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

NATIONAL RESTAURANT ASSOCIATION, Plaintiff-Appellant, - against - THE NEW YORK CITY DEPARTMENT OF HEALTH & MENTAL HYGIENE; THE NEW YORK CITY BOARD OF HEALTH; and DR. MARY TRAVIS BASSETT, in her Official Capacity as Commissioner of the New York City Department of Health and Mental Hygiene, Defendants-Respondents.	**New York County** **Index No. 654024/2015**

BRIEF OF *AMICI CURIAE* AMERICAN HEART ASSOCIATION, AMERICAN MEDICAL ASSOCIATION, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, CHANGELAB SOLUTIONS, COALITION FOR ASIAN AMERICAN CHILDREN AND FAMILIES, MEDICAL SOCIETY OF THE STATE OF NEW YORK, NATIONAL ASSOCIATION OF CHRONIC DISEASE DIRECTORS, NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS, NATIONAL ASSOCIATION OF LOCAL BOARDS OF HEALTH, NEW YORK ACADEMY OF MEDICINE, NEW YORK STATE PUBLIC HEALTH ASSOCIATION, NEW YORK STATE AMERICAN ACADEMY OF PEDIATRICS, PUBLIC HEALTH ASSOCIATION OF NEW YORK CITY, PUBLIC HEALTH LAW CENTER, AND THE FOOD TRUST, IN SUPPORT OF DEFENDANTS-RESPONDENTS

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PRELIMINARY STATEMENT

Hypertension – high blood pressure – is the second-leading cause of preventable death in the United States. Only smoking ends more lives prematurely.[1] Recognizing the urgency of this public health crisis, the New York City Board of Health and Mental Hygiene (DOHMH) 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. That modest and sensible alert could help save the lives of thousands of New Yorkers.

The Rule, N.Y.C. Health Code § 81.49, is now in effect. Chain restaurants across New York City currently inform their customers – including the millions of New Yorkers who suffer from hypertension or are at risk for the condition – about the presence of high levels of sodium in certain menu items.[2] Unfortunately, unlike some of its members, the National Restaurant Association (NRA) did not take the advent of the Rule as an opportunity to better inform customers,[3] or to encourage the reformulation of menu items so that patrons would *not* be consuming a full

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

[2] *See* Dan Goldberg, *With Court's Blessing, City to Begin Enforcing Sodium Rule June 6*, POLITICO (May 26, 2016), http://www.politico.com/states/new-york/city-hall/story/2016/05/with-courts-blessing-city-to-begin-enforcing-sodium-rule-june-6-102251

[3] *See* Allison Aubrey, *High Sodium Warnings Hit New York City Menus*, NPR (Dec. 1, 2015), quoting Zane Tankel, CEO of Applebee's restaurants in New York ("We want our guests to have as much information as needed to make informed decisions when dining in our restaurants").

day's worth of sodium in a single turkey sandwich or a bowl of soup,[4] or to join with leading food manufacturers in reducing the amount of sodium in their products.[5]

Instead, the NRA decided to file a lawsuit.

The NRA has now lost in the trial court and lost again in seeking a preliminary injunction pending appeal. It faces a very steep climb to reverse the decision of the Supreme Court. First, the NRA must overcome "an exceedingly strong presumption of constitutionality," *Schulz v. State Executive*, 108 A.D.3d 856, 857 (3d Dep't 2013), with respect to the sodium warnings rule. Second, it must contend with the sound reasoning of the Supreme Court, which rejected the NRA's claims in full. Record on Appeal (ROA) at 11.

There are no valid grounds for disturbing the Supreme Court's reasoned judgment. Hypertension is a risk factor that may shorten the lives of some 12,000

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[4] *See* Food & Drug Administration, *Draft Guidance for Industry: Voluntary Sodium Reduction Goals* (June 21, 2016) ("encouraging food reformulation and new product development"), *at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm494732.htm

[5] *See, e.g.*, *Mars Becomes First Food Giant to Call for FDA Salt Guidelines*, *at* http://www.bloomberg.com/news/articles/2016-04-13/mars-becomes-first-food-giant-to-call-for-fda-salt-guidelines; *Nestle Supports Lower Sodium Targets*, *at* http://www.nestleusa.com/media/pressreleases/nestle-supports-lower-sodium-targets ("Nestlé is committed to helping people consume no more than 2,000 milligrams of sodium per day, as recommended by the World Health Organization (WHO) – a target that is lower than the current U.S. Dietary Guidelines recommendation of 2,300 milligrams per day…. This is why we encourage our industry colleagues, along with others in both the private and public sector, to join forces and combine our varied expertise to help people move toward healthier eating patterns, including a diet lower in sodium.").

New York City residents each year.[6] Warnings about sodium are critical for New York residents who are at high risk, including African-Americans, people age 51 and over, and those who have high blood pressure, diabetes, or kidney disease. Underscoring the scale of the crisis, these vulnerable groups who are in particular need of the warnings make up more than half of the City's adult population. More than one in four adults in the City has been told by a health professional that she already suffers from hypertension,[7] meaning that there are almost two million New Yorkers for whom a reduction in sodium consumption is crucial for improved health and a longer life.

Notwithstanding the NRA's attempt to sow doubt and uncertainty about the contribution of sodium consumption to hypertension, there is clear scientific consensus regarding the link. Government agencies and public health organizations at every level – from the Food and Drug Administration to the Centers for Disease Control and Prevention, from the American Heart Association to the American Medical Association, agree on the need to inform consumers, especially those at risk of hypertension and related disease, about the presence of high levels of sodium in food and the importance of limiting sodium in their diet.

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[6] *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

[7] New York City Department of Health and Mental Hygiene, *Epiquery: NYC Interactive Health Data System - Community Health Survey 2014*, *at* http://nyc.gov/health/epiquery

The three legal claims of national import that the NRA asserts – that the Rule violates the First Amendment, that it is arbitrary and capricious, and that it is preempted by federal law – do not stand up to serious inspection. First, the Rule comports with the First Amendment, which *favors* factual disclosures in the commercial context. Second, far from being arbitrary or capricious, the Rule's lines are in fact drawn with a keen understanding of the boundaries of the Board's authority. Third, the Rule is not preempted by federal law: savings clauses in the Nutritional Labeling and Education Act explicitly preserve "warnings" of this type.

The sodium rule is a necessary, scientifically sound, and legally well-grounded measure, carefully designed to work within the boundaries of New York law and the federal Constitution, as well as to coordinate with the City's larger effort to reduce hypertension among its residents.[8] The Board of Health has taken a modest but vital step to provide information to consumers that may help to save their lives.

The judgment of the Supreme Court should be affirmed.

[8] *See* Tom Farley, SAVING GOTHAM 113, 161 (2015).

STATEMENT OF INTEREST OF *AMICI CURIAE*

The American Heart Association (AHA), the American Medical Association (AMA), and the other medical and public health organizations that have signed this brief,[9] 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 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 the NRA's challenge depends on assertions that run counter to accepted medical science.

First, despite the NRA's attempts to muddy the waters, the medical and scientific communities are in broad agreement regarding the need for most New Yorkers, particularly those at greatest risk for hypertension, to reduce their current over-consumption of sodium.

Second, there exists no medical or scientific controversy about the content of the warning: the "total daily recommended limit" of sodium intake is in fact 2,300 mg, and "high sodium intake" in fact "can increase blood pressure and risk of heart disease and stroke."

[9] Statements of Interest for the individual *amici curiae* appear in Appendix A to this brief and in the Motion for Leave to File.

Third, this case raises three legal issues with critical national repercussions for medical and public health organizations like amici: how the First Amendment applies to required science-based warnings, what constitutes arbitrary and capricious action by health agencies, and when local law may be preempted by the federal Nutrition Education and Labeling Act.

ARGUMENT

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

The requirement that chain restaurants post a warning statement and 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. Expert agencies, with the support of public health organizations, continue to recommend a reduction in sodium consumption and to advocate for increased opportunities for consumers to monitor and control their sodium intake. In the words of the Centers for Disease Control and Prevention (CDC): "Most of the sodium we consume is in the form of salt, and the vast majority of sodium we consume is in processed and restaurant foods. Your body needs a small amount of sodium to work properly, but too much sodium is bad for your health."[10]

In just the past several months, the federal Departments of Agriculture and Health & Human Services have released the final Dietary Guidelines for Americans

[10] CDC, *Salt*, at https://www.cdc.gov/salt

for 2015-2020, which expressly recommend that adults "[c]onsume less than 2,300 milligrams (mg) per day of sodium,"[11] and the Food and Drug Administration (FDA) has issued its first-ever draft guidance to industry on voluntary targets to "reduce sodium in . . . commercially processed, packaged, and prepared foods,"[12] which aims to reduce average sodium intake to 2,300 mg per day in 10 years[13] because "[t]he science supporting the relationship between sodium reduction and health is clear."[14] Providing consumers with more information, and encouraging the reduction of sodium in prepared foods so that consumers seeking to lower their sodium intake have "increased food choice,"[15] are precisely the goals that New York City, like these federal agencies, has embraced.

