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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

BRIEF OF *AMICI CURIAE* AMERICAN HEART ASSOCIATION, AMERICAN MEDICAL ASSOCIATION, CALIFORNIA MEDICAL ASSOCIATION, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, CHANGELAB SOLUTIONS, AND PUBLIC HEALTH LAW CENTER IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Date: May 20, 2021
Time: 1:30 p.m.
Judge: Edward M. Chen
Courtroom: 5, 17th Floor

Trial Date: October 25, 2021

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Expert Reports

HSR	Expert Report of David Hammond, Ph.D., June 12, 2020
KSR	Supplemental Expert Report of Dr. Richard A. Kahn, June 12, 2020
SR	Expert Report of Hilary Seligman, Sept. 18, 2020
WSR	Expert Report of Walter Willett, June 11, 2020
WRR	Expert Rebuttal Report of Walter Willett, Sept. 18, 2020

Other Abbreviations

AAP	American Academy of Pediatrics
ABA	American Beverage Association
ADA	American Diabetes Association
AMA	American Medical Association
APHA	American Public Health Association
CDC	Centers for Disease Control and Prevention
DGAC	Dietary Guidelines Advisory Committee
FDA	U.S. Food and Drug Administration
GRAS	Generally Recognized As Safe
HHS	U.S. Dept. of Health and Human Services
IOM	Institute of Medicine (now "National Academy of Medicine")
NFP	Nutrition Facts Panel
NIFLA	National Institute of Family & Life Advocates
RCT	Randomized controlled trial
SSB	Sugar-sweetened beverage
T2D	Type 2 diabetes

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici curiae are national and California public health and medical organizations, who seek to share their expertise with the Court to explain why the challenged warning is a factual and uncontroversial statement reflecting the consensus of the public health and medical communities. Some *amici* were directly involved in the rulemakings at the Food and Drug Administration (FDA) that are the subject of certain arguments in this case, and thus are well positioned to provide the Court with an accurate account of those rulemakings. Warnings and other health-related disclosures that help the public to make informed choices about their health are of critical importance to *amici*'s work. Specific information about each *amicus* appears in the Appendix.[1]

INTRODUCTION AND SUMMARY OF ARGUMENT

Drinking beverages with added sugar can cause weight gain. Weight gain increases the risk of obesity and type 2 diabetes (T2D). These are facts, and they are uncontroversial.

Clearly communicating these facts is an urgent priority for the City and County of San Francisco. Almost half of all adults in San Francisco are overweight or obese. SR ¶ 10.[2] They face significantly increased risk of T2D, heart disease, and stroke.[3] Although uncontroversial, the facts about sugar-sweetened beverages (SSBs) are not yet known to many San Franciscans – including many people with prediabetes or T2D – who consume SSBs at high levels. SR ¶¶ 41-42.

San Francisco's warning is a reasonable response to a serious problem, enhancing individuals' ability to make informed choices about their health. "Protection of the robust and free flow of accurate information is the principal First Amendment justification for protecting commercial speech, and requiring disclosure of truthful information promotes that goal." *CTIA - The Wireless Ass'n v. Berkeley* [*CTIA II*], 928 F.3d 832, 852 (9th Cir. 2019), *cert. denied* (2019). Therefore, factual and uncontroversial disclosures and warnings attached to commercial advertisements are

[1] This Memorandum of Law is filed pursuant to the Court's Order to Permit Filing of Amicus Briefs, February 12, 2021. No counsel of any party to this proceeding authored any part of this brief. No party or party's counsel, or person other than *amici* and their members, contributed money to the preparation or submission of this brief. None of the *amici* issue stock; no publicly held corporation owns 10% or more of the stock in any *amicus curiae*.

[2] References to Expert Reports are abbreviated throughout as in San Francisco's Memorandum. *See* Table of Abbreviations, *supra*, after Table of Authorities.

[3] CDC, *Adult Obesity Causes & Consequences* (2020), https://bit.ly/3utU1qy; *see also* SR ¶¶ 12-13.

subject to a deferential standard of First Amendment review, which requires only that the statement be reasonably related to a substantial government interest and not "unjustified or unduly burdensome." *Am. Beverage Ass'n v. City & Cty. of San Francisco* [*ABA III*], 916 F.3d 749, 755-56 (9th Cir. 2019) (*en banc*) (citing *Nat'l Inst. of Family & Life Advocates [NIFLA] v. Becerra*, 138 S. Ct. 2361, 2372 (2018) and *Zauderer v. Ofc. of Discipl. Counsel*, 471 U.S. 626, 651 (1985)).[4]

That standard is met here. SSBs' contribution to weight gain, and weight gain's connection to obesity and T2D, are factual and uncontroversial. These facts are established by scientific evidence and are recognized by virtually every major public health authority. The warning requirement is neither unjustified nor unduly burdensome: it is reasonably related to San Francisco's substantial interest in the ability of its citizens to make informed decisions about their health and, far from drowning out advertisers' messages, it leaves fully 90% of the space to be dedicated to product promotion.

Plaintiffs seek to manufacture controversy by misrepresenting the warning and the evidence that supports it. They incorrectly represent the warning as suggesting to reasonable consumers that SSBs cause weight gain under *isocaloric* conditions (*i.e.*, when calorie intake from other sources is adjusted so that overall caloric intake stays constant), and they broadly and repeatedly mischaracterize the statements of FDA.

