as nutrition labeling of restaurant food – the NRA scarcely mentions the Affordable Care Act, which requires such labeling, in its arguments on preemption. But even if it did, any argument that the sodium rule was preempted would, as noted, be foreclosed by the safety warning exception contained in the ACA. See § 4205(d)(2).

¹¹⁵ Nutrition Labeling and Education Act of 1990 § 6(c). Pub. L. 101-535, 104 Stat. 2353.

addition, the ACA and NLEA explicitly provide that federal law does not have any preemptive effect beyond what is directly stated in the labeling statutes. ACA § 4205(d)(1)¹¹⁶; NLEA § 6(c).¹¹⁷ That is, in addition to the fact that there is no direct preemption of the sodium rule, there can be no implied or indirect preemption of the measure either.

A. A Strong Presumption Against Preemption Operates In This Case.

Preemption is generally disfavored, particularly in the area of public health. As the Second Circuit held in rejecting the restaurant industry’s challenge to New York City’s menu labeling law,

[W]e start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress. The presumption against preemption is heightened where federal law is said to bar state action in fields of traditional state regulation. Given the traditional primacy of state regulation of matters of health and safety, courts assume that state and local regulation related to [those] matters ... can normally coexist with federal regulations. As a result, where the text of a preemption clause is ambiguous or open to more than one plausible reading, courts have a duty to accept the reading that disfavors pre-emption.

NYSRA, 556 F.3d at 123 (citations and internal quotations omitted).

B. The Sodium Warning Is Neither A Health Claim Nor A Nutrient Content Claim As Defined By Federal Law.

The sodium warning is neither a health claim nor a nutrient content claim, and therefore cannot be preempted on those grounds. As is apparent from the plain meaning of ‘claim,’ health and nutrient content claims are positive marketing statements about the beneficial effects of food products or their ingredients. The NLEA provisions in question are intended to prevent food manufacturers from falsely promising their products will *improve* consumers’ health, not to prevent the government from requiring warnings about negative health consequences.

The legislative history of the NLEA corroborates this interpretation. For example, Rep. Jim Slattery remarked that the NLEA would “restrict the types of health claims food companies

¹¹⁶ “Nothing in the amendments made by this section shall be construed—(1) to preempt any provision of State or local law, unless such provision . . . is expressly preempted.”

¹¹⁷ See also *NYSRA*, 556 F.3d at 123 (“Helpfully, the NLEA is clear on preemption, stating that it ‘shall not be construed to preempt any provision of State law, unless such provision is *expressly preempted* under [21 U.S.C. § 343-1(a)] of the [FDCA].’ . . . (21 U.S.C. § 343-1 note) (emphasis added).”

can make about their products.” 136 Cong. Rec. E3636-02 (Oct. 27, 1990). And Rep. Henry Waxman, the Act’s sponsor, stated that the law would ensure that “only truthful claims [would] be made on foods,” and that the health claim provision was being enacted in response to a proliferation of unfounded claims by food sellers. 136 Cong. Rec. H12951-02 (Oct. 26, 1990).

FDA regulations and guidance also confirm that ‘health claims’ are positive statements. Federal regulations provide a comprehensive list of permissible health claims, and every single one is a claim relating to positive health outcomes or to the reduction of disease risk.¹¹⁸ See 21 C.F.R. §§ 101.70 *et seq.* Additionally, when outlining the method of petitioning for new health claims, the FDA requires a summary of the scientific data to provide “the basis upon which authorizing a health claim can be justified as providing the health *benefit*.” 21 C.F.R. § 101.70(f) (emphasis added). Clearly, warnings about negative health outcomes do not constitute ‘health claims.’

Further demonstrating this exclusive definition, the law explicitly prohibits foods with high levels of sodium from carrying a ‘health claim’ like “Low in...” See 21 C.F.R. § 101.14(e)(3); *cf. id.* at §§ 101.14(a)(4), (d)(2)(vi), (e)(3). This prohibition would make no sense if the definition of health claims included warnings about the negative effects of sodium.

