



throughout the United States and do not conform to their packaging. Plaintiffs seek monetary relief on behalf of the proposed Classes (as defined herein) to restore monies to the members of the proposed Classes. Plaintiffs allege the following based upon personal knowledge as well as publicly available information and investigation by their counsel as to themselves, and as to all other matters, upon information and belief. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

### **NATURE OF THE ACTION**

2. Defendant leads the market for infant formula, following a brief decline in 2022 when contamination issues at its Sturgis, Michigan plant forced a recall and decreased production to address those issues.<sup>2</sup>

3. Defendant sells itself to new parents as a trusted company. However, Abbott never discloses that the Products contained or had a material risk of containing Heavy Metals (hereafter, the “Omissions”). The Omissions would be material to any parent purchasing formula for their infant.

4. Babies rely on breastmilk and/or infant formula for their nutrition and growth. The U.S. Dietary Guidelines for Americans and the American Academy of Pediatrics recommends breastfeeding babies exclusively for about six months from birth and continuing afterwards along

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<sup>2</sup> Forbes, *Once Slowed By Shutdown, Abbott Says Baby Formula Franchise Back Leading U.S. Market*, Jan. 24, 2024, available at <https://www.forbes.com/sites/brucejapsen/2024/01/24/once-shutdown-abbott-labs-says--baby-formula-franchise-back-leading-us-market/> (last accessed March 6, 2025); Abbott News Release, *Abbott Reports Fourth-Quarter and Full-Year 2023 Results; Issues 2024 Financial Outlook*, Jan. 24, 2024, available at <https://www.abbottinvestor.com/static-files/d62c72af-f479-4d79-9746-8934204a6587> (last accessed March 6, 2025).

with introduction of solid foods until they are 12 months old and beyond.<sup>3</sup> However, according to the Centers for Disease Control and Prevention (“CDC”), only 46.5% of babies under three months old are exclusively breastfed, and the percentage of babies exclusively breastfed through six months drops to 27.2%.<sup>4</sup> For babies younger than six months, the CDC recommends that breast milk or infant formula are the only things they eat for their nutrition, and while supplementing with some solid food, breastmilk, or infant formula is recommended up to when they are 24 months old.<sup>5</sup> Therefore, a significant number of babies rely on infant formula for their growth and nutrition in the first year of their lives and beyond.

5. Reasonable parents, like Plaintiffs, trust manufacturers, like Defendant, to sell infant formula that is healthy, nutritious, and free from the presence or material risk of harmful toxins, contaminants, and chemicals. They certainly expect the infant formula they feed their infants to be free of the risk or presence of Heavy Metals, substances known to have significant and unsafe developmental and health consequences as detailed herein.

6. Consumers lack the knowledge or capability necessary to determine whether Defendant’s Products do in fact contain (or have a material risk of containing) Heavy Metals or ascertain the true nature of the ingredients in the Products. Reasonable consumers must and do rely on Defendant to properly and fully disclose what its Products contain. Full disclosure of risks

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<sup>3</sup> CDC, *Infant and Toddler Nutrition: Recommendation and Benefits*, available at [https://www.cdc.gov/infant-toddler-nutrition/breastfeeding/?CDC\\_AAref\\_Val=https://www.cdc.gov/nutrition/infantandtoddlernutrition/breastfeeding/recommendations-benefits.html](https://www.cdc.gov/infant-toddler-nutrition/breastfeeding/?CDC_AAref_Val=https://www.cdc.gov/nutrition/infantandtoddlernutrition/breastfeeding/recommendations-benefits.html) (last accessed March 6, 2025).

<sup>4</sup> CDC, *About Breastfeeding Data*, available at <https://www.cdc.gov/breastfeeding-data/about/index.html> (last accessed March 6, 2025).

<sup>5</sup> CDC, *When, What, and How to Introduce Solid Foods*, available at <https://www.cdc.gov/infant-toddler-nutrition/foods-and-drinks/when-what-and-how-to-introduce-solid-foods.html#:~:text=What%20foods%20to%20introduce%20first,foods%20from%20different%20food%20groups> (last accessed March 6, 2025).

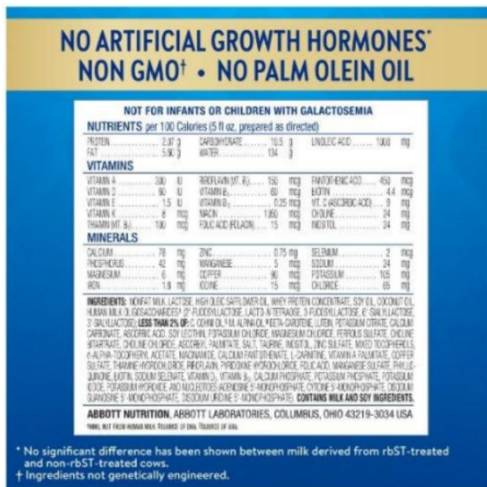
is especially important for products like infant formula, which is fed to hours-, days- or months-old babies. Any parent would deem such information material to his or her purchasing decisions.

7. Defendant’s packaging is designed to induce reasonable consumers to believe in the high quality and safety of its infant formula while omitting any information about the inclusion (or material risk of inclusion) of Heavy Metals.

8. For example, the packaging emphasizes that the Infant Formulas are healthy and made with nutritious ingredients that help support proper development and growth:



9. The packaging on the Infant Formulas also stresses that there are no detrimental, harmful, or genetically engineered ingredients.



10. Defendant states the Infant Formulas contain nutritious ingredients such as Docosahexaenoic Acid (“DHA”), prebiotics such as human milk oligosaccharides (“HMO”), and lutein and beta-carotene.<sup>6</sup>



11. Based on the messaging and overall impression communicated by the packaging and the material nondisclosures, no reasonable consumer could expect or understand that the Infant Formulas contained or risked containing Heavy Metals, especially in these circumstances because the developmental and physical risks created by ingestion of Heavy Metals by infants are well-recognized.

12. Defendant’s website provides further context to demonstrate that the Products’ packaging is deceptive, unfair, and misleading by promising a healthy product that poses no risks to any infants. Specifically, Defendant promises on its website: (1) to give babies “the very best,

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<sup>6</sup> Similac, *What’s in Similac Formula? Baby Formula Ingredients & Nutrition*, available at <https://www.similac.com/baby-formula-ingredients.html> (last accessed March 6, 2025).

with nutrition [parents] can trust to keep [babies] fed, happy, and healthy;”<sup>7</sup> (2) that parents “can be confident in the nourishment of Similac;”<sup>8</sup> and (3) that its Products are “enriched with key vitamins, minerals, and nutrients to help give your little one a strong start.”<sup>9</sup> This information is inconsistent with, if not directly contradictory to, the Omissions.

13. Instead, to induce reasonable consumers to believe in the quality and safety of its Products and justify a price that reflects a premium, Defendant chose to focus on promoting its Infant Formulas on its packaging as high quality and made with nutritious ingredients and to not disclose the true quality of the Products.

14. On information and belief, Defendant was knowingly, recklessly, and/or intentionally selling Infant Formulas that contained detectable levels of arsenic, cadmium, lead, and mercury, all known to pose health risks to humans, and particularly to infants.<sup>10</sup>

15. Testing from 2022 and 2023, which includes Defendant’s own testing as well as Plaintiffs’ testing, shows that at least one heavy metal was present in all but two of the 121 samples tested, meaning only 1.65% had non-detectable levels of any Heavy Metals.

16. Plaintiffs’ testing confirmed the presence of detectable levels of Heavy Metals in the Infant Formulas:

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<sup>7</sup> Similac, *The Similac Difference*, available at <https://www.similac.com/the-similac-difference.html> (last accessed March 7, 2025).

<sup>8</sup> Similac, *Why Similac*, available at <https://www.similac.com/why-similac.html> (last accessed March 7, 2025).

<sup>9</sup> Similac, *The Similac Difference*, available at <https://www.similac.com/the-similac-difference.html> (last accessed March 7, 2025).

<sup>10</sup> Healthy Babies Bright Futures’ Report: *What’s in My Baby’s Food?*, available at [https://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2020-04/BabyFoodReport\\_ENGLISH\\_R6.pdf](https://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2020-04/BabyFoodReport_ENGLISH_R6.pdf) (last accessed March 7, 2025) (“HBBF Report”).

Infant Formula	Level of Heavy Metal in parts per billion (“ppb”)
Similac® Soy Isomil	59.3 ppb (Arsenic)
Similac® Soy Isomil	11.4 ppb (Cadmium)
Similac® Total Comfort	39.2 ppb (Arsenic)
Similac® Total Comfort	3.0 ppb (Lead)
Similac® 360 Total Care	6.7 ppb (Arsenic)
Similac® Advance	3.0 ppb (Lead)
Similac® Pro Advance	10.1 ppb (Mercury)
Similac® NeoSure	7.8 ppb (Arsenic)
Similac® NeoSure	3.6 ppb (Lead)

17. Third party testing also confirmed the presence of two Heavy Metals in another of Defendant’s Products:<sup>11</sup>

Infant Formula	Level of Arsenic	Level of Lead
Similac® Advance OptiGRO Powder – Milk-Based	4.6 ppb	2 ppb

18. Defendant has publicly taken the position that Heavy Metals are ubiquitous and that trace levels occur in almost everything that infants and children consume. Defendant also has previously conceded that Heavy Metals are present in its Infant Formula.

19. Arsenic, cadmium, lead, and mercury are all known to pose health risks to humans, and particularly to infants.<sup>12</sup>

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<sup>11</sup> *Id.* at 20, 34.

<sup>12</sup> *See generally id.*

20. Science supports that the presence of Heavy Metals at any level in infant formula is harmful due to accumulation and the vulnerability of infants.

21. Exposure to Heavy Metals has significant and dangerous health consequences. A recent report by the U.S. House of Representatives' Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform highlighted the material risk of the inclusion of Heavy Metals in baby food, spurred by the knowledge that “[e]ven low levels of exposure can cause serious and often irreversible damage to brain development.”<sup>13</sup>

22. Despite the known health risks, Defendant knowingly chose to not disclose to consumers that the Infant Formulas contain (or have a material risk of containing) Heavy Metals. Nowhere on the Infant Formulas' packaging is it disclosed that they contain (or have a material risk of containing) Heavy Metals.

23. The Infant Formulas' packaging does not include any type of disclaimer or disclosure regarding the presence of Heavy Metals that would inform consumers of their presence or risk. Likewise, nothing on the packaging states that ingestion of Heavy Metals can be unsafe or accumulate over time resulting in developmental issues, poisoning, injury, and/or disease.

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<sup>13</sup> U.S. House of Representatives, Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, Staff Report, *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury*, Feb. 4, 2021, available at <https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf> (last accessed March 7, 2025) (“Congressional Committee Report”); *see also* U.S. House of Representatives, Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, Staff Report, *New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby Foods*, Sept. 29, 2021, available at <https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/ECP%20Second%20Baby%20Food%20Report%209.29.21%20FINAL.pdf> (last accessed March 7, 2025) (“Second Congressional Committee Report”).



24. Instead, to induce reasonable consumers to believe in the quality and safety of its Products and to justify a price that reflects a premium, Defendant chose to focus on promoting its Infant Formulas on its packaging as high quality and made with nutritious ingredients.

25. Defendant's marketing strategy reflects the concerns raised by the World Health Organization ("WHO") and UNICEF in its report acknowledging the troubling marketing efforts by infant formula milk manufacturers.<sup>14</sup> This report raises deep concerns over the lasting and pervasive negative effects from the false and misleading information received by parents such as Plaintiffs through such aggressive marketing efforts by infant formula manufacturers such as Defendant.<sup>15</sup>

26. Heavy Metals can be harmful, in that, with accumulation, they risk inhibiting the growth and development of a child, even if the amount in Defendant's formula would not cause (physical) injury on its own.

27. It is undisputed that government agencies and other experts acknowledge there are no known safe levels of heavy metals. For example, as governmental and medical experts testified:

- Conrad Choiniere, Director of the Office of Analytics and Outreach in the U.S. Food and Drug Administration's ("FDA") Center for Food Safety and Applied Nutrition: "However overall exposure adds up because many of the foods we eat contain these contaminants in small amounts. This is not to say that we should not be concerned. On the contrary, for the contaminants we are

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<sup>14</sup> WHO, *How the Marketing of Formula Milk Influences our Decisions on Infant Feeding*, February 22, 2022, available at <https://www.who.int/teams/maternal-newborn-child-adolescent-health-and-ageing/formula-milk-industry> (last accessed March 7, 2025).

<sup>15</sup> National Public Radio, *Infant Formula Promoted In 'Aggressive' and 'Misleading' Ways, Says New Global Report*, March 1, 2022, available at <https://www.npr.org/sections/goatsandsoda/2022/03/01/1082775961/infant-formula-promoted-in-aggressive-and-misleading-ways-says-new-global-report> (last accessed March 7, 2025).

discussing today, we have not identified safe levels of exposure for developmental outcomes.”<sup>16</sup>

- Dr. Aparna Bole, pediatrician speaking on behalf of the American Academy of Pediatrics: “There is no known safe level of exposure to these metals for children. Exposure to toxic elements has a disproportionate effect on infants and toddlers because their brains are rapidly developing, especially during their first 1,000 days.”<sup>17</sup>
- Dr. Karagas, Professor and Chair of the Department of Epidemiology at the Geisel School of Medicine at Dartmouth College: “Arsenic, cadmium, mercury and lead, shown here, circled in these red circles, they do not have any known physiologic essential function in the body and there is no known safe level to our knowledge.”<sup>18</sup>

28. Based on Defendant’s packaging, overall impression, and related material omissions, no reasonable consumer had any reason to know or expect that the Infant Formulas contained Heavy Metals. Furthermore, reasonable parents, like Plaintiffs, who were feeding the Infant Formulas to their babies (multiple times a day) would consider the mere presence (or risk) of Heavy Metals a material fact when considering whether to purchase the Infant Formulas.

29. Defendant knows its customers trust the quality of its Products that are manufactured for the most vulnerable population—infants—and expect the Infant Formulas to be

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<sup>16</sup> Transcript from Public Meeting, *Closer to Zero Action Plan: Impacts of Toxic Element Exposure and Nutrition at Different Crucial Developmental Stages for Babies and Young Children*, Nov. 18, 2021, available at <https://www.fda.gov/media/155396/download?attachment> at 32 (last accessed March 6, 2025).