The Rule embodies and gives effect to the consensus among expert agencies and organizations. The salt-shaker icon must appear next to menu items that contain

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[11] US Dept. of Agric., US Dept. of Health & Human Servs., DIETARY GUIDELINES FOR AMERICANS, 2015-2020, at xiii, *at* http://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf

[12] FDA, *Draft Guidance for Industry* (June 21, 2016), *at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm494732.htm

[13] FDA, *Sodium Reduction*, *at* http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm253316.htm

[14] FDA, *FDA Issues Draft Guidance to Food Industry for Voluntarily Reducing Sodium in Processed and Commercially Prepared Food* (June 1, 2016), *at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm503874.htm

[15] *Id. See also* Thomas R. Frieden, *Sodium Reduction—Saving Lives by Putting Choice Into Consumers' Hands*, JAMA (June 1, 2016) (CDC director noting that "[c]urrently, consumers cannot choose how much sodium to consume because more than 70% of the sodium consumed is in food before it reaches the table. Half of adults report attempting to reduce their sodium intake, yet 90% consume excess sodium. Past educational efforts have placed the burden on the consumer, with the result that sodium intake has not changed."), *at* http://jama.jamanetwork.com/article.aspx?articleid=2527053

sodium in excess of "the total daily recommended limit (2,300 mg)." N.Y.C. Health Code § 81.49. The textual warning conveys the well-established conclusion that "[h]igh sodium intake can increase blood pressure and risk of heart disease and stroke." *Id*. The Rule thus reflects a national consensus among expert health groups.

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

As noted, high blood pressure is the second-leading cause of preventable death in the United States. It is responsible for approximately 395,000 premature deaths a year – about one in six deaths of all adults.[16] Overconsumption of salt is the major dietary factor increasing blood pressure.[17] Over 100,000 deaths per year in the United States are attributable specifically to high dietary salt, more than any other single dietary factor.[18]

Eighty-six percent of adults in the United States consume more than the Tolerable Upper Intake Level (UL) of sodium.[19] The UL is the daily ceiling

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

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

[18] Goodarz Danaei et al., *The Preventable Causes of Death in the United States: Comparative Risk Assessment of Dietary, Lifestyle, and Metabolic Risk Factors*, 6 PLOS MED. e1000058 (2009), *at* http://www.ncbi.nlm.nih.gov/pubmed/19399161

[19] CDC, *Prevalence of Excess Sodium Intake in the United States - NHANES, 2009–2012*, 64 MORBIDITY & MORTALITY WKLY RPT. 1393 (2016), *at* https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6452a1.htm; IOM, *Strategies to Reduce Sodium Intake in the U.S.* 427 (App. F, T. F-5) (2010).

recommended by the National Academy of Medicine/Institute of Medicine (IOM),[20]

> intended to specify the level above which the risk for harm begins to increase, and is defined as the highest average daily intake of a nutrient that is likely to pose no risk of adverse health effects for nearly all persons in the general population. As intake increases above the UL, the potential risk for adverse effects increases.[21]

According to the IOM, "Members of the general population should be advised not to routinely exceed the UL."[22] Yet mean daily sodium consumption for adults is 3,592 mg,[23] almost 1,300 mg more than the 2,300 mg recommended by the federal government.[24]

Studies have demonstrated that reducing sodium consumption would produce tremendous benefits. Lowering daily intake by 1,200 mg would prevent between 44,000 and 92,000 deaths annually in the United States, along with 60,000 to 121,000 new cases of heart disease, 32,000 to 66,000 strokes, and 54,000 to 99,000 myocardial infarctions.[25] The decline in cardiovascular events would be at least as large as the decline expected from a 50% reduction in tobacco

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[20] USDA, DIETARY GUIDELINES 2015-2020*, supra* n.11, at xiii.
[21] IOM, *Dietary Reference Intakes for Calcium and Vitamin D* (2011), at 6, *at* http://www.ncbi.nlm.nih.gov/books/NBK56058
[22] INST. OF MEDICINE, *Dietary Reference Intakes (DRIs): Tolerable Upper Intake Levels, Vitamins* (visited Sept. 5, 2016), *at* https://www.nationalacademies.org/hmd/~/media/Files/Activity%20Files/Nutrition/DRIs/New%20Material/4_%20UL%20Values_Vitamins%20and%20Elements.pdf
[23] USDA, *What We Eat in America, NHANES 2011-2012*, T1 (2014), *at* http://www.ars.usda.gov/SP2UserFiles/Place/80400530/pdf/1112/Table_1_NIN_GEN_11.pdf
[24] CDC, *Salt Home*, *at* http://www.cdc.gov/salt/index.htm
[25] Kirsten Bibbins-Domingo et al., *Projected Effect on Dietary Salt Reductions on Future Cardiovascular Disease*, 362 NEW. ENG. J. MED. 590, 593 (2010). *See also* Frieden, *supra* n.15, JAMA (June 1, 2016) ("Over a decade, this reduction could prevent up to an estimated 500,000 deaths and may save an estimated $100 billion in health care costs.").

use.[26] Reducing average population sodium intake to 2,300 mg could save $18 billion in health care expenses and 312,000 quality-adjusted life years, valued at $32 billion annually.[27]

The harms of current levels of sodium consumption result principally from their association with elevated blood pressure, which is the single most important modifiable cause of cardiovascular disease, accounting for 62% of strokes and 49% of coronary heart disease worldwide.[28] An estimated 32.6% of U.S. adults aged 20 and over suffer from hypertension, with considerably higher rates for African-American adults, and another 36.3% exhibit pre-hypertension (less elevated, but still higher than normal, blood pressure).[29] Middle-aged and older individuals in the United States have a 90% chance of developing hypertension in their lifetimes.[30]

Besides its effect on blood pressure, high salt consumption is associated independently with stroke and left ventricular hypertrophy, as well as with

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[26] *Id.* at 595.
[27] Kartika Palar & Roland Sturm, *Potential Societal Savings From Reduced Sodium Consumption in the U.S. Adult Population*, 24 AM. J. HEALTH PROMOTION 49 (2009).
[28] He & MacGregor, *supra* n.17, at 363.
[29] Dariush Mozaffarian et al., *Heart Disease and Stroke Statistics—2015 Update*, 1331 CIRCULATION e29, e114, e118 (2015).
[30] Ramachandran Vasan et al., *Residual Lifetime Risk for Developing Hypertension in Middle-Aged Women and Men*, 287 JAMA 1003 (2002).

stomach cancer, kidney disease, osteoporosis, asthma, and other health problems.[31]

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

While they may differ on some details, medical and public health experts agree about the harms of excess sodium consumption and the benefits of reducing sodium consumption below current levels.[32]

Researchers recently reviewing the cumulative evidence have confirmed the 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 [cardiovascular disease]"[33]; "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."[34]

The scientific consensus includes the National Academy of Medicine / Institute of Medicine ("evidence reviewed … consistently indicates an association in the general population between excessive sodium intakes and increased risk of

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[31] He & MacGregor, *supra* n.17, at 370-72.
[32] Dariush Mozaffarian et al., *Global Sodium Consumption and Death from Cardiovascular Causes*, 371 NEJM 624, 625, 633 n.7 (2014).
[33] Paul Whelton & Lawrence Appel, *Sodium and Cardiovascular Disease: What the Data Show*, 27 AM. J. HYPERTENSION 1143, 1145 (2014).
[34] Nancy Aburto et al., *Effect of Lower Sodium Intake on Health: Systematic Review and Meta-Analyses*, 346 BMJ f1326 (2013), *at* http://www.bmj.com/content/bmj/346/bmj.f1326.full.pdf

CVD")[35]; the World Health Organization (WHO) ("Higher sodium intake [i]s associated with higher risk of incident stroke, fatal stroke and fatal coronary heart disease")[36]; 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").[37]

The federal government concurs. As the FDA recently stated: "[E]vidence continues to support the association between increased sodium consumption and blood pressure. … Thus, the evidence continues to support mandatory declaration of sodium on the Nutrition Facts label."[38]

The Dietary Guidelines Advisory Committee (DGAC) Scientific Report for 2015, based on a thorough review of nutrition science by national experts, reaffirmed the link between sodium overconsumption and hypertension.[39] The

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[35] IOM, SODIUM INTAKE IN POPULATIONS: ASSESSMENT OF EVIDENCE 108 (Brian Strom et al. eds., 2013).
[36] WHO, *Guideline: Sodium Intake for Adults and Children* 1 (2012, reprinted 2014), *at* http://www.who.int/nutrition/publications/guidelines/sodium_intake_printversion.pdf
[37] Robert Eckel et al., *2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk*, 129 (25 Supp. 2) CIRCULATION S76, S89 (2014).
[38] 81 FED. REG. 33742 (May 27, 2016) (references omitted), *at* https://www.federalregister.gov/articles/2016/05/27/2016-11867/food-labeling-revision-of-the-nutrition-and-supplement-facts-labels#h-44
[39] 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").

