

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

**CHARLOTTE WILLOUGHBY,  
LAKENDREA CAMILLE MCNEALY,  
SHAYLYNN DOXIE, BRITTNEY  
GRAY, KATALEENA HELMICK,  
LANI HOLLOWAY, ASHLEY POPA  
and DENIEGE REVORD**, individually  
and on behalf of a class of similarly situated  
individuals,

**PLAINTIFFS,**

V.

**ABBOTT LABORATORIES.**

**DEFENDANT.**

Case No. 1:22-cv-01322

**DEMAND FOR JURY TRIAL**

## CONSOLIDATED CLASS ACTION COMPLAINT

1. Plaintiffs Charlotte Willoughby, LaKendra Camille McNealy, Shaylynn Doxie, Brittney Gray, Katalena Helmick, Lani Holloway, Ashley Popa, and Deniege Revord (collectively, “Plaintiffs”), individually and on behalf of all others similarly situated, by and through their undersigned attorneys, bring this Class Action Complaint against Defendant Abbott Laboratories (“Defendant”) for its knowing, reckless, and/or intentional practice of failing to disclose the lack of quality control in manufacturing infant formula and also failing to disclose the presence of arsenic, cadmium, lead, or mercury (collectively, “Heavy Metals”) in its Similac®

powdered infant formulas (“Products” or “Infant Formulas”).<sup>1</sup> The Infant Formulas are sold throughout the United States and do not conform to their packaging. Plaintiffs seek both injunctive and monetary relief on behalf of the proposed Classes (as defined herein), including requiring full disclosure of the lack of quality controls and disclosure of the risk or presence of Heavy Metals on the Products’ packaging, and restoring monies to the members of the proposed Classes. Plaintiffs allege the following based upon personal knowledge as well as 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 is a one of the primary manufacturers of infant formula in the U.S. and previously held 40% of the market share.<sup>2</sup> Devastatingly, it has recently been disclosed that Defendant ignored its duties to ensure proper quality control measures when making food for the most vulnerable population – infants – and instead manufactured infant formula in “egregiously unsanitary” conditions with failing quality control measures.<sup>3</sup> In fact, members of Congress have stated that “‘it feels like there’s just corruption from the top down at that plant...Abbott appears

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<sup>1</sup> “Products” or “Infant Formula(s)” as to the Heavy Metals allegations refer to the following Abbott Laboratories products: Similac® Pro Advance, Similac® 360 Total Care, Similac® Soy Isomil, Similac® Advance OptiGRO Powder – Milk-Based, Similac® Neosure, and Similac® Total Comfort powdered infant formulas. Discovery may reveal additional products that contain levels of Heavy Metals. Plaintiffs reserve their right to include any such products in this action.

<sup>2</sup><https://www.cnn.com/amp/2022/05/25/watch-live-house-grills-fda-commissioner-abbott-executive-on-baby-formula-shortage.html> (last accessed May 25, 2022)

<sup>3</sup> *Id.*

to have a long-running ‘culture problem’ at the plant, not just a few instances of food safety violations.”<sup>4</sup>

3. Yet, Defendant chose to sell itself to new parents as a trusted company and nowhere did it disclose the lack of quality control and unsanitary conditions where it manufactured its infant formula or that the formula contained or had a material risk of containing Heavy Metals (collectively hereafter the “Omissions”). Both of which 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 with introduction of solid foods until they are 12 months old and beyond.<sup>5</sup> However, according to the Centers for Disease Control and Prevention (“CDC”), only 46.3% of babies under three months old are exclusively breastfed, and the percentage of babies exclusively breastfed through six months drops to 25.8%.<sup>6</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

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<sup>4</sup> <https://www.politico.com/news/2022/05/25/abbott-fda-congress-testimony-00035224> (last accessed May 25, 2022).

<sup>5</sup> CDC, *Infant and Toddler Nutrition: Recommendation and Benefits*, available at <https://www.cdc.gov/nutrition/infantandtoddlernutrition/breastfeeding/recommendations-benefits.html> (last accessed May 17, 2022).

<sup>6</sup> CDC, *Key Breastfeeding Indicators*, available at <https://www.cdc.gov/breastfeeding/data/facts.html> (last accessed May 17, 2022).

old.<sup>7</sup> Therefore, a significant number of babies rely on infant formulas 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 and made in sanitary conditions with quality control measures. They certainly expect the 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. They would also expect that the manufacturing of the infant formula would not be without proper quality control procedures and in “egregiously unsanitary” conditions.

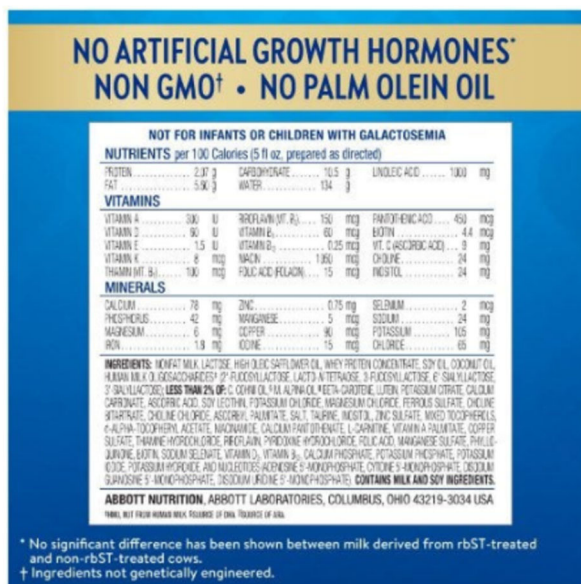
6. Consumers lack the knowledge to determine if quality control procedures are followed and if conditions are sanitary in the manufacturing of the Products. Consumers also lack the scientific knowledge necessary to determine whether the Defendant’s Products do in fact contain (or have a material risk of containing) Heavy Metals or to ascertain the true nature of the ingredients and quality of the Products. Reasonable consumers therefore must and do rely on Defendant to properly and fully disclose what its Products contain. This is especially true for products such as infant formula, the contents of which include the risk or presence of Heavy Metals, including arsenic, lead, cadmium, and mercury, that are being fed to hours-, days- or months-old babies. Such information would be material to any reasonable parent’s purchasing decisions.

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<sup>7</sup> CDC, *When, What, and How to Introduce Solid Foods*, available at <https://www.cdc.gov/nutrition/InfantandToddlerNutrition/foods-and-drinks/when-to-introduce-solid-foods.html> (last accessed May 17, 2022).



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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>8</sup>



11. Based on the messaging and 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. This is especially true as the development and physical risks created by ingestion of Heavy Metals by infants is well-recognized.

12. Likewise, this same packaging promising healthy, high quality and safe products would not lead reasonable consumers to expect or understand that the Infant Formula was manufactured by a company that allowed “egregiously unsanitary” conditions” and without proper quality control procedures.

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<sup>8</sup> <https://www.similac.com/baby-formula-ingredients.html> (last accessed May 17, 2022).

13. Defendant's website provides further context to demonstrate that the Products' packaging is deceptive 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, with nutrition [parents] can trust to keep [babies] fed, happy, and healthy;"<sup>9</sup> (2) that parents "can be confident in the nourishment of Similac;"<sup>10</sup> and (3) that its Products are "enriched with key vitamins, minerals, and nutrients to help give your little one a strong start."<sup>11</sup> This is all in direct contradiction to the Omissions.

14. First, the FDA recently testified that "[t]he inspection results were shocking," and "We had no confidence in integrity of the quality program at the facility."<sup>12</sup> This same inspection revealed "cracks in vital equipment, a lack of adequate hand washing, evidence of previous bacterial contamination, and water leaks in areas where formula is produced."<sup>13</sup>

15. During the recent Congressional hearing concerning Defendant, Rep. Debbie Dingell (D-MI) stated: "I have to be really clear about why we're here today: because Abbott Nutrition has *consistently failed for years to implement basic safety procedures* at [the manufacturing plant]."<sup>14</sup> (emphasis added). "It feels like there's just corruption from the top down

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<sup>9</sup> <https://www.similac.com/the-similac-difference.html> (last accessed May 17, 2022).

<sup>10</sup> <https://www.similac.com/why-similac.html> (last accessed May 17, 2022).

<sup>11</sup> <https://www.similac.com/the-similac-difference.html> (last accessed May 17, 2022).

<sup>12</sup> <https://www.nytimes.com/2022/05/25/health/fda-baby-formula-shortage.html> (last accessed May 25, 2022).

<sup>13</sup> <https://www.reuters.com/world/us/us-fda-defends-baby-formula-shortage-response-congress-2022-05-25/> (last accessed May 25, 2022).

<sup>14</sup> <https://www.washingtonexaminer.com/policy/congress-grills-abbott-executive-over-failures-in-infant-formula-plant-shutdown> (last accessed May 25, 2022).

at that plant," Rep. Kim Schrier, D-Wash., said. And Christopher Calamari, Abbott's senior vice president for U.S. Nutrition, acknowledged that Defendant "had let the public down."<sup>15</sup>

16. Despite the known control failures and the risks that creates, Defendant knowingly chose to not disclose to consumers that the Infant Formulas were manufactured without basic quality controls and in unsanitary conditions. Nowhere on the Infant Formulas' packaging is the lack of proper manufacturing controls or material risk of contamination from failing to ensure safe manufacturing processes disclosed.

