## UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS

Monica Castro, Damary Santa, and Nancy Helmold, individually and on behalf of all others similarly situated in California, Massachusetts, Illinois, Florida, Michigan, Minnesota, Missouri, New Jersey, New York, and Washington,

Plaintiffs,

- against -

Abbott Laboratories,

Defendant

# **CLASS ACTION COMPLAINT**

Plaintiffs Monica Castro, Damary Santa, and Nancy Helmold (collectively "Plaintiffs"), by their counsel, allege the following upon information and belief, except for allegations pertaining to Plaintiffs, which are based on personal knowledge:

## **BACKGROUND FACTS**

1. The American Academy of Pediatrics (AAP) has, for many years, recommended that infants be breast fed for the first 12 months of life.<sup>1</sup>

2. For those infants for whom breastfeeding is not possible or desired, there are regulated, FDA-approved infant formulas. Infant formula is defined as "a food . . . for special dietary use for infants [0-12 months] by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk." 21 C.F.R. § 106.3.

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<sup>&</sup>lt;sup>1</sup> Jennifer L. Pomeranz, Maria J. Romo Palafox, and Jennifer L. Harris. "<u>Toddler drinks, formulas, and</u> <u>milks: Labeling practices and policy implications</u>." Preventive medicine 109 (2018): 11-16 (citing American Academy of Pediatrics (AAP) Committee on Nutrition and World Health Organization (WHO) findings).

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3. After 12 months, experts recommend whole plain cow's milk, along with water and healthy food, as part of a balanced diet.<sup>2</sup>

4. "Feeding infants and toddlers, including the transition from only breastfeeding or infant formula with iron, to the regular family diet is "critical for establishing healthy dietary preferences and preventing obesity in children."<sup>3</sup>

5. Since 2006, rates of breastfeeding have increased, resulting in a decrease in sales of infant formula.<sup>4</sup>

6. To make up for declining sales of infant formulas, Defendant and other makers of infant formula have introduced products marketed as "transition formulas," "follow-on formulas," "weaning formulas," "toddler milks" and "toddler drinks" to toddlers aged 12 to 36 months.<sup>5</sup>

7. Available market data shows that advertising spending on "transition formulas" quadrupled between 2006 and 2015, and since 2018 the sales of "toddler milks" nationwide have averaged over \$500 million per year.<sup>6</sup>

<sup>4</sup> Fuchs GJ, Abrams SA, Amevor AA, et al; American Academy of Pediatrics, Committee on Nutrition. Older Infant-Young Child "Formulas". Pediatrics. 2023:152(5).

<sup>5</sup> Jennifer L. Pomeranz, Maria J. Romo Palafox, and Jennifer L. Harris. "<u>Toddler drinks, formulas, and</u> <u>milks: Labeling practices and policy implications</u>." Preventive medicine 109 (2018): 11-16.

Attia, S., Fuchs, G., Toddler Formula, Young Child Formula, Growing Up Milk: The Wild West of Young Child Nutrition, J. Pediatric Gastroenterol Nutr. 2023:401.

<sup>&</sup>lt;sup>2</sup> Lott M, Callahan E, Welker Duffy E, Story M, Daniels S. Healthy Beverage Consumption in Early Childhood: Recommendations from Key National Health and Nutrition Organizations. Technical Scientific Report. Healthy Eating Research; 2019. Available at: http://healthyeatingresearch.org.

<sup>&</sup>lt;sup>3</sup> Jennifer L. Harris, and Jennifer L. Pomeranz, "<u>Infant formula and toddler milk marketing:</u> <u>opportunities to address</u> harmful practices and improve young children's diets." Nutrition Reviews (2020).

<sup>&</sup>lt;sup>6</sup> Choi YY, Ludwig A, Harris JL. US toddler milk sales and associations with marketing practices. Public Health Nutr. 2020; 23(6):1127–1135; Dinesh Thakur, U.S. Baby Infant Formula Market, 2018-2032, Allied Market Research Report A10849 (2022)

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8. "Toddler milks," like FDA-regulated infant formulas, are milk powders with added nutrients, are generally sold in the same size metal cans as FDA-regulated infant formulas, are labeled similarly to FDA-regulated infant formulas, and are sold on the same shelves in stores as FDA-regulated infant formulas, even though toddlers aged 12 to 36 months have different dietary needs from infants aged 0 to 12 months.

9. Toddler milk products contain higher saturated fat and sodium and "added sweeteners, including sugar, glucose syrup solids, and honey"—added sugars that are not recommended for children under the age of two."<sup>7</sup>

# Defendant Misleads Consumers That Its "Toddler Drinks" Are Appropriate for <u>Children Over 12 Months</u>

10. Defendant Abbott Laboratories ("Defendant" or "Abbott") has for decades manufactured, distributed and marketed infant formula under the brand name "Similac".

11. For more than four years preceding the filing of this Complaint, and continuing today, Defendant has also manufactured, distributed, and marketed two milk-based powders, "Go & Grow Toddler Drink by Similac" and "Pure Bliss Toddler Drink by Similac," purporting to meet, and be necessary for, the nutritional needs of children between 12 and 36 months ("Toddler Drinks").

12. The labels of Defendant's infant formulas and Defendant's "Toddler Drinks" are deliberately similar:

<sup>&</sup>lt;sup>7</sup> J. Harris, F. Fleming-Milici, et al., Baby Food FACTS Nutrition and marketing of baby and toddler food and drinks, UConn Rudd Center for Food Policy & Obesity January 2017, p. 6.

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13. Defendant's "Toddler Drinks" are also labeled "stage 3" so as to imply to caregivers that they are the next nutritionally recommended product for them to purchase after infant formula, which is numbered "stage 1" and supplemental formula, which is numbered "stage 2." In fact, "Toddler Drinks" are not nutritionally recommended at all.<sup>8</sup> Experts recommend that children above

<sup>&</sup>lt;sup>8</sup> The use of such a numbering system runs contrary to the recommendations of the American Academy of Pediatrics and the World Health Organization. Fuchs GJ, Abrams SA, Amevor AA, et al; American Academy of Pediatrics, Committee on Nutrition. Older Infant-Young Child "Formulas". Pediatrics. 2023:152(5); World Health Organization. Infant and young child feeding. Available at: https://www.who.int/news-room/fact-sheets/detail/infant-and-young-child-feeding.

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12 months be given plain cow's milk, as well as water and healthy foods.





14. Thus, Defendant's "Toddler Drinks" area labeled in a manner designed to give caregivers of toddlers the false impression that the product is nutritionally appropriate for children in the targeted age group -12 to 36 months – when in fact they are not.<sup>9</sup>

# Defendant's Labels Mislead Consumers By Emphasizing Health, Not Sugar

15. As Abbott is well aware, consumers seek out and prefer healthful foods and beverages, especially for their children, and are willing to pay more for, or purchase more often, products marketed and labeled as healthy. For instance, a Nielsen 2015 Global Health & Wellness Survey found that "88% of those polled are willing to pay more for healthier foods."<sup>10</sup>

16. Abbott is a sophisticated marketing company that leverages this knowledge in its marketing strategy for its "Toddler Drinks," prominently touting on their labels the respects in which these products are healthy and nutritious.

<sup>&</sup>lt;sup>9</sup> See Maria J Romo-Palafox and JL Pomeranz et al., "Infant formula and toddler milk marketing and caregiver's provision to young children," Journal of Maternal and Child Nutrition, vol. 16,3 (2020).

<sup>&</sup>lt;sup>10</sup> Nancy Gagliardi, "Consumers Want Healthy Foods—And Will Pay More For Them," *Forbes* (Feb. 18, 2015) (citing Neilson, Global Health & Wellness Survey, at 11 (Jan. 2015)).

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17. The label of Defendant's "Go & Grow Toddler Drink by Similac" represents that it provides "28 Important Nutrients for Growth and Development," as well as "Immune Support," "Brain Development," "Digestive Health," "5 HMO Prebiotics," "DHA," "Lutein," "Vitamin E" and "Total Care," and does *not* contain "artificial growth hormones," "GMOs," or "Palm Olein Oil."

18. The label of Defendant's "Pure Bliss Toddler Drink with Probiotics by Similac" represents that it contains "Probiotics," "DHA," and "Milk from Grass-Fed Cows," and does *not* contain "added corn syrup solids," "artificial growth hormones," "antibiotics," or "GMOs."

19. These representations, individually and especially in combination, are designed and intended to convince consumers that Defendant's "Toddler Drinks" are healthy food choices and will benefit health rather than detract from it.