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."[40]

As this summary suggests, the only serious debate about sodium intake levels among health researchers is whether the federal government's currently recommended ceiling of 2,300 mg[41] is sufficiently *low*. The WHO strongly recommends that adult sodium intake be reduced to below 2,000 mg, and lower than that for children[42]; "[t]he American Heart Association recommends that Americans should aim to eat no more than 1,500 mg of sodium per day"[43]; and the Dietary Guidelines note that for adults with prehypertension and hypertension (i.e., more than half of the nation's population[44]) limiting sodium intake "to 1,500 mg per day can result in even greater blood pressure reduction."[45]

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.

[40] *Id*. at 90.

[41] *See, e.g*., CDC, *Get the Facts*, https://www.cdc.gov/salt/pdfs/Sodium_Dietary_Guidelines.pdf ("The 2015–2020 Dietary Guidelines for Americans recommend that Americans consume less than 2,300 milligrams (mg) of sodium per day as part of a healthy eating pattern.").

[42] WHO, *Guideline*, *supra* n.36, at 2.

[43] AHA, *How Much Sodium Should I Eat Per Day?*, *at* http://sodiumbreakup.heart.org/sodium-411/how-much-sodium-do-you-need

[44] CDC, *High Blood Pressure Facts* (Feb. 19, 2015), *at* http://www.cdc.gov/bloodpressure/facts.htm

[45] USDA, DIETARY GUIDELINES 2015-2020, *supra* n.11, at 34.

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 relies on a handful of outlier studies, ROA 274, that have been widely criticized as containing "severe methodological flaws"[46]; "weak research methodology"[47]; "[e]rrors"[48]; "a variety of … methodological issues," including "pooling of biased data"[49]; "methodological limitations"[50]; and as otherwise raising "major concerns."[51] As the director of the CDC recently observed in the Journal of the American Medical Association, "The debate about dietary sodium reduction stems in part from a few studies with inconsistent findings at lower levels of estimated sodium intake. These reports have created a false aura of scientific controversy around dietary salt."[52]

Identified methodological flaws of these studies have included: (1) using insufficient urine samples, resulting in unreliable measurements of sodium

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[46] Feng He & Graham MacGregor, *Salt Intake and Mortality*, 27 AM. J. HYPERTENSION 1424, 1424 (2014).
[47] Norman Campbell et al., *Is Reducing Dietary Sodium Controversial? Is It the Conduct of Studies With Flawed Research Methods That Is Controversial? A Perspective From the World Hypertension League Executive Committee*, 17 J. CLINICAL HYPERTENSION 85, 85 (2015).
[48] Laura Cobb et al., *Methodological Issues in Cohort Studies That Relate Sodium Intake to Cardiovascular Disease Outcomes*, 129 CIRCULATION 1173, at 8 (2014).
[49] Whelton & Appel, *supra* n.33, at 1143-44.
[50] Aburto, *supra* n.34, at 2.
[51] Nancy Cook et al., *Lower Levels of Sodium Intake and Reduced Cardiovascular Risk*, 129 CIRCULATION 981, 981 (2014).
[52] Frieden, *supra* n.15.

intake[53]; (2) incorrectly applying the accepted formula for estimating sodium intake from urine samples[54]; (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[55]; (4) drawing data from studies not designed to investigate the relation between sodium intake and cardiovascular disease[56]; (5) "post hoc choice of nontraditional cut points" for grouping sodium intake levels, which "can dramatically influence findings"[57]; 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."[58] The meta-analysis that is the NRA's principal scientific authority, ROA 285,[59] includes data from one study so flawed that it had previously been retracted,[60] a fact ignored by the authors of the meta-analysis.

The recent McMaster University study by Mente et al.[61] that the NRA relies

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[53] Whelton & Appel, *supra* n.33, at 1143; Campbell, *supra* n.47, at 85.
[54] Christof Majoor & Liffert Vogt, *Can Sodium Excretion From Single Fasting Urine Really Be Used for Estimation of Dietary Sodium Intake?*, 32 J. HYPERTENSION 2500, 2500 (2014).
[55] *E.g.*, He & MacGregor, *Salt Intake, supra* n.46, at 1424; Campbell, *supra* n.47, at 85.
[56] Whelton & Appel, *supra* n.33, at 1143.
[57] *Id.* at 1144.
[58] Feng He et al., *Effect of Longer Term Modest Salt Reduction on Blood Pressure: Cochrane Systematic Review and Meta-Analysis of Randomised Trials*, 346 BMJ f1325 (2013), http://www.bmj.com/content/bmj/346/bmj.f1325.full.pdf
[59] 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).
[60] He et al., *supra* n.58.
[61] Andrew Mente et al., *Associations of Urinary Sodium Excretion With Cardiovascular Events in Individuals With and Without Hypertension*, THE LANCET (May 20, 2016), *at* http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(16)30467-6.pdf

on contains the same methodological flaws. Leading government and public health scientists and organizations have roundly disputed the study's results and questioned its methodology, noting that the findings are "not valid" (American Heart Association)[62]; that it contains "bad science" and ignores flaws pointed out in earlier studies (WHO)[63]; and that it and similar studies contain "paradoxical findings based on inaccurate sodium measurements" and "other methodologic limitations" (CDC).[64] Observing that "[i]n science, conflicting evidence from studies with methods of different strengths is not uncommon," the CDC team, writing in the New England Journal of Medicine, noted that "studies that measure sodium intake vary widely in their methods and should be judged accordingly" because "[a]ccurate measurement matters."[65] The CDC team concluded pointedly that the McMaster study and others with the same methodological flaws should not "lead to erroneous conclusions and delay effective public health action to reduce blood pressure and save lives."[66]

The chief additional authority relied on by the NRA for the assertion that

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[62] American Heart Association Comment strongly refutes study findings on sodium consumption, *at* http://newsroom.heart.org/news/american-heart-association-strongly-refutes-study-findings-on-sodium-consumption

[63] Ian Johnston, *Lancet Attacked for Publishing Study Claiming Low-Salt Diet Could Kill You*, INDEPENDENT (May 20, 2016), *at* http://www.independent.co.uk/news/science/salt-diet-heart-disease-death-lancet-a7040546.html

[64] Mary E. Cogswell et al., *Dietary Sodium and Cardiovascular Disease Risk—Measurement Matters*, NEJM (JUNE 1, 2016) , *at* http://www.nejm.org/doi/pdf/10.1056/NEJMsb1607161

[65] *Id*.

[66] *Id*.

the health impacts of sodium consumption have become controversial – the IOM sodium intake report,[67] ROA 123, § 18 – 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],"[68] and "the available evidence … is consistent with population-based efforts to lower excessive dietary sodium intakes." The only question for the IOM was whether intake levels should be reduced even further to as low as 1,500 mg/day.[69] The report called for further research on that question.[70]

The NRA's procedurally problematic eleventh-hour submissions to the Supreme Court, ROA 949 (Ricardo Supp. Aff. (Feb. 24, 2016)), do not call into question the benefits of reducing sodium intake. Two of the three submissions were editorial comments on a study of patients with heart failure.[71] ROA 965, 968. In a responsive affidavit submitted to the Supreme Court, the lead author of one of those pieces, noting that the NRA had "misinterpreted" the comments, Hummel Aff. at ¶ 1, ROA 976, explained that "observations made in a study of people with

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[67] IOM, SODIUM INTAKE IN POPULATIONS, *supra* n.35, at 108.
[68] *Id.* at 122.
[69] *Id.* at 124.
[70] *Id.* at 125.
[71] Scott Hummel & Matthew Konerman, Dietary Sodium Restriction in Heart Failure: A Recommendation Worth Its Salt?, 4 JACC: HEART FAILURE 36 (2016), *at* http://heartfailure.onlinejacc.org/article.aspx?articleid=2479147; Clyde Yancy, *The Uncertainty of Sodium Restriction in Heart Failure: We Can Do Better Than This*, 4 JACC: HEART FAILURE 39 (2016), *at* http://heartfailure.onlinejacc.org/article.aspx?articleid=2479152

heart failure to inform a standard of care for that specific subpopulation cannot and should not be applied to the general population as a whole," because heart failure can affect "how the body handles fluids and salt." *Id.* at ¶ 3, ROA 976. Moreover, the NRA misrepresented the recommended sodium restrictions even for those with heart failure. *Id.* at ¶ 2. In any event, those recommendations, which apply to "a relatively small proportion of the population," *id.* at ¶ 3, do not "detract[] from … the general population recommended daily limit of 2,300 mg," *id.* at ¶ 2, which is based on a "body of scientific evidence [that] establishes that high sodium intake can increase … the risk of heart disease and stroke." *Id.* at ¶ 4.