17. 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, and not disclose the true quality of the Products.

18. Second, 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>16</sup>

19. Recent testing conducted on five of the Similac® Infant Formulas confirmed the presence of Heavy Metals, to include:

Infant Formula	Level of Heavy Metal in parts per billion ("ppb")
Similac® Soy Isomil	11.4 ppb Cadmium
Similac® 360 Total Care	6.7 ppb Arsenic
Similac® Pro Advance	10.1 ppb Mercury

<sup>15</sup>*Id.*

<sup>16</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 May 17, 2022) ("HBBF Report").



Infant Formula	Level of Heavy Metal in parts per billion (“ppb”)
Similac® Neosure	7.8 ppb Arsenic
Similac® Total Comfort	9.7 ppb Arsenic

20. Independent testing also confirmed the presence of two Heavy Metals in another of Defendant’s products:<sup>17</sup>

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

21. Arsenic, cadmium, lead, and mercury, are all known to pose health risks to humans, and particularly to infants.<sup>18</sup>

22. 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 including 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>19</sup>

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<sup>17</sup> *Id.* at 20, 34.

<sup>18</sup> *See, generally, id.*

<sup>19</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,” February 4, 2021, available at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf> (last accessed May 17, 2022) (“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,” September 29, 2021, available at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/ECP%20>

23. 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.

24. 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.

25. 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, made with nutritious ingredients.

26. 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>20</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>21</sup>

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[Second%20Baby%20Food%20Report%209.29.21%20FINAL.pdf](#) (last accessed May 17, 2022) ("Second Congressional Committee Report").

<sup>20</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 May 17, 2022).

<sup>21</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 May 17, 2022).

27. Based on Defendant's packaging and related 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.

28. 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 properly and safely manufactured and free from the risk and actual presence of 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, and that these consumers will pay for infant formulas they believe possess these qualities. Defendant also knows no reasonable consumer would knowingly provide his or her children with infant formula that contained Heavy Metals or was manufactured in “egregiously unsanitary” conditions without proper quality control procedures.

29. 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.

30. The material Omissions are deceptive, misleading, unfair, and/or false because the Infant Formulas were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and/or contain (or risk containing) undisclosed Heavy Metals.

31. 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.

32. 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**

33. 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.

34. 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**

35. Plaintiff Charlotte Willoughby ("Plaintiff Willoughby") is, and at times relevant hereto was, a citizen of the State of Illinois and a resident of Palatine, Illinois. She purchased the Infant Formula, including Similac® Neosure for household use.

36. From May to July 2019, Plaintiff Willoughby was a citizen of Indiana, but she was residing in Palatine, Illinois, and she purchased the Infant Formula for her children from a Jewel-Osco Grocery Store in Palatine, Illinois, during that approximate applicable limitations period.

37. Plaintiff Willoughby believed she was feeding her children healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Willoughby saw and relied upon the packaging of the Infant Formula. During the time she purchased and fed her children the Infant Formula, and due to the Omissions by Defendant, she was unaware the Infant Formula was manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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. Plaintiff would be willing to purchase Similac® products in the future if she could be certain that they were safely manufactured and do not contain (or have a material risk of containing) Heavy Metals.

38. Plaintiff LaKendrea Camille McNealy (“Plaintiff McNealy”) at times relevant hereto was a citizen of the State of Minnesota and currently resides in the State of Texas. She purchased the Infant Formula, including Similac® Soy Isomil for household use.

39. Plaintiff McNealy purchased the Infant Formula for her child from Walmart in Apple Valley, Minnesota, from approximately December of 2018 until March of 2019.

40. Plaintiff McNealy believed she was feeding her child healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff McNealy saw and relied upon the packaging of the Infant Formula. During the time she purchased and fed her children the Infant Formula, and due to the Omissions by Defendant, she was unaware the Infant Formula was manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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. Plaintiff would be willing to purchase Similac® products in the future if she could be certain that they were safely manufactured and do not contain (or have a material risk of containing) Heavy Metals.

41. Plaintiff Shaylynn Doxie (“Plaintiff Doxie”) is, and at all times relevant hereto has been, a citizen of the State of California and a resident of Sacramento, California. She purchased the Infant Formula, including Similac Pro-Advance and Similac 360 Total Care for household use.

42. Plaintiff Doxie purchased the Infant Formula for her child from retail outlets such as Target, CVS, Rite Aid, Walmart, and Amazon during and within the applicable limitations period.

43. Plaintiff Doxie believed she was feeding her child healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Doxie saw and relied upon the packaging of the Infant Formula. During the time she purchased and fed her children the Infant Formula, and due to the Omissions by Defendant, she was unaware the Infant Formula was manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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. Plaintiff would be willing to purchase Similac® products in the future if she could be certain that they were safely manufactured and do not contain (or have a material risk of containing) Heavy Metals.

44. Plaintiff Brittney Gray (“Plaintiff Gray”) at all times relevant hereto was a citizen of the State of Hawaii and a resident of Honolulu, Hawaii. She purchased the Infant Formula, including Similac® Pro-Advance for household use.

45. Plaintiff Gray purchased the Infant Formula for her child from Fry’s Food and Drug Store, Walmart, and Safeway, in Hawaii, during and within the statutory applicable limitations period.

46. Plaintiff Gray believed she was feeding her child healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Gray saw and relied upon the packaging

of the Infant Formula. During the time she purchased and fed her children the Infant Formula, and due to the Omissions by Defendant, she was unaware the Infant Formula was manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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. Plaintiff would be willing to purchase Similac® products in the future if she could be certain that they were safely manufactured and do not contain (or have a material risk of containing) Heavy Metals.

47. Plaintiff Kataleena Helmick (“Plaintiff Helmick”) at all times relevant hereto was a citizen of the State of Nebraska and a resident of Auburn, Nebraska. She purchased the Infant Formula, including Similac® Pro-Advance for household use.

48. Plaintiff Helmick purchased the Infant Formula for her child from Walmart in Nebraska, during and within the applicable limitations period.

49. Plaintiff Helmick believed she was feeding her child healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Helmick saw and relied upon the packaging of the Infant Formula. During the time she purchased and fed her children the Infant Formula, and due to the Omissions by Defendant, she was unaware the Infant Formula was manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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. Plaintiff would be willing to purchase Similac® products in the future if she could be certain that they were safely manufactured and do not contain (or have a material risk of containing) Heavy Metals.

50. Plaintiff Lani Holloway (“Plaintiff Holloway”) at all times relevant hereto was a citizen of the State of Texas and a resident of Trenton, Texas. She purchased the Infant Formula, including Similac® Pro-Advance for household use

51. Plaintiff Holloway purchased the Infant Formula for her child from Walmart in Sherman, Texas, during and within the applicable limitations period.

52. Plaintiff Holloway believed she was feeding her child healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Holloway saw and relied upon the packaging of the Infant Formula. During the time she purchased and fed her children the Infant Formula, and due to the Omissions by Defendant, she was unaware the Infant Formula was manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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. Plaintiff would be willing to purchase Similac® products in the future if she could be certain that they were safely manufactured and do not contain (or have a material risk of containing) Heavy Metals.

53. Plaintiff Ashley Popa (“Plaintiff Popa”) at all times relevant hereto was a citizen of the Commonwealth of Pennsylvania and a resident of New Castle, Pennsylvania. She purchased the Infant Formula, including Similac® Pro-Advance for household use

54. Plaintiff Popa purchased the infant formula for two separate babies from Walmart and Giant Eagle in New Castle, Pennsylvania and from Target in Boardman, Ohio during and within the applicable limitations period.

55. Plaintiff Popa believed she was feeding her children healthy and nutritious infant formula. Prior to purchasing the Infant Formula, Plaintiff Popa saw and relied upon the packaging of the Infant Formula. During the time she purchased and fed her children the Infant Formula, and



due to the Omissions by Defendant, she was unaware the Infant Formula was manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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. Plaintiff would be willing to purchase Similac® products in the future if she could be certain that they were safely manufactured and do not contain (or have a material risk of containing) Heavy Metals.

56. Plaintiff Deniege Revord (“Plaintiff Revord”) at all times relevant hereto was a citizen of the State of Michigan and a resident of Pinconning, Michigan. She purchased the Infant Formula, including Similac® Pro-Advance and Similac® Total Comfort for household use

57. Plaintiff Revord purchased the Infant Formula for her child on Amazon, and from Walmart and Meijer in Michigan, during and within the applicable limitations period.

