

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

**Dominique Lopez, Bianca Raya, Laurie Thomas, and Amanda Seutter,**  
individually and on behalf of a class of  
similarly situated individuals,

**PLAINTIFFS,**

v.

**MEAD JOHNSON NUTRITION  
COMPANY and MEAD JOHNSON &  
COMPANY, LLC,**

**DEFENDANT.**

Case No.

**DEMAND FOR JURY TRIAL**

**CLASS ACTION COMPLAINT**

1. Plaintiffs Dominique Lopez, Bianca Raya, Laurie Thomas, and Amanda Seutter (“Plaintiffs”), individually and on behalf of all others similarly situated, by and through their undersigned attorneys, bring this Class Action Complaint against Defendant Mead Johnson Nutrition Company and Defendant Mead Johnson & Company, LLC (collectively, “Defendant” or “Mead Johnson”), for its knowing, reckless, and/or intentional practice of failing to disclose the lack of quality controls in manufacturing its infant formula and also failing to disclose the presence of Heavy Metals in its Enfamil® infant formulas (“Products” or “Infant Formulas”).<sup>1</sup>

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<sup>1</sup> As used herein, “Heavy Metals” includes arsenic, cadmium, and lead. “Products” or “Infant Formula(s)” as to the Heavy Metals allegations refer to the following Mead Johnson powdered infant formula products: Enfamil A.R., Enfamil Gentlease, Enfamil Enspire Gentlease, Enfamil NeuroPro, Enfamil NeuroPro Sensitive, Enfamil Nutramigen, and Enfamil ProSobee. Discovery

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. Mead Johnson is one of the primary manufacturers of infant formula in the United States and previously held 39.6% of the market share for powdered infant formula.<sup>2</sup> As a trusted manufacturer and vendor of products consumed exclusively by babies and young children, it carries a duty of the highest importance to implement and maintain quality control when manufacturing its products. When a company selling vital products, such as Defendant who sells infant formula, knowingly fails to ensure the safety of its products, it must not allow dangerous toxins or contaminants, such as Heavy Metals, to be consumed by its unsuspecting consumers. Rather, these companies have a duty to disclose material risks of contamination—allowing consumers to make informed decisions about the risks they are willing to take (especially with

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may reveal additional products that contain Heavy Metals and/or the presence of additional contaminants or heavy metals. Plaintiffs reserve their rights to amend and include any such products or heavy metals in this action.

<sup>2</sup> *Market Share of the Leading Vendors of Baby Formula (Powder) in the United States in 2016, Based on Dollar Sales*, available at <https://www.statista.com/statistics/443975/market-share-of-the-leading-us-baby-formula-powder-companies/> (last accessed January 25, 2024).

the health of their infants) and assess the true value of the product they are considering for purchase. Defendant failed to do so in this case.

3. In August 2023, the FDA found that Defendant ignored its duties to ensure proper quality control measures in its manufacturing facilities.<sup>3</sup> This came after Defendant voluntarily recalled two batches of infant formula products in February 2023 due to bacterial contamination.<sup>4</sup> The FDA then inspected Defendant's facilities and found such poor quality control conditions that it issued a formal "warning letter" to the company for violations of the Food, Drug, and Cosmetic Act (FDCA).<sup>5</sup> The FDA issued the warning because "manufacturers are responsible for ensuring they make safe products," and the letter was "intended to help the industry improve the safety of their manufacturing practices," indicating that existing practices failed to uphold the company's duties.<sup>6</sup> Unfortunately, the inspections and warning letter failed to prevent another recall of Defendant's formula. In December 2023, Defendant voluntarily recalled hundreds of thousands of infant formula products that were similarly at risk of bacterial contamination yet again due to its failure to implement adequate quality control measures.<sup>7</sup>

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<sup>3</sup> FDA, *FDA Issues Warning Letters to Three Infant Formula Manufacturers*, available at <https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-three-infant-formula-manufacturers> (last accessed January 21, 2024) ("FDA Issues Warning Letters to Three Infant Formula Manufacturers").