ARGUMENT

I. THE WARNING IS FACTUAL AND UNCONTROVERSIAL.

The required warning consists of three factual statements: (1) Drinking SSBs can cause weight gain; (2) Weight gain increases the risk of obesity; and (3) Weight gain increases the risk of

[4] The *en banc* panel may have treated the requirement that the disclosure be "'reasonably related' to a substantial government interest," 916 F.3d at 755, as subsumed under "not unjustified or unduly burdensome" in a three-factor test that did not specifically mention "reasonably related." *Id.* at 756. In any event, the Court found that an earlier, larger version of the warning did not pass muster because it was "unduly burdensome." The Court therefore did not consider the other factors, including whether the statement was factual and uncontroversial, so that *Zauderer* review applied in the first place. The Court reasoned that, because the warning failed *Zauderer* review, it could not survive any higher level of scrutiny.

T2D. The literal truth of each is so well established as to be wholly uncontroversial,[5] and none is misleading. *Cf. CTIA II*, 928 F.3d at 847 (upholding required warning because each component was literally true and not misleading).

Plaintiffs do not dispute Statements (2) and (3). Nor could they. Of course weight gain increases the risk of obesity. People cannot become obese without gaining weight. The connection is not merely theoretical: weight gain, including that from SSB consumption, can cause obesity. SR ¶ 26. And there is no scientific dispute that weight gain increases the risk of T2D. WSR ¶ 64 (citing meta-analyses). "Excess weight is an established risk factor for type 2 diabetes."[6] In fact, 89% of diabetes patients are overweight or obese.[7]

Unable to challenge the evidence that weight gain increases the risk of obesity and T2D, Plaintiffs argue that it is false – or at least controversial or misleading – to state that "Drinking beverages with added sugar(s) can cause weight gain." It is not.

A. SSB Consumption Leads to Weight Gain.

The "evidence that SSB intake is causally related to increased risk of obesity" is "compelling" and "meets all key criteria commonly used to evaluate causal relationships in epidemiology,"[8] rendering it uncontroversial.

There have been two long-term, well-powered (large) randomized controlled trials (RCTs) on point. KSR ¶ 47.[9] In one, a definitive study of over 500 children, those receiving 8 ounces per day of an SSB had a significantly greater increase in body weight and fat after 18 months than children receiving a similar sugar-free drink.[10] In the other large trial, overweight and obese

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[5] *NIFLA* introduced one further, narrow circumstance in which a disclosure may be controversial, and therefore subject to more stringent review: if "the compelled statement took sides in a heated political controversy." *CTIA II*, 928 F.3d at 845. That circumstance is not relevant here.

[6] Robert Eckel *et al.*, *Obesity and Type 2 Diabetes*, 34 DIABETES CARE 1424, 1424 (2011), http://bit.ly/2M2oNFH.

[7] CDC, *National Diabetics Statistics Report 2020* at 9 (2020), https://bit.ly/3kcjmRm.

[8] Frank Hu, *Resolved: There Is Sufficient Scientific Evidence That Decreasing Sugar-Sweetened Beverage Consumption Will Reduce the Prevalence of Obesity and Obesity-Related Diseases*, 14 OBESITY REVIEWS 606, 612 (2013), https://bit.ly/3s0n0Ac.

[9] Dr. Kahn criticizes both studies for not keeping total calorie intake constant between the two test groups. KSRR ¶ 47. But in real life, people don't keep their total calorie intake constant when they increase or decrease SSB consumption, as evidenced by the results of non-isocaloric studies.

[10] Janne de Ruyter *et al.*, *A Trial of Sugar-Free of Sugar-Sweetened Beverages and Body Weight in Children*, 367 NEJM 1397 (2012) (discussed at WSR ¶ 43), https://bit.ly/3qtZknz.

adolescent SSB drinkers who received interventions to motivate reduced SSB consumption experienced significantly less increase in body-mass index than those in a control group.[11] The results are corroborated by smaller-scale, well-designed RCTs.[12]

The evidence from RCTs is further corroborated by large prospective cohort studies (long-term investigations tracking a population without intervention) across various populations, including African-American women (59,000 subjects, 10 years),[13] middle-aged Chinese adults in Singapore (43,000+ subjects, 5+ years),[14] and U.S. nurses and health professionals (120,000+ subjects in 3 cohorts, 12-20 years).[15] A review by the Harvard School of Public Health concluded: "Findings from well-powered prospective cohorts have consistently shown a significant association … between SSB consumption and long-term weight gain and risk of type 2 diabetes."[16] Highly respected systematic reviews of the overall scientific evidence, including both RCTs and cohort studies, also conclusively establish that SSB consumption can cause weight gain.[17]

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[11] Cara Ebbeling *et al.*, *A Randomized Trial of Sugar-Sweetened Beverages and Adolescent Body Weight*, 367 NEJM 407 (2012) (*see* WSR ¶ 41), https://bit.ly/2ZqjOBU. (Dr. Kahn criticizes the study because the difference between the two groups did not persist significantly after a year without further intervention, but that shows only that the interventions did not make lasting changes in adolescent behavior, not that reducing SSB consumption did not reduce weight gain.)

[12] *E.g.* Kelly Higgins & Richard Mattes, *A Randomized Controlled Trial Contrasting the Effects of 4 Low-Calorie Sweeteners and Sucrose on Body Weight in Adults with Overweight or Obesity*, 109 AM. J. CLIN. NUTR. 1288 (2019), http://bit.ly/3bohC3b; Janet James *et al.*, *Preventing Childhood Obesity by Reducing Consumption of Carbonated Drinks*, 328 BMJ 1237 (2004), https://bit.ly/2ZqlOtO; Anne Raben *et al.*, *Sucrose Compared with Artificial Sweeteners*, 76 AM. J. CLIN NUTR. 721 (2002), http://bit.ly/3udKVhs.