20. In fact, the labeling of Defendant's "Toddler Drinks" causes caregivers to make inaccurate and ill-advised nutritional purchasing decisions. For example, one study of caregiver attitudes concluded that 52% expected products like Defendant's "Toddler Drinks" to "give toddlers nutrition that they wouldn't get from other sources."<sup>11</sup>

21. 70% of persons surveyed believed that products like Defendant's "Toddler Drinks" were suitable for toddlers, despite expert recommendations that they offer "no unique nutritional value beyond what could be achieved through a nutritionally adequate diet; furthermore, they contribute added sugars to the diet."<sup>12</sup>

22. Contrary to the recommended nutritional needs of children in this age range, Defendant's "Toddler Drinks" contain added sugars. Defendant's "Go & Grow Toddler Drink" contains 4 grams of added sugar per serving, which represents 16 calories out of 70 calories per serving,

<sup>&</sup>lt;sup>11</sup> Maria J Romo-Palafox and JL Pomeranz et al., <u>Marketing claims on infant formula and toddler milk</u> <u>packages: What do caregivers think they mean?</u>, UCONN Rudd Center for Food Policy & Obesity, September 2019.

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or 22.9% added sugar. Defendant's "Pure Bliss Toddler Drink" contains 4 grams of added sugar per serving, which represents 16 calories out of 80 calories per serving, or 20% added sugar.

Corn Syrup Solids	NOT FOR CHILDREN Nutrition Facts 38 servings per container Serving Size 2 Tablespoons (18g) powder	INGREDIENTS: NOFATINULUSTE KNOL R.OWER OL, SIY OL, GULGOLEVIR COCONUT OL, LESS TRATZUE/SIGIR SP. OLL <sup>4</sup> M. ALPING OL BRITANIA	NO ARTIFICIAL GROWTH HORMONES' NON-GMO <sup>†</sup> • NO PALM OLEIN OIL
	Amount per serving         Bit AVRIE Ling Xean mag           Calories         800           % DV*         % DV*           % DV         % DV*           % DV         % DV*           % DV         % DV*           % DV         % DV           % DV         % DV <td< th=""><th>And Fold buildes time datactersteman and Fold buildes time datactersteman And Fold buildes time datactersteman And Fold buildes time datactersteman And Fold buildes time datactersteman Serving size Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Service service servic</th></td<>	And Fold buildes time datactersteman and Fold buildes time datactersteman And Fold buildes time datactersteman And Fold buildes time datactersteman And Fold buildes time datactersteman Serving size Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Tamaño de la porción 2 cucharadas (15 g) de porder Service service servic	
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COWS NET WT. 24.7 OZ (1.54 LB) (700 g)		DERIVED FROM HIS INSUENCEMENT *WORKEDIENTS NOT EXPERICULTINGER Pat. www.abbott.subjettin © 2022 Abbott.labottinis - Stat Stat Stat	* No significant difference has been shown between milk derived from it and non-rbST-treated cows.

23. The recommendation by key national health and nutrition organizations for children above 12 months is *zero* added sugar.<sup>13</sup>

24. Children who are exposed to added sugars tend to consume more sugars as adults. Specifically, children who consume beverages with added sugars are expected to have greater intakes of sweetened beverages as well as sweetened dairy products as adults.<sup>14</sup>

25. Indeed, although there is a vast body of scientific evidence demonstrating that consuming sugar sweetened beverages harms rather than supports overall health—and immune, heart, and digestive health in particular—Defendant adds up to 4 grams of sugar per serving to its "Toddler Drinks." In light of this sugar content, Abbott's representations that its "Toddler Drinks" are nutritious

<sup>&</sup>lt;sup>13</sup> Consensus Statement, <u>Healthy Beverage Consumption in Early Childhood: Recommendations from Key National Health and Nutrition Organizations</u>, Robert Wood Johnson Foundation, Healthy Eating Research, Sept. 2019. *See also* Maria J Romo-Palafox and JL Pomeranz et al., "Infant formula and toddler milk marketing and caregiver's provision to young children," Journal of Maternal and Child Nutrition, vol. 16,3 (2020).

<sup>&</sup>lt;sup>14</sup> Liem DG, Mennella JA. Sweet and sour preferences during childhood: role of early experiences. Dev Psychobiol. 2002; 41(4):388–395

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and healthy are false and misleading.

26. The claims on the labels of Defendant's "Toddler Drinks" are false and misleading because they focus on the products' purported health benefits while omitting information regarding the health harms of their added sugar content.

27. Although, as with Abbott's "Toddler Drinks," "[sugar sweetened] beverages are often fortified with added nutrients that are advertised as providing health benefits, including vitamins, minerals and other herbals," in reality, "the sugar content and potential adverse effects of some additives outweigh any potential benefit these ingredients may provide, especially among youth."<sup>15</sup> Accordingly, "[1]imiting SSBs has been widely promulgated by public health policy and scientific documents as a prudent strategy for promoting optimal nutrition and health."<sup>16</sup> Even a cursory review of the scientific record demonstrates why this is so.

# Sugar-Sweetened Beverage Consumption is Associated with Increased Risk of <u>Cardiovascular Heart Disease and Mortality</u>

28. The scientific literature demonstrates that consumption of sugar-sweetened beverages has deleterious effects on heart health.

29. In a study of preschool children published in January 2020, researchers found that higher consumption of sugar-containing beverages was significantly associated with elevated CMR (cardiometabolic risk) scores. The researchers stated that their "findings support recommendations to limit overall intake of [sugar-containing beverages] in early childhood, in [an] effort to reduce the potential long-term burden of CMR."<sup>17</sup>

<sup>&</sup>lt;sup>15</sup> Pirotin S., Becker C., Crawford PB, "Looking beyond the marketing claims of new beverages: Health risks of consuming sport drinks, energy drinks, fortified waters and other flavored beverages," Atkins Center for Weight and Health, UC Berkeley (2014) [hereinafter "Pirotin, Looking beyond the marketing claims of new beverages"].

<sup>&</sup>lt;sup>16</sup> Zheng, M., et al., "Substitution of SSB with other beverage alternatives," Academy of Nutrition and Dietetics (2015).

<sup>&</sup>lt;sup>17</sup> Eny, KM, et al., "Sugar-containing beverage consumption and cardiometabolic risk in preschool

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30. Consumption of beverages with added sugars should be avoided in order to avoid longterm threats to cardiovascular health. "[M]ost US adults consume more added sugar than is recommended for a healthy diet. A higher percentage of calories from added sugar is associated with significantly increased risk of CVD mortality. In addition, regular consumption of sugar-sweetened beverages is associated with elevated CVD mortality."<sup>18</sup>

31. Sugar-sweetened beverage consumption is also associated with several CHD risk factors. For example, consumption of sugary beverages has been associated with dyslipidemia,<sup>19</sup> obesity,<sup>20</sup> and increased blood pressure.<sup>21</sup>

# Scientific Evidence Demonstrates Sugar-Sweetened Beverage Consumption Impairs the Immune System

32. The scientific literature demonstrates that consumption of sugar-sweetened beverages

has deleterious effects on immune system function.

33. First, neutrophils are the most common type of white blood cell (leukocytes) and they

children." Prev. Med. Reports 17 (Jan. 14, 2020).

<sup>&</sup>lt;sup>18</sup> Yang, Quanhe, et al., "Added Sugar Intake and Cardiovascular Diseases Mortality Among US Adults," *JAMA*, at E8 (pub. online, Feb. 3, 2014).

<sup>&</sup>lt;sup>19</sup> Elliott S.S., et al., "Fructose, weight gain, and the insulin resistance syndrome," *Am. J. Clin. Nutr.*, Vol. 76, No. 5, pp. 911-22 (2002).

<sup>&</sup>lt;sup>20</sup> Faith, M.S., et al., "Fruit Juice Intake Predicts Increased Adiposity Gain in Children From Low-Income Families: Weight Status-by-Environment Interaction," *Pediatrics*, Vol. 118 (2006) ("Among children who were initially either at risk for overweight or overweight, increased fruit juice intake was associated with excess adiposity gain, whereas parental offerings of whole fruits were associated with reduced adiposity gain."); Schulze, M.B, et al., "Sugar-Sweetened Beverages, Weight Gain, and Incidence of Type 2 Diabetes in Young and Middle-Aged Women," *JAMA*, Vol. 292, No. 8, pp. 927-34 (2004) [hereinafter "Schulze, Diabetes in Young & Middle-Aged Women"]; Ludwig, D.S., et al., "Relation between consumption of sugar-sweetened drinks and childhood obesity: a prospective, observational analysis," *Lancet*, Vol. 257, pp. 505-508 (2001); Dennison, B.A., et al., "Excess fruit juice consumption by preschool-aged children is associated with short stature and obesity," *Pediatrics*, Vol. 99, pp. 15-22 (1997).

<sup>&</sup>lt;sup>21</sup> Hoare, E., et al., "Sugar- and Intense-Sweetened Drinks in Australia: A Systematic Review on Cardiometabolic Risk," *Nutrients*, Vol. 9, No. 10 (2017).