<sup>4</sup> *Id.*; see also FDA, *Reckitt Recalls Two Batches of Prosobee 12.9 oz Simply Plant Based Infant Formula Because of Possible Health Risk*, available at <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/reckitt-recalls-two-batches-prosobee-129-oz-simply-plant-based-infant-formula-because-possible> (last accessed January 21, 2024) ("Reckitt Recalls Two Batches of Prosobee").

<sup>5</sup> FDA Issues Warning Letters to Three Infant Formula Manufacturers, *supra*.

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

<sup>7</sup> FDA, *Reckitt/Mead Johnson Nutrition Voluntarily Recalls Select Batches of Nutramigen Hypoallergenic Infant Formula Powder Because of Possible Health Risk*, available at <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/reckittmead-johnson-nutrition-voluntarily-recalls-select-batches-nutramigen-hypoallergenic-infant> (last accessed

4. Unsurprisingly, Defendant's Products also contain other dangerous toxins: Heavy Metals. As detailed below, individuals, especially infants, who consume Heavy Metals risk developing serious adverse health effects – a risk which most consumers are aware of and strongly prefer to avoid in food they feed children (who are more vulnerable to those risks than others). Yet, Defendant chose to sell itself to new parents as a trusted company, without disclosing the lack of quality control where it manufactured its infant formula or that the formula contained or had a material risk of containing Heavy Metals (collectively, the "Omissions"), both of which would be material to any parent purchasing formula for their infant.

5. Infants 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>8</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>9</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

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January 21, 2024) ("Mead Johnson Nutrition Voluntarily Recalls Select Batches of Nutramigen"); *see also What's Causing the Latest Baby Formula Recall*, available at <https://time.com/6553508/baby-formula-recall-shortage/> (last accessed January 21, 2024).

<sup>8</sup> CDC, *Infant and Toddler Nutrition: Recommendation and Benefits*, available at <https://www.cdc.gov/nutrition/infantandtoddlernutrition/breastfeeding/recommendations-benefits.html> (last accessed January 21, 2024).

<sup>9</sup> CDC, *Facts: Key Breastfeeding Indicators*, available at <https://www.cdc.gov/breastfeeding/data/facts.html> (last accessed January 21, 2024).

when they are 24 months old.<sup>10</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.

6. Reasonable parents, like Plaintiffs, trust and depend on 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 with reliable 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.

7. Consumers lack the knowledge and opportunity to determine if quality control procedures are followed in the manufacturing of the Products. Consumers also lack the scientific knowledge necessary to determine whether 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, or cadmium, that are being fed to hours-, days- or months-old babies. Such information would be material to any reasonable parent's purchasing decisions.

8. Defendant's packaging is designed to induce reasonable consumers to believe in the high quality and safety of its infant formula while omitting any information about the inclusion (or material risk of inclusion) of Heavy Metals and the utter failure to use quality control measures in its manufacturing.

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<sup>10</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 January 21, 2024).

9. For example, the packaging emphasizes that the Infant Formulas are healthy and made with nutritious ingredients that help support proper development and growth.<sup>11</sup>



10. The packaging on the Infant Formulas also stresses that there are no detrimental, harmful, and genetically engineered ingredients:<sup>12</sup>



11. On these packages and others, Defendant states the Infant Formulas contain nutritious ingredients such as Docosahexaenoic Acid (“DHA”), prebiotics such as human milk

<sup>11</sup> <https://www.enfamil.com/products/enfamil-neuropro-infant-formula/powder-tub-20-7-oz-tub/> (last accessed January 21, 2024).

<sup>12</sup> <https://www.enfamil.com/products/enfamil-neuropro-gentlease-formula/powder-tub-19-5-oz-tub/> (last accessed January 25, 2024).

oligosaccharides (“HMO”), probiotics, and desirable (naturally occurring) minerals such as selenium.