[13] Julie Palmer *et al.*, *Sugar-Sweetened Beverages and Incidence of Type 2 Diabetes Mellitus in African American Women*, 168 ARCH. INTERN. MED. 1487 (2008), https://bit.ly/3qEyc5C.

[14] Andrew Odegaard *et al.*, *Soft Drink and Juice Consumption and Risk of Physician-diagnosed Incident Type 2 Diabetes*, 171 AM. J. EPIDEMIOLOGY 701 (2010), https://bit.ly/2ZweuNc.

[15] Dariush Mozaffarian *et al.*, *Changes in Diet and Lifestyle and Long-Term Weight Gain in Women and Men*, 364 NEW ENGLAND J. MED. 2392 (2011), https://bit.ly/3rXYiAG.

[16] Hu, *Resolved*, *supra* note 8, at 606.

[17] *See* Lisa Te Morenga *et al.*, *Dietary Sugars and Body Weight: Systematic Review and Meta-Analyses of Randomised Controlled Trials and Cohort Studies*, 346 BMJ e7492, e7492 (2012), (finding strong evidence that "intake of free sugars or sugar sweetened beverages is a determinant of body weight"), https://bit.ly/2NyvuQh; Vasanti Malik *et al.*, *Intake of Sugar-Sweetened Beverages and Weight Gain*, Abstract, 84 AM. J. CLINICAL NUTR. 274 (2006) ("The weight of epidemiologic and experimental evidence indicates that a greater consumption of SSBs is associated with weight gain and obesity"), https://bit.ly/3pEd5z2; Miriam Vos *et al.*, *Added Sugars and Cardiovascular Disease Risk in Children: A Scientific Statement from the American Heart Association*, 135 CIRCULATION e1017, e1033 (2017) ("Higher SSB and added sugars intake has been strongly linked to excess weight gain and an increased risk of obesity" in children and adolescents), https://bit.ly/3uwvAc4.

B. Whether SSB Consumption Leads to Weight Gain under Isocaloric Conditions Is Immaterial.

Plaintiffs seek to counter the scientific evidence linking SSB consumption and weight gain by pointing to studies finding the link inconclusive *under isocaloric conditions*. *E.g.*, Pl. Mem. at 18. But that is irrelevant. In the real world, caloric intake does not stay constant when more SSBs are consumed because SSBs tend to be consumed in large part in addition to, rather than instead of, other sources of calories. WRR ¶ 39, WSR ¶ 38. Nor is it likely that consumers would understand the warning to refer to isocaloric conditions.

Because much of the effect of SSBs on weight gain is due to the fact that SSBs increase caloric intake, "adjusting" for total energy intake would "artificially underestimate the association between SSBs and body weight."[18] To assess whether football increases the risk of brain damage, for example, one would not design a study that adjusts for frequency or severity of head injuries. The issue is not whether severe head injuries suffered while playing football are more detrimental than other equally severe head injuries. Rather, football players are more likely to develop brain damage precisely *because* they are more likely to suffer frequent and severe head injuries. Similarly, SSB drinkers gain more weight, largely *because* SSBs lead them to consume more calories. The warning makes no claim that SSB calories are more detrimental than other calories.

Nor does it matter why SSB consumption does not lead to a corresponding reduction in intake of other calories. Whether it is explained by liquids' tendency to satisfy hunger less than do solid foods, *see* WSR ¶¶ 61-62; WRR ¶ 40, habit, or other mechanisms, RCTs and cohort studies show that greater SSB consumption in a population results in more weight gain in that population.

Plaintiffs' refrain that "a calorie is a calorie," Pl. Mem. at 3, 23, 29, is beside the point. SSB consumption tends to result in overall greater overall calorie consumption. Consequently, it is both true that "Drinking beverages with added sugar(s) can cause weight gain," and true in practice that drinking such beverages often *does* cause weight gain.[19]

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[18] Hu, *Resolved*, *supra* note 8, at 608.

[19] It is similarly irrelevant whether SSBs increase diabetes risk in ways other than weight gain. In fact, the 2015 DGAC noted evidence that SSBs increase the risk of T2D in adults even beyond their contribution to weight gain. 2015 DGAC, *Sci. Report*, at 344, https://bit.ly/3bkR0jL. But the San Francisco warning makes no claim on that score either. It states only that weight gain increases T2D risk, an undisputed fact.

C. SSB Consumption Causes Weight Gain *Because* It Can Increase Caloric Imbalance.

Plaintiffs argue that weight gain is caused not by SSB consumption, but by "caloric imbalance" (consuming more calories than one expends). Pl. Mem. at 17-18. But those are not rival explanations. Caloric imbalance explains why SSBs lead to weight gain. Simply put, the more one consumes SSBs, the greater the risk that one will consume more calories than one needs.

To say that a soda drinker's weight gain is caused by caloric imbalance and therefore not caused by soda consumption is comparable to a criminal defendant charged with pushing a victim out the window arguing that the fall was caused not by being pushed, but by gravity.

Similarly, the fact that concussions are caused by hard hits to the head does not make false the statement that playing football can cause concussions. To the contrary, it explains why the statement is true: Playing football increases the risk of hard hits to the head, much as consuming SSBs increases the risk of caloric imbalance.