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act as the immune system's first line of defense. Neutrophils ordinarily protect the body by traveling to the source of an infection or pathogen where they digest and destroy invading microorganism. But consuming sugar-sweetened beverages like the challenged Toddler Drink products causes blood sugar to rise quickly. This in turn activates an enzyme called protein kinase C, which leads to dysfunction in neutrophils significantly reducing the ability of this important part of the immune system to protect the body and fight off infection.<sup>22</sup>

34. Second, high blood sugar is associated with the inability of immune cells to properly "tag" foreign pathogens so they can be destroyed.<sup>23</sup>

35. Third, high blood sugar contributes to multiple defective immune responses, including a decrease in IL-6, a chemical messenger necessary for a proper immune response.<sup>24</sup>

36. Accordingly, Abbott's marketing its Toddler Drinks as providing "Immune Support" is false, or at least highly misleading.

# The Added Sugar in Toddler Drinks Harms the Gut Microbiota

37. Scientific evidence demonstrates that sugar-sweetened beverage consumption harms gut microbiota and the gut barrier. Diet plays a central role in shaping the microbiota that make up the gut biome in human digestive tracts. In fact, studies "suggest that diet has a dominant role over other possible variables such as ethnicity, sanitation, hygiene, geography, and climate, in shaping the gut microbiota."<sup>25</sup>

<sup>&</sup>lt;sup>22</sup> Jafar N, et al., "The Effect of Short-Term Hyperglycemia on the Innate Immune System," *Am. J. Med. Sci.* Vol. 351(2), 201-11 (Feb. 2016).

<sup>&</sup>lt;sup>23</sup> Margaret K. Hostetter, "Handicaps to Host Defense: Effects of Hyperglycemia on C3 and Candida albicans," *Diabetes* 1; 39 (3): 271–275 (Mar. 1990).

<sup>&</sup>lt;sup>24</sup> Spindler MP et al., "Acute hyperglycemia impairs IL-6 expression in humans," *Immun. Inflamm. Dis.* 19;4(1):91-7 (Jan. 2016).

<sup>&</sup>lt;sup>25</sup> De Filippo, C., et al., "Impact of diet in shaping gut microbiota revealed by a comparative study in children from Europe and rural Africa," *PNAS*, Vol. 107, No. 33, 14691-14696 (August 17, 2010) [hereafter "De Filippo, Diet-Induced Dysbiosis of the Intestinal Microbiota"]; *see also* Brown, K, et

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38. Studies also show that certain types of nutrients have specific effects on the gut microbiota. Relevant here, "diets rich in simple sugars favor the expansion of [harmful microbial] organisms"<sup>26</sup> in at least four separate ways. First, simple sugars serve as a nutrient for harmful bacteria and "[r]ecent studies have shown that high intake of sugars increase the relative abundance of [harmful] Proteobacteria in the gut, while simultaneously decreasing the abundance of [beneficial] Bacteroidetes."<sup>27</sup> Second, high sugar diets result in "lost gut microbial diversity."<sup>28</sup> Third, because consuming sugar increases bile output, "[r]efined sugars," also "mediate the overgrowth of opportunistic[, harmful] bacteria like C. difficile and C. perfringens,"<sup>29</sup> which feed on the bile. Fourth, sugar "can impact gut colonization by the microbiota independently of their ability to serve as nutrients" since both "fructose and glucose silence a critical colonization factor, called Roc, in a widely distributed gut commensal bacterium B. thetaiotaomicron."<sup>30</sup>

al., "Diet-Induced Dysbiosis of the Intestinal Microbiota and the Effects on Immunity and Disease," *Nutrients* 4, 1095-1119 (2012) ("the composition of the gut microbiota strongly correlates with diet as demonstrated by a study assessing the relative contributions of host genetics and diet in shaping the gut microbiota" "dietary changes could explain 57% of the total structural variation in gut microbiota whereas changes in genetics accounted for no more than 12% This indicates that diet has a dominating role in shaping gut microbiota").

<sup>&</sup>lt;sup>26</sup> Townsend II, G., et al., "Dietary sugar silences a colonization factor in a mammalian gut symbiont," *PNAS*, Vol. 116, No. 1, 233-238 (January 2, 2019) [hereinafter "Townsend II, Dietary sugar silences a colonization factor"].

<sup>&</sup>lt;sup>27</sup> Satokari, R., "High Intake of Sugar and the Balance between Pro- and Anti-Inflammatory Gut Bacteria," *Nutrients* 12(5), 1348 (published online May 8, 2020) [hereinafter "Satokari, High Intake of Sugar"].

<sup>&</sup>lt;sup>28</sup> Ho Do, M., et al., "High-Glucose or -Fructose Diet Cause Changes of the Gut Microbiota and Metabolic Disorders in Mice without Body Weight Change," *Nutrients* 2018, 10, 761 (June 13, 2018) [hereinafter "Ho Do, High-Glucose or -Fructose Diet Cause Changes of the Gut Microbiota and Metabolic Disorders "]; *see also* Jian-Mei Li, et al., "Dietary fructose-induced gut dysbiosis promotes mouse hippocampal neuroinflammation: a benefit of short-chain fatty acids," *Microbiome*, 7, Article No. 98 (June 29, 2019) ("The abundance of Bacteroidetes was significantly decreased and Proteobacteria was significantly increased in fructose-fed mice") [hereinafter "Jian-Mei Li, Dietary fructose-induced gut dysbiosis"].

<sup>&</sup>lt;sup>29</sup> De Filippo, Diet-Induced Dysbiosis of the Intestinal Microbiota, *supra* n.25.

<sup>&</sup>lt;sup>30</sup> Townsend II, Dietary sugar silences a colonization factor, *supra* n.26 ("dietary simple sugars can

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39. These changes in the gut microbiota composition harm digestive health and increase risk of chronic digestive tract conditions. Specifically, "[e]vidence suggests that the composition of the intestinal microbiota can influence susceptibility to chronic disease of the intestinal tract including ulcerative colitis, Crohn's disease, celiac disease and irritable bowel syndrome . . . ."<sup>31</sup>

40. In sum, "high sugar intake may stagger the balance of microbiota to have increased pro-inflammatory properties and decreased [] capacity to regulate epithelial integrity and mucosal immunity. Consequently, high dietary sugar can, through the modulation of microbiota, promote metabolic endotoxemia, systemic (low grade) inflammation and the development of metabolic dysregulation and thereby, high dietary sugar may have many-fold deleterious health effects, in addition to providing excess energy."<sup>32</sup>

41. Accordingly, Abbott's marketing of its Toddler Drinks as supporting "Digestive Health" is false, or at least highly misleading.

## Added Sugar in Toddler Drinks Harms the Gut Barrier

42. "The gut barrier consists of a specialized, semi-permeable mucosal, and epithelial cell layers that are reinforced by tight junction proteins. Among other functions, this barrier serves to regulate nutrient and water entry and prevents the entry of harmful compounds into extra-luminal tissues" and the blood.<sup>33</sup>

43. When the permeability of the gut or epithelial barrier is increased, this "allows for the influx of adverse substances and may ultimately contribute to the development of metabolic disorders,

suppress gut colonization in a commensal bacterium just by altering the levels of a colonization factor [know as Roc] dispensable for the utilization of such sugars.").

<sup>&</sup>lt;sup>31</sup> De Filippo, Diet-Induced Dysbiosis of the Intestinal Microbiota, *supra* n.25.

<sup>&</sup>lt;sup>32</sup> Satokari, High Intake of Sugar, *supra* n.27.

<sup>&</sup>lt;sup>33</sup> Noble, E., et al., "Gut to Brain Dysbiosis: Mechanisms Linking Western Diet Consumption, the Microbiome, and Cognitive Impairment," *Front Behav. Neurosci.* 11:9 (January 30, 2017).

and cognitive dysfunction."34

44. "A compromised gut barrier makes the intestinal tract potentially vulnerable to the gram-negative bacteria-derived LPS, which upon excess entry into circulation promotes endotoxemia and systemic inflammation."<sup>35</sup>

45. Both fructose and glucose increase gut barrier permeability.

46. First, "[a]lthough dietary fructose was thought to be metabolized exclusively in the liver, evidence has emerged that it is also metabolized in the small intestine and leads to intestinal epithelial barrier deterioration."<sup>36</sup> A high fructose diet, for example, has been found to result in the "thinning of the intestinal mucosa, epithelium, and muscularis mucosae," and the "loss of crypts and glands," among other harmful effects.<sup>37</sup> This "increase[d] intestinal permeability" "precedes the development of metabolic endotoxemia, inflammation, and lipid accumulation, ultimately leading to hepatic steatosis and normal-weight obesity." <sup>38</sup> In addition, "fructose can escape absorption in the small intestine and reach the microbiota in the distal gut, where microbiota-derived products of fructose metabolism enter the host blood."<sup>39</sup> Thus, "excessive fructose consumption" has been shown to "result[] in barrier deterioration, dysbiosis, low-grade intestinal inflammation, and endotoxemia."<sup>40</sup>

<sup>&</sup>lt;sup>34</sup> *Id*.

<sup>&</sup>lt;sup>35</sup> *Id.* (Studies have found "elevated plasma levels of a gavaged fluorescent molecule (FITC-dextran) that is typically unable to cross the gut barrier.").