The NRA further misrepresented one of the editorial comments by reproducing the following statement out of context: "patients reporting sodium restriction had a significantly higher risk for … death or [heart failure] hospitalization." Ricardo Supp. Aff., ¶ 14, ROA 949. In fact, the comment (by Hummel & Konerman, *see supra* n.71) goes on to point out that the correlation, besides depending on sodium intake data of questionable accuracy, could be attributed to "reverse causality," whereby "higher risk individuals might consume less sodium either because they have been instructed to do so or because of the severity of the illness itself," or because low sodium consumption reflected general undernutrition. Ricardo Supp. Aff., Ex. B at 2, ROA 965.

The other editorial offered a similar appraisal of the reported correlation

between sodium restriction and worse outcomes: "It remains likely that sodium restriction as shown in the present data serves more as a marker for advanced disease. Certainly, there are no data to infer causality." Ricardo Supp. Aff., Ex. C at 2, ROA 968. In other words, reduced sodium consumption is often a *consequence* of advanced disease, not a *cause* of poor health outcomes.

Finally, the meta-analysis by Trinquart et al., Ricardo Supp. Aff., Ex. A, ROA 955,[72] is a sociological study finding that scientists tend to collaborate with and cite colleagues who share their views. It does not purport to investigate the strength of evidence for the benefits of sodium reduction. In an affidavit submitted to the Supreme Court, one of that study's co-authors explicitly stated that the meta-analysis does *not* support the argument that the required sodium warning is controversial. Galea Aff., Muschenheim Aff. Ex. O, at ¶¶ 1-3, ROA 974. To the contrary, "there is no disputing that there are large groups of people in our population who can lower their risk of hypertension, stroke, or heart disease by reducing their intake of sodium." *Id.* at ¶ 2.

In sum, the handful of studies favored by the NRA have not upset the settled science establishing the health benefits of reducing sodium consumption. The consensus among expert agencies and organizations and their scientists remains that

[72] Ludovic Trinquart et al., *Why Do We Think We Know What We Know?*, INT'L J. EPIDEMIOLOGY (Feb. 17, 2016) *at* http://ije.oxfordjournals.org/content/early/2016/02/17/ije.dyv184.full.pdf+html

individuals – particularly individuals suffering from or at risk of hypertension – should not consume more than 2,300 mg of sodium per day.

2. Recent high-quality research corroborates the health benefits of reducing sodium intake.

The NRA's characterization of a few outlier studies as novel developments that call into question well-accepted views about sodium, *see* NRA Opening Brief (NRA Br.) at 30, is quite misleading. The outsize media attention paid to these studies stems from novelty, not accuracy.[73] It is an unfortunate truism that scientific studies that present a novel hypothesis or unusual result – even dubious studies – are more likely to get published than studies that confirm an established principle.[74] The presence of a few such studies at any time is a normal feature of the scientific landscape. It does not generally mean – and it certainly does not mean here – that a decades-long scientific consensus has been overthrown.

To the contrary: Studies of higher quality continue to find poor health outcomes associated with increased sodium consumption. For example, a recent

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[73] Richard Horton, *Offline: What is Medicine's 5 Sigma?* 385 THE LANCET 1380 (disapproving studies with "invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance").

[74] Paul E. Smaldino & Richard McElreath, *The Natural Selection of Bad Science*, arXiv:1605.09511 (May 31, 2016), *at* https://arxiv.org/abs/1605.09511 (noting "increasing pressures for novelty" and the "problem . . . that positive results in support of some novel hypothesis are more likely to be published than negative results, particularly in high-impact journals"); John Oliver, *Scientific Studies*, *at* https://www.youtube.com/watch?v=0Rnq1NpHdmw

study[75] tracked pre-hypertensive individuals over periods of 18 months to four years, with follow-up for five to ten years, measuring sodium intake through multiple 24-hour urine samples – the "gold standard"[76] for determining sodium intake. The study found a linear association between lower sodium levels and lower incidence of cardiovascular disease events. Another recent cohort study, tracking participants for ten years and also employing repeated 24-hour urine collection, found higher sodium intake to be associated with increased risk of coronary heart disease in people with hypertension.[77]

Similar conclusions were reached by recent meta-analyses that were more rigorous than the Graudal study relied on by the NRA. ROA 285. A 2013 compilation of 36 randomized controlled trials that met rigorous criteria found that reducing sodium consumption lowered blood pressure at all levels of sodium consumption.[78] 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

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[75] Cook, *supra* n.51.
[76] Cobb, *supra* n.48, at 8-9. This detail is crucial. The studies cited by the NRA relied on a single urine sample, or at most a single 24-hour collection, widely deemed insufficient to estimate sodium intake reliably given the high day-to-day variability in sodium consumption and excretion.
[77] Michel Joosten et al., *Sodium Excretion and Risk of Developing Coronary Heart Disease*, 129 CIRCULATION 1121 (2014).
[78] Aburto, *supra* n.34.

high and normal blood pressure, without ill effects.[79] 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."[80]

That scientific consensus about reducing sodium intake has only *strengthened* in recent years is illustrated by the recent issuance of the Dietary Guidelines for Americans 2015-2020 by the U.S. Department of Agriculture and Department of Health & Human Services,[81] the FDA's promulgation of draft sodium-reduction guidance for the food industry,[82] and the continuing urgent support of public health organizations for a reduction of sodium intake.[83]

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

There is no merit to the suggestion, NRA Br. at 12, that public health

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[79] He, et al., *supra*, n.58.

[80] Pasquale Strazzullo et al., *Salt Intake, Stroke, and Cardiovascular Disease: Meta-Analysis of Prospective Studies* 339 BMJ 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.

[81] *See supra* n.11.

[82] *See supra* n.12.

[83] *See, e.g.*, Nancy Brown, CEO, American Heart Assn., *Sodium: The Sneaky Source of a Silent Killer*, HUFF. POST (May 20, 2016) ("The more salt in your diet, the more problems for your body. The science behind this could fill a library. The dangers of ignoring it could fill a morgue"), *at* http://www.huffingtonpost.com/nancy-brown/sodium-the-sneaky-source_b_10062210.html

measures should balance the dangers of excessive sodium consumption against the dangers of insufficient sodium consumption. Most Americans consume much more sodium than they need.[84] The IOM defines Adequate Intake (AI) for American adults as 1,200 to 1,500 mg/day, depending on age.[85] Calculations based on 2003-2008 data indicate that 0.6% of Americans consume less than 1,500 mg/day, in sharp contrast to the 90.7% who consume more than the IOM's upper level (UL) of 2,300 mg/day.[86] Even a study cited by the NRA noted that almost no participants "had an intake of less than [1,500 mg] per day [of sodium]," suggesting that "consumption of extremely low amounts of sodium for prolonged periods is rare."[87]

The NRA's contention that consumption of less than 2,800-3,000 mg/day of sodium may be as dangerous as excess consumption, NRA Br. at 12, 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

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[84] CDC, *Prevalence of Excess Sodium Intake in the United States*, *supra* n.19, *at* https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6452a1.htm; CDC, *Salt*, *at* https://www.cdc.gov/salt ("Nearly 9 in 10 American children eat more sodium than recommended").

[85] 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.

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

[87] Andrew Mente et al., *Association of Urinary Sodium and Potassium Excretion with Blood Pressure*, 371 NEJM 601, 609 (2014). ROA 294.

"reverse causality whereby sick people eat less salt … based on clinical recommendations," "rather than lower salt consumption causing illness."[88] More reliable studies have found no significant harms from reducing sodium intake.[89]

4. The NRA is attempting to manufacture a controversy where none exists.

The small constellation of studies and experts relied on by the NRA has not altered the well-established consensus on sodium among the world's most respected governmental and non-governmental medical and public health organizations.[90] But the NRA's effort to manufacture controversy is very much in line with longstanding industry tactics. As one leading expert on hypertension has observed about sodium, "We will always have dissident scientists, regardless of the strength of the evidence … – you will never have 100% of people agreeing. But in this case, we have the consensus of every national and international

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[88] Campbell, *supra* n.47, at 85. *See also* Cook, *supra* n.51, 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").

