

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

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NATIONAL RESTAURANT ASSOCIATION,

Plaintiff-
Petitioner,

- against -

**AFFIDAVIT OF
COMMISSIONER
MARY T. BASSETT**

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

Index No. 654024/2015

Defendants-
Respondents.

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STATE OF NEW YORK)
) SS.
COUNTY OF QUEENS)

Mary T. Bassett, M.D., M.P.H., being duly sworn, states as follows under oath:

1. I am the Commissioner of the Department of Health and Mental Hygiene (the “Department”) of the City of New York and the Chairman of the New York City Board of Health (the “Board”), the other defendants-respondents in this matter. I have held both of these positions since 2014. A copy of my full *curriculum vitae* is attached hereto. This declaration is based on my personal knowledge and expertise in the fields of public health and medicine, conversations with employees of the Department, and my review of records maintained by the agency. I participated in all aspects of identifying the need for and adopting New York City Health Code §81.49, which requires chain restaurants to identify and warn their customers about

menu items that contain more sodium than the daily recommended limit (“Sodium Warning rule”). I am submitting this affirmation in response to the petitioner’s petition to declare the Sodium Warning rule invalid.

2. Pursuant to section 556 of the New York City Charter (“Charter”), the Department is charged with regulating all matters affecting health in the City of New York. This charge specifically includes the responsibility to oversee and control chronic disease¹ in the City. Charter §556 (c)(2). It also includes responsibility for supervising and regulating the City’s food service establishments. Charter §556(c)(9). Indeed, oversight of the City’s restaurants is a historical and core public health function that the Department has performed for many decades. The State of New York has recognized this by designating me, as the Commissioner of the Department, to be the permit-issuing official for food service establishments operating within the City. See 10 N.Y.C.R.R §14-1.190. The Department enforces provisions of the New York City Health Code (the “Health Code”), codified in Title 24 of the Rules of the City of New York, and other applicable laws regulating service of food directly to consumers in New York City, including food that is commercially prepared and sold, or distributed for free, in food service establishments, which are important sources of daily food intake in New York City.

3. Sodium warnings are important because New Yorkers consume too much sodium and the average sodium content of foods offered in chain restaurants is increasing.² Excess sodium intake can increase blood pressure and risk of heart disease and stroke, which are the number one and

¹ Chronic disease is defined as any long-lasting health condition that can be controlled but not cured. According to the World Health Organization, chronic diseases are diseases of long duration and generally slow progression. Chronic diseases, such as heart disease, stroke, cancer, chronic respiratory diseases and diabetes, are the leading cause of mortality globally, representing 63 percent of all deaths. Out of the 36 million people who died from chronic disease in 2008, nine million were under the age of 60.
(<http://www.who.int/mediacentre/factsheets/fs355/en/>, http://www.who.int/nmh/events/un_ncd_summit2011/en/)

² Rudelt A, French A, Harnack L. Fourteen-year trends in sodium content of menu offerings at eight leading fast-food restaurants in the USA. *Public Health Nutrition*. 2013;17(8):1682-88.

number five causes of death nationally^{3,4} and contribute to over 90 percent of deaths due to cardiovascular disease.⁵

4. The United States Department of Agriculture and Department of Health and Human Services recommend that daily sodium intake be less than 2,300 mg because excess sodium consumption increases one's risk of high blood pressure (hypertension), a major risk factor for heart disease and stroke.⁶ New Yorkers are entitled to know if an item on a menu contains more sodium than the federal government recommends they consume in an entire day. Sodium warnings will increase consumer knowledge and allow New Yorkers to make healthier choices. By using a simple icon to identify items with excessively high sodium and placing a warning statement on menus and menu boards, the Sodium Warning rule provides diners with a useful warning at an actionable time, specifically when they are reviewing menus and deciding what they will eat. Also, if restaurants must identify items whose sodium content exceeds the recommended daily limit, a warning requirement may cause some to offer their customers healthier choices.⁷

³ IOM (Institute of Medicine). Sodium Intake in populations: assessment of evidence. Washington, DC: The National Academies Press; 2013.

⁴ Murphy SL, Kochanek KD, Xu JQ, Arias E. Mortality in the United States, 2014. NCHS data brief, no 229. Hyattsville, MD: National Center for Health Statistics. 2015

⁵ Summary of Vital Statistics, 2013. Appendix A. Table M1. The City of New York. February 2015. <http://www.nyc.gov/html/doh/downloads/pdf/vs/appendixa-2013.pdf>.

⁶ Dietary Guidelines For Americans, 2010. 7th Edition. Washington, D.C.: U.S Government Printing Office, December 2010, at p. 21.

⁷ Burger King and Panera Bread reportedly have changed items on their menus to lower their sodium contents and avoid having to post warnings. See Dolmetsch C, Leslie P. "New York City Sued Over New Salt Rules in Fast-Food Fight." Bloomberg Business. 3 Dec. 2015. <http://www.bloomberg.com/news/articles/2015-12-03/new-york-city-sued-over-new-salt-rules-in-fast-food-fight>.

Burden and impact of heart disease and stroke is high nationally

5. Heart disease is the leading cause of death nationally, contributing to one out of every four deaths.⁸ Every year approximately 735,000 Americans suffer heart attacks, and 210,000 of these people will have suffered at least one prior heart attack.⁹

6. Stroke is the fifth leading cause of death nationally, accounting for one out of every twenty deaths.¹⁰ In addition to killing nearly 130,000 Americans each year, stroke significantly impacts quality of life and is a leading cause of long-term disability.^{11,12}

7. In addition to causing loss of life, the costs of cardiovascular disease in terms of dollars and resource allocation are enormous. In 2010, there were more than 12 million visits to doctors' offices that included heart disease as a primary diagnosis.¹³ The estimated direct and indirect costs in 2010 of heart disease and stroke were \$215.6 billion and \$33.6 billion, respectively.¹⁴

Heart disease and stroke can be prevented by controlling hypertension

8. Hypertension is a leading risk factor for heart disease and stroke.¹⁵ Nationally, nearly one-third of adults have hypertension and of them only about half (52 percent) have it under control.¹⁶ Mortality from ischemic heart disease and stroke doubles for every 20 mmHg increase

⁸ Centers for Disease Control and Prevention (CDC). 2008. Heart Disease Facts. <http://www.cdc.gov/heartdisease/facts.htm>. Viewed December 7 2015.

⁹ Mozaffarian D, Benjamin EJ, Go AS, et al. Heart disease and stroke statistics—2015 update: a report from the American Heart Association. *Circulation*. 2015;131:e29-e322.