<sup>&</sup>lt;sup>36</sup> Febbraio, M., et al., "'Sweet death': Fructose as a metabolic toxin that targets the gut-liver axis," *Cell Metab.*7;33(12):2316-2328 (published online October 6, 2021) [hereinafter "Febbraio, Fructose as a metabolic toxin that targets the gut-liver axis"].

<sup>&</sup>lt;sup>37</sup> Jian-Mei Li, Dietary fructose-induced gut dysbiosis, *supra* n.28.

<sup>&</sup>lt;sup>38</sup> Ho Do, High-Glucose or -Fructose Diet Cause Changes of the Gut Microbiota and Metabolic Disorders, *supra* n.28.

<sup>&</sup>lt;sup>39</sup> Townsend II, Dietary sugar silences a colonization factor, *supra* n.26.

<sup>&</sup>lt;sup>40</sup> Febbraio, Fructose as a metabolic toxin that targets the gut-liver axis, *supra* n.36.

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In short, consuming fructose, like that in the Toddler Drinks, has numerous harmful effects on the gut barrier.<sup>41</sup>

47. Glucose also harms the gut barrier. For example, both a "[high glucose diet] and [high fructose diet] increased gut permeability and disrupted the gut barrier."<sup>42</sup> This harms digestive tract health because "damaged gut barriers" lead to endotoxins crossing the epithelial and into the blood stream, resulting in "higher [blood] plasma endotoxin levels."<sup>43</sup>

48. Moreover, high levels of glucose in the blood, known as "[h]yperglycemia[,] markedly interfere[s] with homeostatic epithelial integrity, leading to abnormal influx of immune-stimulatory microbial products and a propensity for systemic spread of enteric pathogens."<sup>44</sup> This happens, at least in part, because "hyperglycemia causes retrograde transport of glucose into intestinal epithelial cells via GLUT2, followed by alterations in intracellular glucose metabolism and transcriptional reprogramming."<sup>45</sup> In short, "experiments establish hyperglycemia as a direct and specific cause for

<sup>43</sup> *Id*.

<sup>45</sup> *Id*.

<sup>&</sup>lt;sup>41</sup> See Satokari, High Intake of Sugar, *supra* n.27 ("consuming high amounts of sugar harms the gut by "increasing small intestinal permeability in healthy humans,"); Ho Do, High-Glucose or -Fructose Diet Cause Changes of the Gut Microbiota and Metabolic Disorders, *supra* n.28 ("diet induced changes in the gut microbiota affect the expression of tight junction proteins and inflammatory cytokines, which leads to increased gut permeability and inflammation"); Febbraio, Fructose as a metabolic toxin that targets the gut-liver axis, *supra* n.36 ("fructose, . . . led to the downregulation of enterocyte tight-junction proteins and subsequent barrier deterioration, which is in agreement with previous rodents and human studies (Jin et al., 2014; Kavanagh et al., 2013; Lambertz et al., 2017; Spruss et al., 2012)."); Young-Eun Cho, et al., "Fructose Promotes Leaky Gut, Endotoxemia, and Liver Fibrosis Through Ethanol-Inducible Cytochrome P450-2E1–Mediated Oxidative and Nitrative Stress," *Hepatology*, Vol. 73, Issue 6, June 2021, 2180-2195 (April 8, 2019) ("fructose intake causes protein nitration of intestinal [tight-junction] and AJ proteins, resulting in increased gut leakiness, endotoxemia, and steatohepatitis with liver fibrosis").

<sup>&</sup>lt;sup>42</sup> Ho Do, High-Glucose or -Fructose Diet Cause Changes of the Gut Microbiota and Metabolic Disorders, *supra* n.28.

<sup>&</sup>lt;sup>44</sup> Thaiss, C., et al., "Hyperglycemia drives intestinal barrier dysfunction and risk for enteric infection," *Science* 359, 1376–1383 (March 23, 2018) ("We have identified glucose as an orchestrator of intestinal barrier function.").

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intestinal barrier dysfunction and susceptibility to enteric infection,"<sup>46</sup> such that "[b]lood glucose concentrations are associated with microbial product influx in humans[.]"<sup>47</sup>

49. Moreover, because consuming "[s]ugar has [] been shown to irritate the lining of the stomach and intestine," it actually "compromises digestive function and the absorption of nutrients" and can "induce diarrhoea [sic], which may lead to further loss of nutrients."<sup>48</sup>

## Excess Sugar Consumption Causes Type 2 Diabetes

50. Diabetes affects 25.8 million Americans, and can cause kidney failure, lower-limb amputation, and blindness. In addition, diabetes doubles the risk of colon and pancreatic cancers and is strongly associated with coronary artery disease and Alzheimer's disease.<sup>49</sup>

51. In 2010, Harvard researchers also performed a meta-analysis of 8 studies concerning sugar-sweetened beverage consumption and risk of type 2 diabetes, involving a total of 310,819 participants. They concluded that individuals in the highest quantile of SSB intake had an average 26% greater risk of developing type 2 diabetes than those in the lowest quantile.<sup>50</sup> Moreover, "larger studies

<sup>&</sup>lt;sup>46</sup> *Id*.

<sup>&</sup>lt;sup>47</sup> *Id.* (Human studies "suggest that similar to their effects in mice, serum glucose concentrations, rather than obesity, may associate with or potentially even drive intestinal barrier dysfunction in humans.").

<sup>&</sup>lt;sup>48</sup> DiNicolantonio JJ, Berger A., "Added sugars drive nutrient and energy deficit in obesity: a new paradigm," *Open Heart* (2016) [hereinafter "DiNicolantonio, Added sugars drive nutrient and energy deficit"].

<sup>&</sup>lt;sup>49</sup> Aranceta Bartrina, J. et al., "Association between sucrose intake and cancer: a review of the evidence," *Nutrición Hospitalaria*, Vol. 28 (Suppl. 4), 95-105 (2013); Garcia-Jimenez, C., "A new link between diabetes and cancer: enhanced WNT/beta-catenin signaling by high glucose," *Journal of Molecular Endrocrinology*, Vol. 52, No. 1 (2014); Linden, G.J., "All-cause mortality and periodontitis in 60-70-year-old men: a prospective cohort study," *Journal of Clinical Periodontal*, Vol. 39, No. 1, 940-46 (October 2012).

<sup>&</sup>lt;sup>50</sup> Malik, Vasanti S., et al., "Sugar-Sweetened Beverages and Risk of Metabolic Syndrome and Type 2 Diabetes," *Diabetes Care*, Vol. 33, No. 11, at 2477 (Nov. 2010).

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with longer durations of follow-up tended to show stronger associations."<sup>51</sup> Thus, the meta-analysis showed "a clear link between SSB consumption and risk of . . . type 2 diabetes."<sup>52</sup>

52. An analysis of data for more than 50,000 women from the Nurses' Health Study,<sup>53</sup> during two 4-year periods (1991-1995, and 1995-1999), showed, after adjusting for confounding factors, that women who consumed 1 or more sugar-sweetened soft drink per day (*i.e.*, 140-150 calories and 35-37.5 grams of sugar), had an 83% greater relative risk of type 2 diabetes compared with those who consumed less than 1 such beverage per month, and women who consumed 1 or more fruit punch drinks per day had a 100% greater relative risk of type 2 diabetes.<sup>54</sup>

53. The result of this analysis shows a statistically significant linear trend with increasing sugar consumption.<sup>55</sup>

54. Most convincingly, an econometric analysis of repeated cross-sectional data published in 2013 established a causal relationship between sugar availability and type 2 diabetes. After adjusting for a wide range of confounding factors, researchers found that an increase of 150 calories per day related to an insignificant 0.1% rise in diabetes prevalence by country, while an increase of 150 calories per day in sugar related to a 1.1% rise in diabetes prevalence by country, a statically-

 $^{52}$ *Id*.

<sup>55</sup> Hu, F.B., et al., "Sugar-sweetened beverages and risk of obesity and type 2 diabetes: Epidemioligic evidence," *Physiology & Behavior*, Vol. 100, 47-54 (2010).

<sup>&</sup>lt;sup>51</sup>*Id.* at 2481.

<sup>&</sup>lt;sup>53</sup> The Nurses' Health Study was established at Harvard in 1976, and the Nurses' Health Study II, in 1989. Both are long-term epidemiological studies conducted on women's health. The study followed 121,700 women registered nurses since 1976, and 116,000 female nurses since 1989, to assess risk factors for cancer, diabetes, and cardiovascular disease. The Nurses' Health Studies are among the largest investigations into risk factors for major chronic disease in women ever conducted. *See generally*"The Nurses' Health Study,"*at* http://www.channing.harvard.edu/nhs.