[89] *E.g.,* Mozaffarian, *Global Sodium, supra* n.32, 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). While rare patients with disorders such as Addison's disease are advised to increase their sodium intake, their conditions are extremely rare (1/100,000 people), and the Rule does not in any way prevent these patients from ingesting sufficient sodium; in fact, the Rule's designations may make it easier for them to do so. *See* NAT'L ASS'N FOR RARE DISORDERS, *Addison's Disease*, *at* http://rarediseases.org/rare-diseases/addisons-disease

[90] *See* Whelton & Appel, *supra* n.33, at 1144 ("the interpretation by Graudal et al. differs from conclusions by authors of previous meta-analyses, the 2013 IOM Committee, American Heart Association Committees, the WHO, and at least 40 national agencies around the world"). *See also* Campbell, *supra* n.47, 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).

organization that has reviewed the topic."[91] On the other side, "we have the world's largest industry, the food industry, a $3-trillion/year industry that takes those dissident scientists and creates public controversy."[92]

Beyond that, the industry has funded research and paid experts in an attempt to foster studies and public statements that reflect its desired outcomes. It is well established that industry-sponsored nutrition-related scientific articles disproportionately reach conclusions favorable to the financial interests of the sponsors, as compared with articles without industry funding.[93] Similarly, experts who are paid by an industry are less likely to opine that the industry's products are harmful.

The NRA's principal scientific expert, David McCarron, ROA 115 (McCarron Aff.), has worked extensively as a paid consultant to the Salt Institute, an industry trade group "dedicated to advancing the many benefits of salt."[94] 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

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[91] Shelley Wood, *Standards Needed for Salt Studies As 'Big Food' Takes Sides*, MEDSCAPE MULTISPECIALTY 3 (Aug. 18, 2014), *at* http://www.medscape.com/viewarticle/830079#vp_3, quoting Professor Norman Campbell.

[92] *Id.*

[93] 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.").

[94] John Tierney, *Salt Wars*, N.Y. TIMES (Feb. 22, 2010), *at* http://tierneylab.blogs.nytimes.com/2010/02/22/salt-wars; *see* Salt Institute, *About Salt Institute* (undated), *at* http://www.saltinstitute.org/about-salt-institute

expertise for a quarter century."[95]

Plaintiff's affiant Susan Finn is former president of the Academy of Nutrition and Dietetics (AND), ROA 99,[96] an organization heavily cited by the NRA, ROA 62, 187, 315, 330, that has been widely criticized for issuing recommendations at odds with the consensus of scientists and public health organizations – though frequently in line with the statements of AND's food industry sponsors.[97] AND is perhaps best known in this vein for its statement, after receiving sponsorship from the National Association of Margarine Manufacturers, that there was "little scientific evidence" for reducing consumption of *trans* fats[98] (which are now, of course, generally banned from the nation's food supply).[99] That episode finds echoes in Finn's claim here that it would be "irresponsible to move forward at this time" on sodium warnings when there is "research on both sides of the issue." ROA 106.

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[95] McCarron Group, *at* http://www.mccarrongroup.com/?page_id=22

[96] Finn also served as President and CEO of the American Council for Fitness & Nutrition (ACFN), *id.*, whose members include the NRA itself, producers of high sodium foods like McDonald's, and trade groups like the National Council of Chain Restaurants, the Snack Food Association, and the Biscuit & Cracker Manufacturers Association. CSPI, *Non-Profit Organizations Receiving Corporate Funding* (2003), *at* http://www.cspinet.org/integrity/nonprofits/american_council_for_fitness_anduhh_nutrition_acfn_.html.

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

[98] Marian Burros, *Additives in Advice on Food?*, N.Y. TIMES (Nov. 15, 1995), *at* http://www.nytimes.com/1995/11/15/garden/eating-well-additives-in-advice-on-food.html. (Finn was a member of the organization's Strategic Planning Committee at the time).

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

The attempt to create controversy about the health effects of sodium is not new. "[A]s early as 1982, the snack industry was systematically distracting attention from the salt–blood pressure issue by encouraging . . . scientists to divert the focus of research elsewhere" with the "intent . . . to delay public health measures."[100] 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."[101]

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."[102]

Similar efforts to create scientific "controversy" have been made in the past: by the tobacco industry, *see United States v. Philip Morris USA, Inc.,* 449 F. Supp. 2d 1, 208 (D.D.C. 2006) (describing "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

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[100] Francesco Cappuccio et al., *Salt: The Dying Echoes of the Food Industry*, Letter, 27 AM. J. HYPERTENSION 279, 279 (2014).
[101] *Id.*; *see also* Michael Moss, SALT SUGAR FAT (2013) at 282, 305, 313 (detailing industry efforts).
[102] Farley, *Saving Gotham*, *supra* n.8, at 124 (2015).

two was still an 'open question.'"); by the oil and gas industry in response to evidence of climate change, *see* Naomi Oreskes and Erik Conway, MERCHANTS OF DOUBT 186-90 (2010) (detailing workings of industry-funded "institute" designed to sow doubt in the media despite consensus among scientists); by the sugar industry, *see* Cristin E. Kearns et al., *Sugar Industry and Coronary Heart Disease Research*, JAMA INTERNAL MEDICINE 5394 (Sep. 12, 2016),[103] (describing Sugar Research Foundation documents showing that in 1960s and 1970s the trade group paid scientists and handpicked studies in an effort to minimize the link between sugar and coronary heart disease); 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)[104] (noting the demise of the allegedly independent Global Energy Balance Network, after revelations of industry influence on the group's scientific claims).

Efforts to manufacture scientific discord around sodium are pulled from the same playbook. *See* Farley, SAVING GOTHAM at 219-26 (detailing industry ties and retracted research underlying the purported "controversy" over sodium levels).

[103] *At* http://archinte.jamanetwork.com/article.aspx?articleid=2548255
[104] *At* http://well.blogs.nytimes.com/2015/12/01/research-group-funded-by-coca-cola-to-disband

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

The food service establishments covered by the sodium warning regulation play an outsize role in contributing to sodium overconsumption. About a quarter of the sodium consumed in the United States comes from restaurants, with a majority from fast food outlets.[105]

According to USDA data from 2005-2008, meals from full-service and fast food restaurants average respectively 2,151 mg and 1,864 mg of sodium per 1000 calories, compared with 1,369 mg for home-cooked food.[106] That statistic, alarming as it is, actually understates how much restaurants increase sodium consumption, because restaurant meals also average significantly more calories.[107] Full-service and fast-food restaurants increase Americans' daily sodium intake by almost 300 mg and over 400 mg respectively.[108] A study of full-service restaurant chains in the Philadelphia area found that one quarter of à la carte entrées exceed the upper limit of 2,300 mg by themselves; over half exceed 1,500 mg.[109] A number of popular restaurant and fast food menu items contain well over 3,000

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[105] CDC, *Vital Signs: Food Categories Contributing the Most to Sodium Consumption—United States, 2007-2008*, 61 (5) MORBIDITY & MORTALITY WKLY RPT. 92, 93 (2012).
[106] USDA Economic Research Service, *Nutritional Quality of Food Prepared at Home and Away From Home, 1977-2008*, 11 (2012), *at* http://www.ers.usda.gov/media/977761/eib-105.pdf
[107] Ruopeng An, *Fast-Food and Full-Service Restaurant Consumption and Daily Energy and Nutrient Intakes in US Adults*, 70 EUR. J. CLINICAL NUTRITION 97, 101 (2016).
[108] *Id.*
[109] Amy Auchincloss et al., *Nutritional Value of Meals at Full-Service Restaurant Chains*, 46 J. NUTR. ED. & BEHAV. 75, 78 T2 (2014).

mg of sodium, with a single order of cheese fries with ranch dressing containing almost 5,000 mg.[110] The mean sodium content of menu offerings at eight leading fast food chains increased 23.4% from 1997-2010.[111]

The health burdens of chain restaurants' high sodium offerings fall disproportionately on vulnerable communities. The economic deprivation of a neighborhood often correlates with the density of fast food restaurants.[112] Among adults aged 20-39, the percentage of calories consumed from fast food significantly increases as income decreases.[113]

A 2009 study found that New York City's fast-food chain restaurants are concentrated disproportionately in predominantly African-American neighborhoods, and that "unhealthy foods [a]re more heavily promoted in African-American communities."[114] Nationally, non-Hispanic Blacks consume a significantly greater proportion of their calories from fast food than do other racial groups.[115]

These disparities are of particular concern, since non-Hispanic Blacks have

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[110] Center for Science in the Public Interest, *High Sodium Restaurant Foods*, *at* http://www.cspinet.org/salt/hsrestaurant.html

[111] Rudelt, Amanda, 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, 1684 (2014). This was during a time of initiatives to reduce sodium intake.