The NRA’s cited examples of ‘health claims’ actually *support* the Rule. The sole apparently negative ‘claim’ quoted by the NRA, *see* NRA App. MOL at 42 n. 48 (“frequent between-meal consumption of foods high in sugars and starches can promote tooth decay”)¹¹⁹ is actually just a preamble to a *positive* health claim – omitted by the NRA – about artificial sweeteners that “‘may reduce the risk of’ ... dental caries.” 21 C.F.R. § 101.80(c)(2)(i)(B).¹²⁰

¹¹⁸ Health claims include statements like “adequate calcium and Vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis” 21 C.F.R. § 101.72, or “low-fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer...” 21 C.F.R. § 101.76.

¹¹⁹ 21 C.F.R. § 101.80(c)(2)(i)(A).

¹²⁰ *Turek v. General Mills*, 662 F.3d 423 (7th Cir. 2011), *cited in* Pl. MOL at 43, provides no meaningful support for the argument that involuntary statements can be claims. The plaintiff in *Turek* was seeking (in addition to damages) an injunction modifying a *voluntary* claim by General Mills about its “chewy bar” products. *See New York State Restaurant Ass’n v. New York City Board of Health (NYSRA I)*, 509

Likewise, claims about “nutrient content” under the NLEA are concerned only with characterizations of nutrient levels that would be interpreted by consumers as *beneficial*. The NRA argues that the sodium warning is a nutrient content claim because it classifies the level of sodium in menu items as “high.” But the lengthy section of the FDA regulations governing nutrient content claims for sodium is concerned only with claims of “low” or “no” sodium or similar statements implying a health benefit. *See* 21 C.F.R. § 101.61. And all other nutrient content claims permitted by the FDA similarly seek to demonstrate *positive* health benefits of various nutrients in foods, such as “high in dietary fiber.” *See* 21 C.F.R. § 101.54 *et seq.*

To find that the sodium warning is preempted as a health or nutrient content claim would be contrary to the plain meaning of the law, its legislative history, and its clear purpose of deterring false claims by food manufacturers that are designed to entice consumers to purchase food products because of the (claimed) health benefits the products provide.

C. Even If The Sodium Warning Were A Health Or Nutrient Content Claim, It Would Be Saved From Preemption By The Safety Warning Exception.

Even if a statement informing consumers about the risks of consuming menu items that exceed the recommended daily limit for sodium were a ‘claim’ falling within the preemptive scope of federal law, that statement would be preserved from preemption by the savings clauses of both the NLEA and the ACA, which explicitly allow local requirements “respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.” NLEA § 6(c); ACA § 4205(d).

The legislative history of the NLEA supports an expansive interpretation of the safety warning exception. Notably, Rep. Waxman (the law’s sponsor), observed that the exception

may be unnecessary because [the NLEA] does not require health warnings and therefore, ... state laws requiring health warnings would not be preempted. Nevertheless, [the safety warning exception] has been included to underscore that State laws requiring warnings pertaining to the safety of foods are not preempted.¹²¹

F.Supp.2d 351, 361-63 (S.D.N.Y. 2007) (finding modification of voluntary claims preempted). And in any event the court in *Turek* did not consider the “warning” exception to NLEA preemption. *See infra* § IV.C.

¹²¹ 136 Cong. Rec. H5836-01 (July 30, 1990).

Senator Hatch stressed that “the carefully crafted uniformity section of this legislation is limited in scope.”¹²² *See also Sciortino v. Pepsico*, 108 F. Supp. 3d 780, 802, 804 (N.D. Cal. 2015) (noting “[t]his legislative history weighs strongly against preemption” in a safety warning case, as does “the plain language ... of the NLEA”).

The NRA’s argument that the safety warning exception should apply only to “inherently dangerous” or “inherently toxic” substances,” NRA App. MOL at 44, finds no grounding in case law. The holding in *Mills v. Giant of Maryland* was merely that lactose intolerance, however uncomfortable, doesn’t implicate “safety” concerns. 441 F. Supp. 2d 104, 109 (D.D.C. 2006). Excess consumption of sodium, in stark contrast, can lead to life-threatening conditions. *See supra* § I.A. *Mills* has no applicability to warnings concerning serious threats to life, the issue in this case. The example embraced by the NRA, California’s Proposition 65,¹²³ *see* NRA App. MOL at 44, actually has a good deal in common with the sodium rule: Prop 65, like the Rule, focuses on chronic disease (cancer) and requires warnings about such innocuous-in-small-amounts substances as alcoholic beverages, salted fish, aspirin, wood dust, caffeic acid (found in coffee), and acrylamides (found in French fries).¹²⁴ Like Prop 65, the sodium rule focuses on long-term health concerns.