<sup>&</sup>lt;sup>54</sup> Schulze, Diabetes in Young & Middle-Aged Women, supra n. 20, at 927-34.

significant 11-fold difference.56

#### Sugar-Sweetened Beverage Consumption is Associated with Increased Risk of Obesity

55. Excess added sugar consumption leads to weight gain and obesity because insulin secreted in response to sugar intake instructs the cells to store excess energy as fat. This excess weight can then exacerbate the problems of excess added sugar consumption, because excess fat, particularly around the waist, is in itself a primary cause of insulin resistance, another vicious cycle. Studies have shown that belly fat produces hormones and other substances that can cause insulin resistance, high blood pressure, abnormal cholesterol levels, and cardiovascular disease. And belly fat plays a part in the development of chronic inflammation in the body, which can cause damage over time, and without any signs or symptoms.

56. A meta-analysis by Harvard researchers evaluating change in Body Mass Index per increase in 1 serving of sugar-sweetened beverages per day found a significant positive association between beverage intake and weight gain.<sup>57</sup>

57. One study of more than 2,000 2.5-year-old children followed for three years found that those who regularly consumed sugar-sweetened beverages between meals had a 240% better chance of being overweight than non-consumers.<sup>58</sup>

58. An analysis of data for more than 50,000 women from the Nurses' Health Study during two 4-year periods showed that weight gain over a 4-year period was highest among women who

<sup>&</sup>lt;sup>56</sup> Basu, S., et al., "The Relationship of Sugar to Population-Level Diabetes Prevelance: An Econometric Analysis of Repeated Cross-Sectional Data," *PLOS Online*, Vol. 8, Issue 2 (February 27, 2013).

<sup>&</sup>lt;sup>57</sup> Malik, V.S., et al., "Sugar-sweetened beverages and BMI in children and adolescents: reanalyses of a meta-analysis," *Am. J. Clin. Nutr.*, Vol. 29, 438-39 (2009).

<sup>&</sup>lt;sup>58</sup> Dubois, L., et al., "Regular sugar-sweetened beverage consumption between meals increases risk of overweight among preschool-aged children," *J. Am. Dietetic Association*, Vol. 107, Issue 6, 924-34 (2007).

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increased their sugar-sweetened beverage consumption from 1 or fewer drinks per week, to 1 or more drinks per day (8.0 kg gain during the 2 periods), and smallest among women who decreased their consumption or maintained a low intake level (2.8 kg gain).<sup>59</sup>

59. A study of more than 40,000 African American women over 10 years had similar results. After adjusting for confounding factors, those who increased sugar-sweetened beverage intake from less than 1 serving per week, to more than 1 serving per day, gained the most weight (6.8 kg), while women who decreased their intake gained the least (4.1 kg).<sup>60</sup>

60. Experimental short-term feeding studies comparing sugar-sweetened beverages to artificially-sweetened beverages have shown that consumption of the former leads to greater weight gain. In one 10-week trial involving more than 40 men and women, the group that consumed daily supplements of sucrose (for 28% of total energy) increased body weight and fat mass—by 1.6 kg for men and 1.3 kg for women—while the group that was supplemented with artificial sweeteners lost weight—1.0 kg for men and 0.3 kg for women.<sup>61</sup>

# Authoritative Bodies Recommend Excluding or Substantially Minimizing Added Sugar Consumption, Especially in the Form of Sugar-Sweetened Beverages

61. Because of the scientific evidence of added sugar's health harms, the FDA has proposed defining "healthy" foods as foods whose added sugar contributes no more than 5% of their calories. The FDA recently published a proposed rule "to update the definition for the implied nutrient content claim 'healthy' to be consistent with current nutrition science and Federal dietary guidance,

<sup>&</sup>lt;sup>59</sup> Schulze, Diabetes in Young & Middle-Aged Women, *supra* n.20.

<sup>&</sup>lt;sup>60</sup> Palmer, J.R., et al., "Sugar-Sweetened Beverages and Incidence of Type 2 Diabetes Mellitus in African American Women," *Archive Internal Med.*, Vol. 168, No. 14, 1487-82 (July 28, 2008).

<sup>&</sup>lt;sup>61</sup> Raben, A., et al., "Sucrose compared with artificial sweeteners: different effects on ad libitum food intake and body weight after 10 wk of supplementation in overweight subjects," *Am. J. Clini. Nutr.*, Vol. 76, 721-29 (2002).

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especially the Dietary Guidelines for Americans (Dietary Guidelines), regarding how consumers can maintain healthy dietary practices."<sup>62</sup> In doing so, the FDA explained, "[e]vidence shows" that "a diet low in added sugars helps individuals achieve a healthy dietary pattern" such that "it is critical that foods" labeled as "healthy' do not contribute to a dietary pattern that contains added sugars over the recommended levels."<sup>63</sup>

62. In order to achieve this, the FDA has proposed "a limit on the amount of added sugars in foods bearing the nutrient content claim 'healthy' to help consumers choose foods that will contribute to a healthy dietary pattern that is lower in added sugars, consistent with current nutrition science and Federal dietary guidance."<sup>64</sup> That limit, "[f]or individual foods," was found to be " $\leq$ 5 percent of the DV [for added sugar] per [Reference Amount Customarily Consumed]," which is " $\leq$ 2 ½ g for adults and children 4 years of age and older[]."<sup>65</sup> In sum, FDA has concluded the scientific evidence supports limiting added sugar to just 5% of calories, or 2.5 grams, in individual foods marketed as healthy due to their nutrient content.

63. The most recent 2020-2025 Dietary Guidelines for Americans state that for individuals 2 to 18 years old, sugar-sweetened beverages "are not necessary in the child or adolescent diet nor are they a component of the USDA Dietary Patterns. . . . Decreasing consumption of sugar-sweetened beverages to reduce added sugars intake will help youth achieve a healthy dietary pattern. Beverages that contain no added sugars should be the primary choice for children and adolescents."<sup>66</sup>

<sup>65</sup> Id.

<sup>&</sup>lt;sup>62</sup> 87 Fed. Reg. 59168, 59168 (Sept. 29, 2022).

<sup>&</sup>lt;sup>63</sup> *Id.* at 59180.

<sup>&</sup>lt;sup>64</sup> Id.

<sup>&</sup>lt;sup>66</sup> U.S. Dep't of Health & Human Servs. and U.S. Dept. of Agric., "Dietary Guidelines for Americans 2020 –2025," at 87 (8th ed.), *available at* https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary\_Guidelines\_for\_Americans\_2020-2025.pdf.

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64. The 2020-2025 Dietary Guidelines for Americans further state that "[m]ost adults' diets include choices across multiple food groups that are not in nutrient-dense forms and therefore cannot accommodate excess calories from sweetened beverages. Intake of sugar-sweetened beverages should be limited to small amounts and most often replaced with beverage options that contain no added sugars, such as water."<sup>67</sup>

65. Numerous other authoritative bodies recommend significantly limiting added sugar and sugar-sweetened beverage consumption. The World Health Organization (WHO) recommends that no more than 10% of an adult's calories, and ideally less than 5%, come from free or added sugar.<sup>68</sup> Additionally, WHO expressly advises "limiting the consumption of . . . sugar-sweetened beverages (i.e. all types of beverages containing free sugars – these include carbonated or non-carbonated soft drinks, fruit or vegetable juices and drinks, liquid and powder concentrates, flavoured water, energy and sports drinks, ready-to-drink tea, ready-to-drink coffee and flavoured milk drinks)[.]"<sup>69</sup>

66. The American Heart Association recommends restricting added sugar to 5% of calories.<sup>70</sup> Based on the average caloric needs, this equates to 12 grams daily for children 4 to 8 years old, up to 25 grams for children up to 18 years old, 25 grams for women, and 38 grams for men. A single Toddler Drink (22g added sugar) thus contains almost twice the daily sugar limit for children 4 to 8 years old, 88% of the daily limit older children and women, and 57% of the daily limit for men.

67. The Heart and Stroke Foundation, in explaining "healthy eating basics," recommends

<sup>69</sup> Id.

<sup>&</sup>lt;sup>67</sup> *Id.* at 102.

<sup>&</sup>lt;sup>68</sup> World Health Organization, "Healthy Diet," *available at* https://www.who.int/news-room/fact-sheets/detail/healthy-diet.

<sup>&</sup>lt;sup>70</sup> Johnson, R.K., et al., on behalf of the American Heart Association Nutrition Committee of the Council on Nutrition, Physical Activity, and Metabolism and Council on Epidemiology and Prevention, "Dietary Sugars Intake and Cardiovascular Health: A Scientific Statement From the American Heart Association," *Circulation*, Vol. 120, 1011-20, at 1016-17 (2009).

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"avoid[ing] sugary drinks."71

68. The Centers for Disease Control and Prevention warns that "[t]oo much sugar in your diet can lead to health problems such as weight gain and obesity, type 2 diabetes, and heart disease" and that "[s]ugary drinks are the leading source of added sugars in the American diet."<sup>72</sup>

69. Public health research has shown that use of products such as the Defendant's "Toddler Drinks" results in prolonged use of expensive, re-branded, powered milk with added sugars instead of transitioning infants to cow's milk, water and other healthy foods. Under World Health Organization standards, the transition to family foods is critical for preventing obesity in young children.<sup>73</sup>

70. According to the Consensus Statement, Healthy Beverage Consumption in Early Childhood: Recommendations from Key National Health and Nutrition Organizations, published by the Robert Wood Johnson Foundation, Division of Healthy Eating Research in September 2019, products like Defendant's "Toddler Drinks" are close to four times more expensive than whole cow's milk, the recommended alternative and a nutritionally superior choice.<sup>74</sup>

71. Defendant's "Toddler Drinks" are sold at a premium price, approximately \$.75 per 15gram serving, which is far more than the value that Plaintiffs and the other members of the Class received. The value of the products Plaintiffs purchased was materially less than the value represented by Defendant.