58. Plaintiff Revord believed she was feeding her child healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Revord saw and relied upon the packaging of the Infant Formula. During the time she purchased and fed her children the Infant Formula, and due to the Omissions by Defendant, she was unaware the Infant Formula was manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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. Plaintiff would be willing to purchase Similac® products in the future if she could be certain that they were safely manufactured and do not contain (or have a material risk of containing) Heavy Metals.

59. As the result of Defendant’s intentionally, recklessly, and/or knowingly deceptive 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, the Infant Formulas were not manufactured in “egregiously unsanitary” conditions without proper quality control procedures, were free of 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. Further, should Plaintiffs encounter the Infant Formulas in the future, they could not rely on the truthfulness of the packaging, absent corrective changes to the packaging and advertising of the Infant Formulas. Damages can be calculated through expert testimony at trial.

60. 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.

61. 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 throughout March 1, 2016, 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 it used “egregiously unsanitary” conditions without proper quality control procedures in manufacturing the Products and 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.

62. Plaintiffs relied upon the Infant Formulas' packaging and the material Omissions, which was 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.

63. 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. The Truth Is Revealed As to The Quality and Nature of Defendant's Unsafe Manufacturing Processes of the Infant Formulas**

64. Defendant was one of the trusted manufacturers of Infant Formulas in the U.S. But recently it was exposed that it “*consistently failed for years to implement basic safety procedures at [the manufacturing plant].*”<sup>22</sup> This is despite that Defendant was manufacturing product for infants that are hours, days and months old.

65. The investigation into Defendant stemmed from a recall and a complaint by a whistleblower who outlined numerous alarming quality control issues, including:

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<sup>22</sup><https://www.washingtonexaminer.com/policy/congress-grills-abbott-executive-over-failures-in-infant-formula-plant-shutdown> (last accessed May 25, 2022).

- (a) Falsification of Records;
- (b) Releasing Untested Formula for sale;
- (c) Lax Cleaning Practices;
- (d) Failure to Take Corrective Measures; and
- (e) Lack of Traceability.<sup>23</sup>

66. Christopher Calamari, Abbott's senior vice president for U.S. Nutrition, acknowledged that Defendant “had let the public down.”<sup>24</sup> And this is unsurprising as the FDA concluded that its inspections showed “egregious unsanitary” conditions like cracks in key equipment that allowed bacteria to enter, a leaking roof and water collecting on the floor. The FDA also told Congress, “We had no confidence in integrity of the quality program at the facility.”<sup>25</sup>

67. As the FDA testified, “[There were] many signs of a disappointing lack of attention to the culture of safety...And this product that is so essential to the lives of our most precious people.”<sup>26</sup>

68. Defendant was in a superior position to know, or to should know, that its Infant Formulas were manufactured in unsanitary conditions and with a lack of quality control.

69. Despite the known control failures and the risks that creates, Defendant knowingly chose to not disclose to consumers that the Infant Formulas were manufactured without basic

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<sup>23</sup>[https://www.marlerblog.com/files/2022/04/Redacted-Confidential-Disclosure-re-Abbott-Laboratories-10-19-2021\\_Redacted-1-1.pdf](https://www.marlerblog.com/files/2022/04/Redacted-Confidential-Disclosure-re-Abbott-Laboratories-10-19-2021_Redacted-1-1.pdf) (last accessed May 25, 2022).

<sup>24</sup>*Id.*

<sup>25</sup> <https://www.nytimes.com/2022/05/25/health/fda-baby-formula-shortage.html> (last accessed May 25, 2022).

<sup>26</sup><https://www.law360.com/productliability/articles/1496444/fda-found-egregious-conditions-at-abbott-baby-food-plant> (last accessed May 25, 2022).



safety controls and unsanitary conditions. Nowhere on the Infant Formulas' packaging does Defendant disclose the lack of proper manufacturing controls or material risk of contamination from failing to ensure safe manufacturing processes.

## **II. Defendant Knew or Should Have Known of the Health Risks Presented to Infants and Children from Heavy Metals And The Likelihood It Was Present in Its Products**

70. While 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. 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>27</sup>

71. 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>28</sup>

72. 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>29</sup>

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<sup>27</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 May 17, 2022) (“Some Baby Food May Contain Toxic Metals”).

<sup>28</sup>FDA, *Metals and Your Food*, available at <https://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/default.htm> (last accessed May 17, 2022) (“Metals and Your Food”).

<sup>29</sup> HBBF Report, *supra*, at 13.



73. 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>30</sup> Even when trace amounts are found in food, these Heavy Metals can alter the developing brain and erode a child’s intelligence quotient (“IQ”).<sup>31</sup>

74. 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>32</sup>

75. 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>33</sup>

76. 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>34</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>35</sup>

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<sup>30</sup> *Id.* at 6.

<sup>31</sup> Congressional Committee Report, *supra*, at 1.

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

<sup>33</sup> *Id.*

<sup>34</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 May 17, 2022).

<sup>35</sup> Jaishankar, M., Tseten, T., Anbalagan, N., Mathew, B. B., & Beeregowda, K. N. (2014).

77. 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 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>36</sup>

78. 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>37</sup>

79. 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>38</sup>

80. 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>39</sup>

### ***Arsenic***

81. 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>40</sup> “[E]ven low levels of arsenic exposure can impact a baby’s

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*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 May 17, 2022).

<sup>36</sup> Consumer Reports: Heavy Metals in Baby Food, *supra*.

<sup>37</sup> Consumer Reports: Heavy Metals in Baby Food, *supra*.

<sup>38</sup> HBBF Report, *supra*, at 1.

<sup>39</sup> Congressional Committee Report, *supra*, at 2.

<sup>40</sup> HBBF Report, *supra*, at 13.

neurodevelopment.”<sup>41</sup> “Studies have shown that consuming products with arsenic over time can lead to impaired brain development, growth problems, breathing problems, and a compromised immune system.”<sup>42</sup>

82. 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>43</sup> Exposure to arsenic can also cause diabetes, atherosclerosis, and cardiovascular disease.<sup>44</sup>

83. Arsenic can cause cancer in humans, as well as diabetes and atherosclerosis, and potentially cardiovascular disease when ingested chronically.<sup>45</sup> Chronic exposure to arsenic has also been associated with dermatological lesions and malignancies.<sup>46</sup>

84. Moreover, “[t]here is no evidence that the harm caused by arsenic is reversible.”<sup>47</sup>

85. 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

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<sup>41</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 May 17, 2022)).

<sup>42</sup> *Id.*

<sup>43</sup> Congressional Committee Report, *supra*, at 10.

<sup>44</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 May 17, 2022) (“Prenatal Arsenic Exposure”).

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

<sup>46</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 May 17, 2022) (“Toxic Element Contamination of Natural Health Products”).

<sup>47</sup> HBBF Report, *supra*, at 3.

limit of arsenic at 10 ppb for human consumption in apple juice (regulated by the FDA) and 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>48</sup>

86. 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>49</sup> The FDA’s limit for inorganic arsenic in bottled water is 10 ppb.<sup>50</sup>

87. Dr. James E. Rogers, the director of food safety research and testing at Consumer Reports had 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>51</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 that unless breastmilk is an option, formula is the only food babies younger than 5 months can eat for their development and growth.

88. Despite this, laboratory tests indicate that Defendant sold Products containing undisclosed arsenic levels at 9.7 ppb, an amount that is especially concerning considering the amount of infant formula consumed by developing children.

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<sup>48</sup> Toxic Heavy Metals in Popular Baby Foods, *supra*.

<sup>49</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 May 25, 2022).

<sup>50</sup> 21 C.F.R. §165.110(b)(4)(iii)(A).

<sup>51</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 May 17, 2022) (emphasis added).

### ***Cadmium***

89. 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.

90. 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>52</sup>

91. Cadmium, like lead, “displays a troubling ability to cause harm at low levels of exposure.”<sup>53</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>54</sup> Compounding such concerns is the fact that cadmium has a prolonged half-life as it “sequesters in [human] tissue.”<sup>55</sup>

92. 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>56</sup>

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

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<sup>52</sup> HBBF Report, *supra*, at 14.

<sup>53</sup> *Id.*

<sup>54</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 May 17, 2022).

<sup>55</sup> Toxic Element Contamination of Natural Health Products, *supra*.

<sup>56</sup> Congressional Committee Report, *supra*, at 29.

***Lead***

94. The Infant Formulas contain (or have a material risk of containing) lead, which is a probable carcinogen.<sup>57</sup>

95. 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.

96. 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.

97. 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>58</sup>

98. Lead is extremely toxic, and its effects cannot be reversed or remediated.<sup>59</sup>

99. 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>60</sup> Additionally, studies have established a link between lead exposure and ADHD.<sup>61</sup>

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<sup>57</sup>American Cancer Society, *Known and Probable Carcinogens*, last revised August 14, 2019, available at <https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html> (last accessed May 17, 2022).

<sup>58</sup> HBBF Report, *supra*, at 13.

<sup>59</sup> Consumer Reports: Heavy Metals in Baby Food, *supra*.

<sup>60</sup> HBBF Report, *supra*, at 7.

<sup>61</sup> Congressional Committee Report, *supra*, at 12.