SSB consumption is a significant part of the explanation for population weight gain. For that reason, reducing soda consumption can contribute significantly to preventing weight gain.

D. The Link Between SSB Consumption and Weight Gain Is Not Controversial.

Far from being controversial, the link between SSBs and weight gain, with consequent health harms, is recognized by virtually every public health authority with relevant expertise. Those authorities also unanimously advise the public to eliminate or limit SSB consumption:

- Centers for Disease Control and Prevention (CDC): "Frequently drinking sugar-sweetened beverages is associated with weight gain/obesity [and] type 2 diabetes";[20] communities are advised to "discourage consumption of sugar-sweetened beverages."[21]
- World Health Organization: "[R]educing consumption of sugar-sweetened beverages would … reduce the risk of … overweight and obesity" in both children[22] and adults.[23]
- American Heart Association: "There is a robust body of evidence that SSB consumption is

[20] CDC, *Get the Facts: Sugar-Sweetened Beverages and Consumption* (2020), http://bit.ly/3drk8sq.
[21] Laura Kahn, *et al.*, CDC, *Recommended Community Strategies and Measurements to Prevent Obesity in the U.S.*, MORB. AND MORT. WEEKLY REP. (July 24, 2009), http://bit.ly/3jZNz5Q.
[22] World Health Org. [WHO], *Reducing Consumption of Sugar-sweetened Beverages to Reduce the Risk of Childhood Overweight and Obesity* (updated 2019), https://goo.gl/5pDE9K.
[23] WHO, *Reducing Consumption of Sugar-sweetened Beverages to Reduce the Risk of Unhealthy Weight Gain in Adults* (updated 2019), https://goo.gl/Pn46gt.

detrimental to health and … associated with increased risk of … T2DM [and] obesity."[24]

- Institute of Medicine (IOM): "[R]esearchers have found strong associations between intake of sugar-sweetened beverages and weight gain…. [The link of SSBs] to obesity is stronger than that observed for any other food or beverage."[25]

- 2015 Dietary Guidelines Advisory Committee (DGAC): "Obesity [and] type 2 diabetes ... are major public health concerns. Added sugars intake negatively impacts … these conditions, and strong evidence supports reducing added sugars intake to reduce health risks."[26]

- 2020 DGAC: "Among the beverages examined in the [Nutrition Evidence Systematic Review], only SSB intake was associated with adiposity and this held in both children and adults…. [I]t is important to continue encouraging only limited intake of this class of beverages."[27]

- American Public Health Association (APHA): "Consumption of [SSBs] is a significant contributor to the obesity epidemic and increases the risk of type 2 diabetes."[28]

- American Academy of Pediatrics (AAP): "Potential health problems [are] associated with high intake of sweetened drinks, [including] overweight or obesity"[29]; pediatricians "should promote a diet free of sugar-sweetened beverages."[30]

- American Diabetes Association (ADA): "Research has shown that drinking sugary drinks is linked to type 2 diabetes"; ADA "recommends that people should avoid intake of sugar-sweetened beverages."[31]

- American Medical Association (AMA): The AMA "acknowledges the adverse health impacts of sugar-sweetened beverage (SSB) consumption, and support[s] evidence-based strategies to reduce the consumption of SSBs," including warning labels.[32]

If it is controversial that SSBs cause weight gain, with its consequent health risks, it is difficult to imagine what health warning might ever be uncontroversial.

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[24] Linda Van Horn *et al.*, *Recommended Dietary Pattern to Achieve Adherence to the American Heart Association/American College of Cardiology (AHA/ACC) Guidelines: A Scientific Statement from the American Heart Association*, 134 CIRCULATION e505 (2016), https://bit.ly/2ZOGiwA. "T2DM" refers to Type 2 Diabetes Mellitus.

[25] IOM, *Accelerating Progress in Obesity Prevention* 167 (2012), https://bit.ly/2NFUYeO.

[26] 2015 DGAC, *Sci. Report*, *supra* note 19, at 346.

[27] 2020 DGAC, *Sci. Report*, Pt. D, Ch. 10, at 26, https://bit.ly/2Mbl8pg. The 2020 DGAC found moderate evidence that "dietary patterns … low in sugar-sweetened foods and beverages … are associated with favorable outcomes related to body weight." *Id.*, Ch. 8, at 18. The 2020 DGAC also found moderate evidence that "higher sugar-sweetened beverage intake is associated with greater adiposity in children." *Id.*, Pt. D, Ch. 10, at 13. The evidence was "limited" for adults, *id.*, largely because fewer well-designed RCTs were published between 2012 and 2019, the period encompassed in its review. *Id.* at 7.

[28] APHA, *Taxes on Sugar-Sweetened Beverages*, APHA Policy Statement 20072 (2012), https://bit.ly/3st6mcG.

[29] AAP, *Policy Statement, Soft Drinks in Schools*, 113 PEDIATRICS 152, 152 (2004), https://bit.ly/37tldvX.

[30] Stephen Daniels, *et al.*, *The Role of the Pediatrician in Primary Prevention of Obesity*, AAP Guidance, 136 PEDIATRICS e275, e275 (2015), https://bit.ly/3k0xQ6F.

[31] ADA, *Myths About Diabetes*, http://bit.ly/3bE6PCc

[32] AMA, *Strategies to Reduce the Consumption of Beverages with Added Sweeteners* (2017), http://bit.ly/3uzQxTG.