¹⁰ Centers for Disease Control and Prevention (CDC). http://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_stroke.htm. Viewed December 18, 2015.

¹¹ Centers for Disease Control and Prevention (CDC). http://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_stroke.htm. Viewed December 18, 2015.

¹² Mozaffarian D, Benjamin EJ, Go AS, et al. Heart disease and stroke statistics—2015 update: a report from the American Heart Association. *Circulation*. 2015;131:e29-e322.

¹³ National Ambulatory Medical Care Survey: 2010 Summary Tables. Table 13. http://www.cdc.gov/nchs/data/ahcd/namcs_summary/2010_namcs_web_tables.pdf.

¹⁴ Mozaffarian D, Benjamin EJ, Go AS, et al. Heart disease and stroke statistics—2015 update: a report from the American Heart Association. *Circulation*. 2015;131:e29-e322.

¹⁵ Mozaffarian D, Benjamin EJ, Go AS, et al. Heart disease and stroke statistics—2015 update: a report from the American Heart Association. *Circulation*. 2015;131:e29-e322.

¹⁶ Nwankwo T, Yoon SS, Burt V, Gu Q. Hypertension among adults in the United States: National Health and Nutrition Examination Survey, 2011-2012. *NCHS Data Brief*. 2013;(133):1-8.

in systolic blood pressure.¹⁷ Blood pressure is measured using millimeters of mercury, or “mmHg”, with a higher number representing a greater force against the walls of the arteries.¹⁸ A recent study found that across different age groups, in both men and women, one-quarter to one-half of mortality from cardiovascular disease can be attributed to hypertension.¹⁹ Hypertension not only contributes to lost lives, but also lives lost too soon. Death from hypertension represents the largest contribution to causes of potential life-years lost, or the years a person would have lived had he or she not died prematurely, accounting for 15 percent of the racial disparity between Black and White deaths before the age of 75.²⁰

A vast body of literature links high sodium intake to risk of high blood pressure, heart disease, and stroke

9. Although hypertension is a complex vascular disease with multifactorial origins, a well-established relationship between sodium intake and blood pressure has been documented in the scientific literature for several decades. Specifically, there is a continuous relationship between sodium and blood pressure; increasing sodium intake increases blood pressure.²¹ The results of one study are shown below, and demonstrate the relationship between sodium intake and blood pressure.²² In this randomized controlled trial, participants consumed either a typical American

¹⁷ U.S. Department of Health and Human Services. The Seventh Report of the Joint National Committee on Prevention, Detection Evaluation, and Treatment of High Blood Pressure. August 2004. <http://www.nhlbi.nih.gov/files/docs/guidelines/jnc7full.pdf>

¹⁸ National Heart, Lung, and Blood Institute. Updated September 10, 2015. <http://www.nhlbi.nih.gov/health/health-topics/topics/hbp>. Viewed December 30, 2015

¹⁹ Patel SA, Winkel M, Ali MK, Narayan KM, Mehta NK. Cardiovascular mortality associated with 5 leading risk factors: national and state preventable fractions estimated from survey. *Annals of Internal Medicine*. 2015;163(4):245-53.

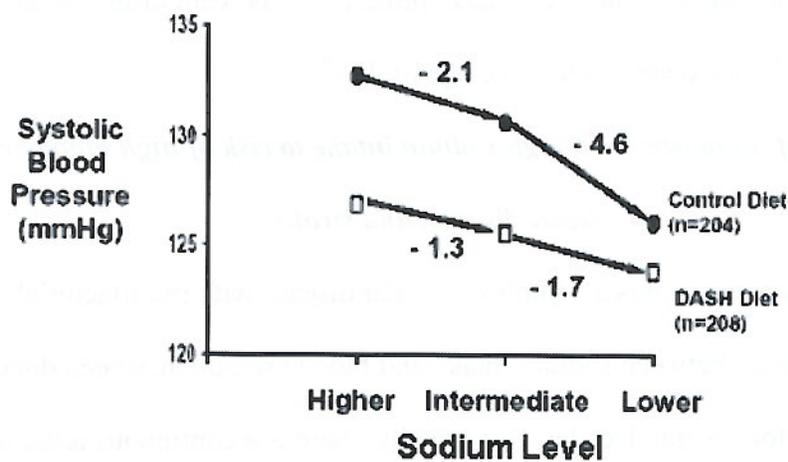
²⁰ Wong MD, Shapiro MF, Boscardin WJ, Ettner SL. Contribution of major diseases to disparities in mortality. *New England Journal of Medicine*. 2002;347(20):1585-92.

²¹ Dietary Guidelines for Americans, 2010. 7th ed. Washington, DC: US Department of Agriculture and US Department of Health and Human Services; 2010.

²² Sacks FM et al. Effects on Blood Pressure of Reduced Dietary Sodium. *New England Journal of Medicine*. 2001;344(1):3-10.

diet or the DASH diet, an eating plan designed to lower blood pressure.^{23, 24} Reducing the sodium intake from a high level of 3,450 mg to a low level of 1,150 mg reduced systolic blood pressure in participants, regardless of which diet they consumed.²⁵ In fact, the effect of reducing sodium intake was twice as great in those consuming the typical American diet compared with those consuming the DASH diet.²⁶

HIGH SODIUM INTAKE IS ASSOCIATED WITH RAISED BLOOD PRESSURE



Source: 2005 Dietary Guidelines for Americans, based on Sacks FM et al. Effects on Blood Pressure of Reduced Dietary Sodium. *NEJM*. 2001;344(1):3-10.

10. A meta-analysis of 31 randomized sodium reduction trials concluded that modest reductions in sodium intake caused significant decreases in blood pressure in participants with and without high blood pressure.²⁷ The data also show a significant dose-response pattern

²³ National Heart, Lung, and Blood Institute. Your guide to lowering your blood pressure with DASH — What is the DASH eating plan? <http://www.nhlbi.nih.gov/health/resources/heart/hbp-dash-how-plan.html>. Viewed December 18, 2015.

²⁴ Sacks FM et al. Effects on blood pressure of reduced dietary sodium. *New England Journal of Medicine*. 2001;344(1):3-10.

²⁵ Sacks FM et al. Effects on blood pressure of reduced dietary sodium. *New England Journal of Medicine*. 2001;344(1):3-10.

²⁶ Sacks FM et al. Effects on blood pressure of reduced dietary sodium. *New England Journal of Medicine*. 2001;344(1):3-10.