<sup>17</sup> *Id.* at 179.

<sup>18</sup> *Id.* at 72.

properly and safely manufactured and to not contain or risk containing Heavy Metals. Defendant also knows its consumers seek out and wish to purchase infant formulas that possess nutritious ingredients free of toxins, contaminants, or chemicals, including Heavy Metals, and that these consumers will pay for infant formulas they believe possess these qualities.

30. Defendant knew that parents would find the Omissions material when deciding whether to purchase the Infant Formulas and that it was in a special position of public trust to those consumers.

31. The Infant Nutrition Council of America (“INCA”), of which Defendant is one of three members, vehemently opposed California’s 2023 Assembly Bill 899 (“AB 899”) claiming that requiring infant formula manufacturers to disclose heavy metals test results would create “significant confusion” and “fear and panic” among consumers and cause them to “mistrust” the manufacturers. INCA also argued that such requirements would cause consumers to change their purchasing behaviors. Following INCA’s public opposition to AB 899, infant formula manufacturers were removed from the bill before it was finalized.

32. The material Omissions are deceptive, unfair, misleading, and/or false because the Infant Formulas contain (or risk containing) undisclosed Heavy Metals.

33. The Omissions allowed Defendant to capitalize on and reap enormous profits from reasonable consumers who paid a premium price for Infant Formulas that did not disclose material information as to the Products’ true quality and value. Defendant continues to wrongfully induce consumers to purchase its Infant Formulas without full disclosure of the Omissions.

34. Plaintiffs bring this proposed consumer class action individually and on behalf of all other members of the Classes (as defined herein), who, from the applicable limitations period

up to and including the present, purchased for household use and not resale any of Defendant's Infant Formulas.

### **JURISDICTION AND VENUE**

35. This Court has original jurisdiction over all causes of action asserted herein under the Class Action Fairness Act, 28 U.S.C. §1332(d)(2), because the matter in controversy exceeds the sum or value of \$5,000,000 exclusive of interest and costs and more than two-thirds of the Class resides in states other than the state in which Defendant is a citizen and in which this case is filed, and therefore any exemptions to jurisdiction under 28 U.S.C. §1332(d)(2) do not apply.

36. Venue is proper in this Court pursuant to 28 U.S.C. §1391, because Plaintiffs suffered injury as a result of Defendant's acts in this District, many of the acts and transactions giving rise to this action occurred in this District, and Defendant conducts substantial business in this District and is headquartered in this District.

### **THE PARTIES**

37. Plaintiff Tiffany Huggins ("Plaintiff Huggins") is, and at times relevant hereto was, a citizen of the State of Washington and a resident of Sequim, Washington. She purchased the Infant Formula, including Similac Pro Advance, Similac 360 Total Care, and Similac Advance, for household use.

38. Plaintiff Huggins purchased the Infant Formula for her child from Walmart in Sequim, Washington, from approximately 2021 until 2022.

39. Plaintiff Huggins believed she was feeding her child healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Huggins saw and relied upon the packaging of the Infant Formula. During the time she purchased and fed her child the Infant Formula, and due to the Omissions by Defendant, she was unaware the Infant Formula contained

(or had a material risk of containing) Heavy Metals and would not have purchased the Infant Formula if that information had been fully disclosed.

40. Plaintiff Lauren Nunez (“Plaintiff Nunez”) is, and at times relevant hereto was, a citizen of the State of California and a resident of Sylmar, California. She purchased the Infant Formula, including Similac 360 Total Care, for household use.

41. Plaintiff Nunez purchased the Infant Formula for her child from Target and Ralph’s in Granada Hills, California and Northridge, California from approximately March 2023 to December 2023.

42. Plaintiff Nunez believed she was feeding her child healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Nunez saw and relied upon the packaging of the Infant Formula. During the time she purchased and fed her child the Infant Formula, and due to the Omissions by Defendant, she was unaware the Infant Formula contained (or had a material risk of containing) Heavy Metals and would not have purchased the Infant Formula if that information had been fully disclosed.

43. As the result of Defendant’s intentionally, recklessly, and/or knowingly deceptive, unfair, and misleading conduct as alleged herein, Plaintiffs were injured when they paid the purchase price or a price premium for the Infant Formula that did not deliver what was promised by Defendant. Plaintiffs paid the purchase price on the reasonable assumptions that the packaging was accurate, did not contain or risk containing Heavy Metals, and posed no potential harm to the physical and mental growth of their babies – long term or short term. Plaintiffs would not have paid this money had they known the truth about the Omissions. Damages can be calculated through expert testimony at trial.

44. Defendant Abbott Laboratories is a Delaware corporation with a principal place of business in Abbott Park, Illinois, in Lake County. Defendant has intentionally availed itself of the laws and markets of this District, and Defendant is subject to personal jurisdiction in this District.

45. Defendant, one of the largest producers of infant formula products in the world, has formulated, developed, manufactured, labeled, distributed, marketed, advertised, and sold the Infant Formulas under the Similac® name throughout the United States, including in this District. It has done so continuously from March 7, 2019, to present (the “Relevant Period”). Defendant knowingly created, allowed, oversaw, and/or authorized the unlawful, fraudulent, unfair, misleading, and/or deceptive packaging and related marketing for the Infant Formulas that did not disclose the presence (or risk) of Heavy Metals. Defendant is also responsible for sourcing ingredients, manufacturing the Products, and conducting all relevant quality assurance protocols, including testing of both the ingredients and finished Infant Formulas.

46. Plaintiffs relied upon the Infant Formulas’ packaging and the material Omissions, which were prepared, reviewed, and/or approved by Defendant and its agents at its headquarters in Illinois and disseminated by Defendant and its agents through the material Omissions from the packaging. The Omissions were nondisclosed material content that a reasonable consumer would consider important in purchasing the Infant Formulas.

47. The Infant Formulas, at a minimum, include:

(a) Similac® Soy Isomil:



(b) Similac® 360 Total Care:



(c) Similac® Pro Advance Label:



(d) Similac® Advance OptiGRO Powder – Milk-Based:





(e) Similac® Neosure:



(f) Similac® Total Comfort:



## FACTUAL ALLEGATIONS

### **I. Defendant Knew or Should Have Known of the Health Risks Presented to Infants and Children from Heavy Metals and The Likelihood They Were Present in Its Products**

48. Although there are no U.S. federal regulations regarding acceptable levels of Heavy Metals in infant formulas, it is not due to a lack of risk. Government agencies and other experts acknowledge there are no known safe levels of heavy metals.

- Conrad Choiniere, Director of the Office of Analytics and Outreach in the FDA’s Center for Food Safety and Applied Nutrition: “However overall exposure adds up because many of the foods we eat contain these contaminants in small amounts. This is not to say that we should not be concerned. On the contrary, for the contaminants we are discussing today, we have not identified safe levels of exposure for developmental outcomes.”<sup>19</sup>
- Dr. Aparna Bole, pediatrician speaking on behalf of the American Academy of Pediatrics: “There is no known safe level of exposure to these metals for children. Exposure to toxic elements has a disproportionate effect on infants and toddlers because their brains are rapidly developing, especially during their first 1,000 days.”<sup>20</sup>
- Dr. Karagas, Professor and Chair of the Department of Epidemiology at the Geisel School of Medicine at Dartmouth College: “Arsenic, cadmium, mercury

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<sup>19</sup> Transcript from Public Meeting, *Closer to Zero Action Plan: Impacts of Toxic Element Exposure and Nutrition at Different Crucial Developmental Stages for Babies and Young Children*, Nov. 18, 2021, available at <https://www.fda.gov/media/155396/download?attachment> at 32 (last accessed March 6, 2025).

<sup>20</sup> *Id.* at 179.

and lead, shown here, circled in these red circles, they do not have any known physiologic essential function in the body and there is no known safe level to our knowledge.”<sup>21</sup>

49. According to Linda McCauley, Dean of the Nell Hodgson Woodruff School of Nursing at Emory University, who studies environmental health effects, “No level of exposure to these [heavy] metals has been shown to be safe in vulnerable infants.”<sup>22</sup>

50. Indeed, the FDA has acknowledged that “exposure to [these four heavy] metals are likely to have the most significant impact on public health” and has prioritized them in connection with its heavy metals workgroup looking to reduce the risks associated with human consumption of heavy metals.<sup>23</sup>

51. Arsenic, lead, mercury, and cadmium—the Heavy Metals found in the Infant Formulas—are neurotoxins, or poisons, which affect the nervous system. Exposure to these Heavy Metals “diminish[es] quality of life, reduce[s] academic achievement, and disturb[s] behavior, with profound consequences for the welfare and productivity of entire societies.”<sup>24</sup>

52. The Heavy Metals “can harm a baby’s developing brain and nervous system” and cause negative impacts such as “the permanent loss of intellectual capacity and behavioral problems like attention-deficit hyperactivity disorder (“ADHD”).”<sup>25</sup> Even when trace amounts are

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<sup>21</sup> *Id.* at 72.

<sup>22</sup> *Some Baby Food May Contain Toxic Metals, U.S. Reports*, available at <https://www.nytimes.com/2021/02/04/health/baby-food-metals-arsenic.html> (last accessed March 7, 2025) (“Some Baby Food May Contain Toxic Metals”).

<sup>23</sup> FDA, *Environmental Contaminants in Food*, available at <https://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/default.htm> (last accessed March 7, 2025) (“Metals and Your Food”).

<sup>24</sup> HBBF Report, *supra*, at 13.

<sup>25</sup> *Id.* at 6.

found in food, these Heavy Metals can alter the developing brain and erode a child's intelligence quotient ("IQ").<sup>26</sup>

53. Because Heavy Metals accumulate in the body, including in the kidneys and other internal organs, the risk they pose grows over time and can remain in one's body for years.<sup>27</sup>

54. Due to their smaller physical size and still-developing brain and organs, infants and toddlers are particularly susceptible to the toxic effects of Heavy Metals because "[t]hey also absorb more of the heavy metals that get into their bodies than adults do."<sup>28</sup>

55. Of additional concern to developing infants are the health risks related to simultaneous exposure to multiple Heavy Metals as "co-exposures can have interactive adverse effects."<sup>29</sup> Heavy Metals disturb the body's metabolism and cause "significant changes in various biological processes such as cell adhesion, intra- and inter-cellular signaling, protein folding, maturation, apoptosis, ionic transportation, enzyme regulation, and release of neurotransmitters."<sup>30</sup>

56. Exposure to Heavy Metals, even in small amounts, can lead to life-long effects. According to Victor Villarreal, Ph.D., Assistant Professor in the Department of Educational

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<sup>26</sup> Congressional Committee Report, *supra*, at 1.

<sup>27</sup> Consumer Reports, *Heavy Metals in Baby Food: What You Need to Know*, Aug. 16, 2018, available at <https://www.consumerreports.org/health/food-safety/heavy-metals-in-baby-food-a6772370847/> (last accessed March 7, 2025) ("Consumer Reports: Heavy Metals in Baby Food").

<sup>28</sup> *Id.*

<sup>29</sup> Morello-Frosch R., Cushing L.J., Jesdale B.M., Schwartz J.M., Guo W., Guo T., Wang M., Harwani S., Petropoulou S.E., Duong W., Park J.S., Petreas M., Gajek R., Alvaran J., She J., Dobraca D., Das R., Woodruff T.J. *Environmental Chemicals in an Urban Population of Pregnant Women and Their Newborns from San Francisco*. *Environ Sci Technol*. 2016 Nov 15;50(22):12464-12472. doi: 10.1021/acs.est.6b03492. Epub 2016 Oct 26. PMID: 27700069; PMCID: PMC6681912. Available at <https://stacks.cdc.gov/view/cdc/80511> (last accessed March 7, 2025).

<sup>30</sup> Jaishankar, M., Tseten, T., Anbalagan, N., Mathew, B. B., & Beeregowda, K. N. (2014). *Toxicity, mechanism and health effects of some heavy metals*. *Interdisciplinary toxicology*, 7(2), 60–72. Available at <https://doi.org/10.2478/intox-2014-0009> (last accessed March 7, 2025).

Psychology at the University of Texas at San Antonio who has studied the effects of Heavy Metals on childhood development, “[t]he effects of early exposure to heavy metals can have long-lasting impacts that may be impossible to reverse.”<sup>31</sup>

57. Because Heavy Metals can bioaccumulate in the body, even regular consumption of small amounts can increase the material risk of various health issues, including the material risk of bladder, lung, and skin cancer; cognitive and reproductive problems; and type 2 diabetes.<sup>32</sup>

58. Research continues to confirm that exposures to food containing arsenic, lead, mercury, and cadmium causes “troubling risks for babies, including cancer and lifelong deficits in intelligence[.]”<sup>33</sup>

59. The FDA and the WHO have declared Heavy Metals “dangerous to human health, particularly to babies and children, who are most vulnerable to their neurotoxic effects.”<sup>34</sup>

### ***Arsenic***

60. The Infant Formulas contain (or have a material risk of containing) arsenic, which can cause cognitive deficits in children who are exposed early in life, and even neurological problems in adults who were exposed as infants.<sup>35</sup> “[E]ven low levels of arsenic exposure can impact a baby’s neurodevelopment.”<sup>36</sup> “Studies have shown that consuming products with arsenic

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<sup>31</sup> Consumer Reports: Heavy Metals in Baby Food, *supra*.

<sup>32</sup> Consumer Reports: Heavy Metals in Baby Food, *supra*.

<sup>33</sup> HBBF Report, *supra*, at 1.

<sup>34</sup> Congressional Committee Report, *supra*, at 2.

<sup>35</sup> HBBF Report, *supra*, at 13.

