UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

THE AMERICAN BEVERAGE ASSOCIATION, CALIFORNIA RETAILERS ASSOCIATION, CALIFORNIA STATE OUTDOOR ADVERTISING ASSOCIATION,

Plaintiffs,

vs.

THE CITY AND COUNTY OF SAN FRANCISCO,

Defendant.

Case No. 3:15-cv-03415 EMC

EXPERT REPORT OF DEAN SCHILLINGER

Hearing Date: April 7, 2016
Time: 1:30 p.m.
Place: Crtrm. 5, 17th Fl.

Trial Date: None set

I. QUALIFICATIONS

1. I am a Professor of Medicine in Residence at the University of California at San Francisco, with a specialty in a General Internal Medicine. From 1995-1999, I was director of the Adult Medical Clinics at San Francisco General Hospital and Trauma Center (SFGH) and from 1999-2003 I was the Director of Clinical Operations for the Department of Medicine at SFGH. I was the Chief of Diabetes Prevention & Control for the California Department of Public Health from 2008-2013. I have served on the Advisory Board of the US National Diabetes Education Program, a partnership of the National Institutes of Health, the Centers for Disease Control and Prevention, and more than 200 public and private organizations.

2. As a primary care physician for 25 years, I have a practice in which about 40% of my patients have Type 2 diabetes (DM2) and about 25% have pre-diabetes (preDM), many of whom I have been caring for on an ongoing basis for more than 20 years.

3. I am also a scholar in the field of diabetes care, diabetes patient education, diabetes prevention, diabetes disparities, and health literacy. I have published more than 180 peer-reviewed articles on these topics, and have received numerous national awards for this work, including from CDC, NIH, and the American Public Health Association. As a leader in the field of health literacy and diabetes, I have contributed to Institute of Medicine (now known as the National Academy of Sciences) reports on Health Literacy, authoring seminal studies on the relationship between limited health literacy on diabetes incidence, diabetes knowledge, diabetes-related communication, blood sugar control, diabetes complications, and other health outcomes. I am the UCSF site director for a National Institutes of Health Center for Type 2 Diabetes Translational Research, a program whose goal is to promote the development of scientific evidence that can be translated into practice and policy for the prevention and control of DM2. I received 2013 Everett Rogers Lifetime Achievement Award from the American Public Health Association and the 2016 James Irvine Leadership Award for my work in diabetes and health communication. My current CV is attached as Exhibit A.

4. To prepare this report, I reviewed the public health science and clinical research immediately relevant to the question of whether sugar-sweetened beverages (SSBs) contribute to obesity, Type 2 diabetes (DM2) and tooth decay, focusing on research conducted in the last 20 years. I

also reviewed and synthesized the clinical guidelines and position statements of major medical, dental, nutrition, and diabetes-related professional associations, as well as those of federal health agencies and entities, such as the Centers for Disease Control and Prevention and the US Dietary Guidelines. Finally, I have harnessed my own (1) clinical experience as a primary care physician and general internist caring for patients with, or at risk of, obesity, DM2 and tooth decay; (2) public health expertise in diabetes prevention and control; (3) extensive body of research in DM2, including its prevention, management and its complications; and (4) knowledge as an international expert in the field of health literacy and its relation to DM2. A list of the documents that I consulted is attached as Exhibit B, but because my opinions are drawn from my cumulative experience, this list cannot be exhaustive.

5. I have not previously provided expert testimony in any court. I am being compensated at a rate of $400 per hour for all of my substantive work in this case. My compensation does not depend on the conclusions I reach.

II. SUMMARY OF OPINIONS

6. The following is a summary of my opinions in this report: (1) Obesity and DM2 have severe and widespread public health consequences; (2) There is a clear scientific consensus that SSB consumption contributes to obesity, DM2, and tooth decay; (3) There is likewise a consensus in the medical, dental, and public health fields that people should reduce their consumption of SSBs to address obesity, DM2, and tooth decay; (4) There is widespread health illiteracy that contributes to SSB consumption because people are unaware of known SSB risks; and (5) Dr. Kahn's credentials are limited.

III. THE PUBLIC HEALTH CONSEQUENCES OF OBESITY AND DIABETES ARE SEVERE AND WIDESPREAD NATIONALLY AND IN SAN FRANCISCO

7. As a primary care physician and former Medical Director of a large clinical operation that had more than 150,000 medical visits during my tenure as director, I have observed first-hand the cumulative adverse health consequences of SSB consumption on the health of San Franciscans, including the resultant explosion of obesity rates and its myriad medical consequences, as well as the unremitting damage to people's oral health in the form of tooth decay and tooth loss. I have also seen

the ravages of DM2 in good people, often young people, who didn't know any better, and consumed SSBs—ravages that include amputations, kidney failure requiring lifelong dialysis, heart attacks, strokes, blindness, and premature death. The explosion of obesity in the US has been well-characterized, as has the problem of tooth decay and cavities, so in this section I will spend only a little time describing these public health phenomena. Rather, I will focus on the somewhat less well-known DM2 epidemic, a disease that has been insidiously and steadily advancing, to the point where now it is encroaching on our children's health, devastating families and communities, and infringing on our nation's economic well-being.