²⁷ He FJ, MacGregor GA. Effect of longer-term modest salt reduction on blood pressure. *Cochrane Database of Systematic Reviews* 2004(1):Art. No.: CD004937.

relationship between sodium and blood pressure – as sodium intake declines, so does blood pressure.²⁸

11. Leading health organizations including the World Health Organization²⁹ and Institute of Medicine,³⁰ as well as numerous scientists and experts have all emphasized the relationship between excess sodium intake and deleterious health outcomes.³¹ Even a modest reduction in sodium has been projected to save lives.³² The 2013 Institute of Medicine report, upon which the petitioner relies, supports the relationship between high dietary sodium intake and adverse cardiovascular outcomes, stating that the “evidence on associations between sodium intake and direct health outcomes is consistent with population-based efforts to lower excessive dietary sodium intakes...”³³

Leading scientific bodies recommend limiting daily sodium intake to 2,300 mg

12. The Sodium Warning rule is based on a national daily sodium limit recommended by leading scientific bodies, including both the Institute of Medicine and Dietary Guidelines for Americans.^{34,35} The Dietary Guidelines for Americans are published by the United States Departments of Agriculture and Health and Human Services and serve as the scientific basis for nutrition messages and consumer materials developed by health professionals. The 2010 Dietary Guidelines for Americans, which are attached hereto, include the recommendation: “Reduce

²⁸ He FJ, MacGregor GA. Effect of longer-term modest salt reduction on blood pressure. Cochrane Database of Systematic Reviews 2004(1):Art. No.: CD004937.

²⁹ WHO. Guideline: Sodium intake for adults and children. Geneva, World Health Organization (WHO), 2012.

³⁰ IOM (Institute of Medicine). Sodium Intake in populations: assessment of evidence. Washington, DC: The National Academies Press; 2013.

³¹ Consensus Statement on Sodium: <http://www.nyc.gov/html/doh/downloads/pdf/cardio/consensus-statement.pdf>. Viewed December 15, 2015.

³² Bibbins-Domingo K, Chertow GM, Coxson PG, et al. Projected effect of dietary salt reductions on future cardiovascular disease. New England Journal of Medicine. 2010;362(7):590-99.

³³ IOM (Institute of Medicine). Sodium Intake in populations: assessment of evidence. Washington, DC: The National Academies Press; 2013.

³⁴ Dietary Guidelines for Americans, 2010. 7th ed. Washington, DC: US Department of Agriculture and US Department of Health and Human Services; 2010.

³⁵ IOM (Institute of Medicine). Sodium intake in populations: assessment of evidence. Washington, DC: The National Academies Press; 2013.

daily sodium intake to less than 2,300 milligrams (mg) [...]”. While the 2015 Dietary Guidelines for Americans have not yet been issued, the Scientific Advisory Committee charged with reviewing the body of scientific and medical evidence in nutrition and preparing an Advisory Report for the Secretaries of the Departments of Agriculture and Health Human Services, affirmed retaining this limit, concluding “The goals for the general population are less than 2,300 mg dietary sodium per day.”³⁶

13. In its 2005 report, the Institute of Medicine established a Tolerable Upper Intake Level (UL) for adults of 2,300 mg per day, citing the adverse effects of higher levels of sodium intake on blood pressure.³⁷ Petitioner falsely contends that this threshold is “not a recommended limit. In fact, in the Report, a summary table specifically states that that a use of an UL for individuals for planning is: “use as a guide to limit intake.”³⁸ The term “Tolerable Upper Intake Level (UL),” is defined as the highest level of daily nutrient intake that is likely to pose no risks of adverse health effects for almost all individuals in the general population. At intakes above the UL, the risk of adverse effects increases.³⁹ It is entirely responsible to warn the general public when the sodium content of a single menu item exceeds the daily threshold at which the risk of adverse effects start to increase.

Americans consume too much sodium

14. Individuals across the country consume too much sodium. Nationally, average sodium consumption exceeds 3,400 mg per day, an amount which exceeds the recommended daily limit

³⁶ US Department of Agriculture. Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Available at: <http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf>. Viewed August 31, 2015.

³⁷ IOM (Institute of Medicine). Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate. Washington, DC: The National Academies Press; 2005.

³⁸ IOM (Institute of Medicine). Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate. Washington, DC: The National Academies Press; 2005.

³⁹ IOM (Institute of Medicine). Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate. Washington, DC: The National Academies Press; 2005.

of 2,300 mg.^{40,41} A 2013 study found that approximately 9 out of 10 Americans (over 4 years old) consume excess sodium and are at risk for high blood pressure attributable to excess sodium intake.⁴² A 2014 modeling study found that 1.65 million annual deaths globally are attributable to excess sodium intake.⁴³

Board of Health Process

15. The rules for food service establishments regulated and permitted by the Department are contained in Article 81 of the Health Code. At the June 10, 2015 meeting of the Board, the Department proposed that the Board of Health adopt §81.49 (Sodium Warning rule) of Article 81 of the Health Code to require chain food service establishments, which serve highly standardized items, to warn diners about menu items containing high amounts of sodium. The Board approved publishing the proposal in the City Record and there was a subsequent seven week public comment period that concluded on July 29, 2015, when a public hearing was held to receive oral comments about the proposed amendment. Ninety-four public comments were received during the public comment period, 87 comments were in support of the proposal. Two additional comments supported the proposal and offered suggestions and one comment supported the proposal contingent on modifications. The Department considered all of the written comments and testimony at the public hearing, and provided the Board with a memorandum summarizing and responding to the testimony and written comments. On September 9, 2015, the Board voted unanimously to adopt the Sodium Warning rule. Copies of documents relating to this process are attached as Exhibits to the Verified Answer submitted herewith.

⁴⁰ Centers for Disease Control and Prevention. Trends in the prevalence of excess dietary sodium intake – United States 2003-2010. Morbidity and Mortality Weekly Report. 2013;62:1021-25.

⁴¹ U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2010. 7th Edition, Washington, DC: U.S. Government Printing Office, December 2010.

⁴² Centers for Disease Control and Prevention. Trends in the prevalence of excess dietary sodium intake – United States 2003-2010. Morbidity and Mortality Weekly Report. 2013;62:1021-25.

⁴³ Mozaffarian D, Fahimi S, Singh GM, et al. Global sodium consumption and death from cardiovascular causes. New England Journal of Medicine. 2014;371(7):624-34.