<sup>36</sup> Senators’ Letter to the FDA, *supra* (citing Dartmouth Toxic Metals Superfund Research Program (2021), Arsenic and Children, <https://sites.dartmouth.edu/arsenicandyou/arsenic-and-children/>) (last accessed March 7, 2025)).

over time can lead to impaired brain development, growth problems, breathing problems, and a compromised immune system.”<sup>37</sup>

61. Arsenic exposure can also cause respiratory, gastrointestinal, hematological, hepatic, renal, skin, neurological and immunological effects, and damage children’s central nervous systems and cognitive development.<sup>38</sup> Exposure to arsenic can also cause diabetes, atherosclerosis, and cardiovascular disease.<sup>39</sup>

62. Arsenic can cause cancer in humans, as well as diabetes and atherosclerosis, and potentially cardiovascular disease when ingested chronically.<sup>40</sup> Chronic exposure to arsenic has also been associated with dermatological lesions and malignancies.<sup>41</sup>

63. Moreover, “[t]here is no evidence that the harm caused by arsenic is reversible.”<sup>42</sup>

64. Based on the risks associated with exposure to higher levels of arsenic, both the U.S. Environmental Protection Agency (“EPA”) and FDA have set limits concerning the allowable limit of arsenic at 10 ppb for human consumption in apple juice (regulated by the FDA) and

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<sup>37</sup> *Id.*

<sup>38</sup> Congressional Committee Report, *supra*, at 10.

<sup>39</sup> States J.C., Singh A.V., Knudsen T.B., Rouchka E.C., Ngalame N.O., Arteel G.E., et al. (2012) *Prenatal Arsenic Exposure Alters Gene Expression in the Adult Liver to a Proinflammatory State Contributing to Accelerated Atherosclerosis*. PLOS ONE 7(6): e38713. Available at <https://doi.org/10.1371/journal.pone.0038713> (last accessed March 7, 2025) (“Prenatal Arsenic Exposure”).

<sup>40</sup> *Id.*

<sup>41</sup> Genuis SJ, Schwalfenberg G, Siy A-KJ, Rodushkin I (2012) *Toxic Element Contamination of Natural Health Products and Pharmaceutical Preparations*. PLOS ONE 7(11): e49676. Available at <https://doi.org/10.1371/journal.pone.0049676> (last accessed March 7, 2025) (“Toxic Element Contamination of Natural Health Products”).

<sup>42</sup> HBBF Report, *supra*, at 3.

drinking water (regulated by the EPA as a maximum contaminant level). The FDA has set the maximum allowable arsenic levels in bottled water at 10 ppb of inorganic arsenic.<sup>43</sup>

65. Although the FDA has not set the action level for arsenic in infant formulas specifically, “the FDA prioritizes monitoring and regulating products that are more likely to be consumed by very young children.”<sup>44</sup> The FDA’s limit for inorganic arsenic in bottled water is 10 ppb.<sup>45</sup>

66. Dr. James E. Rogers, the director of food safety research and testing at Consumer Reports, has said “[t]here is *no safe level of heavy metals*, so the goal should be to have no measurable levels of any heavy metal in baby and toddler foods.”<sup>46</sup> This rings particularly true when considering that, generally, babies who are 12 months or younger heavily rely on infant formula as a key source of nutrients and unless breastmilk is an option, formula is the only food babies younger than 5 months can eat for their development and growth.

67. Despite this, laboratory tests indicate that Defendant sold Products containing undisclosed arsenic levels at 59.3 ppb, an amount that is especially concerning considering the amount of infant formula consumed by developing children.

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<sup>43</sup> Toxic Heavy Metals in Popular Baby Foods, *supra*.

<sup>44</sup> NutritionInsight.com, *FDA Studies Reveal Drop In Infant Rice Cereal’s Arsenic Levels*, March 9, 2020, available at <https://www.nutritioninsight.com/news/fda-studies-reveal-drop-in-infant-rice-cereals-arsenic-levels.html> (last accessed March 7, 2025).

<sup>45</sup> 21 C.F.R. §165.110(b)(4)(iii)(A).

<sup>46</sup> Consumer Reports, *Congressional Report Finds More Problems With Heavy Metals in Baby Food*, updated Oct. 2021, available at <https://www.consumerreports.org/food-safety/problems-with-heavy-metals-in-baby-food-congressional-report-a6400080224/#:~:text=%E2%80%9CThere%20is%20no%20safe%20level,research%20and%20testing%20at%20CR> (last accessed March 7, 2025) (emphasis added).

### *Cadmium*

68. The Infant Formulas also contain (or have a material risk of containing) cadmium, which has been shown to cause anemia, liver disease, and nerve or brain damage in animals that eat or drink it.

69. Cadmium is linked to neurotoxicity, cancer, and kidney, bone, and heart damage. Scientists have reported a “tripling of risk for learning disabilities and special education among children with higher cadmium exposures, at exposure levels common among U.S. children[.]”<sup>47</sup>

70. Cadmium, like lead, “displays a troubling ability to cause harm at low levels of exposure.”<sup>48</sup> The U.S. Department of Health and Human Services has determined that cadmium and cadmium compounds are known human carcinogens, and the EPA has likewise determined that cadmium is a probable human carcinogen.<sup>49</sup> Compounding such concerns is the fact that cadmium has a prolonged half-life as it “sequesters in [human] tissue.”<sup>50</sup>

71. The EPA has set a maximum contaminant level for cadmium in drinking water of 5 ppb, 40 C.F.R. §141.62; the FDA has set a maximum level in bottled water to 5 ppb; and the WHO set a maximum cadmium level in drinking water to 3 ppb.<sup>51</sup>

72. Despite this, laboratory tests indicate that Defendant sold Products containing undisclosed cadmium levels as high as 11.4 ppb.

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<sup>47</sup> HBBF Report, *supra*, at 14.

<sup>48</sup> *Id.*

<sup>49</sup> CDC, Agency for Toxic Substances and Disease Registry, *Public Health Statement for Cadmium*, available at <https://wwwn.cdc.gov/TSP/PHS/PHS.aspx?phsid=46&toxid=15> (last accessed March 7, 2025).

<sup>50</sup> Toxic Element Contamination of Natural Health Products, *supra*.

<sup>51</sup> Congressional Committee Report, *supra*, at 29.



## **Lead**

73. The Infant Formulas contain (or have a material risk of containing) lead, which is a probable carcinogen.<sup>52</sup>

74. No amount of lead is safe for human exposure or consumption. The FDA, CDC, American Academy of Pediatrics, and WHO have all stated that there is no safe level of lead.<sup>53</sup>

75. Lead exposure can seriously harm the brain and nervous system in infants and children and is associated with a range of negative health outcomes such as behavioral problems, decreased cognitive performance, delayed puberty, and reduced postnatal growth.

76. Exposure to lead in foods builds up over time. Build-up can and has been scientifically demonstrated to lead to the development of chronic poisoning, cancer, developmental, and reproductive disorders, as well as serious injuries to the nervous system, and other organs and body systems.

77. Even very low exposure levels to lead can “cause lower academic achievement, attention deficits and behavior problems. No safe level of exposure has been identified.”<sup>54</sup>

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<sup>52</sup>American Cancer Society, *Known and Probable Carcinogens*, last revised August 1, 2024, available at <https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html> (last accessed March 7, 2025).

<sup>53</sup> NPR, *Lead Levels Below EPA Limits Can Still Impact Your Health*, Aug. 13, 2016, available at <https://www.npr.org/sections/thetwo-way/2016/08/13/489825051/leadlevels-below-epalimits-can-still-impact-your-health> (last accessed March 7, 2025); FDA, *Lead in Food and Foodwares*, Jan. 6, 2025, available at <https://www.fda.gov/food/environmental-contaminants-food/lead-food-and-foodwares> (last accessed March 7, 2025); CDC, *Health Effects of Lead Exposure*, available at <https://web.archive.org/web/20240429041027/https://www.cdc.gov/nceh/lead/prevention/health-effects.htm> (last accessed March 7, 2025); Healthychildren.org, *Lead Exposure & Children: FAQs for Families*, available at <https://www.healthychildren.org/English/safety-prevention/all-around/Pages/lead-exposure-and-children-faqs-for-families.aspx#/1> (last accessed March 7, 2025); WHO, *Lead Poisoning*, available at <https://www.who.int/news-room/fact-sheets/detail/lead-poisoning-and-health> (last accessed March 7, 2025).

<sup>54</sup> HBBF Report, *supra*, at 13.

78. Lead is extremely toxic, and its effects cannot be reversed or remediated.<sup>55</sup>

79. One study found that “children age 0 to 24 months lose more than 11 million IQ points from exposure to arsenic and lead in food.”<sup>56</sup> Additionally, studies have established a link between lead exposure and ADHD.<sup>57</sup>

80. Despite this, laboratory tests indicate Defendant sold products containing undisclosed lead levels as high as 4.6 ppb.<sup>58</sup>

### ***Mercury***

81. The Infant Formulas contain (or have a material risk of containing) mercury, which increases the risk for cardiovascular disease. Exposure to mercury has been linked to higher risk of lower IQ scores and intellectual disability.<sup>59</sup>

82. Although there is no maximum contaminant level for mercury in infant formulas, the EPA has set a maximum contaminant level for mercury in drinking water at 2 ppb.<sup>60</sup> Regardless, “there is no known safe level” of exposure to mercury as it is a “highly toxic element.”<sup>61</sup>

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<sup>55</sup> Consumer Reports: Heavy Metals in Baby Food, *supra*.

<sup>56</sup> HBBF Report, *supra*, at 7.

<sup>57</sup> Congressional Committee Report, *supra*, at 12.

<sup>58</sup> HBBF Report, *supra*, at 20, 34.

<sup>59</sup> *Id.* at 14.

<sup>60</sup> Congressional Committee Report, *supra*.

<sup>61</sup> Abstract from Bose-O’Reilly S, McCarty KM, Steckling N, Lettmeier B. Mercury Exposure and Children’s Health. *Curr Probl Pediatr Adolesc Health Care*. 2010 Sep; 40(8):186-215. doi: 10.1016/j.cppeds.2010.07.002. PMID: 20816346; PMCID: PMC3096006 available at <https://pubmed.ncbi.nlm.nih.gov/20816346/#:~:text=Mercury%20is%20a%20highly%20toxic,fr equently%20in%20many%20different%20ways>. (last accessed March 7, 2025).

83. Despite Defendant’s packaging message and overall impression that convey the Infant Formulas are healthy and made with nutritious ingredients, laboratory tests indicate Defendant sold Products containing undisclosed mercury levels as high as 10.1 ppb.

84. The four Heavy Metals – arsenic, cadmium, lead, and mercury – are significant detriments to children.

85. The FDA has acknowledged that “exposure to [these four heavy] metals are likely to have the most significant impact on public health” and has prioritized them in connection with its Toxic Elements Working Group, which is aimed toward reducing human exposure to contaminants in dietary supplements, food and cosmetics.<sup>62</sup>

86. Importantly, and relevant to this lawsuit, action levels do not require companies to disclose the presence of Heavy Metals on the packaging of products that are placed in the market. Action levels only set limits for determining when products cannot be placed in the market.

87. The presence of Heavy Metals and/or other undesirable toxins or contaminants in baby foods have been confirmed by investigations and reports by the U.S. Congress, Healthy

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<sup>62</sup>Metals and Your Food, *supra*.

Babies Bright Futures,<sup>63</sup> Consumer Reports,<sup>64</sup> and Politico,<sup>65</sup> and studies by the FDA,<sup>66</sup> University of Miami, the Clean Label Project, and Ellipse Analytics.<sup>67</sup>

88. Both the Congressional Committee Report, published on February 4, 2021, which acknowledged that Heavy Metals “can endanger infant neurological development,”<sup>68</sup> followed by a second report published on September 29, 2021, revealed alarming levels of Heavy Metals in baby foods.<sup>69</sup> The Congressional Committee Report acknowledged that Heavy Metals—including arsenic, cadmium, lead, and mercury—were present in “significant levels” in numerous commercial baby food products.<sup>70</sup>

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<sup>63</sup> HBBF Report at 12, 20, *supra*.

<sup>64</sup> Consumer Reports, *Heavy Metals in Baby Food: What You Need to Know*, published August 16, 2018, updated September 29, 2021, available at <https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/> (last accessed March 7, 2025) (“Consumer Reports: Heavy Metals in Baby Food”).

<sup>65</sup> Politico, *The FDA’s Food Failure*, April 8, 2022, available at <https://www.politico.com/interactives/2022/fda-fails-regulate-food-health-safety-hazards/> (last accessed March 7, 2025) (“FDA’s Food Failure”).

<sup>66</sup> FDA, *Total Diet Study Elements Results Summary Statistics, Market Baskets 2006 through 2013*, April 15, 2014 (rev. April 2017), available at <https://web.archive.org/web/20220107234158/https://www.fda.gov/media/77948/download> (last accessed March 7, 2025) (“FDA Total Diet Study”).

<sup>67</sup> Gardener, et al., *Lead and Cadmium Contamination in a Large Sample of United States Infant Formulas and Baby Foods*, 651 SCI. TOTAL ENVIRON. 1, 822-827 (2019), available at: <https://www.sciencedirect.com/science/article/abs/pii/S0048969718334442?via%3Dihub> (last accessed March 7, 2025) (“Lead and Cadmium Contamination in Infant Formulas and Baby Foods”).

<sup>68</sup> Laura Reiley, *New Report Finds Toxic Heavy Metals in Popular Baby Foods. FDA Failed to Warn Consumers of Risk*, The Washington Post (Feb. 4, 2021), available at <https://www.washingtonpost.com/business/2021/02/04/toxic-metals-baby-food/> (last accessed March 7, 2025) (“Toxic Heavy Metals in Popular Baby Foods”).

<sup>69</sup> Congressional Committee Report, *supra*; Second Congressional Committee Report, *supra*.

<sup>70</sup> Congressional Committee Report, *supra*.

89. As such, the knowledge of the risks associated with exposure to Heavy Metals is not a new phenomenon. Defendant knew or should have known of the risks associated with the presence of Heavy Metals in foods consumed by infants,<sup>71</sup> and that, over time, these toxins can accumulate and remain in infants' bodies, to their detriment.

90. Despite the material risk and/or actual presence of these unnatural and harmful chemicals, Defendant fails to disclose the presence (or risk) of Heavy Metals in its Products.

## **II. Defendant Falsely Marketed Its Infant Formulas as Healthy and Made with Nutritious Ingredients by Omitting Any Mention of Heavy Metals**

91. Defendant packages, labels, markets, advertises, formulates, manufactures, distributes, and sells its Infant Formulas throughout the United States, including Illinois.