A. Prevalence and Consequences of Obesity

8. In 2011-2012 in the US, 16.9% of 2- to 19-year-olds and 34.9% of adults aged 20 years or older were obese.[1] More than two-thirds of adults were either overweight or obese, nearly 35% were obese, and about 6% were extremely obese. The prevalence of extreme (class III) obesity varied by race/Hispanic origin, with the highest prevalence among non-Hispanic black adults (12.1%) compared with 5.6% in non-Hispanic white adults, 0.9% in non-Hispanic Asian adults, and 5.8% in Hispanic adults.[2]

9. Obesity rates are high locally as well. A 2011 report measured obesity rates among 5th, 7th and 9th graders and found that 32% of San Francisco youth were overweight or obese.[3] In San Francisco, 46.4% of adults are obese or overweight, including 61.7% of Hispanics and 51.3% of African Americans.[4]

10. Obesity has serious consequences for mortality rates. For those who are extremely obese, death rates from heart disease, diabetes and cancer were nearly doubled compared to people classified as normal weight, even after adjusting for confounders such as smoking. Extreme obesity is

[1] C Ogden et al, Prevalence of Childhood and Adult Obesity in the Unites States, 2011-2012. JAMA. 2014 Feb 26;311(8):806-814.

[2] *Id*.

[3] S Babey et al, A Patchwork of Progress: Changes in Overweight and Obesity Among California 5th, 7th, and 9th Graders, 2005-2010, UCLA Center for Health Research Policy and California Center for Public Health Advocacy, Nov. 2011

[4] San Francisco Health Improvement Partnership. California Health Interview Survey (November 2015) Retrieved from http://www.sfhip.org/modules.php?op=modload&name=NS-Indicator&file=indicator&iid=19192667

associated with substantially elevated rates of total mortality, with most of the excess deaths due to heart disease, cancer, and diabetes, and major reductions in life expectancy compared with normal weight.[5] As one prominent study recently put it, "as a result of the substantial rise in the prevalence of obesity and its life-shortening complications such as diabetes, life expectancy at birth and at older ages could level off or even decline within the first half of this century."[6]

11. Obesity also has an immense economic impact. Research published in 2010 into the economic impact of obesity reveals that the annual medical (direct) costs are $161 billion. The indirect costs related to absenteeism and lost productivity, disability, and premature mortality total over $66 billion.[7]

B. Prevalence and Consequences of Type 2 Diabetes

12. Today, 14% of US adults (nearly 1 in 7) have Type 2 diabetes mellitus (DM2). In US minority or low-socioeconomic sub-groups, more than 1 in 5 have DM2.[8] Among individuals with diabetes, about 85% are obese.[9] In addition, nearly 40% of US adults now have pre-diabetes (preDM), a condition in which the fasting blood sugar level is abnormally elevated, but has not yet surpassed the DM2 threshold.[10] These individuals are at high risk of transitioning to DM2 over the next 5-10 years. Thus, nearly one half of US adults are especially vulnerable to acquiring DM2 or suffering its complications.

13. Most shocking of all is the recent observation that DM2, once known as "adult-onset diabetes" or, more colloquially, "Grandma's disease," is affecting younger and younger people. In

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[5] C Kitahara et al, Association Between Class III Obesity (BMI of 40-59 kg/m2) and Mortality: A Pooled Analysis of 20 Prospective Students. PLoS Medicine. 2014 Jul 8;11(7):e1001673.

[6] S.J. Olshansky et al., A Potential Decline in Life Expectancy in the United States in the 21st Century, N. Engl. J. Med. 2005; 352:1138-1145.

[7] Ross A Hammond: The economic impact of obesity in the United States 2010. Diabetes Metab Syndr Obes. 2010 Aug 30;3:285-295.

[8] Menke A et al, Prevalence of and Trends in Diabetes Among Adults in the United States, 1988-2012, JAMA 2015;314(10):1021-1029

[9] Centers for Disease Control and Prevention. Prevalence of Overweight and Obesity Among Adults with Diagnosed Diabetes—United States, 1988–1994 and 1999–2002. MMWR Morb Mortal Wkly Rep. 2004;53:1066-1068

[10] Menke A et al, Prevalence of and Trends in Diabetes Among Adults in the United States, 1988-2012, JAMA 2015;314(10):1021-1029

fact, among minority subgroups, the average age at diagnosis is now below age 50. Twenty-five years ago, diagnosing a child with DM2 was nearly unheard of; children with diabetes uniformly had Type 1 diabetes, an autoimmune disease also known as "juvenile onset diabetes". Now, a large CDC study reveals that approximately one third of all new cases of diabetes in US youth reflect DM2; among minority and lower income youth, over 1/2 to 2/3 of new cases reflect DM2.[11]

14. Another recent study revealed that the prevalence of DM and preDM in US teenagers dramatically increased from 9% in 1999 to 23% in in 2008.[12]. Comparing 2001 to 2009, cases of DM2 among youth ages 10-19 have increased by over 30.5%.[13]

