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, NOTAH
BEGAY III FOUNDATION, PUBLIC HEALTH ASSOCIATION OF NEW YORK CITY,
AND PUBLIC HEALTH LAW CENTER
IN SUPPORT OF DEFENDANTS-RESPONDENTS

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# TABLE OF CONTENTS

TABLE OF AUTHORITIES ................................................................................................. iii
PRELIMINARY STATEMENT .............................................................................................. 1
STATEMENT OF INTEREST OF AMICI CURIAE ............................................................ 3
ARGUMENT ..................................................................................................................... 3

I. THE SODIUM WARNINGS ARE AN APPROPRIATE RESPONSE TO A PUBLIC HEALTH CRISIS ........................................................................................................... 3
   A. Overconsumption Of Sodium Is A Severe Threat To Public Health ..................... 4
   B. The Health Benefits of Reducing Sodium Consumption Are Well Established And Not Scientifically Controversial .............................................................. 5
      1. The dubious studies favored by the NRA do not upset settled science concerning the benefits of reducing sodium intake .................................................... 7
      2. High quality recent research corroborates the health benefits of reducing sodium intake ................................................................................................................. 9
      3. Americans are in no danger of insufficient sodium intake .................................. 10
      4. Scientific “controversy” about healthy levels of sodium intake is a fiction manufactured by the salt and prepared food industries ................................... 11
   C. Fast Food And Other Chain Restaurants Contribute Significantly To Sodium Overconsumption ........................................................................................................ 14
   D. Warnings Are Needed, Because Consumers Lack Awareness Of Their Own Sodium Consumption ......................................................................................... 16

II. THE SODIUM RULE IS NOT ARBITRARY AND CAPRICIOUS; IT IS A REASONABLE RESPONSE TO A PUBLIC HEALTH CRISIS .............................................. 16
   A. The Arbitrary And Capricious Standard Is Easily Met ............................................ 17
   B. The Rule Incorporates Reasonable Line Drawing And The Boundaries Of The Board’s Authority ..................................................................................................... 18
      1. Incremental regulation is not only permissible but often necessary ..................... 19
      2. It is not arbitrary or capricious for an agency to act only to the extent of its own authority ........................................................................................................ 19
      3. The distinctions made by the rule are rational and not arbitrary .......................... 20

III. THE SODIUM WARNING COMPORTS WITH THE FIRST AMENDMENT ............ 21
   A. Factual Warnings About Well-Known Health Risks Are Reviewed Under A Lenient Standard, And The Sodium Rule Easily Passes That Review .......................... 22
   B. The Warning Conveys Factual And Uncontroversial Information To Consumers ......................................................................................................................... 23
   C. Application Of The Lenient Zauderer Standard Is Not Limited To Instances Where The Law Seeks To Prevent Consumer Deception .............................................. 25
IV. THE SODIUM RULE IS NOT PREEMPTED BY FEDERAL LAW. ..................................................26
   A. A Strong Presumption Against Preemption Operates In This Case. .........................26
   B. The Sodium Warning Is Neither A Health Claim Nor A Nutrient Content
      Claim As Defined By Federal Law..................................................................................27
   C. Even If The Sodium Warning Were A Health Or Nutrient Content Claim, It
      Would Be Saved From Preemption By The Safety Warning Exception.....................28

CONCLUSION .................................................................................................................................................30

APPENDIX A: Individual Statements of Interest of Amici Curiae.............................................I
# TABLE OF AUTHORITIES

## CASES

**Amer. Meat Inst. v. USDA,**  
760 F.3d 218 (D.C. Cir. 2014) ................................................................. 25

**Anonymous v. Grievance Comm.,**  
136 A.D.2d 344 (2d Dep't 1988) ................................................................. 22

**Beeman v. Anthem Prescription Mgmt.,**  
58 Cal.4th 329 (2013) ................................................................................. 25

**Chiropractic Ass’n of NY v. Hilleboe,**  
12 N.Y.2d 109 (1962) ................................................................................. 18

**Connecticut Bar Ass’n v. United States,**  
620 F.3d 81 (2d Cir. 2010). ........................................................................... 22

**Consolation Nursing Home v. Comm’r, NY State Dep’t of Health,**  
85 N.Y.2d 326 (1995) .................................................................................. 18, 21