E. Plaintiffs Distort the FDA Record on SSB Risks.

FDA likewise concluded in a 2016 rulemaking that "the evidence on sugar-sweetened beverages and body weight/adiposity [body fat] is strong and consistent." 81 Fed. Reg. 33742, 33803.[33] Nevertheless, Plaintiffs argue that the link between SSBs and weight gain is controversial, pointing to statements in FDA's 2016 Nutrition Facts Panel (NFP) rulemaking, in which the agency was considering whether to add a new line and Daily Value for added sugars to *all* packaged foods (including but not limited to SSBs). Plaintiffs distort the record:

Plaintiffs: "U.S. consensus reports do not support a cause and effect relationship between added sugars consumption and risk of obesity." Pl. Mem. at 10, 18 (quoting 81 Fed. Reg. at 33760). **Context**: Plaintiffs elide the distinction between SSBs and "added sugars," obscuring that FDA's conclusion about SSBs and weight gain was the *opposite* of the one Plaintiffs suggest. FDA declined to conclude that *added sugars* cause weight gain, because a majority of studies of added sugars focus only on beverages but SSBs are not the only sources of added sugars in the diet. FDA actually was clear that there is "strong and consistent" evidence linking SSBs with weight gain and obesity. The agency was not willing to rely *only* on such evidence, given that it was issuing a rule to label added sugars on *all* packaged foods, including non-SSB sources of sugars. 81 Fed. Reg. at 33803.[34] Notably, FDA had no need to do so, as the Dietary Guidelines advise limiting added sugars to less 10% percent of the Daily Value for a 2000-calorie diet, and such advice provides ample basis for labeling of added sugars.

FDA's statement that warnings linking added sugars to obesity and T2D were "not consistent with [its] review of the evidence," 81 Fed. Reg. at 33829, cited by Plaintiffs, Pl. Mem. at 1, is

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[33] FDA, *Food Labeling: Revision of the Nutrition and Supplement Facts Labels* (May 27, 2016).

[34] "A substantial amount of research has been conducted on the association between consumption of sugar-sweetened beverages and risk of chronic disease…. The 2010 DGAC concluded that an increased intake of sugar-sweetened beverages is associated with greater adiposity in children. Since 2010, additional evidence on sugar sweetened beverages and their association with risk of disease has emerged. The 2015 DGAC concluded that there is strong and consistent evidence that intake of added sugars from foods and/or beverages is associated with excess body weight in children and adults. *We note that the majority of the evidence that the 2015 DGAC relied on for this conclusion was from studies on the relationship between intake of sugar-sweetened beverages and body weight. Although the evidence on sugar-sweetened beverages and body weight/adiposity is strong and consistent*, sugar-sweetened beverages represent only 39 percent of food sources of added sugars.… [S]ugar-sweetened beverages may not be an appropriate proxy or surrogate for total added sugars intake." 81 Fed. Reg. at 33803 (emphasis added).

likewise based on the agency's caution in generalizing from the robust data about SSBs to make conclusions about added sugars generally. A commenter had suggested that FDA should adopt a warning label scheme in addition to, or in lieu of, the new line for added sugars on the NFP. Such a proposal was inconsistent with the agency's approach to the NFP, which does "not require warning labels or disclaimers for other nutrients on the label." *Id.*[35] FDA noted, in passing, that such a proposal was "not consistent with our review of the evidence (see our response to comments 136 and 137)," *id.* – referring to the section described just above: FDA simply had no need to extrapolate from the strong evidence about SSBs and weight gain as its basis for labeling overall added sugars. *Id.* at 33803 (Response to Comment 136).

Plaintiffs: "[A]dded sugars, including sugar-sweetened beverages, are no more likely to cause weight gain in adults than any other source of energy." Pl. Mem. at 1, 12 (quoting 79 Fed. Reg. 11880, 11904[36]). **Context**: Plaintiffs twice misleadingly omit the qualifier "under isocaloric controlled conditions." *Id.* Outside research labs, SSBs are *not* consumed under isocaloric controlled conditions. As FDA explained: "Although foods containing solid fats and added sugars do not contribute to weight gain any more than another calorie source, they make up a significant percentage of the American diet and are a source of excess calories." *Id.*

Plaintiffs: Added sugar is "generally recognized as safe" (GRAS) by FDA, such that it may be used in food and beverages "with no limitation other than current good manufacturing practice." Pl. Mem. at 18 (quoting 21 C.F.R. §§ 184.1, 184.1866). **Context**: This conclusion about *added sugars* is largely irrelevant to the evidence on the harms of SSBs. In any event, FDA's determination that added sugar is GRAS dates to 1988, *see* 53 Fed. Reg. 44862,[37] before substantial evidence emerged linking SSBs to weight gain, *see id.* at 44865, and has never been revisited.[38] Moreover, already in 1988, FDA could not determine "whether a significant increase in

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[35] Such a product warning was not within FDA's purview in a rulemaking, under the National Labeling and Education Act, 21 U.S.C. § 323(q)(2)(A), on requiring added sugars in nutritional labeling across all product categories. FDA lacked any legislative mandate to require warnings.
[36] FDA, *Food Labeling: Revision of the Nutrition and Supplement Facts Labels* (Mar. 3, 2014).
[37] Dept. of HHS, *GRAS Status of Corn Sugar, Corn Syrup, Invert Sugar, and Sucrose* (Nov. 7, 1988).
[38] *See* U.S. Govt. Accountability Ofc., *FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)* at 21 (2010), https://bit.ly/3jZYvjS