15. The implications of this dramatic shift in DM2 among youth are devastating: these youth will face a lifetime managing a complex disease, attempting to ward off dread complications that can strike them at the prime of their lives, when they should be raising a family and contributing to society as members of the US workforce. In addition, recent research definitively shows that DM2 in youth is much harder to control than in adults.[14]

16. The effects of DM2 on mortality are significant. For individuals diagnosed between ages 20-60, they experience an average of 5 -7 years of life lost.[15] In addition, DM2 and its common complications—amputations, kidney failure, vision loss—have significant effects on quality of life. It is not an understatement to say that now, in every doctor's office in America, there is a largely invisible war being waged against DM2. To place this war metaphor in perspective, we have calculated, based on US war veteran's data and CDC statistics, that in the 10-year war in Iraq and Afghanistan, 1,572 US soldiers lost a limb in combat. In that same period of time, approximately 730,000 US residents (and over 70,000 Californians) lost a limb to DM2, a nearly 500-fold

[11] The SEARCH Study. National Diabetes Fact Sheet 2011. Retrieved from http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf

[12] May et al., Prevalence of Cardiovascular Disease Risk Factors Among US Adolescents, 1999-2008. Pediatrics. 2012;129(6):1035-1041.

[13] Dabalea et al., Prevalence of Type 1 and Type 2 Diabetes Among Children and Adolescents From 2001 to 2009. JAMA. 2014;311(17):1778-1786.

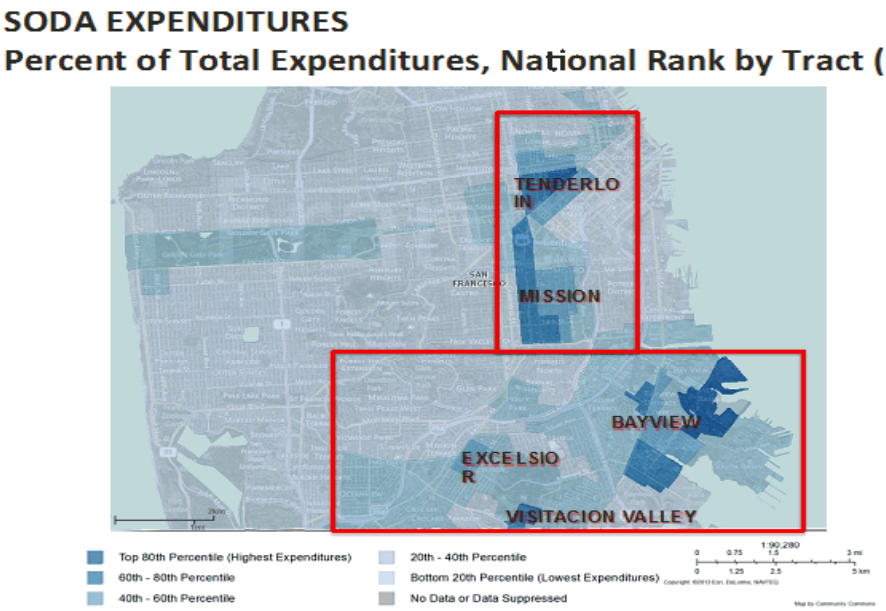
[14] TODAY Study Group et al, A Clinical Trial to Maintain Glycemic Control in Youth with Type 2 Diabetes. N Engl J of Med. 2012 Jun 13;366(24):2247-2256.

[15] EW Gregg et al., Trends in Lifetime Risk and Years of Life Lost Due to Diabetes in the USA, 1985-2011: A Modelling Study. Lancet Diabetes Endocrinol. 2014 Nov;2(11):867-874.

difference.[16, 17, 18] DM2 also results in more frequent hospitalizations. A recent UCLA study found that in California, nearly 1 in 3 patients hospitalized in acute care facilities have diabetes.[19]

17. In San Francisco, as in most cities in the US, the health consequences of DM2 disproportionately affect less fortunate populations. For example, in neighborhoods with large concentrations of minority populations and populations with lower educational attainment, hospitalization rates for uncontrolled diabetes and its consequences (amputations, kidney failure, etc.) are 4 to 8 times higher than in other neighborhoods. These neighborhoods tend to mirror those that consume disproportionately greater amounts of SSBs. Death rates from DM2 in San Francisco are 5 times higher in African Americans. DM2 is the 5th leading cause of death in SF (which is an underestimate, since heart disease, the leading killer, is often a result of DM2); DM2 reduces lifespan of San Franciscans by 8-10 years.[20]

Figure A



[16] Wood D, The World Post. U.S. Wounded In Iraq, Afghanistan Includes More Than 1,500 Amputees. 2012; http://www.huffingtonpost.com/2012/11/07/iraq-afghanistan-amputees_n_2089911.html.