100. Although there is no federal standard for lead in baby food, health experts, including the American Academy for Pediatrics, the Environmental Defense Fund, and Consumer Reports, have agreed that lead in baby foods should not exceed 1 ppb.<sup>62</sup>

101. Despite this, laboratory tests indicate Defendant sold products containing undisclosed lead levels as high as 4.6 ppb.<sup>63</sup>

### ***Mercury***

102. 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>64</sup>

103. 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>65</sup> Regardless, “there is no known safe level” of exposure to Mercury as it is a “highly toxic element.”<sup>66</sup>

104. Despite Defendant’s packaging message conveying that 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.

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<sup>62</sup> Toxic Heavy Metals in Popular Baby Foods, *supra*.

<sup>63</sup> HBBF Report, *supra*, at 20, 34.

<sup>64</sup> *Id.* at 14.

<sup>65</sup> Congressional Committee Report, *supra*.

<sup>66</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 May 18, 2022).

105. The four Heavy Metals – Arsenic, Cadmium, Lead, and Mercury – are significant detriments to children.

106. 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>67</sup>

107. Importantly, and relevant to this lawsuit, action levels do not require disclosure of 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.

108. 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 Babies Bright Futures,<sup>68</sup> Consumer Reports,<sup>69</sup> and Politico,<sup>70</sup> and studies by the FDA,<sup>71</sup> University of Miami, the Clean Label Project, and Ellipse Analytics<sup>72</sup> show.

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<sup>67</sup>Metals and Your Food, *supra*.

<sup>68</sup> HBBF Report at 12, 20, *supra*.

<sup>69</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 May 17, 2022) (“Consumer Reports: Heavy Metals in Baby Food”).

<sup>70</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 May 17, 2022) (“FDA’s Food Failure”).

<sup>71</sup> FDA Total Diet Study, April 15, 2014, revised April 2017, available at <https://www.fda.gov/media/77948/download> (last accessed May 17, 2022) (“FDA Total Diet Study”).

<sup>72</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



109. Both the Congressional Committee Report, published on February 4, 2021, which acknowledged that Heavy Metals “can endanger infant neurological development,”<sup>73</sup> followed by a second report published on September 29, 2021, revealed alarming levels of Heavy Metals in baby foods.<sup>74</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>75</sup>

110. As such, the knowledge of the risks associated with exposure to Heavy Metals is not a new phenomenon. Defendant knew or should have known the risks associated with the presence of Heavy Metals in foods consumed by infants,<sup>76</sup> and that, over time, these toxins can accumulate and remain in infants’ bodies, to their detriment.

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

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accessed May 17, 2022) (“Lead and Cadmium Contamination in Infant Formulas and Baby Foods”).

<sup>73</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 May 17, 2022) (“Toxic Heavy Metals in Popular Baby Foods”).

<sup>74</sup> Congressional Committee Report, *supra*; Second Congressional Committee Report, *supra*.

<sup>75</sup> Congressional Committee Report, *supra*.

<sup>76</sup> See, e.g., *FDA Compliance Program Guidance Manual: Toxic Elements in Food and Foodware, and Radionuclides in Food- Import and Domestic*, available at <http://wayback.archive-it.org/7993/20170404233343/https://www.fda.gov/downloads/Food/ComplianceEnforcement/UCM073204.pdf> (last accessed May 17, 2022); see also 21 CFR §172, available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=172&showFR=1> (last accessed May 17, 2022).

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

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

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

114. 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.”



115. On its website, Defendant “promise[s] to nourish the journey of parents and their babies.”<sup>77</sup> Defendant informs consumers that its Products have “no artificial growth hormones” and “no palm olein oil[.]”<sup>78</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>79</sup>

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<sup>77</sup> <https://www.similac.com/why-similac.html> (last accessed May 17, 2022).

<sup>78</sup> <https://www.similac.com/why-similac.html> (last accessed May 17, 2022).

<sup>79</sup> <https://www.similac.com/why-similac.html> (last accessed May 17, 2022).

116. 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>80</sup>

117. Defendant promotes its “heritage” as “[a] spirit of innovation that began in 1925 and hasn’t stopped since[.]”<sup>81</sup>

118. 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.

119. 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.

120. 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.

121. 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.

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<sup>80</sup><https://www.similac.com/baby-tools-resources/baby-questions.html> (last accessed May 17, 2022).

<sup>81</sup><https://www.similac.com/why-similac.html> (last accessed May 17, 2022).

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

122. 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.

123. 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.

124. 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>82</sup>

125. 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.

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

127. 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.

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

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<sup>82</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 May 17, 2022).

129. 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.

130. A recent consumer survey done by Plaintiffs' counsel ("Consumer Survey") demonstrates such an expectation.<sup>83</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

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

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

133. Defendant also knew that monitoring Heavy Metals was likewise important to its health-conscious consumers to protect their babies.

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<sup>83</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.

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

134. 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.

135. 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 the contaminants when compared to other products in a given category.<sup>84</sup>

136. 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>85</sup>

137. 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

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

<sup>84</sup> Clean Label Project Purity Award, available at <https://cleanlabelproject.org/purity-award/> (last accessed May 17, 2022).

<sup>85</sup> Business Wire, *Bobbie is First-Ever Infant Formula to Receive the Clean Label Project Purity Award and Certification as a Pesticide-Free Product*, January 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 May 17, 2022).

139. 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>86</sup> “[T]here are ways for [baby food] manufacturers to significantly reduce or eliminate these [heavy] metals from their products.”<sup>87</sup>

140. 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>88</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>89</sup>

141. In the FDA Total Diet Study, it was also demonstrated that infant formulas can be manufactured without detectable levels of Heavy Metals.<sup>90</sup>

142. Moreover, because of public health efforts, exposure to lead has consistently and notably decreased over the past 40 years.<sup>91</sup> These efforts include increasing awareness of the dangers of even low levels of lead exposure to young children.<sup>92</sup> The progress towards decreasing

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<sup>86</sup> Consumer Reports: Heavy Metals in Baby Food, *supra*.

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

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

<sup>89</sup> *Id.*

<sup>90</sup> FDA Total Diet Study, *supra*, at 7, 10, 17, 20, 68, 71, 95-96.

<sup>91</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/#R6> (last accessed May 17, 2022).

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

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>93</sup>

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

144. 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.

145. 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.

146. 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.

147. 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.

148. 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.

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<sup>93</sup> *Id.*



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

150. 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.

151. 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.

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

153. 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.

## **VI. Defendant's Packaging Misled Reasonable Consumers Based on The Material Omissions**

154. Defendant's packaging communications misled and deceived reasonable consumers because Defendant omitted that the Infant Formula was manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals, while representing nutritious quality and characteristics.

155. Based on the impression given by the packaging communications and Omissions, no reasonable consumer could expect or understand that the Infant Formulas were manufactured

in “egregiously unsanitary” conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

156. 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.”



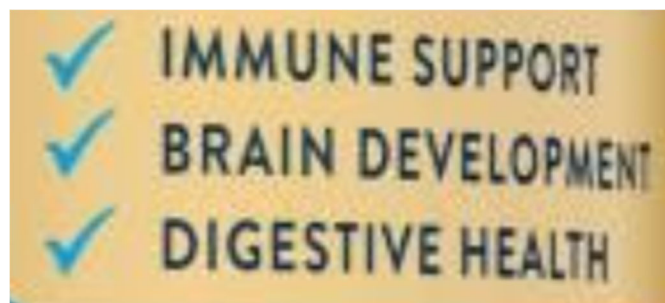
(c) Similac® Pro Advance: “Immune Support” and “Brain & Eye Development.”



(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.”



157. Based on Defendant’s Omissions from these communications on the Products’ packaging, no reasonable consumer could expect or understand that the Infant Formula was

manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

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

159. 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.

160. Plaintiffs’ counsel had five of Defendant’s Infant Formulas tested and that testing confirmed the presence of undisclosed Heavy Metals at the following levels:

Infant Formula	Arsenic (ppb)	Cadmium (ppb)	Lead (ppb)	Mercury (ppb)
Similac® Soy Isomil	6.0	11.4	2.9	<1.8
Similac® 360 Total Care	6.7	1.4	1.5	<1.8
Similac® Pro Advance	2.5	<1.3	3.0	10.1
Similac® Total Comfort	9.7	3.4	1.4	<1.7
Similac® Neosure	7.8	<1.3	3.6	<1.7

161. Independent testing also confirmed two Heavy Metals in another of Defendant’s products:<sup>94</sup>

Infant Formula	Level of Arsenic	Level of Lead
Similac® Advance OptiGRO Powder – Milk-Based	4.6 ppb	3 ppb

<sup>94</sup> HBBF Report, *supra*, at 20, 34.

162. Regardless of level, though, as stated herein, no level of Heavy Metals is safe.<sup>95</sup>

163. Based on the Omissions, a reasonable consumer would not expect the presence of Heavy Metals, nor would a reasonable 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.