[added sugars] would constitute a dietary hazard." 53 Fed. Reg. at 44863. A significant increase in added sugars consumption *has* in fact occurred since then.[39]

Plaintiffs: "The FDA has concluded … that sugar-sweetened beverages "can be a part of a healthy dietary pattern." Pl. Mem. at 19 (quoting 81 Fed. Reg. at 33829). **Context**: In reality FDA said that "*added sugars* can be a part of a healthy dietary pattern" in small quantities. 81 Fed. Reg. at 33829 (emphasis added). What can be included in a healthy diet are "nutrient dense foods with small amounts of added sugars, such as whole-grain breakfast cereals or fat-free yogurt" or "limited amounts of added sugars ... to improve the palatability" of tart fruits and vegetables, *id.* at 33818, not SSBs. A single 20-ounce Coke contains 130% of the Daily Value for added sugars.[40]

Plaintiffs: "[A]dded sugars are not chemically different than sugars that are naturally present in foods." Pl. Mem. at 23 (quoting 81 Fed. Reg. at 33773). **Context**: This is irrelevant. FDA distinguishes between added and naturally present sugars in foods in labeling, even though they are chemically identical, because added sugars are linked to an excess of empty calories.[41]

Plaintiffs: "The recommendation that individuals not consume more than 10% of their daily calories in the form of added sugar is not based on … any determination that consuming more than that amount causes weight gain." Pl. Mem. at 26. **Context**: In reality, FDA repeatedly tied high consumption of added sugars to issues with "weight management." *E.g.* 79 Fed. Reg. at 11903, 11904; 81 Fed. Reg. at 33818. Federal dietary guidelines are based on the need to consume sufficient amounts of various vital nutrients without exceeding overall calorie limits. Because calories from added sugars do not contribute nutrients, 79 Fed. Reg. at 11903, "it is very unlikely that [most people] can consume a high quality diet … to meet nutrient needs as well as a significant amount of added sugars and still stay within calorie limits." 81 Fed. Reg. at 33806.

("Since 1982, FDA has not systematically reconsidered the safety of substances considered to be GRAS as new scientific information has come to light.").

[39] *See* Elyse Powell *et al.*, *Added Sugars Intake Across the Distribution of US Children and Adult Consumers: 1977–2012*, 116 J. ACAD. NUTR. & DIETETICS 1543 (2016), https://bit.ly/3dtoWgG (finding significant increase in added sugars consumption in U.S. from 1977 to 2003, only partly offset by a decline from 2003 to 2012).

[40] *See* Coca-Cola Co., *Coca-Cola*, https://bit.ly/2NwknrC (click "Nutrition Facts").

[41] "We … disagree that there is no material difference between added and intrinsic sugars for purposes of achieving a healthy dietary pattern to avoid excess discretionary calories from added sugars and reduced risk of chronic disease." 81 Fed. Reg. at 33762.

Exceeding calorie limits, of course, leads to weight gain.

In sum, FDA findings support, rather than undermine, the factual basis and reasonableness of San Francisco's SSB warning. The Ordinance is based on a view of the science fully congruent with that of FDA. Ruling that the City cannot develop a more effective means of communicating a known public health hazard would threaten "the happy incident[] of the federal system that a single courageous state [or locality] may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., diss.). Required calorie counts on restaurant menus, for example, originated in a city, before they were adopted by states and then by the nation as a whole.[42] The Court should be wary of a regime that would stifle such innovation.

F. The Warning Is Not Misleading.

Finally, the warning is not "misleading and, in that sense, untrue." *CTIA II*, 928 F.3d at 847. Plaintiffs complain that the warning misleadingly implies: (1) SSBs cause weight gain, even when consumed in moderation, Pl. Mem. at 10; and (2) "[T]here is something uniquely and inherently harmful" about SSBs, compared to other sources of added sugars or of calories. *Id.* at 11. But neither of these implications is misleading, except on the most strained interpretations.

Even moderate consumption – to say nothing of what may be *perceived* as moderate consumption[43] – does increase the risk of weight gain. Replacing just 8 ounces of SSB a day with the same amount of water or diet beverage results in less weight gain.[44] And SSBs *are* uniquely harmful. The Institute of Medicine, citing the 2010 DGAC Scientific Report, described the link between SSBs and obesity as "stronger than that observed for any other food or beverage."[45] SSBs are the largest source of added sugars in the American diet, *id.* ¶ 8, SR ¶ 24, without counterbalancing nutritional benefits, WSR ¶ 9, and are particularly unlikely to be compensated for with a reduction in other calories. *Id.* at ¶¶ 61-62; WRR ¶¶ 13, 39; SRR ¶ 13.

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[42] Christine Cusick, *Menu Labeling Laws: A Move from Local to National Regulation*, 51 SANTA CLARA L. REV. 989 (2011), https://bit.ly/3s7WlSo.
[43] *See* SR ¶ 42 (noting diabetes patients who think drinking "a couple" of SSBs a day is "fine").
[44] *See* An Pan *et al.*, *Changes In Water and Beverage Intake and Long-Term Weight Changes*, 37 INT'L J. OBESITY 1378 (2013), https://bit.ly/3uy0Uak; de Ruyter, *supra* note 10.
[45] IOM, *Accelerating Progress*, *supra* note 25.