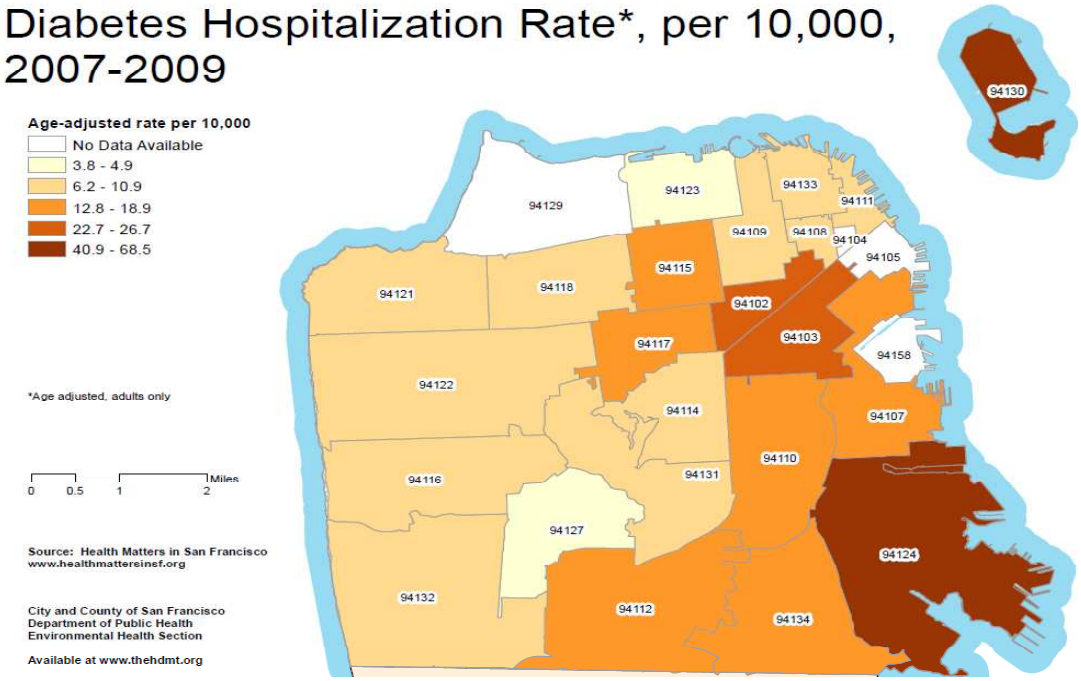
[17] Coalition A. Fact Sheet: Diabetes and Lower Extremity Amputations. 2008; http://www.amputee-coalition.org/fact_sheets/diabetes_leamp.html.

[18] http://www.diabetes.org/diabetes-basics/statistics/

[19] http://healthpolicy.ucla.edu/publications/Documents/PDF/2014/DiabetesPB_FINAL_5-13-14.pdf

[20] Data obtained from SF Department of Public Health (February 2016).

Figure B



18. Aggregate data tends to obscure the qualitative experience of the burdens of DM2. Authentic clinical narratives can help bring this qualitative experience to light; there is a long tradition in clinical medicine of using narratives to enhance understanding and motivate changes that improve patient outcomes. As such, attached as Exhibit C to this report are narratives describing three real cases from my practice that demonstrate the burdens of DM2 in patients who were longtime SSB consumers (and who were unaware of the hazards of SSB consumption until they had suffered its consequences). These cases should be thought of archetypes of the interplay between the health illiteracy so common in US society (*see infra* Section VI), the ubiquitous exposure to and intake of SSBs, and the onset of the complications of DM2.

19. Like obesity, diabetes is a costly disease. In 2012, the American Diabetes Association estimated that the total costs of diagnosed diabetes in the US rose to $245 billion in 2012, from $174 billion in 2007, a 41% increase over a five-year period.[21] Of the $245 billion, $176 billion were from direct medical costs and $69 billion from reduced productivity. People with diagnosed diabetes incurred average medical expenditures of about $13,700 per year, of which about $7,900 was

[21] American Diabetes Association. Economic Costs of Diabetes in the US in 2012. Diabetes Care. 2013;36(4):1033-1046.

attributed to diabetes. People with diagnosed diabetes, on average, had medical expenditures approximately 2.3 times higher than what expenditures would be in the absence of diabetes. For the cost categories analyzed, care for people with diagnosed diabetes consumed more than 1 in 5 health care dollars in the U.S., and more than half of that expenditure was directly attributable to diabetes.

20. A recent study in the American Heart Association journal found that SSBs are directly related to 184,000 deaths per year worldwide, with over 25,000 deaths directly related to SSBs occurring in the US per year. In the US (a high consumer of SSBs, ~1.3/day), among adults less than 45 years old, 9.6% of women's deaths and 12.5% of men's deaths were attributable to SSBs. Because SSBs contribute to chronic diseases such as obesity and DM2, which have major impacts on symptoms, disability and quality of life, these investigators also calculated the number of "disability-adjusted life year" (DALYs), which are summary metrics that measure how many years of healthy life are lost due to disability or death. In the US, a total of 831,754 DALYs are lost among adults, due just to SSBs each year, representing over 1% of all US DALYs.[22]

IV. CONSUMING SSBs CONTRIBUTES TO OBESITY, DIABETES AND TOOTH DECAY

21. There is a clear scientific consensus that SSBs contribute to obesity and DM2 at a minimum through a two-step process, whereby the effects of SSBs on DM2 act through an intermediate step of excessive caloric intake and/or weight gain. Whether the effects of SSBs on DM2 are *augmented* by an additional single-step mechanism whereby fructose (a main ingredient of SSBs) directly alters liver metabolism, blunts the satiety mechanisms in the brain (e.g. preventing the curbing of appetite that normally accompanies a high calorie meal, as has been shown in numerous studies), or fosters insulin resistance due to the high and rapid blood sugar spikes that accompany SSB consumption, is the subject of continuing discussion. Dr. Kahn is referring to this additional one-step process when he contends that it is debatable whether SSBs *uniquely* contribute to obesity and DM2. But he does not identify any scientific debate, and there is none, over whether SSBs contribute to obesity and DM2 through the two-step process.