164. 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>96</sup> A portion of the funding would be for educational outreach about heavy metals in foods.<sup>97</sup>

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

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

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

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

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<sup>95</sup> Some Baby Food May Contain Toxic Metals, *supra*.

<sup>96</sup> FDA FY 2023 Budget Proposal, *supra*.

<sup>97</sup> *Id.*

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

168. 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 may contain Heavy Metals.

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

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

171. 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.

172. 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.

173. 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.

174. 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.

175. The Omissions make the Infant Formulas' packaging deceptive. Reasonable consumers, like Plaintiffs, would consider the facts that Infant Formula was manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals when considering what infant formula to purchase.

176. 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.

177. 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 the presence of Heavy Metals.

178. Defendant knew or should have known the Infant Formulas contained or may contain undisclosed levels of Heavy Metals that were inconsistent with Defendant's packaging.

179. 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.

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



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

182. Moreover, reasonable consumers, such as Plaintiffs and the Class members, would have no reason to doubt or question Defendant's statements regarding the quality of the Infant Formulas. Based on the impression given by the packaging, no reasonable consumer could expect or understand the Infant Formula was manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

183. 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.

184. As a result of Defendant's deceptive 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**

185. 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 was manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals, they would not have purchased the Infant Formulas.

186. 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**

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

188. 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>98</sup> The FDA has also released a study showing the presence of Heavy Metals in baby foods, including infant formulas.<sup>99</sup>

189. Defendant was also put on notice that it had improper manufacturing processes and quality control procedures by the FDA investigation earlier this year.

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

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

191. 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.

192. 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>98</sup> Congressional Committee Report, *supra*; Second Congressional Committee Report, *supra*.

<sup>99</sup> FDA Total Diet Study, *supra*, at 7, 10, 17, 20, 68, 71, 95-96.

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

194. 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**

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

196. 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 "egregiously unsanitary" conditions without proper quality control procedures where it manufactured the Infant Formula and that contained (or had a material risk of containing) Heavy Metals. Defendant intentionally concealed these material facts from Plaintiffs.

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

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

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

200. Based on Defendant concealing material facts from Plaintiffs, Plaintiffs could not reasonably discover that the Infant Formula was manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

201. Plaintiffs did not know that the Infant Formula was manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contained (or had a material

risk of containing) Heavy Metals. Instead, Defendant only represented that the Infant Formulas were healthy, nutritious, and made of high quality to support growing infants.

**CLASS ACTION ALLEGATIONS**

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

All persons who, from March 1, 2016, to the present, purchased the Infant Formulas for household use, and not for resale (the “Class”).

203. Plaintiff Willoughby brings this action individually and on behalf of the following Illinois Subclass:

All persons who are citizens of Illinois who, from March 1, 2016, to the present, purchased the Infant Formulas for household use, and not for resale (the “Illinois Subclass”).

204. Plaintiff McNealy brings this action individually and on behalf of the following Minnesota Subclass:

All persons who are citizens of Minnesota who, from March 1, 2016, to the present, purchased the Infant Formulas for household use, and not for resale (the “Minnesota Subclass”).

205. Plaintiff Doxie brings this action individually and on behalf of the following California Subclass:

All persons who are citizens of California who, from March 1, 2016, to the present, purchased the Infant Formula for household use, and not for resale (the “California Subclass”).

206. Plaintiff Gray brings this action individually and on behalf of the following Hawaii Subclass:

All persons who are citizens of Hawaii who, from March 1, 2016, to the present, purchased the Infant Formula for household use, and not for resale (the “Hawaii Subclass”).

207. Plaintiff Helmick brings this action individually and on behalf of the following Nebraska Subclass:

All persons who are citizens of Nebraska who, from March 1, 2016, to the present, purchased the Infant Formula for household use, and not for resale (the “Nebraska Subclass”).

208. Plaintiff Holloway brings this action individually and on behalf of the following Texas Subclass:

All persons who are citizens of Texas who, from March 1, 2016, to the present, purchased the Infant Formula for household use, and not for resale (the “Texas Subclass”).

209. Plaintiff Popa brings this action individually and on behalf of the following Pennsylvania Subclass:

All persons who are citizens of Pennsylvania who, from March 1, 2016, to the present, purchased the Infant Formula for household use, and not for resale (the “Pennsylvania Subclass”).

210. Plaintiff Revord brings this action individually and on behalf of the following Michigan Subclass:

All persons who are citizens of Michigan who, from March 1, 2016, to the present, purchased the Infant Formula for household use, and not for resale (the “Michigan Subclass”).

211. Collectively, the Illinois, Minnesota, California, Hawaii, Nebraska, Texas, Pennsylvania, and Michigan Subclasses are referred to as the “State Subclasses.”

212. 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.

213. 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.

214. 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.

215. 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 the Infant Formula was manufactured in “egregiously unsanitary” conditions
- (d) whether Defendant knew the Infant Formula was manufactured without proper quality control procedures;
- (e) whether Defendant knew or should have known that the Infant Formulas contained or may contain Heavy Metals;
- (f) whether Defendant failed to disclose the Omissions;
- (g) whether the claims of the Plaintiffs and the Classes serve a public benefit;
- (h) whether Defendant’s packaging is false, deceptive, and misleading based on the Omissions;
- (i) whether the Omissions are material to a reasonable consumer;
- (j) whether the Omissions are likely to deceive a reasonable consumer;

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

(l) whether Defendant breached its duty of care;

(m) whether Defendant breached its duty to disclose;

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

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

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

(q) whether Defendant violated the laws of the State of Hawaii;

(r) whether Defendant violated the laws of the State of Nebraska;

(s) whether Defendant violated the laws of the State of Texas;

(t) whether Defendant violated the laws of the State of Pennsylvania;

(u) whether Defendant violated the laws of the State of Michigan;

(v) whether Defendant breached its implied warranties;

(w) whether Defendant engaged in unfair trade practices;

(x) whether Defendant engaged in false advertising;

(y) whether Defendant made fraudulent omissions;

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

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

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

216. 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.

217. 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.

218. 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.

219. 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.

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

221. 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 or, Alternatively, Plaintiff Willoughby and the Illinois Subclass**

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

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



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

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

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

227. 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”).

228. Defendant engaged in a deceptive 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.

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

230. 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.

231. Defendant’s concealment, Omissions, and other deceptive 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.

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

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

234. Defendant's concealment, Omissions, and other deceptive 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.

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

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

237. The facts concealed, omitted, or not disclosed by Defendant that the Infant Formula was manufactured in "egregiously unsanitary" conditions without proper quality control procedures and 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.

238. If Plaintiffs and the Class members had known that the Infant Formula was manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals, they would not have paid the price premium they paid for the Infant Formulas.

239. 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.

240. 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 were not manufactured in "egregiously unsanitary" conditions without proper quality control procedures and 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 were manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contain or risk containing Heavy Metals.

241. 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.

242. 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.

243. 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**

### **Breach of Implied Warranty of Merchantability Against Defendant on Behalf of the Class or, Alternatively, the Illinois, Minnesota, Hawaii, Nebraska, Pennsylvania, and Michigan Subclasses**

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

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

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

247. 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).

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

249. The Infant Formulas were not fit for their ordinary use (consumption by infants with no development or health risks) as they were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals that do not conform to the packaging.

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

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

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

253. 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 and that the Infant Formula was manufactured safely; however, Defendant failed to mention or disclose it was manufactured in “egregiously unsanitary”

conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

254. 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 were not manufactured in "egregiously unsanitary" conditions without proper quality control procedures and 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 were manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contain or risk containing Heavy Metals.

255. 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 III**  
**Fraudulent Misrepresentation by Omission Against Defendant  
on Behalf of the Class or, Alternatively, the State Subclasses**

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

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

258. Plaintiffs and the Class were ordinary non-business consumers who trusted Defendant to manufacture, distribute, market, and sell Infant Formulas that were not manufactured in "egregiously unsanitary" conditions without proper quality control procedures and did not contain (or have a material risk of containing) Heavy Metals.

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

260. Defendant failed to disclose the Omissions.

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

262. Defendant knew or should have known the Infant Formulas were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

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

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

265. 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.

266. Defendant knows reasonable consumers expected the Infant Formulas to not be manufactured in “egregiously unsanitary” conditions without proper quality control procedures and not contain (or have a material risk of containing) Heavy Metals.

267. 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 are manufactured in safe conditions with proper quality control procedures, and that these consumers will pay for infant formulas they believe possess these qualities.

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

269. Defendant knew that Plaintiffs and the Class could not reasonably have been expected to learn or discover the Omissions.

270. 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.

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

272. 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 were not manufactured in "egregiously unsanitary" conditions without proper quality control procedures and do not contain (or have a material risk of containing) Heavy Metals.

273. 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' reliance on the Omissions was justifiable.

274. 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 were not manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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 were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contain or risk containing Heavy Metals.

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

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

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

277. Defendant knew or should have known the Infant Formulas were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

278. 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.