Finally, the extraordinary accumulation of evidence regarding the threat of hypertension and the urgency of reducing excess sodium consumption makes irrelevant the NRA’s stated concern that local governments will routinely seek to evade preemption by claiming that any disclosure mandate is a “warning,” NRA App. MOL at 44. Whatever the plausibility of such an argument in other circumstances, it certainly has no place in the context of the Board’s effort to save the lives of thousands of New Yorkers every year.

In sum, there exist no grounds for finding the sodium warning preempted by federal law.

¹²² 136 Cong. Rec. 516607-02 S1611 (Oct. 24, 1990).

¹²³ Safe Drinking Water And Toxic Enforcement Act of 1986, Cal. Health & Safety Code § 25249.5 *et seq.* (requiring warning signs stating, in effect, “This product contains a chemical known to the State of California to cause cancer”).

¹²⁴ State of California, Office of Environmental Health Hazard Assessment, *List of Chemicals Known to the State to Cause Cancer or Reproductive Toxicity* (Dec. 4, 2015), at http://oehha.ca.gov/prop65/prop65_list/files/P65single120415.pdf

V. THE NRA HAS FAILED TO DEMONSTRATE GROUNDS FOR IMPOSING A PRELIMINARY INJUNCTION.

“A party seeking the drastic remedy of a preliminary injunction has the burden of demonstrating, by clear and convincing evidence, (1) a likelihood of ultimate success on the merits, (2) the prospect of irreparable injury if the provisional relief is withheld, and (3) a balancing of the equities in the movant’s favor.” *Temple-Ashram v. Satyanandji*, 84 A.D.3d 1158, 1161 (2d Dep’t 2011) (internal quotation marks and citation omitted). *See also Mazurek*, 520 U.S. at 972 (“a preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, by a *clear showing*, carries the burden of persuasion”) (emphasis in original).

This already considerable burden is even heavier in this case:

Notably, where, as here, the constitutionality of legislation is challenged, the burden becomes more difficult as there exists an exceedingly strong presumption of constitutionality. Furthermore, with the decision to grant or deny a request for a preliminary injunction committed to the sound discretion of the trial court, ... review is limited to whether [the] Supreme Court has either exceeded or abused its discretion as a matter of law.

Schulz v. State Executive, 108 A.D.3d 856, 857 (3d Dep’t 2013).¹²⁵ *See also Nobu Next Door, LLC v. Fine Arts Hous., Inc.*, 4 N.Y.3d 839, 840 (2005) (“Our power to review such decisions is thus

¹²⁵ The analysis is not altered by the NRA’s citation to cases about the appropriateness of injunctive relief in cases involving constitutional challenges. NRA App. MOL at 14. The passage the NRA cites from *Med. Malpractice Ins. Ass’n v. Cuomo*, 138 A.D.2d 177, 181-82 (1st Dep’t 1988) immediately continues: “The granting of such preliminary relief is contingent upon a demonstration that the moving party is likely ultimately to succeed on the merits and that, in the absence of a preliminary injunction, it will suffer irreparable injury. In addition, the moving party must demonstrate that a balancing of the equities favors its position.” *Id.* at 182. Tellingly, the Court of Appeals reversed the Appellate Division’s decision to sustain a preliminary injunction in that case. *Med. Malpractice Ins. Ass’n v. Cuomo*, 74 N.Y.2d 651 (1989). The NRA similarly omits a crucial passage from *Tucker v. Toia*, 54 A.D.2d 322, 326 (4th Dep’t 1976), *quoted at* NRA App. MOL at 14. The elided portion of the opinion reads in full: “Plaintiffs’ argument and the State’s counterarguments in favor of upholding the statute’s validity involve aspects of constitutional law too weighty to have been briefed adequately in the short time available to the parties before this motion was heard at Special Term and too complex for Special Term to resolve in the even shorter time available to it before its decision was required.” *Id.* In other words, the problem in that case was that there was not adequate time to brief the issues; here, by contrast, there was full briefing – and any shortenings of time were the product of the NRA having waited until early December 2015 – *after* the effective date of the Rule – to bring their challenge. *See* Notice of Adoption, at <http://www.nyc.gov/html/doh/downloads/pdf>

limited to determining whether the lower courts' discretionary powers were exceeded or, as a matter of law, abused."); *Horsfall v. Schuler*, 217 A.D. 146, 147 (2d Dep't 1926) ("We have frequently announced the rule that this court will not interfere with the discretion of the [trial court] in granting or refusing an injunction pendente lite, save in exceptional cases").