92. Defendant's Infant Formulas are available at numerous retail and online outlets. The Infant Formulas are widely advertised.

93. Defendant advertises its Infant Formulas as the “#1 Pediatrician Recommended Brand for Immune Support,” “#1 Brand Fed in Hospitals,” and “#1 Brand Chosen by Parents.”



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<sup>71</sup> See, e.g., FDA, *Compliance Program Guidance Manual: Toxic Elements in Food and Foodware, and Radionuclides in Food- Import and Domestic (FY 08, 09, 10)*, available at <http://wayback.archive-it.org/7993/20170404233343/https://www.fda.gov/downloads/Food/ComplianceEnforcement/UCM073204.pdf> (last accessed March 7, 2025); see also 21 CFR §172, available at <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-172> (last accessed March 7, 2025).

94. On its website, Defendant “promise[s] to nourish the journey of parents and their babies.”<sup>72</sup> Defendant informs consumers that its Products have “no artificial growth hormones” and “no palm olein oil[.]”<sup>73</sup> Defendant claims that it “continues to give moms new ways to nourish their babies with options like hypoallergenic, soy, organic, sensitive, and non-GMO formulas.”<sup>74</sup>

95. Defendant touts its innovations to its Infant Formula and provides thorough information about the ingredients in its formulas to consumers on a FAQ section of its website.<sup>75</sup>

96. Defendant promotes its “heritage” as “[a] spirit of innovation that began in 1925 and hasn’t stopped since[.]”<sup>76</sup>

97. Based on Defendant’s decision to wholly omit mention of the presence of Heavy Metals in its Infant Formulas, and to instead package its Infant Formulas as healthy and made with nutritious ingredients, it had a duty to ensure that the Products’ packaging was true and not misleading.

98. Defendant intentionally omitted the presence (or material risk) of Heavy Metals in the Infant Formulas in order to induce and mislead reasonable consumers to purchase its Infant Formulas.

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<sup>72</sup> Similac, *Why Similac*, available at <https://www.similac.com/why-similac.html> (last accessed March 7, 2025).

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> Similac, *Frequently Asked Questions- From Infant Nutrition and Feeding Methods to Our Latest Innovations*, available at <https://www.similac.com/baby-tools-resources/baby-questions.html> (last accessed March 7, 2025).

<sup>76</sup> Similac, *Why Similac*, available at <https://www.similac.com/why-similac.html> (last accessed March 7, 2025).

99. With Defendant marketing its Infant Formulas as healthy and made with nutritious ingredients to nourish babies, Defendant clearly recognizes the importance of its Infant Formula to the development of infants.

100. As a result of the material undisclosed information, a reasonable consumer would have no reason to suspect the presence (or material risk) of Heavy Metals in the Infant Formulas without conducting his or her own scientific tests (which are time consuming and expensive) or reviewing third-party scientific testing of these Products.

**III. Due to the Presence and Material Risk of Heavy Metals in the Infant Formulas, the Packaging Was Materially Misleading**

101. At all times during the Relevant Period, Defendant knew or should have known the Infant Formulas contained undisclosed Heavy Metals and were not sufficiently tested for the presence and material risk of Heavy Metals.

102. Defendant's Infant Formulas contained undisclosed levels of Heavy Metals due to Defendant's failure to monitor for the presence in the ingredients and finished products. Defendant was aware of this risk and failed to disclose it to Plaintiffs and the Classes despite having a duty to disclose.

103. A former employee of Defendant has called attention to the U.S. Congress about Defendant's apparent failure to administer and impose internal quality controls.<sup>77</sup>

104. Despite the known risks of exposure to Heavy Metals, Defendant has intentionally, recklessly, and/or knowingly sold the Infant Formulas without disclosing to consumers like Plaintiffs the presence or material risk of arsenic, mercury, cadmium, and lead.

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<sup>77</sup> CNN, *Whistleblower Alerted FDA to Alleged Safety Lapses at Baby Formula Plant Months Before Recalls, Complaint Shows*, April 28, 2022, available at <https://www.cnn.com/2022/04/28/health/baby-formula-whistleblower/index.html> (last accessed March 7, 2025).

105. Defendant knew or should have known that Heavy Metals pose health risks to infants.

106. Defendant knew or should have known that it owed consumers a duty of care to prevent or, at the very least, minimize the presence of Heavy Metals in the Infant Formulas to the extent reasonably possible.

107. Defendant knew or should have known it owed consumers a duty of care to adequately test for Heavy Metals in the Infant Formulas.

108. Defendant knew consumers purchased the Infant Formulas based on the reasonable expectation that Defendant manufactured the Infant Formulas to the highest standards. Based on this consumer expectation, Defendant knew or should have known consumers reasonably inferred that Defendant would hold the Infant Formulas to the highest standards for preventing the inclusion of Heavy Metals in the Infant Formulas, which would include testing the Infant Formulas’ ingredients and finished products for Heavy Metals.

109. A consumer survey done by Plaintiffs’ counsel (“Consumer Survey”) demonstrates such an expectation.<sup>78</sup>

Consumer Survey	Yes	No
Do you expect a company to test for arsenic, cadmium, lead, and/or mercury in infant formula that will be fed to infants?	376	30
Do you expect a company to disclose if there were detectable levels, or risk, of arsenic, cadmium, lead, and/or mercury in an infant formula?	364	42

110. Plaintiffs’ counsel conducted a second survey to determine whether reasonable consumers would expect Similac powdered infant formula products to contain heavy metals such

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<sup>78</sup> All Consumer Survey respondents were parents with children aged anywhere from 0 to 4 years old nationwide, including 13 respondents in Illinois, and all of whom had purchased infant formula within the past 3 years.



as arsenic, cadmium, lead, or mercury, and what impact, if any, the risk of the presence of such heavy metals would make on respondents' purchasing decisions.

111. The results of the second survey were consistent with the first. After reviewing images of the Infant Formulas' packaging, 88.9% of respondents would *not* expect Similac infant formula to contain Heavy Metals. Respondents were more likely to expect the formula to contain insect parts than Heavy Metals.

	Would expect		Would not expect		Don't know/ No opinion	
	N	%	N	%	N	%
Contain heavy metals (e.g., arsenic, cadmium lead, mercury)	28	6.9%	359	88.9%	17	4.2%
Contain insect parts	31	7.7%	359	88.1%	17	4.2%

112. Based on the foregoing, reasonable consumers, like Plaintiffs, would consider the inclusion (or material risk of inclusion) of Heavy Metals a material fact when considering what infant formulas to purchase.

113. Defendant knew that monitoring for Heavy Metals in its ingredients and Infant Formulas was not only important, but also critical.

114. Defendant also knew that monitoring for Heavy Metals in its ingredients and Infant Formulas was likewise important to its health-conscious consumers to protect their babies.

#### **IV. Infant Formulas Can Be Manufactured Without Measurable Levels of Heavy Metals**

115. In contrast to the levels of Heavy Metals found in Defendant's Infant Formulas, other infant formula manufacturers have produced formula products that have non-detectable Heavy Metals.

116. The Clean Label Project tests products for more than 400 contaminants, including heavy metals, chemicals, and plastics, and presents its Purity Award to companies with products with the lowest levels of contaminants when compared to other products in a given category.<sup>79</sup>

117. Bobbie, a manufacturer of infant formula (recognized by the Clean Label Project for manufacturing products that were free from detectable levels of Heavy Metals) was a recipient of the Clean Label Project's Purity Award.<sup>80</sup>

118. Plaintiffs' counsel had Bobbie Organic Infant Formula independently tested and that testing confirmed the presence of Heavy Metals at non-detectable levels:

Infant Formula	Arsenic (ppb)	Cadmium (ppb)	Lead (ppb)	Mercury (ppb)
Bobbie Organic Infant Formula	<2.2	<1.3	<1.0	<1.7

119. This testing confirms infant formula manufacturers can manufacture infant formulas with Heavy Metals levels that are not measurable.

120. Additionally, testing by Consumer Reports identified baby food products with Heavy Metal levels low enough to not cause concern, as well as some products with Heavy Metal levels that were not measurable.<sup>81</sup> “[T]here are ways for [baby food] manufacturers to significantly reduce or eliminate these [heavy] metals from their products.”<sup>82</sup>

<sup>79</sup> Clean Label Project, *Purity Award*, available at <https://cleanlabelproject.org/purity-award/> (last accessed March 7, 2025).

<sup>80</sup> Business Wire, *Bobbie is First-Ever Infant Formula to Receive the Clean Label Project Purity Award and Certification as a Pesticide-Free Product*, Jan. 25, 2022, available at <https://www.businesswire.com/news/home/20220125005905/en/Bobbie-Is-First-Ever-Infant-Formula-To-Receive-The-Clean-Label-Project-Purity-Award-and-Certification-as-a-Pesticide-Free-Product> (last accessed March 7, 2025).

<sup>81</sup> Consumer Reports: Heavy Metals in Baby Food, *supra*.

<sup>82</sup> *Id.*

121. In testing conducted by Consumer Reports, approximately one-third of tested products had levels of Heavy Metals that were below levels of concern and other products had immeasurable levels of Heavy Metals.<sup>83</sup> As stated by Dr. James E. Rogers, the Consumer Reports Director of Food Safety Research and Testing, “Every category of food was represented in that lower-risk group. That indicates that there are ways for manufacturers to significantly reduce or eliminate these [heavy] metals from their products.”<sup>84</sup>

122. In the FDA Total Diet Study, it was also demonstrated that infant formulas can be manufactured without detectable levels of Heavy Metals.<sup>85</sup>

123. Moreover, because of public health efforts, exposure to lead has consistently and notably decreased over the past 40 years.<sup>86</sup> These efforts include increasing awareness of the dangers of even low levels of lead exposure to young children.<sup>87</sup> The progress towards decreasing childhood exposure to lead was so impressive that the CDC identified “childhood lead poisoning prevention as 1 of 10 great U.S. public health achievements during 2001 to 2010.”<sup>88</sup>

124. Defendant knew or should have known it could control the levels of Heavy Metals in the Infant Formulas in order to achieve non-detectable or zero levels by adequately monitoring

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<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> FDA Total Diet Study, *supra*, at 7, 10, 17, 20, 68, 71, 95-96.

<sup>86</sup> Dignam, T., Kaufmann, R. B., LeStourgeon, L., & Brown, M. J. (2019). *Control of Lead Sources in the United States, 1970-2017: Public Health Progress and Current Challenges to Eliminating Lead Exposure*. Journal of public health management and practice: JPHMP, 25 Suppl 1, Lead Poisoning Prevention (Suppl 1 LEAD POISONING PREVENTION), S13–S22. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6522252/> (last accessed March 7, 2025).

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

its ingredients for Heavy Metals and adjusting any formulation to reduce ingredients that contained higher levels of Heavy Metals.

125. Defendant also knew it was not monitoring and testing for Heavy Metals in the Infant Formulas. Defendant knew its failure to monitor and test for Heavy Metals in the Infant Formulas continued throughout the Relevant Period.

126. Defendant's marketing was misleading due to its failure to properly and sufficiently monitor and test for Heavy Metals and for failure to disclose on the packaging of the Products the presence (or material risk) of Heavy Metals in the Infant Formulas.

127. Defendant knew or should have known consumers paid a price premium for its Products and expected Defendant to test and monitor for Heavy Metals and disclose on the packaging of the Products the presence or material risk of Heavy Metals in the Infant Formulas and ingredients.

128. At all times during the Relevant Period, Defendant did not monitor or test for Heavy Metals in the Infant Formulas and ingredients and Defendant did not disclose on the packaging of the Products the presence or material risk of Heavy Metals.

129. Defendant knew or should have known that consumers reasonably expected it to test for and monitor the presence of Heavy Metals in the Infant Formulas and ingredients, and to disclose the presence or material risk of any levels of Heavy Metals in its Products.

130. Defendant knew or should have known the Infant Formulas contained or risked containing Heavy Metals that were inconsistent with its marketing.

131. Defendant knew or should have known that, in order to comply with its marketing, consumers expected them to ensure the Infant Formulas were monitored and tested for Heavy Metals, and to disclose the presence (or material risk) of Heavy Metals.

132. Defendant knew, yet failed to disclose, its lack of testing and knowledge of the risk or presence of Heavy Metals in the Infant Formulas' ingredients.

133. Defendant's Omissions are false, misleading, and crafted to deceive the public as they create an image that the Infant Formulas are healthy, nutritious, and safe from the risk or presence of Heavy Metals.

134. Moreover, reasonable consumers, such as Plaintiffs and the Class members, would have no reason to doubt Defendant's statements regarding the quality of the Products. Defendant's nondisclosure and/or concealment of the presence (or risk) of Heavy Metals in the Infant Formulas alleged herein intended to and did, in fact, cause consumers like Plaintiffs and the members of the Class, to purchase Products they would not have if the true quality and ingredients were disclosed.

**V. Defendant's Packaging Misled Reasonable Consumers Based on the Overall Impression and Material Omissions**

135. The Infant Formulas' packaging communications misled and deceived reasonable consumers because Defendant omitted that the Infant Formula contained (or had a material risk of containing) Heavy Metals, while representing nutritious quality and characteristics.

136. Based on the overall impression given by the packaging communications and Omissions, no reasonable consumer could expect or understand that the Infant Formulas contained (or had a material risk of containing) Heavy Metals.

137. The Infant Formula packaging communications include, but are not limited to:

(a) Similac® Advance OptiGRO Powder: "Brain Nourishing," "Eye Health," "Growth and Development," and "Complete nutrition for baby's first year."



(b) Similac® NeoSure: “Brain Nourishing,” “Eye Health,” “Growth and Development,” and “Enriched Nutrition.”



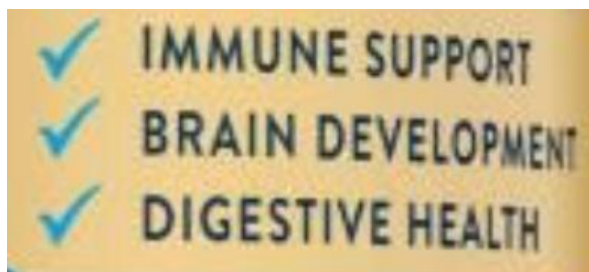
(c) Similac® Pro Advance: “Immune Support” and “Brain & Eye Development.”