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

280. Defendant actively and knowingly concealed from and failed to disclose to Plaintiffs and the Class that the Infant Formulas included were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contained undisclosed levels or material risk of Heavy Metals that do not conform to the Products’ packaging.



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

282. 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.

283. Defendant knows its customers trust the quality of its products and expect Defendant's Infant Formulas not be manufactured in unsafe and low quality conditions and to be free of the risk or presence of 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.

284. Due to the Omissions on the Infant Formulas' packaging, Defendant had a duty to disclose the whole truth about the "egregiously unsanitary" conditions without proper quality control procedures and that the Infant Formula contained (or had a material risk of containing) Heavy Metals.

285. 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.

286. 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.

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

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

289. 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.

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

291. Defendant intentionally concealed its unsanitary manufacturing conditions and the presence or material risk of Heavy Metals in the Infant Formulas with intent to defraud and deceive Plaintiffs and the Class.

292. 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.

293. 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 were not manufactured in "egregiously unsanitary" conditions without proper quality control procedures and 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 were manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contain or risk containing Heavy Metals.

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

**COUNT V**

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

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

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

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

298. Defendant knew or should have known the Infant Formulas were not of the true quality and ingredients advertised because they were manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

299. Defendant's pattern of knowing concealment, Omissions, and other deceptive conduct were likely to deceive or cause misunderstanding and did in fact deceive Plaintiff

McNealy and the Minnesota Subclass with respect to the Infant Formulas' quality, ingredients, and suitability for consumption by infants with no development or health risks.

300. Defendant intended for Plaintiff McNealy 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.

301. 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.

302. 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.

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

304. The facts concealed, omitted, or not disclosed by Defendant were material facts in that Plaintiff McNealy, the Minnesota Subclass, and any reasonable consumer would have considered them in deciding whether to purchase the Infant Formulas. Had Plaintiff McNealy 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.

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

306. As a direct and proximate result of Defendant's conduct, Plaintiff McNealy and the Minnesota Subclass suffered actual damages by: ((1) paying a premium price for Products they reasonably believed were not manufactured in "egregiously unsanitary" conditions without proper quality control procedures and 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 were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contain or risk containing Heavy Metals.

307. Plaintiff McNealy 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.

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

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

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

310. Defendant is a “person” within the meaning of the Minnesota Uniform Deceptive Trade Practices Act (“MUDTPA”).

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

312. Defendant knew or should have known the Infant Formulas were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

313. Defendant’s Omissions, concealment, and other deceptive conduct were likely to deceive or cause misunderstanding and did in fact deceive Plaintiff McNealy 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.

314. Defendant intended that Plaintiff McNealy 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.

315. 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.

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

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

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

319. 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.

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

321. As a direct and proximate result of Defendant's conduct, Plaintiff McNealy and the Minnesota Subclass suffered actual damages by: (1) paying a premium price for Products they reasonably believed were not manufactured in "egregiously unsanitary" conditions without proper quality control procedures and 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. Plaintiff McNealy and the members of the Minnesota Subclass would not have purchased the Infant Formulas at all had they known of the Omissions.

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

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

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

325. Plaintiff McNealy 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").

326. Plaintiff McNealy 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.

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

328. Defendant's Omissions and use of other deceptive 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.

329. Defendant knew or should have known the Infant Formulas did not have the quality and ingredients described above because they were manufactured in "egregiously unsanitary" conditions without proper quality control procedures and included undisclosed (or material risk of) Heavy Metals.

330. The Omissions were likely to deceive or cause misunderstanding and did in fact deceive Plaintiff McNealy 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.

331. 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.

332. The Omissions were made to customers in Minnesota, including Plaintiff McNealy and the Minnesota Subclass, thus the cause of action serves the public benefit of informing Minnesota consumers about "egregiously unsanitary" conditions without proper quality control procedures and that the Products contained (or had a material risk of containing) Heavy Metals.

333. The facts concealed, omitted, or not disclosed by Defendant were material facts in that Plaintiff McNealy, the Minnesota Subclass, and any reasonable consumer would have considered them in deciding whether to purchase the Infant Formulas. Had Plaintiff McNealy 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.

334. Defendant intended that Plaintiff McNealy 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.

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

336. As a direct and proximate result of Defendant's conduct, Plaintiff McNealy and the Minnesota Subclass suffered actual damages by: (1) paying a premium price for Products they reasonably believed were not manufactured in "egregiously unsanitary" conditions without proper quality control procedures and 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 were manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contain or risk containing Heavy Metals.

337. Plaintiff McNealy 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.

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

**COUNT VIII**

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

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

340. Plaintiff McNealy at times relevant hereto was a citizen of the State of Minnesota.

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

342. The Omissions were made in connection with the sale of the Infant Formulas to Plaintiff McNealy and the Minnesota Subclass.

343. Defendant knowingly acted, used, and employed fraud, false pretenses, and deceptive 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 and were manufactured in “egregiously unsanitary” conditions without proper quality control procedures.

344. Defendant knew or should have known the Infant Formulas did not have the quality reasonable consumers expected because they were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and included undisclosed (or material risk of) Heavy Metals that do not conform to the packaging. Defendant intended for Plaintiff McNealy and the Minnesota Subclass to rely on the Infant Formulas’ packaging in deciding whether to purchase the Infant Formulas.

345. 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. Plaintiff McNealy 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.

346. The facts concealed, omitted, or not disclosed by Defendant were material facts in that Plaintiff McNealy, the Minnesota Subclass, and any reasonable consumer would have considered them in deciding whether to purchase the Infant Formulas. Had Plaintiff McNealy 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.

347. Defendant's Omissions were made to customers in Minnesota, including Plaintiff McNealy and the Minnesota Subclass, thus the cause of action serves the public benefit of informing Minnesota consumers about "egregiously unsanitary" conditions without proper quality control procedures and that the Products contained (or had a material risk of containing) Heavy Metals.

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

349. As a direct and proximate result of Defendant's conduct, Plaintiff McNealy and the Minnesota Subclass suffered actual damages by: (1) paying a premium price for Products they reasonably believed were not manufactured in "egregiously unsanitary" conditions without proper quality control procedures and 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 were manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contain or risk containing Heavy Metals.

350. Plaintiff McNealy 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.

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

### **COUNT IX**

#### **Violations of California's Consumers Legal Remedies Act, California Civil Code §§1750, *et seq.*, Against Defendant on Behalf of Plaintiff Doxie and the California Subclass**

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

353. Plaintiff Doxie and each California Subclass member is a "consumer," as that term is defined in California Civil Code section 1761(d).

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

355. Defendant is a "person" as that term is defined in California Civil Code section 1761(c).

356. Plaintiff Doxie 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).

357. 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.

358. The Omissions were material as reasonable consumers such as Plaintiffs and the Class would deem that the Infant Formula was manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals important in determining whether to purchase the Infant Formulas.

359. As a direct and proximate result of these violations, Plaintiff Doxie 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.

360. Plaintiff Doxie gave written notice and a demand upon Defendant pursuant to the CLRA by certified letter dated March 11, 2022 concerning the Heavy Metals omission, and has not received any response from Defendant. Accordingly, Plaintiff Doxie and the California Subclass seek injunctive and equitable relief and restitution herein.

361. In accordance with CLRA §1782(b), Plaintiffs and the Class are entitled, under CLRA §1780, to recover and obtain the following relief for Defendants’ violations of CLRA §§1770(a)(5), (7), (9), and (16) for the Heavy Metal 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).

362. Plaintiffs seek an award of attorneys' fees pursuant to, *inter alia*, California Civil §1780(e) and California Code of Civil Procedure §1021.5.

363. Defendant's conduct is ongoing and continuing, such that prospective injunctive relief is necessary as to all Omissions, especially given Plaintiff Doxie's desire to purchase these Products in the future if she can be assured that the Infant Formula was not manufactured in "egregiously unsanitary" conditions without proper quality control procedures and does not contain Heavy Metals.

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

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

365. 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.

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

367. Defendant failed to disclose that the Products were manufactured in "egregiously unsanitary" conditions without proper quality control procedures and the presence (or material risk) of Heavy Metals.

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

369. Defendant's conduct is ongoing and continuing, such that prospective injunctive relief is necessary, especially given Plaintiff Doxie's desire to purchase these Products in the future if she can be assured that the Infant Formula is as advertised, is manufactured in safe and sanitary conditions, and does not contain Heavy Metals.

370. Plaintiff Doxie and members of the California Subclass are entitled to injunctive and equitable relief, and restitution in an amount to be determined at trial.

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

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

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

**Fraudulent**

373. Defendant failed to disclose the Omissions.

**Unlawful**

374. 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**

375. 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 their conduct, if any, does not outweigh the gravity of the harm to their victims.

376. 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.

377. 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.

378. In accordance with California Business & Professions Code §17203, Plaintiff Doxie, on behalf of herself and the California Subclass, seeks an order enjoining Defendant from continuing to conduct business through fraudulent or unlawful acts and practices and to commence a corrective advertising campaign. Defendant's conduct is ongoing and continuing, such that prospective injunctive relief is necessary, especially given Plaintiff Doxie's desire to purchase these Products in the future if she can be assured that the Infant Formula was not manufactured in "egregiously unsanitary" conditions without proper quality control procedures and did not contain (or have a material risk of containing) Heavy Metals.