16. The Board took this step because the Board and the Department are charged with the control of not just communicable diseases but also of chronic diseases, such as cardiovascular disease and related risk factors. These chronic conditions now cause a higher toll of preventable deaths than all of the prevalent communicable diseases combined.⁴⁴ The burden of these chronic conditions also consumes more of society's resources.⁴⁵

17. With respect to the Sodium Warning rule, the Department and Board chose to focus on sodium because its contribution to the epidemic of hypertension and cardiovascular disease is both unique and well-established in the scientific literature. By warning consumers of menu items containing high amounts of sodium, §81.49 will allow New Yorkers when dining in chain establishments regulated by the Department to make choices that can reduce their risk of heart attack and stroke. These and other issues related to the Sodium Warning rule are discussed in greater detail below.

New Yorkers consume too much sodium and experience associated health consequences

18. New York City has unique local data about the sodium intake of its residents, making the need for action clear. New York City residents consume an average of 3,239 mg per day⁴⁶, or 40 percent more than the daily limit recommended by the federal government. This level is comparable to sodium consumption levels nationwide.^{47,48} In 2013, 28.5 percent of New York

⁴⁴ World Health Organization - Noncommunicable Diseases (NCD) Country Profiles, 2014. http://www.who.int/nmh/countries/usa_en.pdf. Viewed December 15, 2015.

⁴⁵ Gerteis J, Izrael D, Deitz D, et al. Multiple Chronic Conditions Chartbook. AHRQ Publications No, Q14-0038. Rockville, MD: Agency for Healthcare Research and Quality; 2014. Viewed December 18, 2015.

⁴⁶ Angell SY, Yi S, Eisenhower D, Kerker BD, Curtis CJ, Bartley K, Silver LD, Farley TA. Sodium intake in a cross-sectional, representative sample of New York City adults. *American Journal of Public Health*. 2014;104(12):2409-16.

⁴⁷ Centers for Disease Control and Prevention. Trends in the prevalence of excess dietary sodium intake – United States 2003-2010. *Morbidity and Mortality Weekly Report*. 2013;62:1021-25.

⁴⁸ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans*, 2010. 7th Edition, Washington, DC: U.S. Government Printing Office, December 2010.

City adults reported being told by a health professional that he or she has hypertension.⁴⁹ In 2012, there were 12,000 and 20,000 hospitalizations for heart attack and stroke, respectively, for New York City residents visiting New York State hospitals.⁵⁰

19. The national features and impact of heart disease are reflected locally as heart disease is also the leading cause of death in New York City, claiming nearly 17,000 lives in 2013.⁵¹ Combined, heart disease and stroke kill more than 18,000 New Yorkers yearly, accounting for one-third of all deaths.⁵² In addition, many lives are cut short by heart disease and stroke. In 2013, heart disease was the second leading cause of premature death, defined as death before the age of 65.⁵³ In 2013, over 73,000 and 10,000 total years of potential life were lost due to heart disease and stroke, respectively, before the age of 75.⁵⁴

Communities of color bear a greater burden of cardiovascular disease

20. In New York City in 2013, Black and Hispanic adults reported having hypertension at higher rates than Whites and Asian/Pacific Islanders with a prevalence of 36.1 and 32.1 percent, respectively compared with 24.8 and 25.4 percent.⁵⁵

⁴⁹ New York City Department of Health and Mental Hygiene. Epiquery: NYC Interactive Health Data System - Community Health Survey 2013. Unadjusted (crude) estimate. <http://nyc.gov/health/epiquery>. Viewed December 11, 2015.

⁵⁰ New York State Department of Health, Statewide Planning and Research Cooperative System (SPARCS), 2012 (Data Update: April 2014).

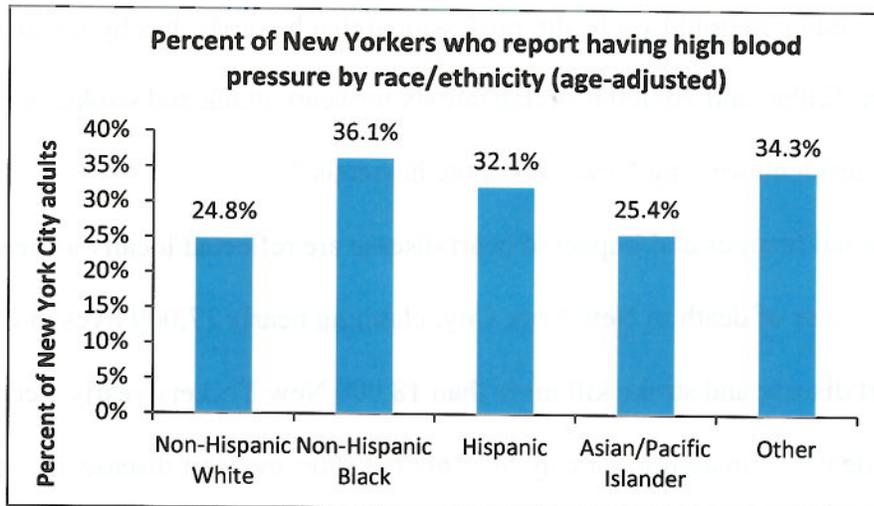
⁵¹ Zimmerman R, Li W, Lee E, et al. Summary of Vital Statistics, 2013: Mortality. New York, NY: New York City Department of Health and Mental Hygiene, Office of Vital Statistics, 2015.

⁵² Zimmerman R, Li W, Lee E, et al. Summary of Vital Statistics, 2013: Mortality. New York, NY: New York City Department of Health and Mental Hygiene, Office of Vital Statistics, 2015.

⁵³ Zimmerman R, Li W, Lee E, et al. Summary of Vital Statistics, 2013: Mortality. New York, NY: New York City Department of Health and Mental Hygiene, Office of Vital Statistics, 2015.

⁵⁴ Zimmerman R, Li W, Lee E, et al. Summary of Vital Statistics, 2013: Mortality. New York, NY: New York City Department of Health and Mental Hygiene, Office of Vital Statistics, 2015.

⁵⁵ New York City Department of Health and Mental Hygiene. Epiquery: NYC Interactive Health Data System - Community Health Survey 2013. Age-adjusted estimate. <http://nyc.gov/health/epiquery>. Viewed December 11, 2015.