The NRA has failed to demonstrate the elements required for imposition of a preliminary injunction, and certainly has not established that the Supreme Court abused its discretion. The Supreme Court's conclusion that the NRA was unlikely to prevail on the merits was – as explained in sections I-IV *supra* – eminently reasonable and entirely justified. The finding that the NRA is not likely to prevail on the merits ends the inquiry – there is no need to inquire into whether the NRA's harm is irreparable or whether the balance of harms favors the City or the NRA. *Doe v. Axelrod*, 73 N.Y.2d at 750. But even if the NRA were able to prevail on the merits of any of its claims, it could show neither irreparable harm nor a balance of equities in its favor.

A. The NRA Has Failed To Demonstrate A Likelihood Of Success On The Merits.

As explained in the preceding sections of this brief, the NRA has not established a likelihood that it will succeed on the merits of this lawsuit. To the contrary, on each of the issues it has raised, the NRA is *unlikely* to prevail. As Supreme Court aptly and succinctly observed,

(1) the Board properly exercised its broad authority in the area of public health by adopting [the Rule]; (2) [the Rule] is not invalid as arbitrary and capricious; (3) [the Rule] does not violate the First Amendment rights of [the NRA's] members because it reasonably requires disclosure of factual information in a purely commercial context; and (4) [the Rule] is not preempted by federal law because it requires a "warning" statement and thus falls within a valid exception to the express preemption provisions of the NLEA.

Sup. Ct. Order at 8.

To obtain a preliminary injunction, the NRA has to establish, based on clear and convincing evidence, *Brookhaven Baymen's Ass'n*, 85 A.D.3d at 1078, *each* of the three elements

/notice/2015/noa-section49-article81.pdf (noting publication date of June 23, 2015 and effective date of December 1, 2015).

required for a preliminary injunction: likelihood of success on the merits, irreparability of injury, and balance of the harms. Therefore, its failure to establish the first element is sufficient ground to deny the injunction, as concluded by the Supreme Court: Because the NRA “has not demonstrated a likelihood of success on the merits” its “motion for preliminary injunction is denied.” Sup. Ct. Order at 8; *see also Pinnacle Charter Sch. v. Bd. of Regents*, 108 A.D.3d 1024, 1025 (4th Dep’t 2013) (preliminary injunction denied where “plaintiffs failed to demonstrate a likelihood of success on the merits with respect to any of their claims”).

B. The NRA Has Failed To Demonstrate Irreparable Harm.

Because the NRA failed on the first element, there was no need for the Supreme Court to consider irreparability of harms or the balance of equities, and there is no need now for this Court to do so. But these elements also do not favor the NRA.

First, neither the constitutional violations nor the economic and business harms alleged by the NRA would constitute irreparable harms, even if the allegations were accurate. The constitutional violations alleged are not the kind that are presumed to be irreparable injuries per se. This is readily apparent with respect to the alleged structural constitutional violations. Cases finding constitutional violations to comprise

irreparable harm per se ... all involve “personal” constitutional rights (coupled with, for example, some physical harm or loss of liberty, i.e., some tangible harm), to be distinguished from provisions of the Constitution that serve “structural” purposes – i.e., a provision of the Constitution relating to the division of power, say, between the States and the federal government, the violation of which is not necessarily accompanied by any tangible harm.