[22] Singh et al.; Global SSB-related morbidity and mortality, DOI: 10.1161/CIRCULATIONAHA.114.010636 (2015).

22. The causal link between dietary sugars and tooth decay has long been firmly established, and the basic biological mechanisms are well understood.[23] In fact, the causal relationship between sugar and tooth decay was definitively established as early as the 1930s, based on a randomized controlled trial carried out in Sweden.[24] We now understand that dietary sugars, including in the form of SSBs, provide a substrate for oral bacteria that cause cavities to flourish and to generate enamel-demineralizing acids.[25] Modifying factors such as fluoride and dental hygiene would not be needed if we tackled the single cause—added sugars.[26] Quantitative analyses show a dose-response relationship between the sugar or its monosaccharide intakes (such as fructose) and the progressive lifelong development of cavities and resultant tooth loss. This results in a substantial dental health burden throughout life.[27] While processed starches have cavity-causing potential when accompanying sucrose, human studies do not provide unequivocal data of their ability to cause cavities in the absence of sugar.[28]

23. SSBs are the single largest source of added sugars in American diets. Moreover, the link between SSB consumption and tooth decay is independently documented.[29, 30] Finally,

[23] US Department of Health and Human Services. Food and Drug Administration Select Committee on GRAS Substances (SCOGS) Opinion: Sucrose. 2015 <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/ucm260083.htm>; FDA Sugars Task Force Report -- III. Dental Caries. *The Journal of Nutrition*. 1986;116:S38-S43.

[24] Bo Krasse. The Vipeholm Dental Caries Study: Recollections and Reflections 30 Years Later. *Journal of Dental Research*. September 2001 80: 1785-1788.

[25] Marshall TA. Preventing dental caries associated with sugar-sweetened beverages. *The Journal of the American Dental Association*. 2013;144:1148-1152.

[26] Sheiham A and James WPT. Diet and Dental Caries: The Pivotal Role of Free Sugars Reemphasized. *Journal of Dental Research*. October 2015 94: 1341-1347.

[27] Sheiham A and James WPT. A reappraisal of the quantitative relationship between sugar intake and dental caries: the need for new criteria for developing goals for sugar intake. *BMC public health*. 2014;14:863.

[28] Sheiham A and James WPT. Diet and Dental Caries: The Pivotal Role of Free Sugars Reemphasized. *Journal of Dental Research*. October 2015 94: 1341-1347.

[29] S Park et al. Association of Sugar-Sweetened Beverages Intake during Infancy with Dental Caries in 6-year olds. Clin Nutr Res 2015;4:9-17.

[30] E Bernabe et al, Sugar-sweetened beverages and dental caries in adults: A 4-year prospective study. J. Dent. 2014;42:952-958.

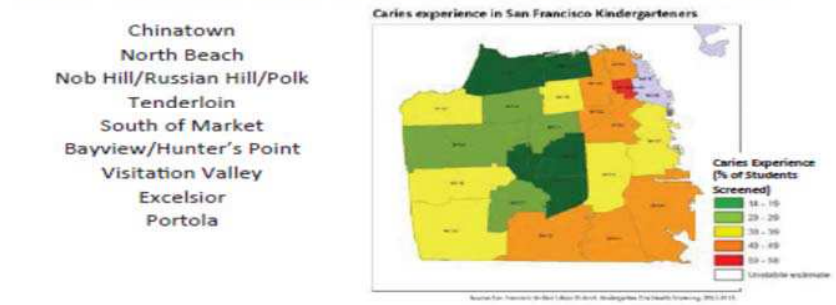
community interventions to reduce exposure to and consumption of SSBs have shown dramatic reductions in cavities,[31] bolstering the causal link.

24. Tooth decay is the single most common chronic disease of childhood in the United States and can lead to pain, infection, and tooth loss. In 2011–12, 58% of children ages 6–9 years had dental caries in at least one primary or permanent tooth. In California, by the third grade, 71 percent of students have experienced caries. Despite steady decreases in the incidence of cavities in San Francisco over the past five years, tooth decay remains a prevalent local health problem that is concentrated in the most disadvantaged neighborhoods. (See Figure C, below) In recent years, 35% of San Francisco Unified School District (SFUSD) kindergartners had experienced caries and 22% had untreated decay.[32]

Figure C[33]

Children who live in some geographic areas, experience 2-3 times the rate of caries as children in other areas of the city. (Figure 5)

Figure 5: Certain San Francisco neighborhoods have 2-3 times more children with caries



25. The annual cost of tooth decay in the North America in 2010 was estimated to be $30 billion in lost productivity alone; an additional $120 billion was spent on treatment.[34]

[31] G Maupomé et al., Dental Caries in American Indian Toddlers After a Community-Based Beverage Intervention. Ethn Dis. 2010 Autumn;20(4):444-450.