<sup>&</sup>lt;sup>71</sup> Heart and Stroke Foundation, Healthy eating basics, https://www.heartandstroke.ca/healthy-living/healthy-eating/healthy-eating-basics.

<sup>&</sup>lt;sup>72</sup> Centers for Disease Control and Prevention, Know Your Limit for Added Sugars, <u>https://www.cdc.gov/healthyweight/healthy\_eating/sugar.html</u>.

<sup>&</sup>lt;sup>73</sup> World Health Organization, Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children, 2017 (Recommendation 1).

<sup>&</sup>lt;sup>74</sup> Consensus Statement, <u>Healthy Beverage Consumption in Early Childhood: Recommendations from</u> <u>Key National Health and Nutrition Organizations</u>, Robert Wood Johnson Foundation, Healthy Eating Research, Sept. 2019.

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72. Had Plaintiffs and the members of the Class known the truth, they would not have bought the products or would have paid less for them.

73. Defendant's branding and packaging of its "Toddler Drinks" is designed to – and does
– deceive, mislead, and defraud Plaintiffs and other consumers.

74. Defendant sold more of its "Toddler Drinks" at higher prices than it would have in the absence of this deception, resulting in additional profits at the expense of consumers.

#### JURISDICTION AND VENUE

75. Jurisdiction is proper pursuant to Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. § 1332(d)(2), because the amount in controversy exceeds \$5,000,000, exclusive of interest and costs, and at least one member of the class of plaintiffs is a citizen of a state different from the Defendant.

76. The Court has personal jurisdiction over Defendant Abbott Laboratories because it is incorporated in Illinois, and has purposely availed itself of the benefits of conducting business activities in Illinois through the promotion, marketing, distribution and sale of its Toddler Drinks in Illinois as well as other states.

77. Venue is proper in the Northern District of Illinois pursuant to 28 USC §1391 because Defendant resides in this district, because many of the acts giving rise to this action occurred in this district, and the Defendant has purposely availed itself of the benefits of conducting business activities in this district through the promotion, marketing, distribution and sale of its Toddler Drinks in this district.

#### **PARTIES**

78. Plaintiff Monica Castro is a citizen of Cathedral City, California, who purchased the Defendant's Go & Grow Toddler Drink for household use, specifically for consumption by her 1-yearold toddler, paying over \$30 per can for the product.

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79. Plaintiff Damary Santana is a citizen of Charlestown, Massachusetts, who purchased the Defendant's Pure Bliss Toddler Drink for household use, specifically for consumption by her 1-year old toddler, paying over \$30 per can for the product.

80. Plaintiff Nancy Helmold is a citizen of Chicago, Illinois, who purchased the Defendant's Pure Bliss Toddler Drink for household use, specifically for consumption by her 2-yearold toddler, paying over \$30 per can for the product

81. Defendant Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois.

82. During the relevant statutes of limitations for each cause of action alleged, each Plaintiffs purchased the Defendant's Toddler Drink product in reliance on the Defendant's representations about the product.

83. Each Plaintiff purchased the product at the above-referenced price believing that it was necessary and/or valuable to the nutritional needs of his/her toddler.

84. Each Plaintiff was deceived by and relied upon the product's deceptive labeling.

85. Each Plaintiff would not have purchased the product in the absence of Defendant's misrepresentations and omissions.

86. The product was worth less than what each Plaintiff paid for it and he/she would not have paid as much absent Defendant's false and misleading statements and omissions.

#### **CLASS ACTION ALLEGATIONS**

87. While reserving the right to redefine or amend the class definition prior to or as part of a motion seeking class certification, pursuant to Federal Rule of Civil Procedure 23, Plaintiffs seek to represent a class of all persons in the United States, and subclasses of all persons in California, Massachusetts, Illinois, Florida, Michigan, Minnesota, Missouri, New Jersey, New York or Washington who, at any time within the applicable statute of limitations (the "Class Period"),

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purchased, for personal or household use, and not for resale or distribution, any of the Defendant's Toddler Drinks (the "Class").

88. The members in the proposed Class, and each subclass, are so numerous that individual joinder of all members is impracticable, and the disposition of the claims of all Class Members in a single action will provide substantial benefits to the parties and Court.

89. Questions of law and fact common to Plaintiffs and the Class include:

- whether Abbott communicated a message through the packaging and advertising of the Toddler Drinks that they are nutritious, balanced, or healthful, that they support immune, digestive, and heart health, that they are nutritionally appropriate for toddlers;
- whether those messages are material, or likely to be material, to a reasonable consumer;
- whether the challenged claims are false, misleading, or reasonably likely to deceive a reasonable consumer;
- whether Abbott's conduct violates public policy;
- whether Abbott's conduct violates state or federal food statutes or regulations;
- whether Abbott was unjustly enriched;
- the proper amount of damages, including exemplary damages;
- the proper amount of restitution; and
- the proper amount of attorneys' fees.

90. These common questions of law and fact predominate over questions that affect only individual Class Members.

91. Plaintiffs' claims are typical of Class Members' claims because they are based on the same underlying facts, events, and circumstances relating to Abbott's conduct. Specifically, all Class Members, including Plaintiffs, were subjected to the same misleading and deceptive conduct when they purchased the Abbot's Toddler Drinks and suffered economic injury because the products are misrepresented. Absent Abbott's business practice of deceptively and unlawfully labeling its Toddler Drinks, Plaintiffs and Class Members would not have purchased them or would have paid less for them.

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92. Plaintiffs will fairly and adequately represent and protect the interests of the Class, have no interests incompatible with the interests of the Class, and have retained counsel competent and experienced in class action litigation, and specifically in litigation involving the false and misleading advertising of foods and beverages.

93. Class treatment is superior to other options for resolution of the controversy because the relief sought for each Class Member is small, such that, absent representative litigation, it would be infeasible for Class Members to redress the wrongs done to them.

94. Abbott has acted on grounds applicable to the Class, thereby making appropriate final declaratory relief concerning the Class as a whole.

95. As a result of the foregoing, class treatment is appropriate under Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3).

#### CAUSES OF ACTION

# FIRST CAUSE OF ACTION Violations of the California Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 *et seq.* (On Behalf of the California Subclass)

96. Plaintiffs reallege and incorporate the allegations above as if set forth fully herein.

97. The UCL prohibits any "unlawful, unfair or fraudulent business act or practice." Cal.Bus. & Prof. Code § 17200.

98. The acts, omissions, misrepresentations, practices, and non-disclosures of as alleged herein constitute business acts and practices.

#### **Fraudulent**

99. A statement or practice is fraudulent under the UCL if it is likely to deceive to a reasonable consumer, applying an objective reasonable consumer test.

100. As set forth herein, Abbott's health and wellness claims relating to its Toddler Drinks are likely to deceive reasonable consumers and the public.

#### <u>Unlawful</u>

101. The acts alleged herein are "unlawful" under the UCL in that they violate at least he False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 *et seq.*; and the Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.* 

#### <u>Unfair</u>

102. Abbott's conduct with respect to the labeling, advertising, and sale of its Toddler Drinks was unfair because Abbott's conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers, and the utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.

103. Abbott's conduct with respect to the labeling, advertising, and sale of its Toddler Drinks was and is also unfair because it violates public policy as declared by specific constitutional, statutory or regulatory provisions, including but not necessarily limited to the False Advertising Law, portions of the Federal Food, Drug, and Cosmetic Act, and portions of the California Sherman Food, Drug, and Cosmetic Law.

104. Abbott's conduct with respect to the labeling, advertising, and sale of the Toddler Drinks was and is also unfair because the consumer injury was substantial, not outweighed by benefits to consumers or competition, and consumers could not have reasonably avoided it. Specifically, the increase in profits obtained by Abbott through the misleading labeling does not outweigh the harm to Class Members who were deceived into purchasing the Toddler Drinks believing they were appropriate, nutritious, balanced, or healthy when in fact they are of the type that is likely to detriment health.

105. Abbott profited from the sale of the falsely, deceptively, and unlawfully advertised Toddler Drinks to unwary consumers.

106. Plaintiff Castro and California Class Members are likely to continue to be damaged by Abbott's deceptive trade practices, because Abbott continues to disseminate misleading information.

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107. Abbott's conduct caused and continues to cause substantial injury to Plaintiff Castro and other California Class Members. Plaintiff has suffered injury in fact as a result of Abbott's unlawful conduct.