Am. Petroleum Inst. v. Jorling, 710 F. Supp. 421, 431 (N.D.N.Y. 1989). Thus an “asserted violation of the Supremacy Clause cannot, without more, serve as the basis for a finding of irreparable harm.” *Id.* at 432. The same reasoning applies to an alleged violation of structural

constitutional provisions concerning the division of powers among the branches of state or local government.¹²⁶

The NRA's case is no stronger with respect to the sort of First Amendment violations alleged in this case. It is “[w]here a plaintiff alleges injury from a rule or regulation that directly *limits* speech [that] the irreparable nature of the harm may be presumed.” *Bronx Household of Faith v. Bd. of Educ.*, 331 F.3d 342, 349 (2d Cir. 2003) (emphasis added). *See also Goldie’s Bookstore, Inc. v. Superior Court*, 739 F.2d 466, 472 (9th Cir. 1984) (“purposeful unconstitutional *suppression* of speech constitutes irreparable harm for preliminary injunction purposes”) (emphasis added). Although in other contexts the harm of compelling speech is presumed to be equivalent to the harm of suppressing speech, that is manifestly not the case with respect to factual commercial disclosures. *See Zauderer*, 471 U.S. at 651 n.14 (in the context of commercial speech “the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed”). Given that the “constitutionally protected interest in *not* providing any particular factual information ... is minimal,” *id.* at 650 (emphasis in original), it is difficult to see how being required to provide such information could constitute an irreparable constitutional injury.¹²⁷

The unsubstantiated economic losses posited by the NRA likewise fail to establish irreparable harm. A demonstrated irreparable harm may not be speculative. *Kamerling v.*

¹²⁶ *Orange County Legislature v. Diana*, 40 Misc.3d 278, 292-93 (Sup. Ct. Orange Cty. 2013), *see* NRA App. MOL 16, is not to the contrary. The violation of separation of powers in that case provided “sufficient predicate for a finding of irreparable harm,” *id.*, because the plaintiff was the legislature whose powers were being usurped, not a third party that did not like the outcome. The other cases cited by the NRA in support of its contention that structural constitutional violations are presumed to constitute irreparable harm, NRA App. MOL at 16, in fact involved violations of personal constitutional rights, coupled with tangible harms to the plaintiffs. *See Donahue v. Mangano*, 886 F. Supp. 2d 126 (E.D.N.Y. 2012) (violations of Contracts Clause at expense of unions and their members); *Donohue v. Paterson*, 715 F. Supp. 2d 306 (N.D.N.Y. 2010) (same); *Jolly v. Coughlin*, 76 F.3d 468 (2d Cir. 1996) (cruel and unusual punishment and violation of right to free exercise of religion).

¹²⁷ To amici’s knowledge, the only decision that has ever arguably applied the doctrine of irreparable First Amendment injury to factual commercial disclosures is that of the divided panel in *International Dairy Foods Ass’n [IDFA] v. Amestoy*, 92 F.3d 67, 72 (2d Cir. 1996). But that much-criticized decision has essentially been limited to its facts by subsequent rulings of the Second Circuit. *See Conn. Bar Ass’n*, 620 F.3d at 96 n.16; *NYSRA*, 556 F.3d at 134; *NEMA*, 272 F.3d at 115 n.6. In any event, *IDFA* is inapplicable to this case because the court there found that the disclosures at issue were unjustified by any scientific findings of threat to health or safety. *Id.* at 73-74.

Massanari, 295 F.3d 206, 214 (2d Cir. 2002). Here the NRA offers nothing but speculation to justify its contention that its members “will incur irreparable injury to customer relationships and competitive position.” NRA App. MOL, at 16. *Cf. Goldie’s*, 739 F.2d at 472 (the district court “determined that Goldie’s would lose goodwill and ‘untold’ customers. This finding, not based on any factual allegations, appears to be speculative. Speculative injury does not constitute irreparable injury”). *See also GFI Sec., LLC v. Tradition Asiel Sec., Inc.*, 61 A.D.3d 586, 586 (1st Dep’t 2009) (“the speculative claim of lost goodwill” failed to show irreparable harm in support of a preliminary injunction). In general, to support a finding of irreparable harm, a threatened loss of goodwill must not only be imminent, but also must threaten “the very viability of the plaintiff’s business” or “substantial losses of sales beyond those of the [affected] product[s].” *Tom Doherty Associates, Inc. v. Saban Entm’t, Inc.*, 60 F.3d 27, 38 (2d Cir. 1995). The required “clear showing” to this effect will “be infrequently met.” *Id.* It is not credible that the sodium warnings at issue here imminently threaten either the very viability of the businesses of NRA members or substantial losses of sales beyond those of the affected high-sodium products (if that).