12. 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 are well-recognized.

13. 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 improper quality control procedures.



14. 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 that: (1) Defendant "[s]upport[s] the brain in everything" it does with products that "are excellent for routine, everyday feeding;"<sup>13</sup> (2) "[t]he health and safety of infants and children is [Defendant's] top priority," and it is "committed to providing a high quality and safe products [sic] for [its] littlest consumers;"<sup>14</sup> (3) Defendant's "products undergo extensive quality and safety checks throughout the manufacturing process—from raw materials to finished product" and that "samples from every batch [it] produce[s] are tested to ensure the product meets [its] stringent quality standards;"<sup>15</sup> and (4) "[p]arents can be assured that our infant formulas are safe and nutritious feeding options for their infants."<sup>16</sup> This is all in direct contradiction to the Omissions.

15. First, the FDA has cited Defendant for inadequate or nonexistent quality control methods four times since December 2017, three of which were for failing to "establish a system of process controls . . . to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment."<sup>17</sup> Similarly, the fourth citation (following an FDA inspection on July 6, 2022) was for failing to "maintain a

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<sup>13</sup> <https://www.enfamil.com/why-enfamil/enfamil-formula-family/> (last accessed January 21, 2024).

<sup>14</sup> <https://www.enfamil.com/why-enfamil/quality-assurance/> (last accessed January 21, 2024).

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

<sup>16</sup> *Id.*

<sup>17</sup> FDA Dashboard: *Firm Profile for Mead Johnson & Company, LLC*, available at <https://datadashboard.fda.gov/ora/firmprofile.htm?FEI=1812170&/identity/1812170> (last accessed January 21, 2024) ("Mead Johnson FDA Dashboard").



building used in manufacture, processing, packing, or holding of infant formula in a clean and sanitary condition.”<sup>18</sup>

16. Despite known control failures and attendant risks, Defendant knowingly chose to not disclose to consumers that the Infant Formulas were manufactured without basic quality controls. Nowhere on the Infant Formulas’ packaging (or the Defendant’s website or advertisements) is the lack of proper manufacturing controls or the 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 to 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, or lead, all known to pose health risks to humans, and particularly to infants.<sup>19</sup>

19. Independent testing also confirmed the presence of Heavy Metals in two of Defendant’s Infant Formulas:<sup>20</sup>

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

<sup>19</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 January 21, 2024) (“HBBF Report”).

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

Infant Formula	Arsenic (ppb)	Cadmium (ppb)	Lead (ppb)
Enfamil ProSobee Soy Infant Formula	6.2*	6.9	7.8
Enfamil Infant – Infant Formula Milk-Based with Iron, 0-12 months	< 2.2	0.7*	2.0

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

21. Exposure to Heavy Metals has significant and dangerous health consequences. A 2021 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>22</sup>

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

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<sup>21</sup> *See generally, id.*

<sup>22</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://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf> (last accessed January 21, 2024) (“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://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/ECP%20Second%20Baby%20Food%20Report%209.29.21%20FINAL.pdf> (last accessed January 21, 2024) (“Second Congressional Committee Report”).

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

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

25. Defendant's marketing strategy reflects the concerns raised by the World Health Organization ("WHO") and UNICEF in its report acknowledging the troubling marketing efforts by infant formula milk manufacturers.<sup>23</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>24</sup>

26. 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 Plaintiff, 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.

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<sup>23</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 January 21, 2024).

<sup>24</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 January 21, 2024).

27. 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 without proper quality control procedures.

28. 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.

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

30. 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.

31. 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**

32. 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.

33. 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 has intentionally availed itself of the laws and markets of this District and is headquartered and subject to personal jurisdiction in this District.

### **THE PARTIES**

34. Plaintiff Dominique Lopez ("Plaintiff Lopez") is, and at times relevant hereto was, a citizen of the State of California and currently resides in Contra Costa County in the State of California. She purchased the Infant Formula, including Enfamil® Nutramigen, Enfamil® ProSobee, and Enfamil® NeuroPro for household use.