108. In accordance with Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Abbott from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices, and to commence a corrective advertising campaign.

109. Plaintiff and the Class also seek an order for the restitution of all monies from the sale of the Toddler Drinks, which were unjustly acquired through acts of unlawful competition.

110. Because Plaintiff's claims under the "unfair" prong of the UCL sweep more broadly than her claims under the FAL, CLRA, or UCL's "fraudulent" prong, her legal remedies are inadequate to fully compensate her for all of Abbott's challenged behavior.

111. Moreover, because the Court has broad discretion to award restitution under the UCL and could, when assessing restitution under the UCL, apply a standard different than that applied to assessing damages under the CLRA or commercial code, and restitution is not limited to returning to Plaintiff Castro and California Class Members monies in which they have an interest, but more broadly serves to deter the offender and others from future violations, the legal remedies available under the CLRA and commercial code are more limited than the equitable remedies available under the UCL, and are therefore inadequate.

112. Finally, because the procedures for obtaining relief under the UCL are more efficient than under the CLRA or commercial code, Plaintiff's legal remedies are inadequate.

## SECOND CAUSE OF ACTION Violations of the False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 *et seq.* (On behalf of the California Subclass)

113. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if set forth fully herein.

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114. The California False Advertising Law (FAL) provides that "[i]t is unlawful for any person, firm, corporation or association, or any employee thereof with intent directly or indirectly to dispose of real or personal property or to perform services" to disseminate any statement "which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading." Cal. Bus. & Prof. Code § 17500. It is also unlawful under the FAL to disseminate statements concerning property or services that are "untrue or misleading, and which [are] known, or which by the exercise of reasonable care should be known, to be untrue or misleading." *Id*.

115. As alleged herein, the advertisements, labeling, policies, acts, and practices of Abbott relating to the Toddler Drinks were likely to mislead consumers acting reasonably, as to their healthfulness and their benefits given their nutritional profiles.

116. Plaintiff suffered injury in fact as a result of Abbott's actions as set forth herein because she purchased the Toddler Drinks in reliance on Abbott's false and misleading marketing claims stating or suggesting that the Toddler Drinks are nutritious, balanced, and healthful.

117. Abbott's business practices as alleged herein constitute unfair, deceptive, untrue, and misleading advertising pursuant to the FAL because Abbott has advertised the Toddler Drinks in a manner that is untrue and misleading, which Abbott knew or reasonably should have known, and omitted material information from the Toddler Drinks' labeling.

118. Abbott profited from the sale of the falsely and deceptively advertised the Toddler Drinks to unwary consumers.

119. As a result, Plaintiff Castro, the California Class, and the general public are entitled to injunctive and equitable relief, restitution, and an order for the disgorgement of the funds by which Abbott was unjustly enriched.

120. Pursuant to Cal. Bus. & Prof. Code § 17535, Plaintiff Castro, on behalf of herself and

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the California Class, seeks an order enjoining Abbott from continuing to engage in deceptive business practices, false advertising, and any other act prohibited by law, including those set forth in this Complaint.

121. Because the Court has broad discretion to award restitution under the FAL and could, when assessing restitution under the FAL, apply a standard different than that applied to assessing damages under the CLRA or commercial code, and restitution is not limited to returning to Plaintiff Castro and California Class Members monies in which they have an interest, but more broadly serves to deter the offender and others from future violations, the legal remedies available under the CLRA and commercial code are more limited than the equitable remedies available under the FAL, and are therefore inadequate.

122. In addition, because the procedures for obtaining relief under the FAL are more efficient than under the CLRA or commercial code, Plaintiff's legal remedies are inadequate.

## THIRD CAUSE OF ACTION Violations of the Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.* (On behalf of the California Subclass)

123. Plaintiffs reallege and incorporate the allegations above as if set forth fully herein.

124. The CLRA prohibits deceptive practices in connection with the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.

125. Abbott's false and misleading labeling and other policies, acts, and practices were designed to, and did, induce the purchase and use of the Toddler Drinks for personal, family, or household purposes by Plaintiff Castro and California Class Members, and violated and continue to violate the following sections of the CLRA:

- § 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have;
- § 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another;

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- § 1770(a)(9): advertising goods with intent not to sell them as advertised; and
- § 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

126. Abbott profited from the sale of the falsely, deceptively, and unlawfully advertised Toddler Drinks to unwary consumers.

127. Abbott's wrongful business practices constituted, and constitute, a continuing course of conduct in violation of the CLRA.

128. On information and belief, Defendant's actions were willful, wanton, and fraudulent.

129. On information and belief, officers, directors, or managing agents at Defendant authorized the use of the misleading statements about the Products.

130. Pursuant to California Civil Code § 1782, on November 12, 2024, Plaintiff sent written notice of their claims and Abbott's particular violations of the Act to Abbott, but Abbott has failed to implement remedial measures.

131. Plaintiff and the Class have suffered harm and seek (a) actual damages resulting from purchases of the Toddler Drinks sold throughout the Class Period to all Class Members, (b) punitive damages, (c) injunctive relief in the form of modified advertising and a corrective advertising plan, (d) restitution, and (e) attorneys' fees and costs, under Cal. Civ. Code § 1782(d).

# FOURTH CAUSE OF ACTION Violation of Massachusetts Consumer Protection Statute, G.L. c. 93A (On Behalf of the Massachusetts Subclass)

132. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if set forth fully herein.

133. Plaintiff Santana asserts a claim against Defendant for unfair and deceptive trade practices pursuant to G.L. c. 93A, § 2 and 9.

134. Plaintiff Santana and the Massachusetts Class are "persons" within the meaning of G.L. c. 93A, § 1(a) and are entitled to relief under the act in accordance with G.L. 93A, § 9.

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135. Defendant is engaged in "trade and commerce" as defined by G.L. c. 93A, § 1(b).

136. Plaintiff Santana and the Massachusetts Class entered into consumer transactions by purchasing Toddler Drink products manufactured by Defendant.

137. In its labeling and representations concerning its Toddler Drink products, Defendant engaged in unfair methods of competition, unconscionable acts or practices, and unfair practices, in the conduct of trade or commerce, in violations of G.L. c. 93A, § 2.

138. Defendant also engaged in deceptive acts within the meaning of G.L. c. 93A, § 2(a), including by representing that its Toddler Drink products were nutritionally appropriate for toddlers and by representing that those products were healthy and nutritious when in fact they contained added sugars unnecessary and deleterious to the health of the toddlers to whom they were given. Defendant's representations misled Plaintiff Santana and the members of the Massachusetts Class.

139. Defendant engaged in advertising methods that rendered its advertisements false and misleading, such that Plaintiff Santana and the Massachusetts Class would not have purchased Defendant's Toddler Drink products had they known that Defendants' products were not beneficial or necessary to the health of their toddlers.

140. Defendant also violated G.L. c. 93A by manufacturing, selling and/or distributing its Toddler Drink products in a defective condition unreasonably dangerous to users and consumers, including Plaintiff Santana and the members of the Massachusetts Class.

141. As a proximate result of Defendant's violations of G.L. c. 93A, Plaintiff and the members of the Massachusetts Class have suffered damages.

142. By letter dated August 20, 2024, Plaintiff Santana sent a demand for relief to Defendant, in accordance with § 9(3). Defendant did not respond to Plaintiffs' demand for relief by making a written tender of settlement reasonable for the injuries suffered by Plaintiff Santana and the members of the Massachusetts Class.

## FIFTH CAUSE OF ACTION Violation of Massachusetts False Advertising Statute, G.L. c. 266, §91-91B (On Behalf of the Massachusetts Subclass)

143. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if set forth fully herein.

144. Plaintiff Santana asserts a claim against Defendant for false advertising, pursuant to G.L. c. 266, §91-91B.

145. Defendant, with the intent to sell its Toddler Drink products to the public in Massachusetts, or with the intent to increase the consumption of or demand for those products in Massachusetts, caused, directly or indirectly, to be made, published, disseminated, circulated or placed before the public in Massachusetts, advertising or labeling containing assertions, representations or statements of fact which were untrue, deceptive or misleading, and which such Defendant knew, or might on reasonable investigation have ascertained to be untrue, deceptive or misleading.

146. As a proximate result of Defendant's untrue, deceptive or misleading statements, Plaintiff Santana and the members of the Massachusetts Class, have suffered damages, including payment for Defendant's Toddler Drink products at prices greater than the fair value of those products.

147. Plaintiff Santana and the members of the Massachusetts Class are entitled to an injunction against Defendant's continued false advertising and labeling of its Toddler Drink products in Massachusetts.

## SIXTH CAUSE OF ACTION Violation of Illinois Consumer Fraud and Deceptive Business Practices Law 815 Ill. Comp. Stat. § 505/1, et seq. (On Behalf of the Illinois Subclass)

148. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if set forth fully herein.

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149. This claim is brought against Defendant for engaging in unfair and/or unconscionable business practices under 815 Ill. Comp. Stat. §505/1, et seq. (the "Statute")

150. Plaintiff Helmold and the members of the Class are persons within the meaning of the Statute, and purchased Defendant's products for personal use.