If the mere presence of a warning misleadingly implies that a product is harmful in some unique way, or harmful in any quantity, Pl. Mem. at 10, 11, few warnings could withstand scrutiny. Even for a product as uniquely harmful – among products legally sold for human consumption – as tobacco, until 2016 cigarette manufacturers could have argued that warnings about addictiveness and disease risk were misleading because they were not required for cigars, which pose similar risks. *See* 81 Fed. Reg. 28973.[46] Liquor companies could equally well argue that warnings that "alcoholic beverages … may cause health problems, 27 U.S.C. § 215(a)(2), are misleading, because someone might think that consuming one drop would lead to health problems.[47] There is no reason to think that the City's warning is more likely to mislead than are any "health and safety warnings long considered permissible." *NIFLA*, 138 S. Ct. at 2376. The legality of such warnings is unquestioned. *Id.*

In sum, the warning is not misleading. Its claims are factual and uncontroversial.

II. BECAUSE THE WARNING IS NOT UNJUSTIFIED OR UNDULY BURDENSOME, IT DOES NOT OFFEND THE FIRST AMENDMENT.

Because the warning consists only of factual and uncontroversial statements, it is reviewed under the standard set out in *Zauderer*. 471 U.S. 626. It passes muster under that standard because it is "'reasonably related' to a substantial government interest," *ABA III*, 916 F.3d at 755, and is "not unjustified or unduly burdensome." *Id.* at 756.

The warning is reasonably related to the government's interest in promoting greater public understanding of health-related risks and informed consumer decision-making. *See Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 564 (6th Cir. 2012) (upholding health warning on this basis); *New York State Rest. Ass'n [NYSRA] v. New York City Bd. of Health*, 556 F.3d 114, 134 (2d Cir. 2009) (same for required posting of calorie information). Lower levels of consumer awareness of health information are associated with significantly higher rates of SSB consump-

[46] Dept. of HHS, *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act* (May 10, 2016).

[47] If the City tried to avert misunderstandings with a more nuanced warning, far more words would be required, and Plaintiffs would certainly redouble their protests that their own message would get drowned out, constituting an undue burden. Plaintiffs seek to set a bar that no warning could clear.

tion, as well as with higher rates of obesity and T2D. SR ¶ 42. A recent meta-analysis of 23 studies including over 16,000 participants found that SSB warning labels increased attention to Nutrition Facts and increased knowledge of the health risks of SSBs. *Id*. ¶ 43.

The warning is not unduly burdensome. "A disclosure is 'unduly burdensome' when the burden 'effectively rules out' the speech it accompanies." *Nationwide Biweekly Admin., Inc. v. Owen*, 873 F.3d 716, 734 (9th Cir. 2017) (quoting *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136 (1994)). Thus disclosures have been struck down when their length effectively ruled out fitting qualifications on business cards and letterheads, *Ibanez*, 512 U.S. at 146-47, or when a 29-word statement, repeated in as many as 13 languages in text at least as large as the accompanying advertisement, would "drown[] out" the advertiser's message on a billboard, or, "[m]ore likely, … 'effectively rule[] out'" billboard advertising. *NIFLA*, 138 S. Ct. at 2378. The Ninth Circuit sitting *en banc* found that an earlier version of the City's warning would similarly "drown out Plaintiffs' messages and effectively rule out the possibility of having an advertisement," *ABA III*, 916 F.3d at 757, while "the Ordinance's goals could [have been] accomplished with a smaller warning." *Id*. Now, after the size of the required warning has been reduced to a level below which it would be difficult to read when placed on outdoor advertisements, HSR ¶ 25, it is clear that the City's goals could *not* be accomplished with a smaller warning.[48]

The possibility that a warning about negative health consequences may be incongruent with advertisers' messaging or tarnish perceptions of a brand does not, as Plaintiffs suggest, Pl. Mem. at 13-14, 33, constitute an undue burden.[49] If it did, few warnings could survive. Presumably, associating cigarettes with lung cancer is not the branding message manufacturers seek to convey, nor are associations between alcoholic beverages and fetal damage, or between prescription

[48] The Court did not hold that a warning larger than the minimum size needed for legibility would always be unconstitutional. ABA III, 916 F.3d at 757. What matters is that the warning not drown out the message it accompanies. *See also Zauderer*, 471 U.S. 651 n.14 (review of factual disclosures does not call for "'least restrictive means' analysis").

[49] Plaintiffs again seek to trap regulators in a double-bind that would rule out any warning. A warning that persuades consumers to drink fewer sodas "undermines and interferes with" advertisers' intended message, imposing an undue burden. But if the warning does not change consumer behavior, they would argue that it is not reasonably related to San Francisco's goals.

medications and potential side effects of stroke, heart disease, or suicidal thoughts.

Similarly, few warnings could survive if sellers' threats to stop local outdoor advertising if warnings are implemented count as evidence that their messages are drowned out, as Plaintiffs argue. Pl. Mem. at 14, 33. Advertisers do not have a constitutional right to veto any disclosure that they disfavor by threatening to take their ball and go home.

Nor does extending the mandate even to relatively low-calorie SSBs constitute an undue burden. *See* Compl. ¶¶ 69, 115(c), 116(c). Any cut-off point has an element of arbitrariness and – even when fundamental rights are at stake – where reasonable people might differ, courts in general "should defer to the legislature's line-drawing." *Solem v. Helm*, 463 U.S. 277, 311 n.3 (1983). The additional burden is in any event minimal, as most SSB advertising is for either high-calorie products or for the brand in general,[50] and so would be covered by the Ordinance regardless. San Francisco's choosing 25 calories instead of a slightly higher cut-off does not make the Ordinance unconstitutional.