**CTIA-The Wireless Ass’n v. City of Berkeley,**  

**Discount Tobacco City & Lottery, Inc. v. U.S.,**  
674 F.3d 509 (6th Cir. 2012) ....................................................................... 23, 24, 25

**E. Fougera & Co. v. City of New York,**  
224 N.Y. 269 (1918) .................................................................................. 19

**Entm’t Software Ass’n v. Blagojevich,**  
469 F.3d 641 (7th Cir. 2006) ..................................................................... 22

**Envtl. Def. Ctr., Inc. v. EPA,**  
344 F.3d 832 (9th Cir. 2003) ..................................................................... 25

**Grossman v. Baumgartner,**  
17 N.Y.2d 345 (1966) ................................................................................ 17, 18

**Hymowitz v. Eli Lilly & Co.,**  
136 Misc.2d 482 (Sup. Ct. N.Y. Cty. 1987) ............................................... 20

**Ibanez v. Florida Dept. of Bus. and Prof. Reg.,**  
512 U.S. 136 (1994) .................................................................................. 23
Louisville Gas Co. v. Coleman,
277 U.S. 32 (1928).............................................................................. 20

Matsen v. New York State Dep’t of Motor Vehicles,
— A.D. 3d — , 2015 WL 8373521 (3d Dep't Dec. 10, 2015)................................. 17

Mills v. Giant of Maryland,
441 F. Supp. 2d 104 (D.D.C. 2006).............................................................. 29

Montgomery v. Daniels,
38 N.Y.2d 41 (1975). ............................................................................... 17, 19, 20

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77 N.Y.2d 340 (1991).............................................................................. 18, 19

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272 F.3d 104 (2d Cir. 2001). ..................................................................... 22, 23, 25

New York State Restaurant Ass’n (NYSRA) v. New York City Bd. of Health,
556 F.3d 114 (2d Cir. 2009). ................................................................. 23, 24, 26, 27

Pharm. Care Mgmt. Ass’n v. Rowe,
429 F.3d 294 (1st Cir. 2005)..................................................................... 25

Riley v. Nat’l Fed’n of the Blind,
487 U.S. 781 (1988)................................................................................. 22

Safelite Grp., Inc. v. Jepsen,
764 F.3d 258 (2d Cir. 2014)..................................................................... 22

Sciortino v. Pepsico,

United States v. Philip Morris USA, Inc.,

United States v. Philip Morris,
556 F.3d 1095 (D.C. Cir. 2009)................................................................. 24

Zauderer v. Office of Disciplinary Counsel,
471 U.S. 626 (1985).................................................................................. 22, 23, 24, 25

STATUTES & REGULATIONS
Affordable Care Act § 4205, codified at 21 U.S.C. § 343(q)(5).............................. 21, 26

21 C.F.R. § 101.72 ....................................................................................................................... 28
21 C.F.R. § 101.76 ....................................................................................................................... 28
21 C.F.R. § 101.80(c)(2)(i)(A) .................................................................................................... 28
N.Y. Civil Practice Law & Rules § 7803(3) ............................................................................... 17
N.Y.C. City Charter § 553 ......................................................................................................... 18
N.Y.C. Health Code § 81.50 ..................................................................................................... 21

OTHER LEGAL AUTHORITIES
136 Cong. Rec. H5836-01 (July 30, 1990) ............................................................................. 29
79 FED. REG. 11879 (Jun. 2, 2014) ......................................................................................... 6

ARTICLES, STUDIES, BOOKS & REPORTS
Aburto, Nancy, et al., Effect of Lower Sodium Intake on Health: Systematic Review and Meta-Analyses, 346 BRIT. MED. J. f1326 (2013) ......................................................................................... 6, 7, 10, 11

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Auchincloss, Amy, et al., Nutritional Value of Meals at Full-Service Restaurant Chains, 46 J. NUTR. ED. & Behav. 75, 78 T2 (2014) ........................................................................................................... 15

Bibbins-Domingo, Kirsten, et al., Projected Effect on Dietary Salt Reductions on Future Cardiovascular Disease, 362 NEW. ENG. J. MED. 590 (2010). ...................................................... 4, 5

Burros, Marian, Group’s Pursuit of Cash Draws Fire, MILWAUKEE J. SENTINEL (Dec. 6, 1995) .................................................................................................................. 12


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Memorandum from Sonia Angell & Daniel Kass to the Members of the Board of Health (Sept. 2, 2015) .......................................................................................................................... 21, 23


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PRELIMINARY STATEMENT

Hypertension – high blood pressure – is the second-leading cause of preventable death in the United States. Only smoking contributes to more premature deaths. In New York City alone, approximately 12,000 residents each year have their lives shortened by hypertension. More than 29% of adults in the City have been told by a health professional that they suffer from the condition, meaning that there are almost 2 million New Yorkers for whom a reduction in sodium consumption could mean improved health and a longer life.