379. Plaintiff Doxie, on behalf of herself and the California Subclass, also 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 XII**  
**Breach of the Implied Warranty Of Merchantability –**  
**California Uniform Commercial Code,**  
**Cal. Comm. Code §2314, Against Defendant**  
**on Behalf of Plaintiff Doxie and the California Subclass**

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

381. This claim is brought by Plaintiff Doxie on behalf of herself and the California Subclass members.

382. Defendant is and was at all relevant times a merchant as defined by Cal. Comm. Code §2104.

383. A warranty that the Products were in merchantable condition is implied by law pursuant to California Comm. Code §2314.

384. Plaintiff Doxie 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.

385. The Products are and were at all relevant times goods within the meaning of Cal. Comm. Code §2105.

386. 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 that was manufactured in "egregiously unsanitary" conditions without proper quality control procedures. Thus, Defendant

breached its implied warranty of merchantability for the ordinary purpose for which the Products are purchased and used.

387. Defendant cannot disclaim its implied warranty as it knowingly sold Products that were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

388. 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.

389. As a direct and proximate result of Defendant’s breach of the implied warranty of merchantability, Plaintiff Doxie 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 were not manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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 were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contain or risk containing Heavy Metals.

390. Plaintiff Doxie 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 XIII**

**Violation of the Hawaii Uniform Deceptive Trade Practices Act, Haw. Rev.  
Stat. §§ 448-1, *et seq.*, Against Defendant  
on Behalf of Plaintiff Gray and the Hawaii Subclass**

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

392. Plaintiff Gray brings this Court individually and on behalf of the Hawaii Subclass.

393. Hawaii's Uniform Deceptive Trade Practices Act ("UDTPA") provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful."

394. Hawaii's UDTPA further provides that any person who is injured in the person's business or property by reason of anything forbidden or declared unlawful by this chapter may sue for damages sustained by the person.

395. At all relevant times, Plaintiff Gray and the members of the Hawaii Subclass were natural persons who, primarily for personal, family, or household purposes, purchased Defendant's goods or services.

396. At all relevant times, Defendant and Plaintiff Gray and the members of the Hawaii Subclass were either individuals, corporations, firms, trusts, partnerships, limited partnerships, limited liability partnerships, limited liability limited partnerships, limited liability companies, and incorporated or unincorporated associations.

397. Defendant willfully engaged in deceptive and unfair acts and practices and the concealment, suppression, and omission of material facts in connection with trade or commerce in violation of Haw. Rev. Stat. §480-2 as described in the allegations above.

398. Defendant's Omissions in the sale of its Products as detailed above are an act or practice in the conduct of trade or commerce.

399. Defendant's Omissions in the sale of its Products as detailed above impact the public interest.

400. Plaintiff Gray and Hawaii Subclass members were deceived by Defendant's deceptive and unfair acts and practices in that had they known the truth they would not have purchased Defendant's Products or would have paid less for those Products.

401. Instead, as a result of Defendant's Omissions, Plaintiff Gray and Hawaii Subclass members suffered monetary losses in that (1) the actual value of the Products they received was less than the value of the Products as represented denying them of the benefit of their bargain; and (2) Plaintiff Gray and Hawaii Subclass members paid more than the fair market value of the Products they received causing them out-of-pocket damages.

402. Defendant's Omissions in the sale of its Products as detailed above are unfair because they are inequitably enriching Defendant at the expense of Plaintiff Gray and the Hawaii Subclass.

403. Defendant's Omissions in the sale of its Products as detailed above are unfair because they offend public policy and cause consumers substantial injury.

404. Defendant's Omissions in the sale of its Products as detailed above are unfair in that they violate the well-established public policies of protecting babies from avoidable dangers and that the manufacturer of food is responsible for ensuring that it is fit for human consumption.

405. Plaintiff Gray and the Hawaii Subclass have suffered economic injury as a direct and proximate results of Defendant's conduct by: (1) paying a premium price for Products they reasonably believed were not manufactured in "egregiously unsanitary" conditions without proper quality control procedures and 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 were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contain or risk containing Heavy Metals.

406. Defendant’s conduct is ongoing and continuing, such that prospective injunctive relief is necessary, especially given Plaintiff Gray’s desire to purchase these Products in the future if she can be assured that the Infant Formula is as advertised, is manufactured in safe and sanitary conditions, and does not contain Heavy Metals.

407. As a direct and proximate result of the foregoing acts and practices, Defendant has received, or will receive, income, profits, and other benefits which it would not have received if it had not engaged in the violations described in this Complaint.

**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 Plaintiff Popa and the Pennsylvania Subclass**

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

409. Plaintiff Popa brings this claim individually and 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.*

410. Plaintiff Popa, 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 P.S. §201-2(2).

411. 73 P.S. §201-3 declares unlawful “unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce ....”

412. Defendant's business acts and practices alleged herein constituted deceptive acts or practices under the 73 P.S. §201, *et seq.*

413. Defendant has known or reasonably should have known that the Products were manufactured in "egregiously unsanitary" conditions without proper quality control procedures and contained unsafe levels or material risk of toxic Heavy Metals, and that Plaintiff Popa and other members of the Pennsylvania Subclass would reasonably and justifiably rely on the packaging in purchasing the Products.

414. Defendant has intentionally and knowingly omitted material facts with an intent to mislead Plaintiff Popa and the Pennsylvania Subclass.

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

416. Defendant's Omissions were material to Plaintiff Popa 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.

417. As a direct and proximate cause of Defendant's conduct, Plaintiff Popa and members of the Pennsylvania Subclass suffered damages by: (1) paying a premium price for Products they reasonably believed were not manufactured in "egregiously unsanitary" conditions without proper quality control procedures and 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 were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contain or risk containing Heavy Metals.

418. Defendant’s conduct is ongoing and continuing, such that prospective injunctive relief is necessary, especially given Plaintiff Popa’s desire to purchase these Products in the future if she can be assured that the Infant Formula is as advertised, is manufactured in safe and sanitary conditions, and does not contain Heavy Metals.

419. Plaintiff Popa and the Pennsylvania Subclass seek an order enjoining Defendant’s deceptive acts and practices, and awarding attorneys’ fees, and any other just and proper relief available under the UTPCPL.

420. In addition to or in lieu of actual damages, Plaintiff Popa and the Pennsylvania Subclass seek statutory damages for each injury and violation which has occurred. Plaintiff Popa and the Pennsylvania Subclass seek relief under 73 P.S. §201-9.2, including, but not limited to, injunctive relief, actual damages or \$100 per Class Member, whichever is greater, treble damages, and attorneys’ fees and costs.

**COUNT XV**  
**Violations of the Michigan Consumer Protection Act,**  
**MCL §§ 445 *et seq.*, against Defendant**  
**on behalf of Plaintiff Revord and the Michigan Subclass**

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

422. Plaintiff Revord and Michigan Subclass members are residents and citizens of the State of Michigan at all times mentioned herein.

423. Defendant engaged in “trade or commerce” in Michigan, as defined by MCL § 445.902(g), in that it provided goods, property, or services primarily for personal, family, or household purposes, and advertised, solicited, offered for sale, and sold goods or services.

424. The Michigan Consumer Protection Act (“MCPA”), MCL §445.903 provides that “[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce are unlawful[.]”

425. For the reasons discussed herein, Defendant violated and continues to violate the MCPA by engaging in the herein described unconscionable, deceptive, unfair acts, or practices proscribed by MCL §445.903 et seq. Defendant’s acts and practices, including its material Omissions, described herein, were likely to, and did in fact, deceive and mislead members of the public, including consumers acting reasonably under the circumstances, to their detriment.

426. Defendant failed to disclose the material Omissions.

427. Defendant’s Omissions were material because they were likely to deceive reasonable consumers to induce them to purchase the Products without being aware that the Products were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contained or risked containing Metals. As a direct and proximate result of Defendant’s unfair and deceptive acts or practices, Plaintiff Revord and the Michigan Subclass suffered damages by: (1) paying a premium price for Products they reasonably believed were not manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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 were not manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contain or risk containing Heavy Metals.

428. Defendant’s deceptive trade practices caused injury in fact and actual damages to Plaintiff Revord and the Michigan Subclass in the form of the loss or diminishment of value of the Products Plaintiff Revord and the Michigan Subclass purchased, which allowed Defendant to



profit at the expense of Plaintiff Revord and the Michigan Subclass. The injuries Plaintiff Revord and the Michigan Subclass suffered were to legally protected interests. The gravity of the harm of Defendant's actions is significant and there is no corresponding benefit to consumers of such conduct.

429. Defendant's conduct is ongoing and continuing, such that prospective injunctive relief is necessary, especially given Plaintiff Revord's desire to purchase these Products in the future if she can be assured that the Infant Formula is as advertised and was not manufactured in unsafe conditions and does not contain Heavy Metals.