151. Defendant misrepresented the substantive, quantitative, qualitative, and/or compositional attributes of its Toddler Drink products.

152. Plaintiff Helmold and the members of the Illinois Class relied on the statements, omissions and representations of Defendant concerning Defendant's Toddler Drink products, and Defendant knew or should have known the falsity of those statements, omissions and representations.

153. Plaintiff Helmold and the members of the Illinois Class have suffered damages because they would not have purchased Defendant's Toddler Milk products or paid as much for those products if the true facts concerning those products had been disclosed.

## SEVENTH CAUSE OF ACTION Breach of Express Warranty (On behalf of all Classes)

154. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if set forth fully herein.

155. Through the labeling of its Toddler Drinks, Abbott has and has continued to make affirmations of fact or promises, or description of goods, that, *inter alia*, the products offer complete, balanced nutrition, are beneficial to health, and provide specific health benefits.

156. These affirmations and descriptions include:

- "Important Nutrients for Growth and Development"
- "Immune Support"
- "Brain Development"
- "Digestive Health"

- "5 HMO Prebiotics"
- "Probiotics" and
- "Milk from Grass-Fed Cows,"

157. These representations were "part of the basis of the bargain," in that Plaintiffs and the members of all the Classes purchased the Toddler Drinks in reasonable reliance on those statements.

158. Abbott breached its express warranties by selling Toddler Drinks that do not meet the above affirmations, promises, and product descriptions because scientific evidence demonstrates that a balanced, nutritious diet excludes sugar-sweetened beverages, and otherwise limits added sugar for children above 12 months, whereas regular consumption of the Toddler Drinks is detrimental, rather than beneficial to health.

159. Abbott's breach actually and proximately caused injury in the form of the lost purchase price that Plaintiffs and Class Members paid for the Toddler Drinks.

160. As a result, Plaintiff seeks, on behalf of themselves and other Class Members, actual damages resulting from Abbott's breaches of express warranty, including, without limitation, expectation damages.

## EIGHTH CAUSE OF ACTION Breach of Implied Warranty of Merchantability (On behalf of all Classes)

161. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if set forth herein.

162. Abbott, through its acts set forth herein, in the sale, marketing, and promotion of the Toddler Drinks bearing statements outlined in paragraph 157, made representations, that, *inter alia*, the products offer complete, balanced nutrition, are beneficial to health, and provide specific health benefits.

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163. Abbott is a merchant with respect to the goods of this kind which were sold to Plaintiffs and the Class, and there were, in the sale to Plaintiffs and the Class, implied warranties that those goods were merchantable.

164. However, Abbott breached that implied warranty because a balanced, nutritious diet excludes sugar-sweetened beverages for children above 12 months, and otherwise limits added sugar to less than 5% of calories, whereas regular consumption of the Toddler Drinks is detrimental, rather than beneficial to health.

165. As an actual and proximate result of Abbott's conduct, Plaintiffs and the Class did not receive goods as impliedly warranted by Abbott to be merchantable in that they did not conform to promises and affirmations made on the container or label of the goods.

166. As a result, Plaintiffs seek actual damages, including, without limitation, expectation damages.

## NINTH CAUSE OF ACTION Unjust Enrichment (On behalf of all Classes)

167. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if fully set forth herein.

168. Plaintiffs plead this claim in the alternative.

169. Plaintiffs and Class Members conferred upon Abbott an economic benefit, in the form of profits resulting from the purchase and sale of the Toddler Drinks.

170. Abbott's financial benefits resulting from their unlawful and inequitable conduct are economically traceable to Plaintiffs' and Class Members' purchases of the Toddler Drinks and the economic benefits conferred on Abbott are a direct and proximate result of its unlawful and inequitable conduct.

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171. It would be inequitable, unconscionable, and unjust for Abbott to be permitted to retain these economic benefits because the benefits were procured as a direct and proximate result of its wrongful conduct.

172. As a result, Plaintiffs and Class Members are entitled to equitable relief including restitution and/or disgorgement of all revenues, earnings, profits, compensation and benefits which may have been obtained by Abbott as a result of such business practices.

## TENTH CAUSE OF ACTION Negligent Misrepresentation (On behalf of all Classes)

173. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if fully set forth herein.

174. Abbott marketed the Toddler Drinks in a manner conveying to reasonable consumers that the products promote general health and wellness, and provide specific health benefits, like immune support and digestive health.

175. Abbott's misrepresentations regarding the Toddler Drinks are material to a reasonable consumer because they relate to human health, both generally and specifically to immune support and digestive health. Reasonable consumers would attach importance to such representations and would be induced to act thereon in making purchase decisions.

176. In selling the Toddler Drinks, Abbott acted in the ordinary course of its business and had a pecuniary interest in Plaintiffs and Class Members purchasing the Toddler Drinks.

177. Abbott owed a duty of care to Plaintiffs, not to provide false information when they were making purchase decisions regarding the Toddler Drinks.

178. Abbott knew or had been negligent in not knowing that the Toddler Drinks did not promote health, but instead, consuming sugar sweetened beverages, like the Toddler Drinks, harms rather than supports overall health of the average consumer and harms rather than supports immune,

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heart, and digestive health in particular. Abbott had no reasonable grounds for believing its misrepresentations were not false and misleading.

179. Abbott intends that Plaintiffs and other consumers rely on these representations, as evidenced by Abbott's intentional and conspicuous placement of the misleading representations on the Toddler Drinks packaging.

180. Plaintiffs and Class Members have reasonably and justifiably relied on Abbott's misrepresentations when purchasing the Toddler Drinks, and had the correct facts been known, would not have purchased them at the prices at which they were offered.

181. Therefore, as a direct and proximate result of Abbott's negligent misrepresentations, ss and Class Members have suffered economic losses and other general and specific damages, in the amount of the Toddler Drinks' purchase prices, or some portion thereof, and any interest that would have accrued on those monies, all in an amount to be proven at trial.

## ELEVENTH CAUSE OF ACTION Intentional Misrepresentation (On behalf of all Classes)

182. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if set forth in full herein.

183. Abbott marketed the Toddler Drinks in a manner conveying to reasonable consumers that the Products promote general health and wellness, as well as providing specific health benefits, like supporting immune support and digestive health. However, consuming sugar sweetened beverages like the Toddler Drinks harms, rather than supports the overall health of toddlers and harms rather than supports their health. Therefore, Abbott has made misrepresentations about the Toddler Drinks.

184. Abbott's misrepresentations regarding the Toddler Drinks are material to a reasonable consumer because they relate to human health, both generally and specifically to immune support and

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digestive health. A reasonable consumer would attach importance to such representations and would be induced to act thereon in making purchase decisions.

185. At all relevant times, Abbott knew that the misrepresentations were misleading, or has acted recklessly in making the misrepresentations, without regard to their truth.

186. Abbott intends that Plaintiffs and other consumers rely on these misrepresentations, as evidenced by its intentional and conspicuous placement of the misleading representations on the Toddler Drinks' packaging.

187. Plaintiffs and members of the Class have reasonably and justifiably relied on Abbott's intentional misrepresentations when purchasing the Toddler Drinks; had the correct facts been known, they would not have purchased the products at the prices at which the products were offered.

188. Therefore, as a direct and proximate result of Abbott's intentional misrepresentations, Plaintiffs and Class Members have suffered economic losses and other general and specific damages, in the amount of the Toddler Drinks' purchase prices, or some portion thereof, and any interest that would have accrued on those monies, all in an amount to be proven at trial.

#### **PRAYER FOR RELIEF**

Wherefore, Plaintiffs, on behalf of themselves and all other similarly situated, pray for the

entry of judgment against Defendant as to each cause of action, and the following remedies:

- A. An Order declaring this action to be a proper class action, appointing Plaintiffs as class representatives, and appointing undersigned counsel as class counsel;
- B. An Order requiring Defendant to bear the costs of class notice;
- C. An Order enjoining Defendant from using any challenged labeling or marketing that is found to be false, misleading or unlawful;
- D. An Order compelling Defendant to conduct a corrective advertising campaign;
- E. An Order compelling Defendant to destroy all misleading and deceptive labels and advertising materials;

- F. An Order requiring Defendant to pay restitution and to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, or untrue or misleading advertising;
- G. An Order requiring Defendant to pay compensatory, statutory and punitive damages where permitted by law;
- H. An award of pre- and post-judgment interest where available;
- I. An award of attorneys' fees and costs;
- J. Such other and further relief as the Court deems necessary, just or proper.

# JURY DEMAND

Plaintiffs demand a trial by jury on all claims so triable.

Dated January 14, 2025

Respectfully submitted,

# **REESE LLP**

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Counsel for Plaintiffs and the Proposed Classes

# **ClassAction.org**

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: <u>Class Action Lawsuit Says Similac Go &</u> <u>Grow, Pure Bliss Toddler Drinks Are Not as Healthy as Advertised Due to Sugar Content</u>