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

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

[114] Hilmers et al., *Neighborhood Disparities, supra* n.112, at 1650.

[115] CDC, *Caloric Intake, supra* n.113, at 2.

higher rates of hypertension and consequent cardiovascular disease than other racial groups in the United States – indeed "among the highest in the world"[116] – possibly reflecting "a greater sensitivity to the deleterious effects of diet."[117] Blood pressure has been found to fall more sharply in response to decreases in dietary sodium among African Americans, both with and without hypertension, than among other racial groups.[118]

The potential benefits of sodium warnings in chain restaurants are clear.

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

The need for sodium warnings is further underscored by findings that, even when generally aware that sodium consumption should be limited, "consumers seem unable to accurately estimate their own sodium intake."[119] 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.[120] In a study of consumers of fast food meals from several national fast food chains, participants on average estimated that their meals

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[116] Am. Heart Ass'n, *Heart Disease and Stroke Statistics – 2016 Update*, CIRCULATION (Dec. 16, 2015), e100, http://circ.ahajournals.org/content/early/2015/12/16/CIR.0000000000000350
[117] Frank Sacks et al., *Effects on Blood Pressure of Reduced Dietary Sodium and the Dietary Approaches to Stop Hypertension (DASH) Diet*, 344 NEJM 3, 8 (2001).
[118] *Id.* at 6.
[119] IOM, STRATEGIES, *supra* n.19, at 42.
[120] *Id.* at 41.

contained 820 mg of sodium, when in fact the meals contained an average of 1,831 mg – more than three-quarters of the federal government's recommended daily upper limit,[121] and more by itself than the American Heart Association's suggested target for optimal hearth health.[122]

II. THE SODIUM RULE COMPORTS WITH THE FIRST AMENDMENT.

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

A. Factual Warnings About Well-Known Health Risks Are Reviewed Under The Lenient Standard In *Zauderer*.

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

[121] Scott Burton et al., *Food for Thought: How Will the Nutrition Labeling of Quick Service Restaurant Menu Items Influence Consumers' Product Evaluations, Purchase Intentions, and Choices?*, 85 J. RETAILING 258, 261 T1 (2009).
[122] Amer. Heart Ass'n, *Why Should I Limit Sodium?*, *at* https://www.heart.org/idc/groups/heart-public/@wcm/@hcm/documents/downloadable/ucm_300625.pdf

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'l Electrical Manufacturers Ass'n* (*NEMA*) *v. Sorrell*, 272 F.3d 104, 114 (2d Cir. 2001).

Thus, in asserting that intermediate or strict scrutiny rather than the permissive *Zauderer* standard applies to the sodium warnings, the NRA "overlooks material differences between disclosure requirements and outright prohibitions on speech." *Anonymous v. Grievance Comm.*, 136 A.D.2d 344, 348 (2d Dep't 1988) (quoting *Zauderer*, 471 U.S. at 651). All that a law requiring warnings need show is "a rational connection between the purpose of a commercial disclosure requirement and the means employed." *NEMA*, 272 F.3d. at 115. In other words, such a law is subject only to "rational basis review." *Connecticut Bar Ass'n v. United States*, 620 F.3d 81, 96 (2d Cir. 2010).[123]

Deferential rational basis review applies to, among other things, required

[123] 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 in the NRA Br. at 44-45); or because they involved mandated disclosures about something other than the speaker's own products or services (*Safelite Grp., Inc. v. Jepsen*, 764 F.3d 258, 263-64 (2d Cir. 2014)).

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*, 139 F. Supp. 3d 1048, 1071 (N.D. Cal. 2015); *see also NEMA*, 272 F.3d at 114 ("mandated disclosure of accurate, factual, commercial information" is reviewed under the *Zauderer* standard). The Rule readily meets both conditions.

The required warning statement contains neither opinion nor questionable facts. It states simply:

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

Each aspect of this statement is uncontroversially true. The sodium content of any labeled item is greater than 2,300 milligrams. 2,300 milligrams of sodium is in fact the daily limit recommended by the U.S. government.[124] And every expert federal agency and prominent public health organization in this country agrees that high sodium intake can increase blood pressure and the risk of coronary heart disease and stroke for a significant portion of the American public.

Even if the overall benefits of the Rule were controversial, as the NRA

[124] USDA, DIETARY GUIDELINES, *supra* n.11, at 21.

argues, that would not subject the Rule to a more stringent standard of review. Factual statements are "uncontroversial" within the meaning of *Zauderer* when there is no reasonable controversy about their truth, regardless of disputes over policy. *See New York State Restaurant Ass'n (NYSRA) v. New York City Bd. of Health,* 556 F.3d at 133-34 (applying *Zauderer* to NYC menu labeling rule, and rejecting restaurants' argument that more rigorous scrutiny should apply because "the *significance* of the facts" to be disclosed was disputed) (emphasis added); *Disc. Tobacco*, 674 F.3d at 569 ("[W]hether a disclosure is scrutinized under *Zauderer* turns on whether the disclosure conveys factual information …, not on whether the disclosure … incites controversy").

There is no reasonable controversy about the truth of the warnings. Even if the proper treatment protocols for patients with extreme heart failure are not settled, and even if there is some disagreement as to just how much sodium consumption should be reduced in at risk populations and in the general population, the Dietary Guidelines' recommendation that daily sodium consumption of less than 2,300 mg is generally safer is *not* controversial.

A statement may be "factual and uncontroversial" even if some scientists disagree with some aspect of it. If scientific unanimity were required for *Zauderer* review to apply, any imaginable science-based disclosure – about health risks, environmental hazards, or other vital information – would be subject to

heightened review under the First Amendment. As one court recently observed,

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

CTIA-The Wireless Ass'n v. City of Berkeley, 158 F.Supp.3d 897, 904 (N.D. Cal., Jan. 27, 2016).

Reasonable (and non-coercive) public health measures cannot be stalled *ad infinitum* by an impossible quest for unanimity or absolute certainty. "All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action it appears to demand at a given time."[125]

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 and public health organizations, support the claim that overconsumption of sodium is a significant health risk to American chain restaurant consumers. *See supra* § I.

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

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

The NRA's claim in the Supreme Court that *Zauderer* applies only when the government's interest is in preventing consumer deception or confusion, NRA Br. at 39-40, has been rejected by every U.S. Court of Appeals to have directly addressed the issue, along with the California Supreme Court.[126]

Still, it would not matter if *Zauderer* were so limited, since the sodium rule reveals high levels of sodium in many menu items – like breads and muffins[127] – where consumers might not expect it. It is precisely because restaurant meals may be deceptively high in sodium that the warnings are necessary.

C. The Sodium Rule Readily Passes Review Under *Zauderer*.

The rule easily meets the lenient *Zauderer* standard. It was enacted in order to increase New Yorkers' knowledge about the (often unexpectedly) high levels of sodium in certain restaurant foods and to make dining out easier for individuals – especially at-risk individuals – who are trying to limit their sodium consumption. ROA 189 (Notice of Adoption). Given the prevalence of hypertension among the City's residents and the gravity of the health consequences of that condition, *see*

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[126] *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).

[127] *See* CDC, *Vital Signs*, *supra* n.105, at 94 T. F-8 (bread and rolls are the number one sodium-contributing food category for all age groups in the United States).

supra § I.A, the Board had more than a reasonable basis for enacting the law. In the context of 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). Nevertheless, the Board provided more than ample evidence.[128]

The sole remaining requirement is that the Rule not be "unduly burdensome," *Zauderer*, 471 U.S. at 651, which it is not. 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 to the First Amendment analysis. The symbols and the warning statement do not interfere with restaurants' ability to convey their own message. And they provide essential information to consumers. Far from violating the First Amendment, the Rule embodies it.

The sodium rule is, in sum, wholly consistent with the First Amendment.

[128] *See* Notice of Adoption, ROA 189, and citations therein; Memorandum from Sonia Angell & Daniel Kass to the Members of the Board of Health (Sept. 2, 2015), ROA 863, at 3 (summarizing and responding to comments received regarding the proposed Rule).

III. IN ADOPTING THE SODIUM RULE THE BOARD ACTED PRACTICALLY AND THOUGHTFULLY, NOT ARBITRARILY AND CAPRICIOUSLY.

The Board adopted the Sodium Rule in response to the crisis of hypertension in New York City. It exercised its regulatory authority and expert judgment to protect the health of the City's residents, especially the millions of those residents who are particularly vulnerable to high blood pressure and its attendant health effects.