(d) Similac® Soy Isomil: “Brain Nourishing,” “Eye Health,” and “Growth and Development.”



(e) Similac® 360 Total Care: “Immune Support,” “Brain Development,” & “Digestive Health.”



(f) Similac® Total Comfort: “Brain Nourishing,” “Eye Health,” and “Growth & Development,” and “Easy-to-Digest” and “Complete Nutrition for Delicate Tummies.”



(g) Various Similac® infant formula products: “#1 Infant Formula Brand.”



138. Based on Defendant’s Omissions from these communications on the Products’ packaging and overall impression, no reasonable consumer could expect or understand that the Infant Formula contained (or had a material risk of containing) Heavy Metals.

139. The Omissions wrongfully convey to consumers that Defendant’s Infant Formulas have certain nutritious quality and characteristics that they do not actually possess.

140. For instance, although Defendant misleadingly causes consumers to believe its Infant Formulas do not contain Heavy Metals due to the material Omissions, the Infant Formulas do in fact contain undisclosed Heavy Metals, which is material information to reasonable consumers.

141. Plaintiffs’ testing confirmed the presence of undisclosed Heavy Metals in the Infant Formulas:



Infant Formula	Level of Heavy Metal in parts per billion (“ppb”)
Similac® Soy Isomil	59.3 ppb (Arsenic)
Similac® Soy Isomil	11.4 ppb (Cadmium)
Similac® Total Comfort	39.2 ppb (Arsenic)
Similac® Total Comfort	3.0 ppb (Lead)
Similac® 360 Total Care	6.7 ppb (Arsenic)
Similac® Advance	3.0 ppb (Lead)
Similac® Pro Advance	10.1 ppb (Mercury)
Similac® NeoSure	7.8 ppb (Arsenic)
Similac® NeoSure	3.6 ppb (Lead)

142. Third party testing also confirmed two Heavy Metals in another of Defendant’s Products.<sup>89</sup>

Infant Formula	Level of Arsenic	Level of Lead
Similac® Advance OptiGRO Powder – Milk-Based	4.6 ppb	2 ppb

143. Previous testing, which includes Defendant’s own testing as well as Plaintiffs’ testing, shows that at least one heavy metal was present in all but two of the 121 samples tested, meaning only 1.65% had non-detectable levels of any Heavy Metals.

144. Regardless of level, though, as stated herein, no level of Heavy Metals is safe.<sup>90</sup>

145. Based on the Omissions and the overall impressions from the packaging statements, a reasonable consumer would not expect the presence of Heavy Metals, nor would a reasonable

<sup>89</sup> HBBF Report, *supra*, at 20, 34.

<sup>90</sup> Some Baby Food May Contain Toxic Metals, *supra*.

consumer be able to detect the presence of Heavy Metals in the Infant Formulas without conducting his or her own scientific tests or reviewing scientific testing conducted on the Products.

146. In fact, the FDA recently requested \$1.2 billion from the U.S. Congress for its Foods Program for initiatives such as reduction of heavy metals in foods for infants and young children.<sup>91</sup> A portion of the funding would be for educational outreach about heavy metals in foods.<sup>92</sup>

147. Baby food manufacturers are now required to test their products monthly for heavy metals and make those test results publicly available on their websites. For example, Plum Organics and Nurture now disclose heavy metals test results for their products on their websites through QR codes on the products' packaging.<sup>93</sup> Abbott has chosen to not do the same.

148. Reasonable consumers must and do rely on Defendant to honestly report what its Infant Formulas contain.

149. Plaintiffs relied on the Products' packaging when making their purchasing decisions.

150. Plaintiffs' expectations and reliance are consistent with reasonable consumers as shown by the Consumer Survey done by Plaintiffs' counsel:

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<sup>91</sup> FDA FY 2023 Budget Proposal, *supra*.

<sup>92</sup> *Id.*

<sup>93</sup> See Plum's heavy metals test results for pouches available at <https://plumorganics.com/heavy-metals-test-results-for-pouches/> and for snacks available at <https://plumorganics.com/heavy-metal-test-results-for-snacks/>; Plum Organics Stage 2 banana + pumpkin, available at <https://plumorganics.com/products/banana-pumpkin-baby-food/>; Nurture heavy metals test results available <https://www.happyfamilyorganics.com/product-finder-results/>; HappyBaby Organics Clearly Crafted Stage 2 Green Beans, Spinach, & Pears, available at <https://www.target.com/p/happybaby-clearly-crafted-green-beans-pears-38-spinach-baby-food-pouch-4oz/-/A-50704733#lnk=sametab> (last accessed March 5, 2025).

Consumer Survey	Yes	No
After seeing the label would you expect arsenic, cadmium, lead, and/or mercury in the infant formula?	79	327

Consumer Survey	Very important	Important	Not at all important
Please select how important, if at all, would it be to your purchasing decision if the infant formula you purchased contained, or risked containing, even a small amount of arsenic, cadmium, lead, and/or mercury.	318	75	13

151. In a second consumer survey, the results also supported that the presence or risk of Heavy Metals is important to consumers’ purchasing decisions. In that survey, of the respondents who would not expect Similac infant formula to contain Heavy Metals, 85.9% said that knowledge of the risk that the formula could contain Heavy Metals would decrease the likelihood of purchase. Even those who responded that they did expect Similac formulas to contain Heavy Metals, more than half of them said that if they learned that there was no risk of Heavy Metals, it would increase their likelihood of purchase.

152. In light of Defendant’s communications regarding the quality of the Infant Formulas and its commitment to innovative formulas and nutritious ingredients, Defendant knew or should have known the Infant Formulas contained or risked containing Heavy Metals.

153. Defendant had a duty to ensure the Infant Formulas were not deceptively, unfairly, misleadingly, and/or falsely marketed and all material information was properly and fully disclosed.

154. Defendant acted knowingly, recklessly, and/or intentionally with its deceptive, unfair, and misleading packaging based on the material Omissions.

155. Defendant knew that properly and sufficiently monitoring the Infant Formulas for Heavy Metals in their ingredients and finished Infant Formulas was not only important, but also critical.

156. Additionally, Defendant knew or should have been aware that a reasonable consumer would be feeding the Infant Formula multiple times each day to his or her baby, making it a significant source of food and nutrition for the child. This leads to an infant's repeated exposure to the Heavy Metals.

157. Finally, Defendant knew or should have known it could control the levels of Heavy Metals in the Infant Formulas by properly monitoring their ingredients for Heavy Metals and adjusting any formulation to reduce ingredients that contained or may contain higher levels of Heavy Metals.

158. The Omissions are material and reasonably likely to deceive reasonable consumers, such as Plaintiffs, in their purchasing decisions. This is true especially considering the long-standing campaign by Defendant to market the Infant Formulas as healthy and made with nutritious ingredients, and to induce consumers, such as Plaintiffs, to purchase the Products.

159. The Omissions make the Infant Formulas' packaging deceptive, unfair, and misleading. Reasonable consumers, like Plaintiffs, would consider the facts that Infant Formula contained (or had a material risk of containing) Heavy Metals when considering what infant formula to purchase.

160. At all times during and throughout the Relevant Period, Defendant knew it was not meeting safe manufacturing standards and also sufficiently and consistently monitoring or testing the Infant Formulas or their ingredients for Heavy Metals.

161. Defendant's packaging was misleading due to Defendant's failure to disclose the true quality of the Infant Formulas based on its unsafe manufacturing processes and the presence or material risk of Heavy Metals.

162. Defendant knew or should have known the Infant Formulas contained or risked containing undisclosed levels of Heavy Metals that were inconsistent with Defendant's packaging.

163. Defendant knew or should have known that reasonable consumers expected it to have strong and adequate manufacturing processes and ensure the Infant Formulas and ingredients were monitored and tested for Heavy Metals to ensure compliance with Defendant's packaging.

164. Defendant knew or should have known consumers paid premium prices because the Omissions were not disclosed.

165. The Omissions are material and render the Infant Formulas' packaging deceptive, unfair, and misleading as without full disclosure, reasonable consumers believe the Infant Formulas are high quality, healthy, and nutritious products.

166. The Omissions were intended to and did, in fact, cause consumers like Plaintiffs and the members of the Class, to purchase products they would not have if the true quality and ingredients were disclosed or for which they would not have paid a premium price.

167. As a result of Defendant's deceptive, unfair, and misleading packaging of the Infant Formulas, Defendant was able to generate substantial sales, which allowed Defendant to capitalize on, and reap enormous profits from, consumers who paid the purchase price or premium for the Infant Formulas that were not as advertised.

**PLAINTIFFS' RELIANCE WAS REASONABLE  
AND FORESEEN BY DEFENDANT**

168. Plaintiffs read and relied upon the packaging of the Infant Formulas when making their purchasing decisions. Had they known Defendant omitted and failed to disclose the Infant

Formula contained (or had a material risk of containing) Heavy Metals, they would not have purchased the Infant Formulas.

169. A reasonable consumer would consider the packaging of a product when deciding whether to purchase it.

**DEFENDANT’S KNOWLEDGE AND  
NOTICE OF ITS BREACH OF ITS IMPLIED WARRANTIES**

170. Defendant had sufficient notice of its breach of implied warranties. Defendant has, and had, exclusive and superior knowledge of the manufacturing processes, physical and chemical make-up of the Infant Formulas, and whether the ingredients contained Heavy Metals.

171. Moreover, Defendant was put on notice by February and September of 2021, when Congress publicly released findings regarding the presence of Heavy Metals in baby foods.<sup>94</sup> The FDA has also released a study showing the presence of Heavy Metals in baby foods, including infant formulas.<sup>95</sup>

172. Defendant did not change its packaging to include any disclaimer on the Omissions.

**PRIVITY EXISTS WITH PLAINTIFFS AND THE PROPOSED CLASS**

173. Defendant knew that reasonable consumers such as Plaintiffs and the proposed Class members would be the end purchasers of the Infant Formulas and the targets of its advertising, marketing, packaging, and statements.

174. Defendant intended that the packaging and implied warranties would be considered by the end purchasers of the Infant Formulas, including Plaintiffs and the proposed Class members.

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<sup>94</sup> Congressional Committee Report, *supra*; Second Congressional Committee Report, *supra*.

<sup>95</sup> FDA Total Diet Study, *supra*, at 7, 10, 17, 20, 68, 71, 95-96.

175. Defendant directly marketed to Plaintiffs and the proposed Classes through its packaging.

176. Plaintiffs and the proposed Class members are the intended beneficiaries of the implied warranties.

**APPLICABILITY OF EQUITABLE TOLLING AND  
THE DISCOVERY RULE TO THE STATUTE OF LIMITATIONS**

177. Fraudulent concealment and/or the discovery rule toll Plaintiffs' claims.

178. The statute of limitations is tolled for all of Plaintiffs' statutory consumer protection and common law claims due to Defendant's fraudulent concealment of the fact that the Infant Formula contained (or had a material risk of containing) Heavy Metals. Defendant intentionally concealed these material facts from Plaintiffs.

179. Defendant knew the Omissions were a material consideration for any parent buying infant formulas.

180. Defendant violated the relevant state consumer fraud acts by deceiving customers as to the true nature, quality, and makeup of the Infant Formulas.

181. The discovery rule also protects Plaintiffs' Illinois Consumer Fraud and Deceptive Business Practices Act and unjust enrichment claims.

182. Based on Defendant concealing material facts from Plaintiffs, Plaintiffs could not reasonably discover that the Infant Formula contained (or had a material risk of containing) Heavy Metals without conducting their own scientific tests (which are time consuming and expensive) or reviewing third-party scientific testing.

183. Plaintiffs did not know that the Infant Formula contained (or had a material risk of containing) Heavy Metals. Instead, Defendant only represented that the Infant Formulas were healthy, nutritious, and of high quality to support growing infants.

**CLASS ACTION ALLEGATIONS**

184. Plaintiffs bring this action individually and on behalf of the following classes pursuant to Rules 23(a), 23(b)(2) and (3), and 23(c)(4) of the Federal Rules of Civil Procedure:

**Nationwide Class:** All persons who, from March 7, 2019, to the present, purchased the Infant Formulas for household use, and not for resale (the “Class”).

**Illinois Subclass:** All persons who are citizens of Illinois who, from March 7, 2019, to the present, purchased the Infant Formulas for household use, and not for resale (the “Illinois Subclass”).

**Washington Subclass:** All persons who are citizens of Washington who, from March 7, 2019, to the present, purchased the Infant Formulas for household use, and not for resale (the “Washington Subclass”).

**California Subclass:** All persons who are citizens of California who, from March 7, 2019, to the present, purchased the Infant Formula for household use, and not for resale (the “California Subclass”).

**Minnesota Subclass:** All persons who are citizens of Minnesota who, from March 7, 2019, to the present, purchased the Infant Formula for household use, and not for resale (the “Minnesota Subclass”).

**New York Subclass:** All persons who are citizens of New York who, from March 7, 2019, to the present, purchased the Infant Formula for household use, and not for resale (the “New York Subclass”).

**Pennsylvania Subclass:** All persons who are citizens of Pennsylvania who, from March 7, 2019, to the present, purchased the Infant Formula for household use, and not for resale (the “Pennsylvania Subclass”).

185. Collectively, the Illinois, Washington, California, Minnesota, New York, and Pennsylvania Subclasses are referred to as the “State Subclasses.”



186. Excluded from the Class and State Subclasses (collectively, “Classes”) are the Defendant, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, all governmental entities, and any judge, justice, or judicial officer presiding over this matter.

187. This action is brought and may be properly maintained as a class action. There is a well-defined community of interests in this litigation and the members of the Classes are easily ascertainable.