The “substantial time, resources and money [that NRA members] would have to devote to complying with the Sodium Mandate,” NRA App. MOL at 17, also do not support a finding of irreparable injury. “[O]rdinary compliance costs are typically insufficient to constitute irreparable harm.” *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005). That conclusion is particularly applicable in this case, where there has been no showing that compliance costs would in fact be substantial. To the contrary, the plausibility of the NRA’s contention that compliance costs would be substantial is undermined by restaurants’ use of changeable (and increasingly digital) menu boards¹²⁸ and the frequency with which menu boards – and printed menus – are changed to accommodate changes in price, new offerings, or special promotions.¹²⁹ The allegation

¹²⁸ *See, e.g.*, Brian McClimans, *Keeping Up With Menu Content: The Food Industry Is Changing – and So Must Your Signage*, *QSR MAGAZINE* (July 2015), at <https://www.qsrmagazine.com/outside-insights/keeping-menu-content>

¹²⁹ *See, e.g.*, Panera Bread Company, Form 10-K (2014) at 2, at <https://www.panerabread.com/content/dam/panerabread/documents/financial/2014/2014-fiscal-form-10-k.pdf> (“We regularly review and innovate our menu offerings”); McDonald’s Corporation, Form 10-K (2014), at 2, at

that the costs of compliance are prohibitive is further belied by the fact that a number of covered chains have already updated their menus to comply.¹³⁰

The NRA has fallen far short of demonstrating by clear and convincing evidence that its members would suffer any irreparable harm, whether constitutional or economic.

C. The Balance Of Equities Favors The City.

The balance of harms tilts strongly in favor of the City. The costs of redesigning menus pale in comparison to the loss of benefits to health if the Rule is prevented from going into effect. As noted, any economic harms NRA members might suffer would be comparatively minor. And any constitutional interest that might be violated is “minimal.” *Zauderer*, 471 U.S. at 651. On the other side of the balance are the lives that could be extended by informing consumers when they are in danger of excessive sodium consumption. The 12,000 New York City residents who have their lives shortened by hypertension every year and the almost 2 million New Yorkers for whom a reduction in sodium consumption could mean improved health and a longer life¹³¹ vastly outweigh the costs of compliance with the Rule.

The NRA’s response to these facts seems not to grasp the urgency of the public health crisis that motivated the Rule. Reducing sodium intake for just one month has been found to reduce blood pressure significantly.¹³² The NRA’s contention that “[a]ny argument that immediate enforcement is necessary immediately to ‘save lives’ is belied by the fact that the Board adopted the Sodium Mandate only late last year, ... and included a three-month enforcement grace period,” NRA App. MOL at 18, is meritless. A similar argument could be made for delaying virtually any public health measure: it is almost always true that the measure could have been implemented

<http://www.sec.gov/Archives/edgar/data/63908/000006390815000016/mcd-12312014x10k.htm> (“[W]e are continuously evolving our menu to meet our customers’ needs”).

¹³⁰ Allison Aubrey, *Judge Rules NYC Can Require Sodium Warnings On Restaurant Menus*, NPR (updated Feb. 25, 2016), at <http://www.npr.org/sections/thesalt/2016/02/24/467964321/judge-rules-nyc-can-require-sodium-warnings-on-restaurant-menus/> See also John Surico, *New York City Can Require Sodium Warnings, Judge Rules*, N.Y. TIMES (Feb. 24, 2016) (chains including Subway, T.G.I. Friday’s, Applebee’s and the Regal Entertainment Group have already acted to comply), at <http://www.nytimes.com/2016/02/25/nyregion/salt-new-york-city-can-require-sodium-warnings-judge-rules.html>

¹³¹ NYC Dep’t of Health and Mental Health, Community Health Survey (2013), Notice of Adoption at 1.

¹³² Sacks et al., *Effects on Blood Pressure*, *supra* n. 93.

sooner. And the fact that restaurants were given a grace period to ease the costs of compliance and to sort out legal issues hardly licenses the NRA's gamesmanship in refraining from filing a legal challenge until (past) the 11th hour, and then citing that as a reason for further delays.