[32] San Francisco Health Improvement Partnership, San Francisco Children's Oral Health Strategic Plan: 2014-2017 (Nov. 2014). Available at http://assets.thehcn.net/content/sites/sanfrancisco/Final_document_Nov_2014_20141126111021.pdf

[33] *Id.*

[34] S Listl et al., Global Economic Impact of Dental Diseases. J Dent Research. 2015 Oct;94(10):1355-1361.

V. THERE IS A CONSENSUS IN THE MEDICAL, DENTAL, AND PUBLIC HEALTH ESTABLISHMENTS THAT THE POPULATION SHOULD REDUCE SSB CONSUMPTION TO ADDRESS OBESITY, DIABETES, AND TOOTH DECAY

26. In response to the epidemic levels of obesity, DM2, and tooth decay in the US, an overwhelming preponderance of medical, dental and public health professional entities and societies now encourage the reduction or cessation of SSB consumption. These entities both encourage the consistent counseling of patients regarding the hazards of SSBs and recommendations to reduce or quit SSB consumption, as well as advocating for systems, policy, and environmental interventions to reduce exposure to SSBs in schools, workplaces, neighborhoods, and communities.

27. A few of these organizations and their recommendations are discussed here. The Centers for Disease Control published in 2010 a Guide to Strategies for Reducing the Consumption of Sugar-Sweetened Beverages. In its 2016 Standards of Care, the American Diabetes Association (the same entity for which Dr. Kahn previously served as Chief Science Officer until 2009) states: "People with diabetes and those at risk should avoid SSBs in order to control weight and reduce their risk…"[35] The American Diabetes Association's "Diabetes Myths" webpage for consumers states: "The American Diabetes Association recommends that people should avoid intake of sugar-sweetened beverages to help prevent diabetes.[36] The American Association of Diabetes Educators, in its 2015 document entitled, *Healthy Eating: Priority Recommendation and Discussion Topics For Diabetes Treatment and Prevention,*[37] includes in its first recommendation: "eliminate sugar-sweetened beverages". In the 2010 US Surgeon General's Report, the Surgeon General recommends "Reducing consumption of sodas and juices with added sugars" as a choice people can make to prevent obesity and diabetes.[38] In January 2016, The California Dental Association, in support of a bill to impose a public health fee on SSBs, states that "CDA supports efforts to inform consumers of the scientifically

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[35] Diabetes Care Jan 2016, ADA Standards of Care

[36] http://www.diabetes.org/diabetes-basics/myths/. Last accessed February 2016.

[37] American Diabetes Association of Diabetes Educators. Healthy Eating. (April 29, 2015). Retrieved from https://www.diabeteseducator.org/docs/default-source/default-document-library/practice-synopsis-final_healthy-eating.pdf?sfvrsn=0

[38] U.S. Department of Health and Human Services. The Surgeon General's Vision for a Healthy and Fit Nation. Rockville, MD: U.S. Department of Health and Human Services, Office of the Surgeon General, January 2010, at 5.

proven health risks of SSB consumption... SSBs are the single largest source of added sugars in the American diet and one of the most significant contributors to dental decay in children – the most common chronic childhood disease, experienced by more than two-thirds of children in California."[39] The American Academy of Pediatrics recommends "minimiz[ing]" or "eliminat[ing]" consumption of SSBs.[40] The American Academy of Pediatric Dentistry encourages dentists to educate their patients to increase public awareness of the negative effects of frequent SSB consumption on infant, child, and adolescent nutrition, oral health, and general health including obesity.[41]

28. In addition, in my experience, it is now the standard of care that physicians and allied health professionals, when counseling patients at risk of obesity or DM2, or when counseling parents of children who are at risk of obesity or DM2, always carefully assess SSB consumption, and counsel those who consume SSBs regularly to reduce or eliminate consumption due to the known hazards of SSBs on weight gain and the acquisition of DM2. In the pediatric setting, 99% of pediatricians and general practitioners provide counseling to either all children, or overweight or obese children, regarding limiting or eliminating SSBs.[42] In addition, CDC recommends screening and counseling about sugar-sweetened beverage consumption as part of routine dental care.[43]

29. The FDA has proposed a rule that the nutrition facts panel display a percent daily recommended value for added sugars to help people limit their consumption of added sugars to 10% of daily calories or less, a limit recommended by the 2015 Dietary Guidelines Advisory Committee. Numerous prominent public health organizations have endorsed this proposal, including the following: Action for Healthy Food, American Diabetes Association ("The Association supports FDA's proposal to establish a DRV of 10 percent of total energy intake from added sugars""); American Heart Association ("AHA is extremely pleased that the FDA has decided to expand its original proposal and

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[39] http://www.cda.org/advocacy/legislation/major-legislative-issues

[40] Barlow SE, Committee E. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. Pediatrics. 2007;120 Suppl 4:S164-92.

[41] http://www.aapd.org/assets/1/7/G_InfantOralHealthCare.pdf

[42] HR Wethington et al., Physician Practices Related to Use of BMI-For-Age and Counseling for Childhood Obesity Prevention: A Cross-Sectional Study. BMC Fam Pract. 2011 Aug 3;12:80.