Recognizing the urgency of this public health crisis, the New York City 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 sodium rule – which applies to the same establishments already covered by the City’s menu labeling law – represents a significant additional step in public health protection. And it is one 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.

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 in particular need of the warnings make up more than half of the City’s adult population.

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

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2 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
3 NYC Dep’t of Health and Mental Health, Community Health Survey (2013), Notice of Adoption at 1.
high levels of sodium in certain menu items. 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.” Unfortunately, the National Restaurant Association (NRA) has not taken the advent of the Rule as an opportunity to better inform customers, nor 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.

Fortunately for the health of New Yorkers, the NRA’s suit stands little chance of success. 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 causes of and treatment for hypertension 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. Far from arbitrary or capricious, the Rule’s lines are in fact drawn with a keen understanding of the boundaries of the Board’s authority. The Rule works in harmony with the First Amendment, which favors factual disclosures in the commercial context. Finally, the Rule is not preempted by federal law: the presumption against preemption of local public health measures runs strongly here; the preemption provisions of the Nutrition Labeling and Education Act (NLEA) regarding health “claims” do not apply in this context; and, even if they did, the explicit savings clause in the federal menu labeling law would except the Rule from preemption.

The Rule is a necessary, scientifically sound, and legally well-grounded measure. It should be upheld.

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STATEMENT OF INTEREST OF AMICI CURIAE

The American Heart Association (AHA) and the other medical and public health organizations that have signed this memorandum 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 petitioner’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.

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, however, continue to contribute

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

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.\(^14\)

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

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\(^8\) Harvard School of Public Health, Smoking, High Blood Pressure and Being Overweight, supra n. 1.
\(^10\) 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).
\(^13\) 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
\(^15\) Kirsten Bibbins-Domingo et al., Projected Effect on Dietary Salt Reductions on Future Cardiovascular Disease, 362 NEW. ENG. J. MED. 590, 593 (2010).
events would be at least as large as the decline expected from a 50% reduction in tobacco use.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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).\textsuperscript{19} Middle-aged and older individuals in the United States have a 90% chance of developing hypertension in their lifetimes.\textsuperscript{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.\textsuperscript{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 of reducing sodium consumption below current levels.\textsuperscript{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]”)\textsuperscript{23}; the World Health

\textsuperscript{16} Id. at 595.
\textsuperscript{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).
\textsuperscript{18} He & MacGregor, Comprehensive Review, supra n. 9, at 363.
\textsuperscript{19} Dariush Mozaffarian et al., Heart Disease and Stroke Statistics—2015 Update, 1331 CIRCULATION e29, e114, e118 (2015).
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\textsuperscript{21} He & MacGregor, Comprehensive Review, supra n. 9, at 370-72.
\textsuperscript{22} Dariush Mozaffarian et al., Global Sodium Consumption and Death from Cardiovascular Causes, 371 NEW ENG. J. MED. 624, 625, 633 n.7 (2014).
\textsuperscript{23} IOM, SODIUM INTAKE IN POPULATIONS: ASSESSMENT OF EVIDENCE 108 (Brian Strom et al. eds., 2013).
Organization (WHO) (“Higher sodium intake [i]s associated with higher risk of incident stroke, fatal stroke and fatal coronary heart disease”)\textsuperscript{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”).\textsuperscript{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”\textsuperscript{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.”\textsuperscript{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 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.\textsuperscript{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 for Americans advisory committee (DGAC) report for 2015, submitted after two years of public notice and comment and a thorough review of nutrition

\textsuperscript{25} Robert Eckel et al., 2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk, 129 (25 Supp. 2) CIRCULATION S76, S89 (2014).
\textsuperscript{26} Paul Whelton & Lawrence Appel, Sodium and Cardiovascular Disease: What the Data Show, 27 AM. J. HYPERTENSION 1143, 1145 (2014).
\textsuperscript{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
science by national experts, reaffirmed the link between sodium overconsumption and hypertension. 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.”