Source: NYC Community Health Survey, 2013

21. Race/ethnic disparities in the prevalence of hypertension disease as well as death from heart disease and stroke are evident in New York City. Death from heart disease and stroke is 9 percent and 45 percent higher, respectively, in Black adults compared to Whites.⁵⁶ Further, premature mortality, or death before the age of 65 years, from these same diseases is 80 percent higher among Blacks than Whites in New York City, highlighting a largely preventable and unacceptable number of Black lives lost too soon.⁵⁷

Studies that challenge the relationship between sodium and health outcomes do not outweigh decades of evidence and authoritative national recommendations

22. Petitioner relies on two specific studies, which they claim “undermine the view that consumption above the 2,300 mg UL ... has any adverse consequences for the general population.” While these studies add to the scientific discourse, they do not undermine the credibility of the national recommendations. The conclusions of Andrew Mente⁵⁸ and Niels

⁵⁶ New York City Department of Health and Mental Hygiene. Epiquery: NYC Interactive Health Data System – Vital Statistics 2013. <http://nyc.gov/health/epiquery>. Viewed December 11, 2015.

⁵⁷ Internal DOHMH analysis based on NYC Vital Statistics data, 2013.

⁵⁸ Mente A, et al. Association of urinary sodium and potassium excretion with blood pressure. *New England Journal of Medicine*. 2014;371(7):601-11.

Graudal⁵⁹ have been called into question by leading experts in the field due to methodological concerns, including how they measured sodium intake, and study design. These concerns are explained in numerous published critical reviews by recognized national and international experts.^{60,61,62,63,64} Petitioner also relies on Dr. David McCarron, a researcher and consultant who provides services for compensation to food and pharmaceutical industries, including the Salt Institute, an industry trade association.⁶⁵

Numerous health organizations encourage Americans to reduce their sodium intake

23. Many international, national, and local health organizations encourage individuals to reduce their sodium intake for good health through educational initiatives, including the World Health Organization,⁶⁶ American Heart Association,⁶⁷ the Centers for Disease Control and Prevention,⁶⁸ and the Academy of Nutrition and Dietetics.⁶⁹ Although Susan Finn, a former president of the Academy of Nutrition and Dietetics, submitted a statement on the petitioner's

⁵⁹ Graudal et al. Compared with usual sodium intake, low- and excessive-sodium diets are associated with increased mortality: a meta-analysis. *American Journal Hypertension*. 2014;27(9):1129-37.

⁶⁰ Oparil S. Low sodium intake--cardiovascular health benefit or risk? *New England Journal of Medicine*. 2014;371(7):677-9.

⁶¹ American Heart Association. Excessive sodium consumption has dire impact on global health, new study finds. Press Release. August 13, 2014. Available at: <http://newsroom.heart.org/news/excessive-sodium-consumption-has-dire-impact-on-global-health-new-study-finds>. Viewed December 15, 2015.

⁶² Campbell NR, Lackland DT, Niebylski ML, Nilsson PM. 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. *Journal of Clinical Hypertension*. 2015;17(2):85-6.

⁶³ Whelton PK, Appel LJ. Response to "The data show a U-shaped association of sodium intake with cardiovascular disease and mortality". *American Journal of Hypertension*. 2015;28(3):426-7.

⁶⁴ Whelton PK, Appel LJ. Sodium and cardiovascular disease: what the data show. *American Journal of Hypertension*. 2014;27(9):1143-5.

⁶⁵ The McCarron Group. Clients. http://www.mccarrongroup.com/?page_id=206. Viewed December 18, 2015.

⁶⁶ World Health Organization. Healthy Diet. <http://www.who.int/mediacentre/factsheets/fs394/en/> Viewed December 15, 2015.

⁶⁷ American Heart Association. Sodium and Salt. http://www.heart.org/HEARTORG/GettingHealthy/NutritionCenter/HealthyEating/Reducing-Sodium-in-a-Salty-World_UCM_457519_Article.jsp#.VnsiydIrJQI. Viewed December 15, 2015.

⁶⁸ Centers for Disease Control. Most Americans should consume less sodium. <http://www.cdc.gov/salt/>. Viewed December 15, 2015.

⁶⁹ Academy of Nutrition and Dietetics. The facts on sodium and high blood pressure. Reviewed February 2015. <http://www.eatright.org/resource/health/wellness/heart-and-cardiovascular-health/the-facts-on-sodium-and-high-blood-pressure>. Viewed December 15, 2015.

behalf, the Academy of Nutrition and Dietetics advises consumers, through its educational materials, to reduce intake of sodium to below the daily limit of 2,300 mg.⁷⁰

Restaurant food is a large contributor to dietary sodium

24. Excess sodium consumption is not a new problem. Despite various interventions by public health organizations to increase consumer awareness and curb consumption, research shows that sodium intake has been rising among both sexes and nearly all age groups since the 1970s.⁷¹ There are two changes in nutrition patterns contributing to this trend – 1) the increased frequency with which people eat away from home and 2) the ubiquity of processed food in the retail environment. Commercially processed and packaged foods are readily available and often contain high levels of sodium at the time of purchase.⁷² Together, processed and restaurant food contribute to a majority (77 percent) of average dietary sodium intake. Only approximately 11 percent of dietary sodium comes from salt added either at the table (6.2 percent) or while cooking (5.1 percent).⁷³

Americans are consuming more of their food calories away from home

25. Restaurants are an increasingly important source of food for Americans. Estimates show that US consumption of food prepared away from home nearly doubled in approximately the last

⁷⁰ For example:

Academy of Nutrition and Dietetics. The facts on sodium and high blood pressure. Reviewed February 2015. <http://www.eatright.org/resource/health/wellness/heart-and-cardiovascular-health/the-facts-on-sodium-and-high-blood-pressure>. Viewed December 15, 2015.

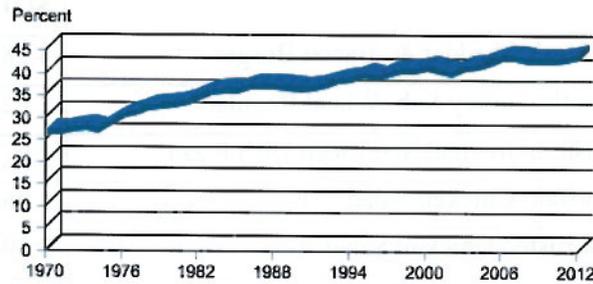
⁷¹ Briefel RR, Johnson CL. Secular trends in dietary intake in the United States. Annual Review of Nutrition. 2004; 24:401-31.

⁷² Gillespie C, Maalouf J, Yuan K, et al. Sodium content in major brands of US packaged foods, 2009. The American Journal of Clinical Nutrition. 2015;101(2):344-53.