In writing the Rule, the Board did what agencies do: it drew lines necessary to administer a policy within its jurisdiction. The Board required warnings in restaurants, rather than in all food retailers, because its inspectors visit only restaurants[129]; 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,[130] and because chain restaurants' standardized operations "mak[e] compliance both feasible and reliable"[131]; it required that any item (including meals) containing more than 2,300 milligrams of sodium be identified with a warning icon because that is a straightforward symbol easily understood by restaurant patrons.[132] The Board was not obligated to conduct empirical studies

[129] Notice of Adoption, ROA 189, at 1 ("The Department issues permits to and inspects FSEs [food service establishments] in New York City to ensure safe and healthy dining options").
[130] *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]").
[131] Memorandum of Angel & Kass, *supra* n.128, at 2.
[132] *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").

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 the arbitrary and capricious standard. The NRA has not carried its heavy burden of proving otherwise.

A. The Scope of Review Is Narrow.

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

The NRA asks this court to substitute its judgment for the considered judgment of a Board of expert public health practitioners. But "[a]n administrative

agency's exercise of its rule-making powers is accorded a high degree of judicial deference, especially when," as here, "the agency acts in the area of its particular expertise." *Consolation Nursing Home v. Comm'r, NY State Dep't of Health*, 85 N.Y.2d 326, 331 (1995). The party challenging the regulation bears "the heavy burden of showing that the regulation is unreasonable and unsupported by *any* evidence." *Id*. at 331-32 (emphasis added); *accord N.Y. State Health Facilities Ass'n, Inc. v. Axelrod*, 77 N.Y.2d 340, 349-50 (1991). That is a burden the NRA cannot meet.

In the field of public health, the courts' inquiry is a particularly limited one. "The police power is exceedingly broad, and the courts will not substitute their judgment of a public health problem for that of eminently qualified physicians" – like the Board[133] – "in the field of public health." *Grossman*, 17 N.Y.2d at 350; *see also 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

[133] There is no dispute that the physicians and scientists who compose the Board of Health are "eminently qualified." N.Y. City Charter § 553.

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 While Recognizing The Boundaries Of The Board's Authority.

Rather than try to establish that no evidence supports the Rule – a necessary standard that the NRA cannot meet – the restaurant association criticizes the measure's scope, (1) deeming it underinclusive and (2) questioning the Board's line-drawing. NRA Br. at 49-52. These attacks are unavailing – and in any case irrelevant in the context of the rational basis review called for under Article 78.

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

The Board has leeway, under Article 78's deferential standard of review, to approach a complex health problem like hypertension incrementally. *See N.Y. State Health Facilities Ass'n,* 77 N.Y.2d at 350 ("Merely because respondent has attempted to address part of a perceived concern … provides no basis for invalidating the regulations"); *E. Fougera & Co. v. City of New York*, 224 N.Y. 269, 278 (1918) ("It is not important that the ordinance fails to compel disclosure to all the world. Laws are not invalid because they fall short of the maximum of attainable efficiency"). A contrary "all-or-nothing" rule would make it impossible for boards of health to function. Thus there is no basis for the NRA's argument that the Rule is arbitrary because it does not require the sodium warnings to

appear in *all* restaurants or all food service establishments. *See* NRA Br. at 49-52. The scope of the Rule reflects the limits of the Board's jurisdiction, as well as its reasoned judgment of a practicable method to address a pressing health issue. This judgment is owed considerable deference.

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

Several of the NRA's challenges involve complaints that the Board excluded establishments over which it does not exercise jurisdiction. *See, e.g.*, NRA Br. at 4, 50-52 (contending that it is improper to apply the Rule to chain restaurants but not to other food retailers such as convenience stores or grocery stores). The Health Department inspects restaurants, but not convenience stores or grocery stores. Notice of Adoption, ROA 189. 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.

Moreover, the sharp increase in recent years both in the number of meals eaten outside the home and in the portion size and sodium content of those meals

provides a more-than-rational basis for a Rule focusing on restaurants and similar food service establishments.[134] The Rule covers establishments where the combined sodium content of the meal is likely to far exceed recommended amounts. *See supra* § I.B.3.

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

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

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

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

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

The lines drawn by the Board are eminently reasonable. For example, the Board determined that the Rule was best applied to larger chain restaurants because they account for approximately one third of all restaurant traffic in New York and their highly standardized operational processes place them in the best position to comply with the warning label requirement.[135] The NRA argues vaguely that the Rule creates a "patchwork of covered and non-covered establishments." NRA Br. at 50. But the restaurant association still doesn't address the reasons for that supposed "patchwork": jurisdictional limitations and differential capacity. It does not meet the standard of showing that the City's stated reasons for drawing these lines lack any rational basis.

The NRA has pointed to other marginal issues – such as the reasonable requirements that a menu item available with a choice of toppings be labeled with an icon if at least one of those toppings causes it to exceed 2,300 milligrams of sodium, or that each item on the menu (whether à la carte or a meal) should be labeled with its total sodium content, NRA Br. at 53-55 – but it has not explained why restaurants cannot simply break out the toppings or the dishes separately if they care about fine-grained accuracy. And it has offered no other, less "arbitrary"

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[135] *See* Memorandum of Angell & Kass, *supra* n.128, at 3 ("Because chain FSEs [food service establishments] have highly standardized food procurement, preparation, and operational processes, they can comply with this warning label requirement; the menu items that will bear icons always contain at least 2,300 milligrams of sodium. Addressing the food served in chain establishments regulated by DOHMH is rational and an appropriate part of DOHMH's broad and comprehensive strategy to address the burden of cardiovascular disease in New York City").

method for the City to have employed. The NRA certainly has not shown, as it must to prevail, that the Rule is "unsupported by *any* evidence." *Consolation Nursing Home*, 85 N.Y.2d at 332 (emphasis added). And given the vast amount of health data supporting the Rule, *see supra* at §§ I.B, C, D, the NRA cannot make such a showing.

In sum, it is within the Board's discretion to make reasonable distinctions, whether between venues or among menu items, and whether based on administrative feasibility, a desire to move incrementally, or limitations on regulatory authority. The party contesting a regulation must carry "the heavy burden of showing that the regulation is unreasonable and unsupported by any evidence." *Consolation Nursing Home*, 85 N.Y.2d. at 331-32.

That is a standard the NRA has not met.

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

Federal law does not prohibit the sodium warnings required by the Board of Health. The menu labeling provision of the Patient Protection and Affordable Care Act (ACA)[136] contains an explicit exemption from preemption for "warnings" of this type. ACA § 4205(d)(2) ("Nothing in the amendments made by this section shall be construed ... to apply to any State or local requirement respecting a statement in the labeling of food that provides for a warning

[136] Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119.

concerning the safety of the food or component of the food"). The very same exemption appears in the Nutrition Labeling and Education Act (NLEA),[137] the statute that section 4205 of the ACA amended to include labeling of restaurant foods. The exception for warnings in both statutes is all that is necessary to remove the sodium rule from the assertion of federal preemption.

The existence of the warning exception is not, however, the only reason that federal preemption does not apply. Indeed, the preemption provision of the NLEA, on which plaintiff relies, NRA Br. at 55-59, doesn't even apply to the Rule. The "claims" that the ACA and NLEA prohibit local governments from regulating are positive, voluntary statements intended to induce consumers to purchase a product, not warnings required by the government itself.

Furthermore, the ACA and NLEA both explicitly provide that federal law does not have any preemptive effect beyond what is directly stated in the labeling statutes. ACA § 4205(d)(1) ("Nothing in the amendments made by this section shall be construed … to preempt any provision of State or local law, unless such provision . . . is expressly preempted"); NLEA § 6(c) (same).[138] In other words, given that the NLEA does not explicitly preempt the sodium rule, it does not impliedly preempt the measure either.

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

[138] *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).")

A. The Safety Warning Exception Precludes Preemption Of The Sodium Labeling Rule.

The savings clauses of both the ACA and the NLEA explicitly preserve from preemption any local requirement "that provides for a warning concerning the safety of the food or component of the food." NLEA § 6(c); ACA § 4205(d). The Rule, which requires express warnings of the consequences of sodium overconsumption, fits easily within these measures.

The legislative history of the NLEA supports an expansive interpretation of the safety warning exception. Notably, Representative Henry 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.[139]

Senator Orrin Hatch stressed that "the carefully crafted uniformity section of this legislation is limited in scope."[140] *See also Sciortino v. Pepsico*, 108 F. Supp. 3d 780, 802, 804 (N.D. Cal. 2015) (noting "[t]his legislative history weighs strongly against preemption" in a safety warning case, as does "the plain language … of the NLEA").