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

189. Questions of law and fact common to Plaintiffs and the Classes include, but are not limited to, the following:

- (a) whether Defendant owed a duty of care;
- (b) whether Defendant owed a duty to disclose;
- (c) whether Defendant knew or should have known that the Infant Formulas contained or had a material risk of containing Heavy Metals;
- (d) whether Defendant failed to disclose the Omissions;
- (e) whether the claims of Plaintiffs and the Classes serve a public benefit;
- (f) whether Defendant’s packaging is false, deceptive, unfair, and misleading based on the Omissions;
- (g) whether the Omissions are material to a reasonable consumer;
- (h) whether the Omissions are likely to deceive a reasonable consumer;

(i) whether Defendant had knowledge that the Omissions were material and false, deceptive, unfair, and/or misleading;

(j) whether Defendant breached its duty of care;

(k) whether Defendant breached its duty to disclose;

(l) whether Defendant violated the laws of the State of Illinois;

(m) whether Defendant violated the laws of the State of Washington;

(n) whether Defendant violated the laws of the State of California;

(o) whether Defendant violated the laws of the State of Minnesota;

(p) whether Defendant violated the laws of the State of New York;

(q) whether Defendant violated the laws of the Commonwealth of Pennsylvania;

(r) whether Defendant breached its implied warranties;

(s) whether Defendant engaged in unfair trade practices;

(t) whether Defendant engaged in false advertising;

(u) whether Defendant made fraudulent omissions;

(v) whether Plaintiff and Class members' claims are tolled based on Defendant's fraudulent concealment;

(w) whether Plaintiffs and members of the Classes are entitled to actual, statutory, and punitive damages; and

(x) whether Plaintiffs and members of the Classes are entitled to declaratory relief.

190. Defendant engaged in a common course of conduct giving rise to the legal rights sought to be enforced by Plaintiffs individually and on behalf of the other members of the Classes.

Identical statutory violations and business practices and harms are involved. Individual questions, if any, are not prevalent in comparison to the numerous common questions that dominate this action.

191. Plaintiffs' claims are typical of those of the members of the Classes in that they are based on the same underlying facts, events, and circumstances relating to Defendant's conduct.

192. Plaintiffs will fairly and adequately represent and protect the interests of the Classes, have no interests incompatible with the interests of the Classes, and have retained counsel competent and experienced in class action, consumer protection, and false advertising litigation.

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

194. Questions of law and fact common to the Classes predominate over any questions affecting only individual members of the Classes.

195. As a result of the foregoing, class treatment is appropriate.

### **CLAIMS FOR RELIEF**

#### **COUNT I**

#### **Violations of Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. §505/1, et seq., Against Defendant on Behalf of the Class**

196. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

197. Plaintiffs and the Class are a "person" within the meaning of 815 Ill. Comp. Stat. §505/1(c).

198. Defendant is a "person" within the meaning of 815 Ill. Comp. Stat. §505/1(c).

199. The Infant Formulas are "merchandise" within the meaning of 815 Ill. Comp. Stat. §505/1(b).

200. There was a sale of merchandise within the meaning of 815 Ill. Comp. Stat. §505/1(d).

201. The conduct described herein constitutes a violation of the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. §505/1, *et seq.* (“ICFA”).

202. Defendant engaged in a deceptive, unfair, and misleading act or practice in violation of ICFA by knowingly concealing, omitting, or failing to disclose the Infant Formulas’ true quality, ingredients, and suitability for consumption by infants with no development or health risks.

203. Defendant’s deceptive acts and practices are continuing.

204. Defendant intended for Plaintiffs and the Class members to rely on and accept as true the Products’ packaging and Omissions in deciding whether to purchase the Infant Formulas, and at what price.

205. Defendant’s concealment, Omissions, and other deceptive, unfair, and misleading conduct were likely to deceive consumers with respect to the Infant Formulas’ quality, ingredients, and suitability for consumption by infants with no development or health risks.

206. Defendant’s concealment, Omissions, and other deceptive, unfair, and misleading conduct were likely to cause consumers to purchase and/or overpay for the Infant Formulas.

207. Defendant’s concealment, Omissions, and other deceptive, unfair, and misleading acts occurred before Plaintiffs and the Class decided to purchase the Infant Formulas.

208. Defendant’s concealment, Omissions, and other deceptive, unfair, and misleading conduct did in fact deceive Plaintiffs and the Class with respect to the Infant Formulas’ quality, ingredients, and suitability for consumption by infants with no development or health risks.

209. Defendant's concealment, Omissions, and other deceptive, unfair, and misleading conduct did in fact deceive and cause Plaintiffs and the Class members to purchase and overpay for the Infant Formulas.

210. Defendant's concealment, Omissions, and other deceptive, unfair, and misleading conduct described herein repeatedly occurred in Defendant's trade or business and were capable of deceiving a substantial portion of the consuming public.

211. The facts concealed, omitted, or not disclosed by Defendant that the Infant Formula contained (or had a material risk of containing) Heavy Metals that do not conform to the packaging are material facts because Plaintiffs and any reasonable consumer would have considered those facts important in deciding whether to purchase the Infant Formulas, and at what price.

212. If Plaintiffs and the Class members had known that the Infant Formula contained (or had a material risk of containing) Heavy Metals, they would not have paid the price premium they paid for the Infant Formulas.

213. If Plaintiffs and the Class members had known that the Infant Formulas did not in fact match the quality and ingredients described above, they would not have purchased the Infant Formulas at all.

214. As a result of Defendant's conduct, Plaintiffs and the Class members have suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or had a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contain or risk containing Heavy Metals.

215. As a result of Defendant's conduct, Plaintiffs and the Class members have suffered actual damages, in that they purchased Infant Formulas that they would not have purchased at all if they had knowledge of the Omissions.

216. As a direct and proximate result of the deceptive, misleading, unfair, and unconscionable practices of the Defendant set forth above, Plaintiffs and the Class members are entitled to actual damages, compensatory damages, penalties, attorneys' fees, and costs, as set forth in Section 10a of the ICFA.

217. Defendant's deceptive, misleading, unfair, and unconscionable practices set forth above were done willfully, wantonly, and maliciously, entitling Plaintiffs and the Class members to an award of punitive damages.

## **COUNT II**

### **Violation of the Washington Consumer Protection Act ("WCPA"), Wash. Rev. Code § 19.86.010, *et seq.*, Against Defendant on Behalf of the Washington Subclass**

218. Plaintiff Huggins incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

219. Plaintiff Huggins, the Washington Subclass members, and Defendant are all "persons" as defined in the WCPA. Wash. Rev. Code § 19.86.010(1).

220. Plaintiff Huggins, the Washington Subclass members, and Defendant engaged in "commerce" as defined in the WCPA while marketing, offering for sale, selling, and purchasing the Infant Formulas in Washington and throughout the United States. Wash. Rev. Code § 19.86.010(2).

221. The WCPA broadly prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Wash. Rev. Code § 19.86.020.

222. Defendant intentionally concealed and suppressed material facts regarding the presence or risk of Heavy Metals in the Infant Formulas.

223. Defendant's misleading Omissions failed to disclose the Infant Formulas contained or risked containing Heavy Metals. Defendant's failure to disclose the material facts set forth above gives rise to a violation of the WCPA.

224. Defendant omitted this material information with the intent to induce consumers, such as Plaintiff Huggins and the Washington Subclass, to purchase the Infant Formulas.

225. Defendant engaged in deceptive, unfair, and misleading practices in the conduct of its trade or commerce.

226. Defendant's deceptive, unfair, and misleading conduct, as alleged herein, is injurious to the public interest as it has the capacity to deceive a substantial part of the public and injure other persons.

227. Defendant's deceptive, unfair, and misleading practices injured and continue to injure the public interest by misleading reasonable consumers into buying products they would not have purchased. These injuries greatly outweigh any potential countervailing benefit to consumers or competition. Defendant has no legally cognizable interest in misleading consumers by failing to disclose a material fact that reasonable consumers consider when making purchasing decisions.

228. As a direct and proximate result of the deceptive, misleading, unfair, and unconscionable practices of the Defendant set forth above, Defendant is liable to Plaintiff Huggins and the Washington Subclass in amounts to be proven at trial, including attorneys' fees, costs, and treble damages, as well as any other remedies the Court may deem appropriate under Washington Revised Code section 19.86.090.

**COUNT III**

**Breach of Implied Warranty of Merchantability Against Defendant on Behalf of the Class or, Alternatively, the State Subclasses**

229. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

230. Defendant is a merchant engaging in the sale of goods to Plaintiffs and the Class.

231. There was a sale of goods from Defendant to Plaintiffs and the members of the Class.

232. At all times mentioned herein, Defendant manufactured and sold the Infant Formulas and, prior to the time the Infant Formulas were purchased by Plaintiffs and the Class, impliedly warranted that the Infant Formulas were of merchantable quality and fit for their ordinary use (consumption by infants with no development or health risks).

233. Plaintiffs and the Class relied on these implied warranties when they purchased the Infant Formulas.

234. The Infant Formulas were not fit for their ordinary use (consumption by infants with no development or health risks) as they contained (or had a material risk of containing) Heavy Metals that do not conform to the packaging.

235. These promises became part of the basis of the bargain between Defendants and Plaintiffs and members of the Class and thus constituted implied warranties.

236. Defendant breached the implied warranties by selling Infant Formulas that contain (or risk containing) Heavy Metals.

237. Defendant was on notice of this breach as it was aware of the inclusion (or risk) of Heavy Metals.



238. Privity exists because Defendant impliedly warranted to Plaintiffs and the members of the Class through the Products' packaging, that the Infant Formulas were healthy, nutritious, and safe for consumption; however, Defendant failed to mention or disclose it contained (or had a material risk of containing) Heavy Metals.

239. As a direct and proximate result of Defendant's breach of its implied warranties, Plaintiffs and the Class suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or had a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

240. Plaintiffs, on behalf of themselves and the Class, seek actual damages for Defendants' failure to deliver goods that conform to their implied warranties and resulting breach.

**COUNT IV**  
**Fraudulent Misrepresentation by Omission Against Defendant  
on Behalf of the Class or, Alternatively, the State Subclasses**

241. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

242. Plaintiffs and members of the Class were buyers and Defendant was a seller in a commercial exchange.

243. Plaintiffs and the Class were ordinary non-business consumers who trusted Defendant to manufacture, distribute, market, and sell Infant Formulas that did not contain (or have a material risk of containing) Heavy Metals.

244. As an infant formulas manufacturer, Defendant is in a special position of trust upon which consumers rely.

245. Defendant failed to disclose the Omissions.

246. Defendant intentionally, knowingly, and/or recklessly made these Omissions to induce Plaintiffs and the Class to purchase the Infant Formulas.

247. Defendant knew or should have known the Infant Formulas contained (or had a material risk of containing) Heavy Metals.

248. Defendant allowed its packaging to intentionally mislead consumers, such as Plaintiffs and the Class.

249. Defendant's packaging did not disclose the Omissions with the intent to deceive and defraud consumers, such as Plaintiffs and the Class.

250. Defendant intended for Plaintiffs and the Class to rely on the Omissions. Defendant knows its customers trust the quality of its Products and that it is in a special position of trust with the public.

251. Defendant knows reasonable consumers expected the Infant Formulas to not contain (or have a material risk of containing) Heavy Metals.

252. Defendant also knows that reasonable consumers seek out and wish to purchase infant formulas that possess high quality ingredients free of toxins, contaminants, or chemicals and that these consumers will pay for infant formulas they believe possess these qualities.

253. Defendant knew that Plaintiffs and the Class were ignorant of the Omissions.

254. Defendant knew that Plaintiffs and the Class could not reasonably have been expected to learn or discover the Omissions without conducting their own scientific tests (which are time consuming and expensive).

255. Defendant was under a duty to disclose the Omissions regarding its Infant Formulas to Plaintiffs and the Class because:

(a) Defendant was in possession of special facts that could not have been discovered by Plaintiffs and the Class.

(b) Defendant's packaging disclosed misleading information to consumers by including the Omissions.

(c) Based on Defendant's partial statements on the Infant Formulas' packaging that gave a misleading impression to reasonable consumers without further information about the Omissions, Defendant assumed the obligation to make a full and fair disclosure of the whole truth.

256. The Omissions were material facts to Plaintiffs and the Class as Plaintiffs and the Class relied on the Omissions when purchasing the Infant Formulas.

257. Plaintiffs and the Class had a right to rely on Defendant's packaging as the truth because customers like Plaintiffs and the Class trust the quality of Defendant's Products and they expect the Infant Formulas do not contain (or have a material risk of containing) Heavy Metals.

258. Plaintiffs and the Class did in fact rely on the material Omissions and purchased the Infant Formulas to their detriment. Given the materiality of the Omissions, Plaintiffs' and the Class's reliance on the Omissions was justifiable.

259. As a direct and proximate result of Defendant's conduct, Plaintiffs and the Class suffered actual pecuniary damages by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

260. Plaintiffs and the Class seek actual damages, declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

**COUNT V**  
**Fraud by Omission Against Defendant on Behalf of the Class  
or, Alternatively, the State Subclasses**

261. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

262. Defendant knew or should have known the Infant Formulas contained (or had a material risk of containing) Heavy Metals.

263. Plaintiffs and the Class and Defendant acted within the context of a business transaction when Plaintiffs and the Class purchased Defendant's Infant Formulas for household or business use, and not for resale.

264. Plaintiffs and the Class were ordinary non-business consumers.

265. Defendant actively and knowingly concealed from and failed to disclose to Plaintiffs and the Class that the Infant Formulas undisclosed levels or material risk of Heavy Metals that do not conform to the Products' packaging.

266. As infant formula manufacturers, Defendant is in a special position of trust upon which consumers rely.

267. Defendant was under a duty to disclose to Plaintiffs and the Class the true quality, characteristics, ingredients and suitability of the Infant Formulas because:

(a) Defendant was in a superior position to know the true state of facts about its Products;

(b) Defendant was in a superior position to know the actual ingredients, characteristics, and suitability of the Infant Formulas for consumption by infants with no development or health risks; and

(c) Defendant knew that Plaintiffs and the Class could not reasonably have been expected to learn about the Omissions without Defendant disclosing it on the Infant Formulas' packaging.

268. Defendant knows its customers trust the quality of its products and expect Defendant's Infant Formulas to not contain or risk containing Heavy Metals. Defendant also knows that consumers seek out and wish to purchase infant formulas that possess high quality ingredients free of toxins, contaminants, or chemicals, and that these consumers will pay for infant formulas that they believe possess these qualities.

269. Due to the Omissions on the Infant Formulas' packaging, Defendant had a duty to disclose that the Infant Formula contained (or had a material risk of containing) Heavy Metals.