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 children; “[t]he American Heart Association recommends that Americans should aim to eat no more than 1500 mg of sodium per day” and IOM recommends reducing sodium intake to 1500 mg for the at-risk groups that comprise more than half the adult U.S. population.

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 handful of outlier studies (see Pet. Memorandum of Law (MOL) at 19) that have been widely criticized as containing “severe methodological flaws”; “weak research methodology”; “[e]rrors”; “a variety of … methodological issues,” including “pooling of biased data”; “methodological limitations,”

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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.


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

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


37 Whelton & Appel, Sodium and Cardiovascular Disease, supra n. 26, at 1143-44.
and as otherwise raising “major concerns.”

Identified methodological flaws of these studies have included: (1) using insufficient urine samples, resulting in unreliable measurements of sodium intake; (2) incorrectly applying the accepted formula for estimating sodium intake from urine samples; (3) inadequately accounting for the possibility of ‘reverse causality,’ i.e., the possibility that diagnosed sickness accounts for reduced sodium consumption, rather than vice versa; (4) drawing data from studies not designed to investigate the relation between sodium intake and cardiovascular disease; (5) “post hoc choice of nontraditional cut points” for grouping sodium intake levels, which “can dramatically influence findings”; 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.” The meta-analysis that is the NRA’s principal scientific authority includes data from one study so flawed that it had previously been retracted, a fact ignored by the authors of the meta-analysis.

The remaining authority relied on by the NRA for the assertion that the health impacts of sodium consumption have become controversial – the IOM sodium intake report 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],” and “the available evidence … is consistent with

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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.
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
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: ASSESSMENT OF EVIDENCE 108 (Brian Strom et al. eds., 2013).
49 Id. at 122.
population-based efforts to lower excessive dietary sodium intakes.” The only question for the IOM was whether intake levels should be reduced all the way down to 1,500 mg/day.\textsuperscript{50} The report called for further research on that question.\textsuperscript{51}

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 Pet MOL at 19, 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 study\textsuperscript{52} 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”\textsuperscript{53} – 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 several years found that both high levels of sodium intake and mild increases in intake were associated with increased blood pressure and incidence of hypertension.\textsuperscript{54} A third study, tracking participants for ten years, also employing repeated 24-hour urine collection, found higher sodium intake to be associated with increased risk of cardiac morbidity and mortality in subject populations at risk of developing

\textsuperscript{50} Id. at 124.
\textsuperscript{51} Id. at 125.
\textsuperscript{52} Nancy Cook et al., Lower Levels (2014), supra n. 39.
\textsuperscript{53} Cobb et al., Sodium Intake, supra, n. 36 at [pg9]. 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.
\textsuperscript{54} Hiroyuki Takase et al., Dietary Sodium Consumption Predicts Future Blood Pressure and Incident Hypertension in the Japanese Normotensive General Population, 4 J. AM. HEART ASSOC. (2015), http://jaha.ahajournals.org/content/4/8/e001959
cardiovascular disease. Similar conclusions were reached by recent meta-analyses that are more rigorous than, for example, the Graudal study relied on by the NRA. A recent meta-analysis of 36 randomized controlled trials that met rigorous criteria found that reducing sodium consumption lowered blood pressure at all levels of sodium consumption. 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. 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.”

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, Pet. MOL at 19, 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.” The Institute of Medicine defines adequate intake (AI) for American adults as 1200 to 1500 mg/day.

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55 Michel Joosten et al., Sodium Excretion and Risk of Developing Coronary Heart Disease, 129 CIRCULATION 1121 (2014).
56 Aburto et al., Effect of Lower Sodium Intake (2013), supra, n. 27.
57 He et al., Effect of Longer Term Modest Salt Reduction, supra, n. 45.
58 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.
59 USDA, DIETARY GUIDELINES, supra n. 12, at 21.
depending on age. 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. Even a study cited by the NRA noted that 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.”

The NRA’s contention that consumption of less than 2800-3000 mg/day of sodium may be as dangerous as excess consumption, Pet. MOL at 19, 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.” More reliable studies have found no significant harms from reducing sodium intake.