The NRA's argument that the safety warning exception should apply only

[139] 136 Cong. Rec. H5836-01 (July 30, 1990).
[140] 136 Cong. Rec. 516607-02 S1611 (Oct. 24, 1990).

to "inherently dangerous" substances, NRA Br. at 60, finds no grounding in case law. The holding in *Mills v. Giant of Maryland*, on which the NRA relies, NRA Br. at 59, 61, was merely that lactose intolerance, however uncomfortable, doesn't implicate "safety" concerns. 441 F. Supp. 2d 104, 109 (D.D.C. 2006). Excess consumption of sodium, in stark contrast, can lead to life-threatening conditions. *See supra* § I.A. *Mills* has no applicability to warnings concerning serious health threats like those at issue in this case. The example embraced by the NRA, California's Proposition 65,[141] *see* NRA Br. at 60, actually has a good deal in common with the sodium rule: like the Rule, Prop 65 addresses a chronic disease (cancer) and requires warnings about substances that are harmful only above certain levels of ingestion and/or at certain levels of frequency: alcoholic beverages, salted fish, caffeic acid (found in coffee), and acrylamides (found in French fries), to name a few.[142] As does the Rule, Prop 65 focuses on improving long-term health by providing consumers with product information that they likely would not otherwise be able to access. *See Sciortino*, 108 F. Supp. 3d at 802 ("The Proposition 65 warning . . . unambiguously implicate[s] safety concerns. Thus, unlike cases in which no safety concerns are raised, the . . . exemption from

[141] Safe Drinking Water And Toxic Enforcement Act of 1986, Cal. Health & Safety Code § 25249.5 *et seq*. (requiring warning signs stating, in effect, "This product contains a chemical known to the State of California to cause cancer").
[142] State of California, Office of Environmental Health Hazard Assessment, *List of Chemicals Known to the State to Cause Cancer or Reproductive Toxicity* (Dec. 4, 2015), *at* http://oehha.ca.gov/proposition-65/proposition-65-list

preemption applies where, as here, such concerns are manifest.")

Finally, the extraordinary accumulation of evidence regarding the threat of hypertension and the urgency of reducing excess sodium consumption makes irrelevant the NRA's stated concern that local governments will "routinely" seek to evade NLEA preemption by claiming that any disclosure mandate is a "warning," NRA Br. at 60. Whatever the plausibility of such an *ipse dixit* 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.

B. Because The Sodium Warning Is Not A 'Claim' Under Federal Law, The Rule Does Not Fall Within The Ambit Of NLEA Preemption.

Even if warnings were not explicitly exempted from preemption, there would be no basis for finding them to be "claims" preempted by the NLEA. The sodium rule stands beyond the scope of preemption because it does not regulate positive, voluntary claims.

Indeed, the entire premise of plaintiff's argument is faulty. The sodium warning is not, as the NRA claims, either a "health claim" or a "nutrient content claim" under the NLEA.[143] As is apparent from the plain meaning of "claim," health and nutrient content claims are positive, voluntary marketing statements about the beneficial effects of food products or their ingredients. An "involuntary

[143] *See* 21 C.F.R. §101.13; 21 C.F.R. §101.13.

claim" is an oxymoron. 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.

FDA regulations provide a comprehensive list of permissible "health claims" (i.e., those to which local laws must be identical); every single one is a claim relating to positive health outcomes or to the reduction of disease risk. *See* 21 C.F.R. §§ 101.70 *et seq*. (*e.g.,* "Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis," 21 C.F.R. § 101.72; "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). The NRA has provided no contrary example to this Court; indeed, the one example of an apparently negative claim that plaintiff provided to Supreme Court, ROA 81, ("frequent between-meal consumption of foods high in sugars and starches can promote tooth decay") was in fact a piece of a larger, *positive* claim – omitted by the NRA – about artificial sweeteners that "'may reduce the risk of'… dental caries." 21 C.F.R. § 101.80(c)(2)(i)(B).

The FDA's method of petitioning for new health claims further confirms the positive nature of a "claim": the FDA requires a summary of the scientific data to provide "the basis upon which authorizing a health claim can be justified as

providing the health *benefit*." 21 C.F.R. § 101.70(f) (emphasis added). Similarly, the FDA explicitly prohibits foods with high levels of sodium from carrying a "health claim" like "Low in…." *See* 21 C.F.R. § 101.14(e)(3); *cf. id.* at §§ 101.14(a)(4), (d)(2)(vi), (e)(3). This prohibition would make no sense if the definition of "health claim" encompassed warnings about the *negative* effects of sodium.

The legislative history of the NLEA corroborates this definition. For example, Representative 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). The Act's sponsor, Henry Waxman, 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).

Claims about "nutrient content" under the NLEA are, similarly, 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." NRA Br. at 59. 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 effects of various nutrients in foods, such as "high in dietary fiber." *See* 21 C.F.R. § 101.54 *et seq.*[144]

States and local governments may not establish rules different from the FDA standards for when companies may make positive, voluntary claims. *See* 21 U.S.C. § 343-1(a)(5) (forbidding states from imposing nutrient content or health claim requirements that are not identical to the federal standard). But that prohibition has no relevance to government-required statements alerting consumers about health effects. The dicta in *Turek v. General Mills*, 662 F.3d 423 (7th Cir. 2011) that plaintiff relies on, NRA Br. at 58, provide no meaningful support for the argument that government-required statements can be "claims" subject to NLEA preemption. At issue in *Turek* was a *private* party's attempt to modify a positive, voluntary statement (i.e., a claim) made by the food manufacturer. *See Turek v. General Mills*, 754 F.Supp.2d 956 ("35% of your daily fiber"); 662 F.3d at 427 (referring to language that "the *plaintiff* wants added to the labeling") (emphasis added). The case did not address a government-initiated statement and the court did not contemplate any such scenario.

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[144] "Nutrient content claims describe the level of a nutrient in the product, using terms such as free, high, and low, or they compare the level of a nutrient in a food to that of another food, using terms such as more, reduced, and lite." FDA, *Label Claims for Conventional Foods and Dietary Supplements* (April 11, 2016), http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm

Instead, as other cases make clear, only rules which purport to govern positive, voluntary statements may be preempted. *See, e.g., New York State Restaurant Ass'n v. New York City Board of Health (NYSRA I),* 509 F.Supp.2d 351, 361-63 (S.D.N.Y. 2007) (finding claims required by City preempted because they were voluntary). That is why the warning exception is – as Representative Waxman observed[145] – unnecessary: because NLEA preemption doesn't apply to involuntary, negative statements (*i.e*., warnings) at all.[146]

To find that the sodium warning is preempted as a nutrient content claim or a health claim would be contrary to the plain meaning of the law, its legislative history, and its evident purpose.

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

Finally, 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 calorie count 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

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[145] *See supra,* n.139.

[146] *Mills v. Giant of Maryland, LLC*, 441 F. Supp. 2d 104 (D.D.C. 2006), aff'd, 508 F.3d 11 (D.C. Cir. 2007), also relied on by plaintiff, NRA Br. at 59, involved not a "claim" but a "standard of identity," a wholly different statutory regime from that which plaintiff asserts is operating in this case. *See id*. at 106; 21 U.S.C. § 343–1(a)(1). The case therefore offers no insight on the scope of preemption here – other than its acknowledgment that health and safety warnings, which would not apply to statements about the "discomfort" of lactose intolerance – would be exempted. *Id*. at 108.

> preemption is heightened where federal law is said to bar state action in fields of traditional state regulation. Given the traditional primacy of state regulation of matters of health and safety, courts assume that state and local regulation related to [those] matters ... can normally coexist with federal regulations. As a result, where the text of a preemption clause is ambiguous or open to more than one plausible reading, courts have a duty to accept the reading that disfavors pre-emption.

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

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 order and judgment of the Supreme Court should be affirmed.

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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 American Medical Association (AMA) is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all United States physicians, residents, and medical students are represented in the AMA's policy making process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. AMA members practice in every medical specialty area and in every state, including New York. The AMA joins this brief on its own behalf and as a representative of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the

AMA and the medical societies of each state, plus the District of Columbia, whose purpose is to represent the viewpoint of organized medicine in the courts.

3. 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.

4. ChangeLab Solutions is a national non-profit 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 smoke-free 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.

5. 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.

6. The Medical Society of the State of New York (MSSNY) comprises physicians, residents and medical students who practice in the State of New York. MSSNY is represented in the AMA House of Delegates and shares the objectives of the AMA to promote the science and art of medicine and the betterment of public health. Among the primary purposes of MSSNY is to enhance the delivery of medical care of high quality to all people in the most economical manner and to promote and maintain high standards in medical education and in the practice of medicine in an effort to ensure that quality medical care is available to the public.

7. 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 Los Angeles County, and that helped secure passage of a Board Motion requiring all Los Angeles 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 Los Angeles 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.

8. 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.

9. 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.

10. 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, non-profit, 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.

11. 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.

12. The New York State American Academy of Pediatrics (NYSAAP) has been advocating for healthier food options for children and families in New York neighborhood grocery stores, bodegas and 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.

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.

15. The Food Trust is a non-profit 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.