⁷³ Mattes RD, Donnelly D. Relative contributions of dietary sodium sources. Journal of the American College of Nutrition. 1991;10(4):383-393.

30 years. Food away from home now accounts for almost one-third of Americans' total calorie intake and over 40 percent of their food dollars.⁷⁴

Food away from home as a share of household food expenditures has risen steadily since 1970, reaching its highest level of 43.1 percent in 2012



Food away-from-home expenditures divided by total food expenditures, for all families and individuals.

Total expenditures on food away from home include expense-account meals, food furnished to inmates and patients, and food and cash donated to schools and institutions. These items are not included in expenditures on food away from home for all families and individuals.

Source: United States Department of Agriculture Economic Research Service, 2014.

High-sodium foods are increasingly common in restaurants

26. Given the frequency with which Americans consume food away from home, the high sodium content of foods found in the restaurant setting is of particular concern. Evidence shows that restaurant food is more sodium-dense than food prepared at home,⁷⁵ and that the sodium content of menu items in leading fast-food restaurants increased by more than 20 percent from 1997 to 2010.⁷⁶ Menu items with very high sodium content are commonplace in the restaurant setting. An analysis of 2014 data from MenuStat, a nutritional database of thousands of foods served by the nation's largest chain restaurants, estimates that roughly 10 percent of menu items across a variety of chain restaurants doing business in New York City contain at least 2,300

⁷⁴ United States Department of Agriculture Economic Research Service. Food Away from Home, 2014. <http://www.ers.usda.gov/topics/food-choices-health/food-consumption-demand/food-away-from-home.aspx>. Viewed December 11, 2015.

⁷⁵ Lin B., Guthrie J. Nutritional quality of food prepared at home and away from home, 1977-2008, EIB-105, U.S. Department of Agriculture, Economic Research Service, December 2012.

⁷⁶ Rudelt A, French A, Harnack L. Fourteen-year trends in sodium content of menu offerings at eight leading fast-food restaurants in the USA. *Public Health Nutrition*. 2013;17(8):1682-88.

milligrams of sodium, the daily recommended limit.⁷⁷ A few examples of menu items containing alarmingly high amounts of sodium and served at chain restaurants are shown here:

EXAMPLES OF NYC MENU ITEMS WITH HIGH SODIUM CONTENT

PRODUCT	SODIUM CONTENT
TGI Friday’s New York Cheddar & Bacon Burger	4,280 mg
Jersey Mike’s Chipotle Turkey Sub, Wheat Regular	2,625 mg
Unos Chicago Classic Individual Size Deep Dish Pizza	4,910 mg
Chili’s Boneless Buffalo Chicken Salad	3,460 mg
Applebee’s Pecan-Crusted Chicken Salad	2,390 mg

Source: company websites, December 2015

New Yorkers need to be warned about risks of high-sodium foods

27. Consumers are not sufficiently aware of the risks posed by excess sodium intake and the pervasiveness of high sodium menu items. While some consumers recognize the link between sodium and blood pressure, there is limited awareness of the link between sodium and other serious health outcomes, including heart disease and stroke.⁷⁸

Consumers lack important information about sodium in the restaurant setting

28. While restaurants have become an important source of food, consumers lack transparent information about the sodium content of foods available in this setting. An estimated 19 to 32 percent of American’s sodium intake comes from restaurants.⁷⁹ The Sodium Warning alerts consumers to items that contain high amounts of sodium and provides actionable information in a setting and at a time when dietary choices are made.

⁷⁷ Internal Calculation based on data from menustat.org.

⁷⁸ Sarmugam R, Worsley A. Current levels of salt knowledge: a review of the literature. *Nutrients*. 2014; 6(12), 5534-59.

⁷⁹ Drewnowski A, Rehm CD. Sodium intakes of US children and adults from foods and beverages by location of origin and by specific food source. *Nutrients*. 2013;5(6):1840-55.

29. There is tremendous variability in the sodium content of food products available in the retail market.⁸⁰ Differences in formulation can result in similar food items containing vastly different amounts of sodium. For example, a large order of French fries from McDonald's contains 290 mg sodium while a large order of Burger King's French fries contains 710 mg sodium.

VARIABILITY BETWEEN SIMILAR MENU ITEMS

PRODUCT	SODIUM CONTENT
FRENCH FRIES	
McDonald's Large French Fries	290 mg
Burger King's Large French Fries	710 mg
SANDWICH	
Quiznos Ultimate Turkey Club, 8"	2,500 mg
Quiznos Chipotle Steak and Cheddar, 8"	1,680 mg
SALAD	
Applebee's Grilled Shrimp n Spinach Salad with regular dressing	2,990 mg
Applebee's Chicken Caesar Salad with regular dressing	1,760 mg

Source: company websites, December 2015

30. Separately, menu items that are promoted as healthy options often contain very high levels amount of sodium; Applebee's Grilled Shrimp 'n Spinach Salad contains 2,990 mg of sodium, far greater than the daily recommended limit. Many consumers would likely be shocked to learn how commonplace it is for restaurants to offer single menu items that contain more sodium than a person should consume in an entire day.

31. It is not surprising that consumers tend to underestimate the sodium content of their menu choices; in one study participants underestimated the sodium content of fast food menu items by over 1,000 mg.⁸¹ Between variations in formulation, misleading health halos, and consumers' tendencies to underestimate sodium content, individuals are making dietary choices in a vacuum

⁸⁰ Jacobson MF, Emami J, Grasmick S. Salt assault: brand-name comparisons of processed food. Washington (DC): CSPI; 2005.

⁸¹ Burton S, Howlett E, Tangari AH. Food for thought: How will the nutrition labeling of quick service restaurant menu items influence consumers' product evaluations, purchase intentions, and choices? *Journal of Retailing*.2009; 85(3), 258-73.

and may unknowingly be ordering items that exceed the recommended daily limit. Without a warning label, it is virtually impossible for consumers to reliably judge whether an item contains an excessive amount of sodium.