430. Plaintiff Revord and the Michigan Subclass seek relief for the injuries they have suffered as a result of Defendant's unfair and deceptive acts and practices, as provided by MCL § 445.911 and applicable law.

**COUNT XVI**  
**Violations of Nebraska Consumer Protection Act,  
Neb. Rev. Stat § 59-1601, 1602, and 1609, Against Defendant  
on Behalf of Plaintiff Helmick and the Nebraska Subclass**

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

432. Plaintiff Helmick asserts this claim on behalf of herself and the Nebraska Subclass members that purchased Defendant's Products.

433. The Nebraska Consumer Protection Act ("NCPA"), Neb. Rev. Stat. §59-1602, specifically prohibits any "unfair or deceptive acts or practices in the conduct of any trade or commerce."

434. Defendant has engaged in unlawful, fraudulent, deceptive and unfair business acts and practices in violation of said statute.

435. Defendant had a duty to disclose that the Products were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and the presence or material risk of Heavy Metals in its Products and remedy same.

436. Defendant violated the NCPA because it engaged in business acts or practices that are unlawful because it knowingly concealed that its Products were not manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contained or risked containing Heavy Metals, and deceived Plaintiff Helmick and the Nebraska Subclass.

437. Defendant’s Omissions regarding “egregiously unsanitary” conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals, were likely to deceive a reasonable consumer, and the information would be material to a reasonable consumer.

438. Defendant’s conduct, as aforesaid, and knowing failure to adequately investigate, disclose, and remedy said conduct, offends established public policy, and the harm caused to consumers greatly outweighs any benefits associated with Defendant’s practices. Defendant’s conduct has also impaired competition within the Infant Formula industry and has prevented Plaintiff Helmick and Nebraska Subclass from making fully informed decisions about whether to purchase said Products and/or the price to be paid to purchase them.

439. Plaintiff Helmick and the Nebraska Subclass have suffered an injury in fact, including the loss of money, as a result of Defendant’s unfair, unlawful, and/or deceptive practices by: (1) paying a premium price for Products they reasonably believed were not manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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 were not manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contain or risk containing Heavy Metals.

440. Had Plaintiff Helmick and the Nebraska Subclass known the truth about the risks and dangers of Defendant’s Products, they would not have purchased and/or paid as much for them.

441. All of the wrongful conduct alleged herein occurred, and continues to occur, in the conduct of Defendant’s business. Defendant’s wrongful conduct is part of a pattern or generalized course of conduct that is still perpetuated and repeated, both in the State of Nebraska and nationwide.

442. Defendant’s conduct is ongoing and continuing, such that prospective injunctive relief is necessary, especially given Plaintiff Helmick’s desire to purchase these Products in the future if she can be assured that the Infant Formula is as advertised, is manufactured in safe and sanitary conditions, and does not contain Heavy Metals.

443. Plaintiff Helmick requests that this Court enter such orders or judgments as may be necessary to enjoin Defendant from continuing its unfair, unlawful, and/or deceptive practices and to restore to Plaintiff Helmick and members of the Nebraska Subclass any money Defendant acquired by its unfair business and competition, including restitution and/or restitutionary disgorgement, and for such other relief set forth below, including an award of attorneys’ fees.

**COUNT XVII**  
**Texas Deceptive Trade Practices and Consumer Protection Act,**  
**Tex. Bus. & Com. Code §§17.41 *et seq.*, Against Defendant**  
**on behalf of Plaintiff Holloway and the Texas Subclass**

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

445. Plaintiff Holloway brings this claim individually and on behalf of the members of the Texas Subclass against Defendant for violations of Texas Deceptive Trade Practices and Consumer Protection Act (“TDTPA”), Tex. Bus. & Com. Code §§17.41 *et seq.*

446. Plaintiff Holloway provided written notice of the Heavy Metals complaint and damages to Defendant in accordance with Tex. Bus. & Com. Code §17.05 by letter dated March 11, 2022.

447. At all material times herein, Defendant engaged in “trade” or “commerce” as defined by the TDTPA.

448. The TDTPA, Tex. Bus. & Com. Code §17.46, makes it unlawful to commit “[f]alse, misleading, and deceptive acts or practices in the conduct of any trade or commerce.”

449. For the reasons discussed herein, Defendant violated and continues to violate the TDTPA by engaging in the herein described unconscionable, deceptive, unfair acts or practices proscribed by TDTPA §§17.41 *et seq.* Defendant’s acts and practices, including its material Omissions, described herein, were likely to, and did in fact, deceive and mislead members of the public, including consumers acting reasonably under the circumstances, to their detriment.

450. Defendant failed to disclose the material information that its Products were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

451. Defendant’s Omissions were material because they were likely to deceive reasonable consumers to induce them to purchase its Products without being aware that said Products were manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contained or risked containing Heavy Metals. As a direct and proximate result of Defendant’s unfair and deceptive acts or practices, Plaintiff Holloway and the Texas Subclass

suffered damages by: (1) paying a premium price for Products they reasonably believed were not manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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 were not manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contain or risk containing Heavy Metals.

452. Defendant’s deceptive trade practices caused injury in fact and actual damages to Plaintiff Holloway and the Texas Subclass in the form of the loss or diminishment of value of the Products Plaintiff Holloway and the Texas Subclass purchased, which allowed Defendant to profit at the expense of Plaintiff Holloway and members of the Texas Subclass. The injuries to Plaintiff Holloway and members of the Texas Subclass were legally protected interests. The gravity of the harm of Defendant’s actions is significant and there is no corresponding benefit to consumers of such conduct.

453. Defendant’s conduct is ongoing and continuing, such that prospective injunctive relief is necessary, especially given Plaintiff Doxie’s desire to purchase these Products in the future if she can be assured that the Infant Formula is as advertised, is manufactured in safe and sanitary conditions, and does not contain Heavy Metals.

454. Plaintiff Holloway and members of the Texas Subclass seek relief for the injuries they have suffered as a result of Defendant’s unfair and deceptive acts and practices, as provided by TDTPA and applicable law.

**COUNT XVIII**  
**Statutory Breach of Implied Warranty,**  
**Tex. Bus. & Com. Code §2.314, Against Defendant**  
**on Behalf of Plaintiff Holloway and the Texas Subclass**

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

456. Plaintiff Holloway brings this cause of action on behalf of herself and the Texas Subclass.

457. Defendant is and was at all relevant times a “merchant” under Texas Business and Commercial Code §§2.104(1) and 2A.103(a)(20), and a “seller” under §2.103(a)(4).

458. The Products are and were at all relevant times “goods” within the meaning of Texas Business and Commercial Code §§2.105(a) and 2A.103(a)(8).

459. A warranty that the Products were in merchantable condition and fit for the ordinary purpose for which infant formulas are used is implied by law, pursuant to Texas Business and Commercial Code §§2.314 and 2A.212.

460. Defendant impliedly warranted that the Products were of merchantable quality and fit for such use. This implied warranty included, *inter alia*, a warranty that the Products that were manufactured, supplied, distributed, and/or sold by Defendant were safe for consumption by infants.

461. Defendant breached the implied warranty of merchantability in that the Products were not in merchantable condition when they were sold to Plaintiff Holloway and the Texas Subclass members because said Products were and are unfit for the ordinary purposes for which such Products are used because they pose a serious safety risk to the babies who consume them.

462. Defendant has been provided notice of these issues, as alleged herein, by letter sent March 11, 2022.

463. As a direct and proximate result of breaches of the implied warranty of merchantability, Plaintiff Holloway and the Texas Subclass have suffered damages by: (1) paying a premium price for Products they reasonably believed were not manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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 were not manufactured in “egregiously unsanitary” conditions without proper quality control procedures and contain or risk containing Heavy Metals.

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

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

465. 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.

466. 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 be manufactured in “egregiously unsanitary” conditions without proper quality control procedures and 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.

467. Defendant was obligated to disclose the Omissions in the Infant Formulas because (1) it had exclusive knowledge of the “egregiously unsanitary” conditions without proper quality

control procedures and 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 (2) 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.

468. 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.

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

470. Plaintiffs and the Class seek actual damages, injunctive and 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 enjoining Defendant from selling the Infant Formulas until the higher and/or unsafe levels of Heavy Metals are removed and the "egregiously unsanitary" conditions without proper quality control procedures are remedied;

C. An order enjoining Defendant from selling the Infant Formulas until the Omissions are disclosed;



D. An order enjoining Defendant from selling the Infant Formulas in any manner suggesting or implying that they are healthy and made from nutritious ingredients;

E. An order requiring Defendant to engage in a corrective advertising campaign and engage in any further necessary affirmative injunctive relief;

F. An order awarding declaratory relief, and any further injunctive relief permitted by law or equity, including enjoining Defendant from continuing the unlawful practices alleged herein, and injunctive relief to remedy Defendant's conduct;

G. 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;

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

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

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

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

M. 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: May 26, 2022

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