In sum, the NRA has failed to establish irreparable harm, whether by clear and convincing evidence (as required) or otherwise. The balance of equities overwhelmingly favors the City.

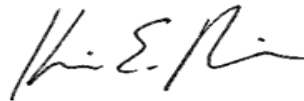
Given the likely outcome of the case, and the seriousness of harm to the public if enforcement of the Rule is stayed further, the NRA asks too much by seeking further delay. This Court will of course have the opportunity to consider the merits of the case in the regular course of appellate proceedings. In the meantime, however, the Rule needs to go into effect.

CONCLUSION

The sodium rule is a reasonable and measured response to a public health crisis. It is backed by well-accepted scientific evidence, and it suffers from no constitutional infirmity. As underscored by the decision of the Supreme Court, the NRA has failed to establish a likelihood of success on the merits.

The request for a preliminary injunction should be denied.

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APPENDIX A

INDIVIDUAL STATEMENTS OF INTEREST OF *AMICI CURIAE*

1. The American Heart Association is a voluntary health organization that, since 1924, has been devoted to saving people from heart disease and stroke – the two leading causes of death in the world. It teams with millions of volunteers to fund innovative research, fight for stronger public health policies, and provide lifesaving tools and information to prevent and treat these diseases. The Dallas-based association with local offices in all 50 states, as well as in Washington DC and Puerto Rico, is the nation’s oldest and largest voluntary organization dedicated to fighting heart disease and stroke.

2. The Center for Science in the Public Interest (CSPI) is a leading national, non-profit advocacy organization for nutrition, health, food safety, and scientific integrity. The organization has worked to achieve recent sodium reductions in school foods as well as sodium labeling on packaged foods. CSPI is currently litigating over FDA’s delay in responding to a 2005 citizen petition questioning whether current levels of sodium in foods should be considered “generally recognized as safe” under federal law. CSPI also supports the New York City Rules, and testified in favor of the initiative.

3. ChangeLab Solutions is a national nonprofit organization that creates innovative laws and policies to ensure everyday health for all, whether that’s providing access to affordable, healthy food and beverages, creating safe opportunities for physical activity, or ensuring the freedom to enjoy smokefree air and clean water. Its solutions address all aspects of a just, vital and thriving community, like food, housing, child care, schools, transportation, public safety, jobs, and the environment. ChangeLab Solutions creates and helps implement legal and policy solutions

designed to increase access to nutritious food while reducing consumption of unhealthy foods, including foods that include excessive amounts of sodium.

4. The Coalition for Asian American Children and Families, the nation's only pan-Asian children's advocacy organization, aims to improve the health and well-being of Asian Pacific American children and families in New York City. Cardiovascular disease is the leading cause of death in Asian American, Native Hawaiian and Pacific Islander communities and behavioral risk factors associated with this disease can be linked specifically to smoking, physical inactivity and nutrition. Because the Coalition is committed to policies promoting the health and safety of the Asian Pacific American population, it supports strategies that reduce excessive sodium consumption.

5. The Food Trust is a nonprofit organization whose mission is to ensure that everyone has access to affordable, nutritious food and information to make healthy decisions. The Food Trust knows that in many neighborhoods throughout the nation residents cannot easily buy healthy foods and that a heavy presence of fast food restaurants and convenience stores sell unhealthy food in these same communities. The Food Trust is aware of research showing that people who live in these underserved neighborhoods are more at risk for serious diet-related diseases like obesity, hypertension and diabetes. The Food Trust believes that policies, such as warning consumers about high levels of sodium in restaurant menu items via labeling, help make the healthy choice the easy choice, and ultimately improve the health of communities.

6. The National Association of Chronic Disease Directors (“NACDD”) is a non-profit public health organization committed to serve the chronic disease directors of each state and U.S. jurisdiction. Founded in 1988, NACDD connects more than 6,000 chronic disease practitioners to advocate for preventive policies and programs, encourage knowledge sharing and develop

partnerships for health promotion. Since its founding, NACDD has been a national leader in mobilizing efforts to reduce chronic diseases and their associated risk factors through state and community-based prevention strategies. In 2010, the Los Angeles County Department of Public Health published an issue brief that drew attention to the issue of sodium and cardiovascular health in LA County, and that helped secure passage of a Board Motion requiring all LA County Departments that buy, sell, or procure food to consult with the Department of Public Health before releasing any Request for Proposal for a new food vendor. With the permission of the LA County Public Health Department, the NACDD's Cardiovascular Health Council Sodium Practice Group adapted this document on reducing excessive sodium consumption and posted it on its website as a template for other states and localities to use.