The rule is designed to support health and healthy choices

32. The Sodium Warning rule is designed to warn consumers about health risks and support healthy choices. By using a simple icon and warning statement, the Sodium Warning rule provides a useful warning at an actionable time and setting to inform consumer choice. In her testimony at the July 29, 2015 public hearing for the Sodium Warning rule, Dr. Marie Bragg, an Assistant Professor at NYU Langone Medical Center who conducts research on environmental and social factors associated with obesity, food marketing, food policy, and health disparities, testified on this particular topic, presenting research showing that few consumers access nutrition information from pamphlets or brochures and that consumers overwhelmingly prefer labels with easy-to-understand language and symbols.⁸² A copy of this testimony is attached as an Exhibit attached to the Verified Answer. The Sodium Warning rule provides essential information that can be succinctly displayed on menus and menu boards. Some patrons may additionally choose to access comprehensive nutrition information provided by restaurants to select foods with more modest sodium content, an exercise that has health benefits. But, this simple warning alerts all patrons to menu items that alone exceed the recommended daily sodium limit. In this way, the Sodium Warning rule will provide a useful complement to calorie labeling on menus in New York City, particularly as calorie labeling was reported to be useful by nearly 80 percent of New York City respondents participating in a 2011 public opinion poll.⁸³ In addition, research on warning and other labeling paradigms demonstrates that labels can increase consumer

⁸² Testimony submitted by Dr. Marie Bragg, Exhibit attached to the Verified Answer.

⁸³ Quinnipiac University Poll . October 20, 2011. Available at: <http://www.quinnipiac.edu/news-and-events/quinnipiac-university-poll/new-york-city/release-detail?ReleaseID=1664>. Viewed June 1, 2015.

knowledge^{84,85,86,87} and facilitate healthier choices.^{88,89,90} Drawing from numerous studies from various topic areas, including food research, literature demonstrates the capacity for labels to help inform consumers and decrease purchase and consumption of certain products.

The rule is tailored to identify items that are incompatible with recommended daily sodium limits

33. The Sodium Warning rule alerts consumers only to those menu options that are absolutely incompatible with the recommended daily sodium limit. Restaurants have many options in presenting their items for sale to consumers. Combination items are included in the Sodium Warning rule because they are presented as default menu options intended to be eaten together. Therefore a warning on a combination meal with a high cumulative sodium content is appropriate.

34. In the case of variable or customizable menu items, restaurants have flexibility in determining how to best incorporate the icons into menus and menu boards in such way that only identifies those items that exceed the sodium threshold specified by the Sodium Warning rule. Additionally, restaurants are at liberty to discontinue or reformulate menu items that would require an icon, thereby obviating the need to even post a warning.

⁸⁴ MacKinnon DP, Nohre L, Pentz MA, et al. The alcohol warning and adolescents: 5-year effects. *American Journal of Public Health*. 2000;90(10):1589-94.

⁸⁵ Wansink, B. How do front and back package labels influence beliefs about health claims? *Journal of Consumer Affairs*. 2003;37(2):305-16.

⁸⁶ Hawley KL, Roberto CA, Bragg MA, et al. The science on front-of-package food labels. *Public Health Nutrition*. 2103;16(3): 430-9.

⁸⁷ Roberto CA, Bragg MA, Schwartz MB. Facts up front versus traffic light food labels: a randomized controlled trial. *American Journal of Preventive Medicine*. 2012;43(2):134-41.

⁸⁸ Bushman BJ. Effects of warning and information labels on consumption of full-fat, reduced-fat, and no-fat products. *Journal of Applied Psychology*. 1998;83(1):97-101.

⁸⁹ Scourboutakos MJ, Corey PN, Mendoza J, et al. Restaurant menu labelling: Is it worth adding sodium to the label? *Canadian Journal of Public Health*. 2014;105(5):e354-e61

⁹⁰ Liu PJ, Roberto CA, Liu LJ, et al. A test of different menu labeling presentations. *Appetite*. 2102;59(3):770-77.

Chain restaurants are a logical setting for the rule

35. The Sodium Warning rule covers chain restaurants because they serve a disproportionate share of New York City meals, offer food items that contain very high levels of sodium, and have standardized menus. This makes compliance with the rule both feasible and reliable. Data from a major market research company, The NPD Group, indicates that major chain restaurants in the New York City metropolitan area accounted for more than one-third of all restaurant traffic in 2007.⁹¹ Contrary to the petitioner's claim, the rule covers all food service establishments that require a Health Department permit and are part of a chain with 15 or more locations nationwide doing business under the same name and offering for sale substantially the same menu items, including chain food service establishments located in stadiums and arenas. This is the same universe of food service establishments covered by the Department's calorie labeling rule.

36. Because chain restaurants have highly standardized food procurement, preparation, and operational processes, they can comply with the Sodium Warning rule; the menu items that will bear icons always contain at least 2,300 mg of sodium. Addressing the food served in chain establishments regulated by the Department is part of the Department's broad and comprehensive strategy to address the burden of cardiovascular disease in New York City. In fact, several chain restaurants have already begun to implement the Sodium Warning rule.

⁹¹ The NPD Group / CREST (marketing research data).



Source: Subway, December 2015

PASTA, SEAFOOD & MORE

- 4-cheese mac & cheese with honey pepper chicken tenders**

Honey pepper sauce & ketchup. (1700 cal) 12.99
- three-cheese chicken penne**

Grilled chicken, cream sauce & mushrooms. Alfredo sauce & Parmesan blend. (1820 cal) 11.99
- shrimp scampi linguine**

Scampi & parmesan sauce. Parmesan blend, zucchini & basil. (890 cal) 12.99
- double crunch shrimp**

Breaded shrimp, rice & sauce. Slaw & fries. (1350 cal) 12.99
- blackened tilapia**

Grilled Cajun-seasoned tilapia, seasonal vegetables & red potatoes. (460 cal) 16.29
- NEW loaded brisket enchiladas**

Sour cream, cheese, salsa verde, fresh jalapeño, rice. (1020 cal) 16.99
- NEW shrimp wonton stir-fry**

Stir-fry vegetables, housemade dumpling sauce, wonton strips, white rice. 14.99
610 CALORIES | 25g PROTEIN
- savory cedar salmon**

Grilled cedar-seasoned salmon, artichoke spread, steamed potatoes & vegetables. 17.29
540 CALORIES | 42g PROTEIN
- hand-battered fish & chips**