270. Defendant acted in bad faith when it intended that Plaintiffs and the Class would rely on the Omissions when purchasing the Infant Formulas, unaware of the undisclosed material facts.

271. Defendant was under a duty to disclose the Omissions because Defendant undertook the disclosure of information about the Infant Formulas on the Infant Formulas' packaging.

272. Defendant failed to discharge its duty to disclose the Omissions.

273. Defendant allowed the Omissions on the Products' packaging to intentionally mislead consumers, such as Plaintiffs and the Class.

274. The facts concealed, omitted, or not disclosed by Defendant to Plaintiffs and the Class are material in that a reasonable consumer would have considered the Omissions material when deciding whether to purchase the Infant Formulas.

275. Defendant knew or should have known the Omissions were material to Plaintiffs' and the Class's decisions to purchase the Infant Formulas and would induce Plaintiffs and the Class to purchase the Infant Formulas.

276. Defendant intentionally concealed the presence or material risk of Heavy Metals in the Infant Formulas with intent to defraud and deceive Plaintiffs and the Class.

277. Plaintiffs and the Class justifiably relied on Defendant's Omissions to their detriment. The detriment is evident from the true quality, characteristics, and ingredients of the Infant Formulas, which is misleading when compared to the Infant Formulas' packaging and represented by Defendant and inherently unfair to consumers of the Infant Formulas, such as Plaintiffs and the Class.

278. As a direct and proximate result of Defendant's conduct, Plaintiffs and the Class suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

279. Plaintiffs and the Class seek actual damages, declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

#### **COUNT VI**

#### **Violation of Minnesota Unlawful Trade Practices Act, Minn. Stat. §325D.13, *et seq.*, Against Defendant on Behalf of the Minnesota Subclass**

280. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

281. Defendant is a "person" within the meaning of the Minnesota Unlawful Trade Practices Act ("MUTPA").

282. Defendant violated the MUTPA by knowingly failing to disclose the Omissions.

283. Defendant knew or should have known the Infant Formulas were not of the true quality and ingredients advertised because they contained (or had a material risk of containing) Heavy Metals.

284. Defendant's pattern of knowing concealment, Omissions, and other deceptive, unfair, and misleading conduct were likely to deceive or cause misunderstanding and did in fact deceive Plaintiffs and the Minnesota Subclass with respect to the Infant Formulas' quality, ingredients, and suitability for consumption by infants with no development or health risks.

285. Defendant intended for Plaintiffs and the Minnesota Subclass to rely on its Omissions, concealment, implied warranties, and/or deceptions regarding the Infant Formulas' quality, ingredients, and suitability for consumption.

286. Defendant's conduct and Omissions described herein occurred repeatedly in its trade or business and were capable of deceiving a substantial portion of the consuming public.

287. Defendant was under a duty to disclose the Omissions, because Defendant undertook the disclosure of information about the Infant Formulas on the Infant Formulas' packaging.

288. Defendant failed to discharge its duty to disclose the Omissions.

289. The facts concealed, omitted, or not disclosed by Defendant were material facts in that Plaintiffs, the Minnesota Subclass, and any reasonable consumer would have considered them in deciding whether to purchase the Infant Formulas. Had Plaintiffs and the Minnesota Subclass known the Infant Formulas did not have the quality advertised by Defendant, they would not have purchased the Infant Formulas or paid the premium price.

290. Defendant's unlawful conduct is continuing, with no indication that it intends to cease this fraudulent course of conduct.

291. As a direct and proximate result of Defendant's conduct, Plaintiffs and the Minnesota Subclass suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

292. Plaintiffs and the members of the Minnesota Subclass would not have purchased the Infant Formulas at all had they known that Infant Formulas do not conform to the packaging.

293. Pursuant to Minn. Stat. §8.31, subd. 3a, and §325D.15, Plaintiffs and the Minnesota Subclass seek actual damages, declaratory relief, attorneys' fees, costs, and any other just and proper relief available thereunder for Defendant's violations of the MUTPA.

#### **COUNT VII**

#### **Violations of Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. § 325D.44, *et seq.*, Against Defendant on Behalf of the Minnesota Subclass**

294. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

295. Defendant is a "person" within the meaning of the Minnesota Uniform Deceptive Trade Practices Act ("MUDTPA").

296. Defendant willingly engaged in deceptive trade practices, in violation of the MUDTPA, by failing to disclose the Omissions.

297. Defendant knew or should have known the Infant Formulas contained (or had a material risk of containing) Heavy Metals.



298. Defendant's Omissions, concealment, and other deceptive, unfair, and misleading conduct were likely to deceive or cause misunderstanding and did in fact deceive Plaintiffs and the Minnesota Subclass with respect to the Infant Formulas' ingredients, uses, benefits, standards, quality, grade, and suitability for consumption by infants with no development or health risks.

299. Defendant intended that Plaintiffs and the Minnesota Subclass would rely on Defendant's Omissions, concealment, implied warranties, and/or deceptions regarding the Infant Formulas' ingredients, uses, benefits, standards, quality, grade, and suitability for consumption by infants with no development or health risks.

300. Defendant's conduct and Omissions described herein occurred repeatedly in its trade or business and were capable of deceiving a substantial portion of the consuming public.

301. The facts concealed or not disclosed by Defendant were material facts in that Plaintiffs, the Minnesota Subclass, and any reasonable consumer would have considered them in deciding whether to purchase the Infant Formulas. Had Plaintiffs and the Minnesota Subclass known the Infant Formulas did not have the quality advertised by Defendant, they would not have purchased the Infant Formulas.

302. Defendant intended that Plaintiffs and the Minnesota Subclass would rely on Defendant's Omissions, concealment, and other deceptive, unfair, and misleading conduct when purchasing the Infant Formulas, unaware of the undisclosed material facts. This conduct constitutes consumer fraud.

303. Defendant's unlawful conduct is continuing, with no indication it intends to cease this fraudulent course of conduct.

304. Defendant was under a duty to disclose the Omissions because Defendant undertook the disclosure of information about the Infant Formulas on the Infant Formulas' packaging.

305. Defendant failed to discharge its duty to disclose the Omissions about the Infant Formulas.

306. As a direct and proximate result of Defendant's conduct, Plaintiffs and the Minnesota Subclass suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contain or risk containing Heavy Metals.

307. Plaintiffs and the members of the Minnesota Subclass would not have purchased the Infant Formulas at all had they known of the Omissions.

308. Pursuant to Minn. Stat. § 8.31, subd. 3a, and § 325D.45, Plaintiffs and the Minnesota Subclass seek actual damages, declaratory relief, attorneys' fees, costs, and any other just and proper relief available thereunder for Defendants' violations of the MUDTPA.

**COUNT VIII**

**Violations of Minnesota False Statement in Advertising Act, Minn. Stat. § 325F.67, et. seq.,  
Against Defendant on Behalf of the Minnesota Subclass**

309. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

310. Plaintiffs and the Minnesota Subclass purchased "goods," specifically the Infant Formulas discussed herein, and are a "person" within the meaning of the False Statement in Advertising Act ("FSAA").

311. Plaintiffs and the Minnesota Subclass purchased the Infant Formulas because of the Omissions asserted on the packaging that were made, published, disseminated, circulated, and placed before the public by Defendant.

312. By engaging in the conduct as described herein, Defendant continues to violate Minn. Stat. § 325F.67.

313. Defendant's Omissions and use of other deceptive, unfair, and misleading business practices include, by way of example, representations that the Infant Formulas were healthy, made from nutritious ingredients, and safe for consumption by infants with no development or health risks.

314. Defendant knew or should have known the Infant Formulas did not have the quality and ingredients described above because they included undisclosed (or material risk of) Heavy Metals.

315. The Omissions were likely to deceive or cause misunderstanding and did in fact deceive Plaintiffs and the Minnesota Subclass with respect to the Infant Formulas' ingredients, uses, benefits, standards, quality, grade, and suitability for consumption by infants with no development or health risks.

316. Defendant's conduct and Omissions described herein occurred repeatedly in Defendant's trade or business and were capable of deceiving a substantial portion of the consuming public.

317. The Omissions were made to customers in Minnesota, including the Minnesota Subclass, thus the cause of action serves the public benefit of informing Minnesota consumers that the Products contained (or had a material risk of containing) Heavy Metals.

318. The facts concealed, omitted, or not disclosed by Defendant were material facts in that Plaintiffs, the Minnesota Subclass, and any reasonable consumer would have considered them in deciding whether to purchase the Infant Formulas. Had Plaintiffs and the Minnesota Subclass known the Infant Formulas did not have the quality as advertised by Defendant, they would not have purchased the Infant Formulas or paid the premium price.

319. Defendant intended that Plaintiffs and the Minnesota Subclass would rely on the deception by purchasing the Infant Formulas, unaware of the Omissions and other undisclosed material facts. This conduct constitutes consumer fraud.

320. Defendant's unlawful conduct is continuing, with no indication that it intends to cease this fraudulent course of conduct.

321. As a direct and proximate result of Defendant's conduct, Plaintiffs and the Minnesota Subclass suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contain or risk containing Heavy Metals.

322. Plaintiffs and the members of the Minnesota Subclass would not have purchased the Infant Formulas at all had they known of the presence or material risk of these Heavy Metals.

323. Pursuant to Minn. Stat. §8.31, subd. 3a, and §325F.67, Plaintiffs and the Minnesota Subclass seek actual damages, declaratory relief, attorneys' fees, costs, and any other just and proper relief available thereunder for Defendant's violations of the FSAA.

**COUNT IX**

**Violations of Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F.69, *et. seq.*,  
Against Defendant on Behalf of the Minnesota Subclass**

324. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

325. The members of the Minnesota Subclass at times relevant hereto were citizens of the State of Minnesota.

326. Defendant is a “person” within the meaning of the Minnesota Prevention of Consumer Fraud Act (“MPCFA”).

327. The Omissions were made in connection with the sale of the Infant Formulas to Plaintiffs and the Minnesota Subclass.

328. Defendant knowingly acted, used, and employed fraud, false pretenses, and deceptive, unfair, and misleading practices in connection with the sale of the Infant Formulas. Specifically, Defendant failed to disclose the Infant Formulas contained levels or material risk of Heavy Metals.

329. Defendant knew or should have known the Infant Formulas did not have the quality reasonable consumers expected because they included undisclosed (or material risk of) Heavy Metals that do not conform to the packaging. Defendant intended for Plaintiffs and the Minnesota Subclass to rely on the Infant Formulas’ packaging in deciding whether to purchase the Infant Formulas.

330. Defendant’s unfair or deceptive acts or practices were likely to deceive reasonable consumers about the Infant Formulas’ quality, ingredients, consumption by infants with no development or health risks, and, by extension, the true value of the Infant Formulas. Plaintiffs and the Minnesota Subclass relied on, and were in fact deceived by, Defendant’s Omissions with

respect to the Infant Formulas' quality, ingredients, and fitness for consumption in deciding to purchase them over competitors' infant formulas.

331. The facts concealed, omitted, or not disclosed by Defendant were material facts in that Plaintiff, the Minnesota Subclass, and any reasonable consumer would have considered them in deciding whether to purchase the Infant Formulas. Had Plaintiffs and the Minnesota Subclass known the Infant Formulas did not have the quality advertised by Defendant, they would not have purchased the Infant Formulas or paid the premium price.

332. Defendant's Omissions were made to customers in Minnesota, including the Minnesota Subclass, thus the cause of action serves the public benefit of informing Minnesota consumers that the Products contained (or had a material risk of containing) Heavy Metals.

333. Defendant's unlawful conduct is continuing, with no indication that it intends to cease this fraudulent course of conduct.

334. As a direct and proximate result of Defendant's conduct, Plaintiffs and the Minnesota Subclass suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

335. Plaintiffs and the members of the Minnesota Subclass would not have purchased the Infant Formulas at all had they known of the presence of these Heavy Metals.

336. Pursuant to Minn. Stat. §8.31, subd. 3a, and §325F.69, Plaintiffs and the Minnesota Subclass seek actual damages, declaratory relief, attorneys' fees, costs, and any other just and proper relief available thereunder for Defendant's violations of the MPCFA.

**COUNT X**

**Violations of California’s Consumers Legal Remedies Act, California Civil Code §§1750, *et seq.*, Against Defendant on Behalf of the California Subclass**

337. Plaintiff Nunez incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

338. Plaintiff Nunez and each California Subclass member is a “consumer,” as that term is defined in California Civil Code section 1761(d).

339. The Infant Formula Products are “goods,” as that term is defined in California Civil Code section 1761(a).

340. Defendant is a “person” as that term is defined in California Civil Code section 1761(c).

341. Plaintiff Nunez and each California Subclass member’s purchase of Defendant’s products constituted a “transaction” as that term is defined in California Civil Code section 1761(e).

342. Defendant’s conduct alleged herein violates the following provisions of California’s Consumers Legal Remedies Act (the “CLRA”):

(a) California Civil Code section 1770(a)(5), by negligently, recklessly, and/or intentionally failing to disclose the Omissions;

(b) California Civil Code section 1770(a)(7), by negligently, recklessly, and/or intentionally representing that the Infant Formula was of a particular standard, quality, or grade, when it was of another;

(c) California Civil Code section 1770(a)(9), by negligently, recklessly, and/or intentionally advertising the Infant Formula with intent not to sell it as advertised; and

(d) California Civil Code section 1770(a) (16), by representing that the Infant Formula has been supplied in accordance with previous representations when it has not.

343. The Omissions were material as reasonable consumers such as Plaintiff Nunez and the California Subclass would deem that the Infant Formula contained (or had a material risk of containing) Heavy Metals important in determining whether to purchase the Infant Formulas.

344. As a direct and proximate result of these violations, Plaintiff Nunez and the California Subclass have been harmed, and that harm will continue unless Defendant is enjoined from using the misleading marketing described herein in any manner in connection with the advertising and sale of the Products.

345. Defendant was given written notice and demand pursuant to the CLRA by certified letter dated March 11, 2022, for the California Subclass' claims, and Defendant did not provide any response. Accordingly, Plaintiffs and the California Subclass seek economic and equitable relief and restitution herein.