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

Notwithstanding 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. The NRA’s proffered authorities may not – 

60 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.
63 Campbell, Is Reducing Dietary Sodium Controversial?, supra, at 85. See also Cook, Lower Levels, supra, 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”).
64 E.g., Mozaffarian, Global Sodium, supra, 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).
65 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, 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).
but they are principally individuals and organizations with ties to the salt industry and packaged and prepared food companies.

The Academy of Nutrition and Dietetics (AND), regularly cited by the NRA, e.g. Pet. MOL at 20, has been widely criticized for “haul[ing] in large sums of money advocating for the food industry.” 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.

Given petitioner’s affiant Susan Finn’s background as former President of AND, Finn Aff., ¶ 2, 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.” 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.” Trans fats have since, of course, generally been banned from the nation’s food supply because of the broad expert consensus regarding their adverse health impacts.

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66 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 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.
The NRA’s principal scientific expert, David McCarron, worked extensively as a paid consultant to the Salt Institute, an industry trade group “dedicated to advancing the many benefits of salt.” 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.”

The academic publications on which the NRA relies are also highly suspect, considering the authors’ industry ties. The Graudal meta-analysis, for example, was co-authored by Michael Alderman, who has also served as a consultant to the Salt Institute. Alderman failed to disclose this clear conflict of interest. Industry connections are material and must be disclosed. There is good reason for this requirement: Industry-sponsored nutrition-related scientific articles disproportionately reach conclusions favorable to the financial interests of the sponsors, as compared with articles without industry funding.

Scientists’ comments on the publicity received by the two PURE studies relied on by the NRA, published at the same time as the methodologically superior study of Mozaffarian et al., 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.”

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72 McCarron Group, http://www.mccarrongroup.com/?page_id=22
74 He & MacGregor, *Salt Intake*, supra n. 34, at 1424.
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.”).
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.”

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.

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.”

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

The food service establishments covered by the sodium warning regulation play an outsized 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.

According to USDA data from 2005-2008, foods 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. That statistic, alarming as it is, actually understates how much restaurants increase sodium consumption, because restaurant meals also

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77 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).
78 Farley, Saving Gotham, supra n. 4, at 124 (2015).
average significantly more calories.\textsuperscript{81} Full-service and fast food restaurants increase daily sodium intake by almost 300 mg and over 400 mg respectively.\textsuperscript{82} 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.\textsuperscript{83} 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.\textsuperscript{84} The mean sodium content of menu offerings at eight leading fast food chains increased 23.4\% from 1997-2010.\textsuperscript{85}

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.\textsuperscript{86} Among adults aged 20-39, the percentage of calories consumed from fast food significantly increases as income decreases.\textsuperscript{87} 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.”\textsuperscript{88} Nationally, non-Hispanic Blacks consume a significantly greater proportion of their calories from fast food than do other racial groups.\textsuperscript{89}

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.”\textsuperscript{90} Blood pressure has been found to fall more

\textsuperscript{81} Ruopeng An, \textit{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.
\textsuperscript{82} Id.
\textsuperscript{83} Amy Auchincloss et al., \textit{Nutritional Value of Meals at Full-Service Restaurant Chains}, 46 J. NUTR. ED. & Behav. 75, 78 T2 (2014).
\textsuperscript{84} Frank Sacks et al., \textit{High Sodium Restaurant Foods}, http://www.cspinet.org/salt/hsrestaurant.html.
\textsuperscript{85} Rudelt et al., \textit{Fourteen-Year Trends}, supra n. 10, at 1684. This was during a time of initiatives to reduce sodium intake.
\textsuperscript{88} Hilmers et al., \textit{Neighborhood Disparities, supra} n. 86, at 1650.
\textsuperscript{89} CDC, \textit{Caloric Intake, supra} n. 87, at 2.
\textsuperscript{90} Frank Sacks, \textit{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).
sharply in response to decreases in dietary sodium among African Americans, both with and without hypertension, than among other racial groups. For these reasons, federal guidelines recommend that African Americans reduce their daily sodium intake to 1500 mg, 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.” 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. 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. And nearly half of Americans do not know how much sodium a healthy individual should consume.