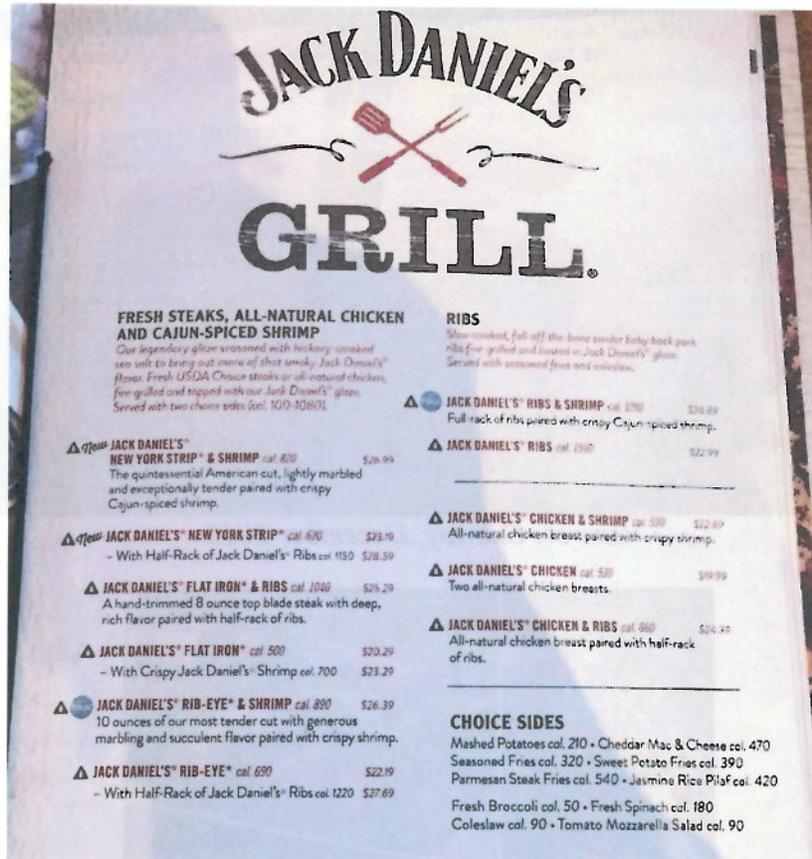
Tartar sauce, slaw & fries. (400 cal) 16.99

Food Allergen? You have a food allergy please talk to the store manager about your needs. Applebee's cannot accommodate severe food allergies. Cross-contamination may occur in our kitchen.

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

MENU LEGEND: Applebee's Signature You'll Be Back Again! Put That!

Source: Applebee's, November 2015



Source: TGI Friday's, December 2015

The scientific community and the public overwhelmingly support the sodium warning

37. Of the 94 comments submitted during the public comment period, 87 comments were in support of the proposal, two comments supported the proposal with suggested modifications and one comment supported the proposal contingent on modifications. Supportive comments came from members of a diverse community of private citizens, including physicians, nutritionists and registered dietitians, community members, and advocates. A number of organizations and individuals from leading academic, research, government, and advocacy organizations also contributed comments in support of the proposal.

38. Numerous international, national, and local organizations expressing support for the proposed amendment include:

- American Heart Association
- Center for Science in the Public Interest
- ChangeLab Solutions
- Public Health Institute
- New York Academy of Medicine
- Coalition for Asian American Children and Families
- National Forum for Heart Disease and Stroke
- Public Health Association of New York City
- National Kidney Foundation*
- Consumers Union
- World Action on Salt and Health
- George Institute for Global Health
- New York State Department of Health, Division of Environmental Health Protection*

Scientists, health professionals, and academics supporting the proposal include:

- Barry Popkin, PhD, University of North Carolina at Chapel Hill
 - Norman Campbell, CM, MD, FRCPC, University of Calgary
 - Walter Willet, MD, DrPH, Harvard School of Public Health
 - Tom Rifai, MD, FACP, Harvard Medical School, St. Joseph Mercy Oakland
 - Alice Litchenstein, DSc, Tufts University
 - Lora Sporny, EdD, Columbia University
 - Andrew Moran, MD, MPH, Columbia University Medical Center
 - Mitchell Elkind, MD, MS, MPhil, New York Presbyterian Hospital
 - LeWanza Harris, MD, MPH, New York Presbyterian Hospital and Columbia University Medical Center
 - Suzanne Steinbaum, DO, North Shore LIJ and Lenox Hill Heart and Vascular Institute of New York
 - Darwin Labarthe, MD, MPH, PhD, Northwestern University Feinberg School of Medicine
 - Marie Bragg, PhD, New York University School of Medicine
 - Steven Havas, MD, MPH, MS, FACP, FAHA, Northwestern University Feinberg School of Medicine
 - Lisa Young, PhD, RD, CDN, New York University
- *Denotes support with suggestions/modifications

39. The statements of these groups and individuals, along with scientific evidence, were considered by the Board before adopting the Sodium Warning rule and are attached as an Exhibit to the Verified Answer.

*The Sodium Warning Rule is an important part of a broader effort to prevent
chronic disease in New York City*

40. The Department and the City employ numerous efforts to reduce cardiovascular disease and promote healthy lifestyles. The Sodium Warning Rule is an important part of this comprehensive strategy. This rule alone will not eliminate the burden of cardiovascular disease in New York City, but it is one important component in a series of policies, programs, and education campaigns to make healthy lifestyles more attainable for New York City residents.

41. Policies to support healthier environments include nutrition standards for child care centers, day camps, and meals and snacks purchased and served by city agencies, as well as improvements to the food service environment by eliminating trans fat and providing calorie information for consumers.

42. Nutrition education through mass media campaigns and programming at farmers' markets and in child care centers help give New Yorkers tools to make healthier choices. Improved access to healthy food in communities is encouraged by the Shop Healthy program which increases healthy options in the food retail setting and Health Bucks coupons which help make fresh, local produce more affordable for low-income New Yorkers.

43. The National Salt Reduction Initiative, a public-private partnership coordinated and led by the Department since 2008, seeks to increase healthy options in the food retail environment by setting voluntary targets for sodium levels in packaged and restaurant food.

44. In the clinical setting, the Primary Care Information Project works with health care providers to use information systems to identify prevention opportunities with patients to reduce their risk factors for heart disease or stroke such as high blood pressure and tobacco use.

Summary

45. Section 81.49 is an important part of an integrated public response by the City and the Department to the burden of cardiovascular disease that impacts many New Yorkers. There is a vast body of scientific literature linking excess sodium intake to high blood pressure and risk of heart disease and stroke. For this reason, federal dietary guidelines recommend that daily sodium intake be limited to less than 2,300 milligrams. Warning consumers of menu items with sodium above this amount, as well as the risks that a high sodium diet poses, is a responsible and appropriate step that will allow them to make informed decisions about their health.

Dated: Queens, New York
January 4, 2016



MARY T. BASSETT, M.D., M.P.H

Sworn to before me on
January 4, 2016



Notary Public

MERRILL THOMAS
Notary Public State of New York
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Qualified in New York County
Commission Expires 9/28/16