Notwithstanding Plaintiffs' arguments, the First Amendment does not set an impossibly high bar for disclosure mandates. It does not limit factual and uncontroversial warnings only to those that are ineffective, vanishingly small, approved by advertisers, and congruent with their branding, or those whose text could never be misconstrued. It does not require that no less burdensome alternative is imaginable. To the contrary, courts apply "a lower level of scrutiny" to factual and uncontroversial disclosures like this one. *NIFLA*, 138 S. Ct. at 2378; *accord ABA III*, 916 F.3d at 755. Indeed, the "reasonable relationship" test of *Zauderer*, 471 U.S. 626, has often been likened to "rational basis" review. *See, e.g.*, *Nationwide*, 873 F.3d at 732. Such deferential review of required disclosures is appropriate because "[t]he extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides." *Zauderer*, 471 U.S. at 651. Therefore, the "constitutionally protected interest in *not* providing any particular factual information … is minimal." *Id.* at 650. Elevating companies' preference to keep their customers in the dark about the harmful effects of their products over the public's interest in important information about health is the opposite of

[50] Rudd Center, *Sugary Drink FACTS 2020* (2020), at 7, https://bit.ly/2ZxNPQ0.

what the First Amendment calls for.

A standard that would strike down virtually any disclosure is incompatible with the Supreme Court's recent affirmation that "we do not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products," *NIFLA*, 138 S. Ct. at 2376, and would impede the flow of vital information that consumers need and the First Amendment favors. A regulation, such as San Francisco's SSB warning, that is reasonably related to the City's goal of informing citizens about serious health risks and does not drown out speakers' messages, accords fully with the Constitution.

CONCLUSION

Because San Francisco's SSB warning consists of only factual and uncontroversial statements, is reasonably related to the City's goal of empowering informed decision-making about matters of health, and does not drown out advertisers' speech, the City's Motion for Summary Judgment should be granted, and Plaintiffs' Motion for Summary Judgment should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 26, 2021, I caused to be filed electronically via the Court's CM/ECF System, and thereby served on all counsel, a true and correct copy of this Brief of *Amici Curiae* American Heart Association, American Medical Association, California Medical Association, Center for Science in the Public Interest, ChangeLab Solutions, and Public Health Law Center.

/s/ *Vanessa Buffington*

Vanessa Buffington

APPENDIX
Identity and Interest of *Amici Curiae*

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

2. The American Medical Association (AMA) is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty and in every state, including California. The AMA and CMA join this brief on their own behalves and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state and the District of Columbia. Its purpose is to represent the viewpoint of organized medicine in the courts.

3. California Medical Association (CMA) is a non-profit, incorporated professional physician association of approximately 50,000 members throughout the State of California. For more than 160 years, CMA has promoted the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession. CMA's membership includes California physicians engaged in the private practice of medicine in all specialties and settings. CMA and its physician members advocate for laws and policies that promote the health of their patients and communities.

4. The Center for Science in the Public Interest (CSPI) is America's Food and Health Watchdog, a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. CSPI does not accept government or corporate donations and is supported by donations from individuals and foundations and subscribers to its *Nutrition Action Healthletter*. CSPI has long advocated for legislation, regulation, and judicial decisions to ensure that food labels are clear and transparent and convey useful public health information. In such efforts, CSPI supports healthy beverage choices through education, pricing strategies, labeling, corporate engagement, and other policies. Major victories include getting sugary drinks out of school foods[51] and successfully petitioning the FDA for a declaration of added sugars and daily value on the Nutrition Facts panel.[52]

5. ChangeLab Solutions works across the nation to advance equitable laws and policies that ensure healthy lives for all. With more than two decades of experience in enacting policy, systems, and environmental changes at local and state levels, the organization focuses on eliminating health disparities by addressing the social determinants of health. ChangeLab Solutions is an interdisciplinary team of lawyers, planners, policy analysts, public health practitioners, and other professionals who collaborate with community-based organizations, local and state governments, and anchor institutions to create thriving, just communities. The organization's priority is assisting communities whose residents are at the highest risk for poor health. ChangeLab Solutions works in many interconnected areas, including access to healthy foods and the broader commercial determinants of health. The warning ordinance at issue in this case is adapted from a model sugary drink warning policy drafted by ChangeLab Solutions.

6. The Public Health Law Center is a public interest legal resource center dedicated to improving health through the power of law. Located at Minnesota's largest law school, the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps community leaders improve health by strengthening public policies, with a focus on health equity, in the belief that

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[51] *See* CSPI, Health Group Calls USDA's National School Nutrition Guidelines Historic, https://bit.ly/3uvGBuh.

[52] *See* CSPI, New Nutrition Facts Labels to Feature Added Sugars, with Daily Value, https://bit.ly/3kASvPb.

everyone deserves the opportunity to be healthy. The Center has prepared dozens of publications on the regulation of sugary drinks and assisted communities considering policies to regulate or tax them. The Center has filed seventy-five briefs as *amicus curiae* in the highest courts of the land, including a dozen briefs addressing the regulation of commercial speech harmful to public health. As the designated provider of legal technical assistance to the State of California's Tobacco Control Program and its grantees, the Center has a particular interest in the government's ability to require companies to warn consumers about the dangers of their products.