7. The National Association of County and City Health Officials ("NACCHO") is a national organization representing the nation's 2,800 local public health departments. Many local health departments are actively engaged in programs aimed at reducing chronic, preventable illnesses. NACCHO supports efforts that protect and improve the health of all people and all communities by promoting national policy, developing resources and programs, seeking health equity and supporting effective local public health practice and systems. NACCHO supports mandatory disclosure of sodium content in foods to give consumers the information they need to make informed decisions related to their health.

8. The National Association of Local Boards of Health ("NALBOH") informs, guides, and is the national voice for local boards of health. Uniquely positioned to deliver technical expertise in governance, leadership and board development, NALBOH is committed to strengthen good governance where public health begins – at the local level. For over 20 years, NALBOH has been engaged in establishing this significant voice for local boards of health on matters of national

public health policy. In line with its commitment to public health, NALBOH supports healthy food policies, including the reduction of overconsumption of sodium.

9. The New York State Public Health Association (“NYSPHA”) is an affiliate of the American Public Health Association and serves as a statewide organization for members from all disciplines in the public health spectrum including state and county health departments, healthcare; policy and advocacy organizations; community based health and human service programs and workers; academia and research. NYSPHA advocates for policies at the national, state and regional levels that support equity in health status and an end to health disparities for all. NYSPHA is among the nation’s oldest, independent, nonprofit public health organizations. It serves as a broad-based statewide organization devoted to promoting and protecting the health of all New Yorkers. As a voice for public health professionals in New York, NYSPHA strongly recommends the implementation of sodium warning labels.

10. The New York Academy of Medicine advances solutions that promote the health and well-being of people in cities worldwide. Established in 1847, The New York Academy of Medicine continues to address the health challenges facing New York City and the world’s rapidly growing urban populations. It accomplishes this through its Institute for Urban Health, home of interdisciplinary research, evaluation, policy and program initiatives. Its current priorities are healthy aging, disease prevention, and eliminating health disparities. A major focus of its work is food and health. For these reasons, it recognizes the health impact of high dietary sodium intake across the lifespan and appreciates and supports the efforts of the NYC Department of Health and Mental Hygiene to address this issue, in part, through the Sodium Warning Label Proposal.

11. The New York State Academy of Pediatrics (“NYSAAP”) has been advocating for healthier food options for children and families in New York neighborhood grocery stores and

bodegas and in restaurants. Food labeling allows families to make informed decisions about what they are purchasing and eating for the adults and the children in each family. NYSAAP supports sodium labeling as information that will help both parents and children make informed choices about their food. It supports the New York City Board of Health in its effort to provide this information to all New Yorkers. Therefore, NYSAAP is pleased to join amici in supporting the New York City sodium labeling regulation and opposing any roll back efforts.

12. The Public Health Association of New York City (“PHANYC”) is an organization of physicians, nurses, educators, health administrators, researchers, students, and health care consumers, with a rich tradition of commitment to improving public health within New York City. Established in 1936, PHANYC is one of the largest affiliates of the American Public Health Association. As part of its mission, PHANYC informs consumers and providers of health care about public health issues; influences public health policy; and advocates for improved public health measures, such as the implementation of sodium warning labels.

13. The Public Health Law Center is a public interest legal resource center dedicated to improving health through the power of law. Located at the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps local, state, and national leaders improve health by strengthening public policies. The Center works with public officials and community leaders to develop, implement and defend effective public health laws and policies, including laws and policies to promote access to healthy foods and to discourage consumption of unhealthy foods, such as excessive sodium. The Center has worked with the American Heart Association and others for five years on legal strategies for reducing excessive sodium consumption in the American diet, has published on options for federal regulation of sodium, and is a member of the National Salt Reduction Initiative led by the City of New York.