346. In accordance with CLRA §1782(b), Plaintiff Nunez and the California Subclass are entitled, under CLRA §1780, to recover and obtain the following relief for Defendant's violations of CLRA §§1770(a)(5), (7), (9), and (16) for the Omissions: (a) Actual damages under CLRA §1780(a)(1); (b) Restitution of property under CLRA §1780(a)(3)(c) Punitive damages under CLRA §1780(a)(4); and (d) Any other relief the Court deems proper under CLRA §1780(a)(5).

347. Plaintiff Nunez, on behalf of herself and the California Subclass, seeks an award of attorneys' fees pursuant to, *inter alia*, California Civil §1780(e) and California Code of Civil Procedure §1021.5.



**COUNT XI**

**Violations of California False Advertising Law, California Business & Professions Code §§17500, *et seq.*, Against Defendant on Behalf of the California Subclass**

348. Plaintiff Nunez incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

349. California’s False Advertising Law prohibits any statement in connection with the sale of goods “which is untrue or misleading.” Cal. Bus. & Prof. Code §17500.

350. As set forth herein, Defendant’s Omissions were false and likely to deceive the public.

351. Defendant failed to disclose that the Products contained (or had the material risk of containing) Heavy Metals.

352. Defendant knew, or reasonably should have known, that these Omissions were untrue or misleading.

353. Plaintiff Nunez and the members of the California Subclass are entitled to economic and equitable relief, and restitution in an amount to be determined at trial.

**COUNT XII**

**Violations of the Unfair Competition Law, California Business & Professions Code §§17200, *et seq.*, Against Defendant on Behalf of the California Subclass**

354. Plaintiff Nunez incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

355. The Unfair Competition Law prohibits any “unlawful, unfair or fraudulent business act or practice.” Cal. Bus. & Prof. Code §17200:

**Fraudulent**

356. Defendant failed to disclose the Omissions.

**Unlawful**

357. As alleged herein, Defendant has advertised the Infant Formula with false or misleading Omissions, such that Defendant's actions violate at least the following laws:

- The CLRA, California Business & Professions Code §§1750, *et seq.*; and
- The False Advertising Law, California Business & Professions Code §§17500, *et seq.*

**Unfair**

358. Defendant's conduct with respect to the labeling, packaging, advertising, marketing, and sale of the Products is unfair because Defendant'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.

359. Defendant's conduct with respect to the labeling, packaging, advertising, marketing, and sale of the Products is also unfair because it violates public policy as declared by specific constitutional, statutory, or regulatory provisions, including, but not limited to, the False Advertising Law and the CLRA.

360. Defendant's conduct with respect to the labeling, packaging, advertising, marketing, and sale of the Products is also unfair because the consumer injury is substantial, not outweighed by benefits to consumers or competition, and not one consumers themselves can reasonably avoid.

361. Plaintiff Nunez, on behalf of herself and the California Subclass, seeks an order for the restitution of all monies from the sale of the Products, which were unjustly acquired through acts of fraudulent, unfair, or unlawful competition.

**COUNT XIII**

**Breach of the Implied Warranty of Merchantability – California Uniform Commercial Code, Cal. Comm. Code §2314, Against Defendant on Behalf of the California Subclass**

362. Plaintiff Nunez incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

363. This claim is brought by Plaintiff Nunez on behalf of the California Subclass.

364. Defendant is and was at all relevant times a merchant as defined by California Commercial Code section 2104.

365. A warranty that the Products were in merchantable condition is implied by law pursuant to California Commercial Code section 2314.

366. Plaintiff Nunez and the members of the California Subclass purchased the Products manufactured and marketed by Defendant by and through Defendant's authorized sellers for retail or online sale to consumers. At all relevant times, Defendant was the merchant, manufacturer, marketer, warrantor, and/or seller of the Products. Defendant knew or had reason to know of the specific use for which its Products were purchased.

367. The Products are and were at all relevant times goods within the meaning of California Commercial Code section 2105.

368. Defendant impliedly warranted that the Products were in merchantable condition and fit for consumption or ingestion by babies. The Products when sold at all times thereafter were not in merchantable condition and did not conform to the promises on the packaging. The Products are not safe for babies based on accumulation of Heavy Metals. Thus, Defendant breached its implied warranty of merchantability for the ordinary purpose for which the Products are purchased and used.

369. Defendant cannot disclaim its implied warranty as it knowingly sold Products that contained (or had a material risk of containing) Heavy Metals.

370. Defendant was provided notice by letter as described above as well as by the FDA inspection and conclusions and testimony to Congress. Affording any further opportunity to cure its breach of implied warranties would be unnecessary and futile here because Defendant has known of and concealed the safety risks attendant to the Infant Formulas.

371. As a direct and proximate result of Defendant's breach of the implied warranty of merchantability, Plaintiff Nunez and members of the California Subclass have suffered damages in an amount to be proven at trial by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

372. Plaintiff Nunez and members of the California Subclass have been excused from performance of any warranty obligations as a result of Defendant's conduct described herein.

#### **COUNT XIV**

#### **Violations of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§201-1 *et seq.*, Against Defendant on behalf of the Pennsylvania Subclass**

373. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

374. Plaintiffs bring this claim on behalf of the members of the Pennsylvania Subclass against Defendant for violations of Pennsylvania's Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§201-1, *et seq.*

375. Plaintiff, Defendant, and members of the Pennsylvania Subclass are “Person[s]” within the meaning of Pennsylvania’s Unfair Trade Practices and Consumer Protection Law (“UTPCPL”), 73 Pennsylvania Statute section 201-2(2).

376. 73 Pennsylvania Statute section 201-3 declares unlawful “unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce[.]”

377. Defendant’s business acts and practices alleged herein constituted deceptive acts or practices under 73 Pennsylvania Statute section 201, *et seq.*

378. Defendant has known or reasonably should have known that the Products contained or had a material risk of containing Heavy Metals, and that Plaintiffs and other members of the Pennsylvania Subclass would reasonably and justifiably rely on the packaging in purchasing the Products.

379. Defendant has intentionally and knowingly omitted material facts with an intent to mislead Plaintiffs and the Pennsylvania Subclass.

380. The above unlawful, unfair, misleading, and deceptive acts and practices by Defendant were immoral, unethical, oppressive and unscrupulous. These acts caused substantial injury to Plaintiffs and the Pennsylvania Subclass that they could not reasonably avoid, and this substantial injury outweighed any benefits to consumers or to competition.

381. Defendant’s Omissions were material to Plaintiffs and the Pennsylvania Subclass because they relate to the quality and safety of the product the consumer is receiving and paying for. A reasonable consumer would attach importance to such misrepresentations and would be induced to act thereon in making purchase decisions.

382. As a direct and proximate cause of Defendant’s conduct, Plaintiffs and members of the Pennsylvania Subclass suffered damages by: (1) paying a premium price for Products they

reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

383. Plaintiffs and the Pennsylvania Subclass seek an order awarding attorneys' fees and any other just and proper relief available under the UTPCPL.

384. In addition to or in lieu of actual damages, Plaintiffs and the Pennsylvania Subclass seek statutory damages for each injury and violation which has occurred. Plaintiffs and the Pennsylvania Subclass seek relief under 73 Pennsylvania Statute section 201-9.2, including, but not limited to, actual damages or \$100 per Class Member, whichever is greater, treble damages, and attorneys' fees and costs.

#### **COUNT XV**

#### **Violations of New York's Deceptive Acts and Practices, N.Y. Gen. Bus. Law §349, Against Defendant on Behalf of the New York Subclass**

385. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

386. New York General Business Law ("GBL") section 349 prohibits "[d]eceptive acts or practices in the conduct of any business, trade, or commerce[.]"

387. In its advertising and sale of goods throughout New York, Defendant conducts business and trade within the meaning of GBL section 349.

388. Defendant violated GBL section 349 by deceptively and misleadingly omitting that the Infant Formulas contained (or had a material risk of containing) Heavy Metals.

389. Defendant's Omissions, concealment, and other deceptive, unfair, and misleading conduct intentionally marketed that the Infant Formulas were of a particular standard, grade, or quality when they in fact contained (or had a material risk of containing) Heavy Metals.

390. Defendant's Omissions, concealment, and other deceptive, unfair, and misleading conduct described herein were directed at the consumer public at-large as they repeatedly occurred in the course of Defendant's business and were capable of deceiving a substantial portion of the consuming public.

391. The facts concealed or not disclosed by Defendant were material facts in that Plaintiffs, the New York Subclass, and other reasonable consumers would have considered them when deciding whether to purchase the Infant Formulas. Had Plaintiffs and members of the New York Subclass known the Infant Formulas did not have the quality, ingredients, and standards as advertised by Defendant, and contained (or had a material risk of containing) Heavy Metals, they would not have purchased the Infant Formulas or paid a premium price.

392. Defendant had exclusive and superior knowledge of the information that was material to Plaintiffs and the New York Subclass that was not reasonably accessible to reasonable consumers. Defendant unfairly and misleadingly failed to disclose such material information to consumers.

393. Defendant has engaged and continues to engage in deceptive, unfair, and misleading conduct in violation of GBL section 349.

394. Defendant intended for Plaintiffs and the New York Subclass to rely on its Omissions, concealment, and other deceptive, unfair, and misleading conduct regarding the Infant Formulas' quality, ingredients, and standards when purchasing the Infant Formulas, unaware of the undisclosed material facts.

395. As a direct and proximate result of Defendant's Omissions, concealment, and other deceptive, unfair, and misleading conduct, Plaintiffs and the New York Subclass suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or

have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

396. Pursuant to GBL section 349(h), Plaintiffs and the New York Subclass seek declaratory relief, full refund, compensatory and punitive damages, actual damages or \$50 (whichever is greater), three times the actual damages (up to \$1,000) to the extent Defendant is found to have acted willfully or knowingly in violating this statute, and attorneys' fees. Plaintiffs and the New York Subclass also seek costs to the extent permitted by law.

#### **COUNT XVI**

#### **Violations of New York's False Advertising Law, N.Y. Gen. Bus. Law §350, Against Defendant on Behalf of Plaintiffs and the New York Subclass**

397. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

398. New York General Business Law ("GBL") section 350 prohibits false advertising in the conduct of any business, trade, or commerce.

399. Pursuant to GBL section 350-a, false advertising is defined as "advertising, including labeling, of a commodity . . . if such advertising is misleading in a material respect . . . [considering] representations made by statement, word, design . . . or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations[.]"

400. Defendant knew or should have known the Infant Formulas did not have the quality, ingredients, and standards as described above because they contained (or had a material risk of containing) undisclosed levels of Heavy Metals.

401. Defendant purposely concealed and did not disclose material facts regarding the presence of Heavy Metals to consumers, such as Plaintiffs and the New York Subclass.



402. The facts concealed or not disclosed by Defendant were material facts in that Plaintiffs, the New York Subclass, and other reasonable consumers would have considered them when deciding whether to purchase the Infant Formulas. Had Plaintiffs and members of the New York Subclass known the Infant Formulas did not have the quality, ingredients, and standards as advertised by Defendant and contained (or had a material risk of containing) Heavy Metals, they would not have purchased the Infant Formulas or paid the price they did.

403. Defendant's conduct caused Plaintiffs and the New York Subclass to suffer actual damages when they purchased the Infant Formulas that were worth less than the price paid and that they would not have purchased at all had they known the Infant Formulas contained (or had a material risk of containing) Heavy Metals.

404. As a direct and proximate result of Defendant's Omissions, concealment, and other deceptive, unfair, and misleading conduct, Plaintiffs and the New York Subclass suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

405. Pursuant to GBL section 350-e, Plaintiffs and the New York Subclass seek declaratory relief, full refund, compensatory and punitive damages, actual damages or \$500 (whichever is greater), three times the actual damages (up to \$10,000) to the extent Defendant is found to have acted willfully or knowingly in violating this statute, and attorneys' fees. Plaintiffs and the New York Subclass also seek costs to the extent permitted by law.

**COUNT XVII**  
**Unjust Enrichment Against Defendant on Behalf of the Class  
or, Alternatively, the State Subclasses**

406. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

407. Substantial benefits have been conferred on Defendant by Plaintiffs and the Class through the purchase of the Infant Formulas. Defendant knowingly and willingly accepted and enjoyed these benefits.

408. Defendant either knew or should have known that the payments rendered by Plaintiffs and the Class were given and received with the expectation that the Infant Formulas would not contain (or have a material risk of containing) Heavy Metals. As such, it would be inequitable for Defendant to retain the benefit of the payments under these circumstances.

409. Defendant was obligated to disclose the Omissions in the Infant Formulas because (1) it had exclusive knowledge that the Infant Formula contained (or had a material risk of containing) Heavy Metals; (2) the Omissions were not known or reasonably accessible to Plaintiffs and the Class; (3) Defendant actively concealed the Omissions; and (4) Defendant made partial statements on the Infant Formulas' packaging that gave a misleading impression to Plaintiffs and the Class and reasonable consumers without further information because the Omissions were not disclosed.

410. Defendant's acceptance and retention of the benefits of the payments from Plaintiffs and the Class under the circumstances alleged herein make it inequitable for Defendant to retain the benefits without payment of the value to Plaintiffs and the Class.

411. Plaintiffs and the Class are entitled to recover from Defendant all amounts wrongfully collected and improperly retained by Defendant, plus interest thereon.

412. Plaintiffs and the Class seek actual damages, declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, pray for judgment against the Defendant as to each and every count, including:

A. An order declaring this action to be a proper class action, appointing Plaintiffs and their counsel to represent the Classes, and requiring Defendant to bear the costs of class notice;

B. An order requiring Defendant to pay restitution 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, untrue or misleading advertising, or a violation of the State Subclass laws, plus pre- and post-judgment interest thereon;

C. An order requiring Defendant to disgorge or return all monies, revenues, and profits obtained by means of any wrongful or unlawful act or practice;

D. An order requiring Defendant to pay all actual and statutory damages permitted under the counts alleged herein;

E. An order requiring Defendant to pay punitive damages on any count so allowable;

F. An order awarding attorneys' fees and costs to Plaintiffs and the Classes; and

G. An order providing for all other such equitable relief as may be just and proper.

**JURY DEMAND**

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: March 7, 2025

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