[43] CDC, Guide to Strategies for Reducing the Consumption of SSBs, 2010, at 28.

require food manufacturers to declare the percent DV on the Nutrition Facts panel.)"; American Institute for Cancer Research; The Prevention Institute ("the agency is appropriately relying upon information from the 2015 Dietary Guidelines Advisory Committee report as well as the robust science upon which that report is based regarding the health risks of added sugars. Ample scientific research provides a basis for establishing a Daily Reference Value (DRV) for added sugars and for requiring the declaration of a percent DV on labels to increase consumer understanding of added sugars in foods.); the Center for Science in the Public Interest; the Center for Science and Democracy at the Union of Concerned Scientists; Association of State Public Health Nutritionists; The Society for Nutrition Education and Behavior; Association of State Public Health Nutritionists; the Nutrition Policy Institute of theUniversity of California; and the Robert Wood Johnson Foundation. Societies that were opposed to the new standards were nearly all non-scientific and non-health-related, but commercial entities with financial conflicts of interest, and included the American Beverage Assocation; National Confectioners Association; Corn Refiners Association; and Snack Food Association.[44]

30. The 2015-2020 Dietary Guidelines for Americans ("2015-2020 USDG"), in accordance with the advisory committee's recommendation and the FDA's percent daily value proposal, recommends a limit of 10% of daily calories from added sugar. As the 2015-2020 USDG notes, "Strong evidence from mostly prospective cohort studies but also randomized controlled trials has shown that eating patterns that include lower intake of sources of added sugars are associated with reduced risk of (cardiovascular disease) in adults, and moderate evidence indicates that these eating patterns are associated with reduced risk of obesity, type 2 diabetes and some types of cancer in adults."

31. People who consume average amounts of SSBs exceed the 2015-2020 USDG's added sugar limit. Based on the 2015-2020 USDG, for a 12 year-old girl, whose daily calorie intake is 1600 calories, she should limit intake of added sugar to <160 calories. On average, 77% of girls aged 12-19

[44] Comments to Docket No. FDA-2012-N-1210 are available at www.regulations.gov.

drink 1 or more SSBs per day. Among those who drink at least some SSBs, the average daily intake for girls aged 12-19 is 286 calories of SSBs per day.[45]

32. Based on the 2015-2020 USDG, for a 20 year-old male, whose daily calorie intake is 2400 calories, he should limit intake of any added sugar to <240 calories. On average, 73% of males aged 20-34 consume 1 or more sugary beverage daily. 20% of these young men consume more than 500 calories/day in SSBs. The average SSB intake for men in this age group is 338 calories per day[46]

33. Based on the 2015-2020 USDG, for a 51 year-old woman, whose daily calorie intake is 1600 calories, she should limit intake of added sugar to <160 calories. On average, 50% of adults 35 or older consume 1 or more sugary drinks daily. On average, adults in this age group consume 236 SSB calories daily, and 12% of them consume more than 500 calories/day in SSBs.[47]

34. Addressing consumption is critical. Decades of science and clinical experience demonstrate that less than half of US adults, and fewer than a third of US children, engage in recommended physical activity on a daily basis.[48] And even this amount of exercise is insufficient to expend the calories consumed with a SSB, as a 140 lb. person walking at 3 miles per hour for 30 minutes consumes approximately 95 calories.[49] Further, there is no evidence that consumers' consumption of high calorie SSBs prompt individuals to engage in compensatory exercise. In fact, those who consume SSBs are also less likely to exercise.[50, 51] Expending calories consumed from SSBs through physical activity largely represents an illusory and unrealistic aspiration for the overwhelming majority of Americans, and does not provide a practical remedy to the harms related to SSBs.

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[45] E. Han, L. Powell, Consumption Patterns of Sugar-Sweetened Beverages in the United States, J Acad Nutr Diet. 2013 January ; 113(1): 43–53.

[46] *Id*.

[47] *Id*.

[48] http://www.cdc.gov/physicalactivity/data/

[49] http://walking.about.com/library/cal/uccalc2.htm

[50] Schulze M et al. Sugar-Sweetened Beverages, Weight Gain, and Incidence of Type 2 Diabetes in Young and Middle-Aged Women. JAMA 2004; 292(8):927-934

[51] Kvaavik E. et al. The stability of soft drinks intake from adolescence to adult age and the association between long-term consumption and lifestyle factors and body weight. Pub Health Nutr 2005;8:149-57

35. A recent natural experiment involving the nation of Mexico provides support for the notion that individuals who curb their SSB consumption will not simply replace this behavior with the consumption of other liquid calories. After Mexico, which is the largest per capita consumer of SSBs and the nation with the highest rate of DM2 in the world, levied a small tax on SSBs, purchases of taxed beverages decreased by an average of 12%. Purchases of untaxed beverages increased by 4%, mainly driven by an increase in purchases of bottled plain water.[52] This study was unable to capture Mexicans' compensatory consumption of non-bottled sources, such as tap or well water (the primary source of drinking water in Mexico). As such, these results significantly underestimate the degree to which water replaced SSBs. The Mexico data indicate that, when people cut back on SSBs, to a significant extent they do in fact choose less or non-caloric alternatives. This body of research in fact demonstrates that, under the right circumstances, individual behavior regarding SSBs can change, and that doing so can lead to salutary patterns of consumption that will reduce obesity, DM2 and tooth decay.