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

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91 Id. at 6.
92 USDA, DIETARY GUIDELINES, supra n. 12, at 24.
93 IOM, STRATEGIES, supra n. 11, at 42.
94 Id. at 41.
do: it drew lines necessary to administer a policy within its jurisdiction. The Board required warnings in restaurants, rather than in all food service establishments, because its inspectors visit only restaurants\(^97\); 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\(^98\); 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.\(^99\) 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*, — A.D. 3d —, 2015 WL 8373521 (3d Dep't Dec. 10, 2015), at *3 (“[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”).

\(^97\) 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.”).

\(^98\) *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].”).

\(^99\) *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 (emph. 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 Board100 – “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

100 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 Pet. MOL at 42-43.* 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 petitioner’s challenges involve complaints that the Board excluded establishments over which it does not exercise jurisdiction. *See Pet. MOL at 42-43* (contending that it is arbitrary and capricious to apply the Rule to restaurants but not convenience 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.¹⁰¹ The Rule covers establishments in which sodium is likely to be consumed in the context of a meal, and 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.


The lines drawn by the Board were eminently reasonable. Petitioner contends there is no rational basis for applying the Rule to chain restaurants with 15 outlets but not to independently owned establishments or smaller chains, Pet. MOL at 43. The Board, however, determined that the Rule was best applied to chain restaurants because they accounted for approximately one-third of all restaurant traffic in New York and their highly standardized operational processes

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placed them in the best position to comply with the warning label requirement.\footnote{See Memorandum from Sonia Angell & Daniel Kass to the Members of the Board of Health (Sept. 2, 2015) at 3-4 (summarizing and responding to comments received regarding the proposed Rule).} 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 does not call arbitrary or capricious. Indeed, the NRA repeatedly (e.g., Pet. MOL at 22) expresses its support for the federal menu labeling rule, which distinguishes between chains with 20 or more outlets and other restaurants. 21 U.S.C. § 343(q)(5)(H). The NRA has not explained why a line between 19- and 20-outlet chains is rational, but a line between 14- and 15-outlet chains is arbitrary and capricious.

Petitioner has pointed to other marginal issues – such as the need to label all toppings with an icon even if only one exceeds 2300 milligrams of sodium – but it has not explained why restaurants cannot simply break out the toppings separately if they care about fine-grained accuracy. The NRA certainly has not shown that the Rule is “unsupported by any evidence.” \textit{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 §§ 1.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. In an Article 78 challenge, the parties contesting a regulation must carry “the heavy burden of showing that the regulation is unreasonable and unsupported by any evidence.” \textit{Consolation Nursing Home}, 85 N.Y.2d. at 331-32. That is a standard that the petitioner in this case has not met, and cannot meet.

\textbf{III. THE SODIUM WARNING COMPORTS WITH THE FIRST AMENDMENT.}

The salt shaker symbols 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.

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 (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).\footnote{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 Pet. MOL, at 56-59); 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)).}

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* § 1.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.\textsuperscript{104}

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 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

\textsuperscript{104} See Notice of Adoption and citations therein; Memorandum of Angell & Kass, *supra* n. 102.
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.\textsuperscript{105} 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 \textit{Zauderer} when there is no reasonable controversy about their truth, regardless of disputes over policy. \textit{See NYSRA}, 556 F.3d at 133-34 (applying \textit{Zauderer} to NYC menu labeling rule, and rejecting restaurants’ argument that more rigorous scrutiny should apply because “the \textit{significance} of the facts” to be disclosed was disputed) (emph. added); \textit{Disc. Tobacco}, 674 F.3d at 569 (“[W]hether a disclosure is scrutinized under \textit{Zauderer} turns on whether the disclosure conveys factual information …, not on whether the disclosure … incites controversy”).

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.”

\textit{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); \textit{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, \textit{see} Naomi Oreskes and Erik Conway, \textit{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

\textsuperscript{105} USDA, \textit{DIETARY GUIDELINES}, \textit{supra} n.12, at 21.
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”)\(^{106}\); 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)\(^{107}\) (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 that *Zauderer* applies only when the government’s interest is in preventing consumer deception or confusion, Pet. MOL at 60-61, has been rejected by every U.S. Court of Appeals to have addressed the issue, along with the California Supreme Court.\(^{108}\)

In addition, 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 muffins\(^{109}\) – where consumers might not expect it. It is precisely because restaurant meals may be deceptively high in sodium that the warnings are necessary.