36. Even if people replace some of their consumption of SSBs with caloric alternatives, significant benefits are expected. A recent study modeled the number of cases of DM2 that would be prevented in California were SSB consumption to decline by 20%.[53] This model estimated that ~1/3 of the consumption of SSBs avoided would be replaced with water, 1/3 with diet drinks, and the final 1/3 with other caloric beverages, such as milk and juice. It found that SSB reductions would still be associated with dramatic reductions in DM2 incidence, despite modest caloric compensation. In a scenario in which Californians reduced SSB consumption by 20%, even if 1/3 of the calories avoided by reducing SSBs were replaced by non-SSB sources, the study determined that over 22,000 new cases of DM2 would be prevented over a 10 year, yielding a savings in healthcare costs over $1.6 billion USD. And nearly 55,000 new cases of DM2 over 10 years would be prevented in California

[52] MA Colchero et al., Beverage Purchases from Stores in Mexico Under the Excise Tax on Sugar Sweetened Beverages: Observational Study. BMJ. 2016 Jan 6;352:h6704.

[53] TA Mekonnen et al., Health Benefits of Reducing Sugar-Sweetened Beverage Intake in High Risk Populations of California: Results from the Cardiovascular Disease (CVD) Policy Model. PLoS One. 2013 Dec 11;8(12):e81723.

were SSB consumption to decline by 50%, again assuming that 1/3 of calories would be substituted from non-SSB sources. This would yield healthcare costs savings in California of over $4 billion.

VI. HEALTH ILLITERACY IN THE PUBLIC IS WIDESPREAD

37. In 2003, the US Department of Education carried out a large-scale assessment of adult health literacy levels. They found that 36% of the US population has either "below basic" or only "basic" health literacy, collectively known as health illiteracy.[54] This means that this large group of Americans is unprepared to make appropriate or informed decisions related to health, health behaviors and healthcare on their own behalf, and for their children and dependents. Health illiteracy is a major health problem in the US and has led the US Surgeon General, the Institute of Medicine and other national bodies to call for urgent public health and civic action to better educate the public.[55]

38. At the San Francisco General Hospital Medicine Clinic, the clinical home of over 2300 patients with DM2 and about 2000 patients with pre-diabetes, my research group showed in a study that nearly 50% of patients are health illiterate. Those who are most vulnerable to health illiteracy include children and youth, minorities, and those with lower educational attainment.[56]

39. Health illiteracy is independently associated with obesity, DM2, and tooth decay.[57, 58] A recent study determined that health illiteracy is the strongest predictor of whether an individual consumes SSBs.[59] For example, those with the lowest level of health literacy consume about 240 more calories from SSBs (about 10% of calories in adult males, the typical caloric value of a 16-ounce SSB)

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[54] National Center for Education Statistics. The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy. (September 2006) Retrieved from https://nces.ed.gov/naal/health.asp

[55] Office of the Surgeon Genearl (US, and Office of Disease Prevention and Health Promotion). Proceedings of the Surgeon General's Workshop on Improving Health Literacy: September 7, 2006, National Institutes of Health, Bethesda, MD. (2006).

[56] National Center for Education Statistics. The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy. (September 2006) Retrieved from https://nces.ed.gov/naal/health.asp

[57] : Sudore R et al. Limited literacy in older people and disparities in health and healthcare access. Journal Am Ger Soc. 2006; 54: 770-76.

[58] AM Horowitz et al., Oral Health Literacy: A Pathway to Reducing Oral Health Disparities in Maryland. J Public Health Dent. 2012 Winter;72 Suppl 1:S26-30.

[59] J Zoellner et al., Health Literacy is Associated with Healthy Eating Index Scores and Sugar-Sweetened Beverage Intake: Findings from the Rural Lower Mississippi Delta. J Am Diet Assoc. 2011 Jul;111(7):1012-1020.

than those in the highest level of health literacy. This suggests that health illiteracy contributes to consumption of SSBs due to a lack of awareness about known SSB risks. This combination of the public's lack of awareness about SSB risks and its overexposure to positive messages about the benefits and pleasures of SSBs provides a clear rationale for increasing the information available to the public that drinking SSBs contributes to obesity, diabetes, and tooth decay.

VII. KAHN'S CREDENTIALS ARE LIMITED

40. I have reviewed the list of Dr. Kahn's publications appended to his report. There is a seventeen-year hiatus in his publication record. The publications between 1969 and 1985 are irrelevant to opinions he offers on the relationship between SSBs and obesity and DM2. Of the 31 publications listed between 2002 and the present, only three of them present original research. The remainder are commentaries, position statements or editorials that would not have been subject to any peer review. In addition to the paucity of original research, Dr. Kahn's views do not appear to be informed by any experience providing patient care; he is not a clinician by training (e.g. not a physician, nutritionist, nurse, physiatrist, or pharmacist).

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