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\(^{107}\) *Available at* [http://well.blogs.nytimes.com/2015/12/01/research-group-funded-by-coca-cola-to-disband](http://well.blogs.nytimes.com/2015/12/01/research-group-funded-by-coca-cola-to-disband).

\(^{108}\) 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); *Envtl. Def. Ctr., Inc. v. EPA*, 344 F.3d 832, 849 (9th Cir. 2003); *Beeman v. Anthem Prescription Mgmt.*, 58 Cal.4th 329 (2013).

\(^{109}\) See CDC, *Vital Signs*, *supra* n. 79, at 94 T. F-8 (bread and rolls are the number one sodium-contributing food category for all age groups in the United States).
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. First, the provisions of the Nutrition Labeling and Education Act (NLEA)\textsuperscript{110} relating to “health claims” and “nutrient claims,” Pet. MOL at 63-64, are irrelevant to the sodium rule. The “claims” that the NLEA prohibits states and cities from regulating are positive statements intended to induce consumers to purchase a product, not warnings required by the government itself. Second, to the extent that the federal menu labeling law, section 4205 of the Affordable Care Act (ACA), applies to the sodium rule, that law contains a specific and express exemption for warnings of the type at issue here.\textsuperscript{111} And third, 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)\textsuperscript{112}; NLEA § 6(c).\textsuperscript{113} 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

\textsuperscript{111} Patient Protection and Affordable Care Act § 4205(d)(2). Pub. L. 111-148, 124 Stat. 119. It is not clear from its submissions whether the NRA means to argue that the sodium warning is preempted as nutrition labeling of restaurant food – petitioner does not mention 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 be foreclosed by the safety warning exception contained in the ACA. See § 4205(d)(2).
\textsuperscript{112} “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.”
\textsuperscript{113} 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).”).
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 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 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 this interpretation of ‘health claims.’ 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. 114 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) (emph. 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.

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114 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.
§ 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 Pet. MOL at 64 (“frequent between-meal consumption of foods high in sugars and starches can promote tooth decay”) is actually just a preamble. The part omitted by the NRA is a positive health claim about artificial sweeteners that “‘may reduce the risk of’ … dental caries.” 21 C.F.R. § 101.80(c)(2)(i)(B).

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 protecting consumers from false claims by food manufacturers that are designed to entice them to purchase food products because of the (claimed) health benefits they 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.”116 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.117

Senator Hatch stressed that “the carefully crafted uniformity section of this legislation is limited in scope.”118 See also Sciortino v. Pepsico, — F. Supp. 3d — , No. C–14–0478 EMC, 2015 WL 3544522 (N.D. Cal. Jun. 5, 2015), at *14, *16 (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 only apply to “inherently dangerous [or toxic] substances,” Pet. MOL at 66-67, 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. Indeed, with respect to sodium, FDA regulations explicitly state that “scientific evidence establishes that diets high in sodium are associated with a high prevalence of hypertension or high blood pressure and with increases in blood pressure with age. . . .” 21 C.F.R. § 101.74(a)(2). Mills has no applicability to warnings concerning serious threats to life, the issue in this case. The extraordinary accumulation of evidence regarding the threat of hypertension and the urgency of reducing excess sodium consumption also 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,” Pet. MOL at 66. Whatever the plausibility

116 Although it isn’t clear whether Petitioners meant to argue that the sodium rule is preempted by the Affordable Care Act’s menu labeling requirements (they do not mention the Affordable Care Act in the preemption section of their Memorandum of Law), any such argument would also be foreclosed by this same safety warning exception.
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.

**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.

The Rule should be upheld.

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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 Notah Begay III Foundation (“NB3F”) is a national non-profit organization dedicated to reducing Native American childhood obesity and type-2 diabetes. NB3F is setting a national standard for investing in evidence-based, community-driven and culturally relevant programs that prevent childhood obesity and type 2 diabetes, ensuring healthy futures for Native American children and their communities. Through grant making, research, evaluation, direct programming and policy advocacy, NB3F invests in and works closely with grass-roots, Native-led organizations across the country that are exploring promising new practices, expanding proven methods, conducting community-based research, and evaluating impact. NB3F also works with Voices for Healthy Kids, a joint initiative of the American Heart Association and the Robert Wood Johnson Foundation to help all children grow up at a healthy weight. Included among the strategies is reducing excessive sodium consumption among children and families.

13. 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.

14. 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.