35. Plaintiff Lopez purchased the Infant Formula for her child from Target, Safeway, and Walmart in Antioch, California, from approximately May 2021 until September 2022.

36. Plaintiff Lopez believed she was feeding her child healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Lopez 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 Formulas were manufactured without proper quality control procedures and contained (or had a material risk of

containing) Heavy Metals and would not have purchased the Infant Formulas if that information had been fully disclosed. Plaintiff Lopez would be willing to purchase Enfamil® 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.

37. Plaintiff Bianca Raya (“Plaintiff Raya”) is, and at times relevant hereto was, a citizen of the State of Illinois and currently resides in Rock Island County in the State of Illinois. She purchased the Infant Formula, including Enfamil® Nutramigen and Enfamil® Gentlease for household use.

38. Plaintiff Raya purchased the Infant Formula for her child from WalMart, Target and Walgreens in Moline, Illinois, from approximately February 2023 until December 2023.

39. Plaintiff Raya believed she was feeding her child healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Raya 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 Formulas were manufactured without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals and would not have purchased the Infant Formulas if that information had been fully disclosed. Plaintiff Raya would be willing to purchase Enfamil® 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.

40. Plaintiff Laurie Thomas (“Plaintiff Thomas”) is, and at times relevant hereto was, a resident of Petersburg, Illinois and currently resides in Menard County in the State of Illinois. She purchased the Infant Formula, including Enfamil® NeuroPro and Enfamil® Gentlease for household use.

41. Plaintiff Thomas purchased the Infant Formula for her children from Hyvee, WalMart, County Market, and other grocery stores in Springfield, Illinois, from approximately 2018 until 2021.

42. Plaintiff Thomas believed she was feeding her children healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Thomas 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 Formulas were manufactured without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals and would not have purchased the Infant Formulas if that information had been fully disclosed. Plaintiff Thomas would be willing to purchase Enfamil® 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.

43. Plaintiff Amanda Seutter (“Plaintiff Seutter”) is, and at times relevant hereto was, a resident of Elk River, Minnesota and currently resides in Sherburne County in the State of Minnesota. She purchased the Infant Formula, including Enfamil® Gentlease for household use.

44. Plaintiff Seutter purchased the Infant Formula for her child from Target in Otsego, Minnesota and Amazon.com, from approximately October 2022 until January 2024.

45. Plaintiff Seutter believed she was feeding her child healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Seutter saw and relied upon the packaging of the Infant Formula. During the time she purchased and fed her child the Infant Formula, and due to the Omissions by Defendant, she was unaware the Infant Formulas were manufactured without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals and would not have purchased the Infant Formulas if that information



had been fully disclosed. Plaintiff Seutter would be willing to purchase Enfamil® 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.

46. As a 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 manufactured with proper quality control procedures, were free of Heavy Metals, and posed no potential harm to the physical and mental growth of her infant – 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.

47. Defendant Mead Johnson Nutrition Company is a Delaware corporation with its "Global Headquarters" at 225 North Canal Street in Chicago, Illinois, in Lake County. In June 2017, Mead Johnson Nutrition Company was acquired by Reckitt Benckiser Group PLC, whose U.S. headquarters are located at 399 Interpace Parkway, Parsippany, New Jersey. Mead Johnson & Company, LLC, is a Delaware corporation with its headquarters at 2400 West Lloyd Expressway in Evansville, Indiana, In Vanderburgh County.

48. Defendant, one of the largest producers of infant formula products in the world, have formulated, developed, manufactured, labeled, distributed, marketed, advertised, and sold the Infant Formulas under the Enfamil® name throughout the United States, including in this

District. Defendant has done so continuously from January 1, 2018, to the present (the “Relevant Period”).

49. 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 improper quality control procedures in manufacturing the Products and the presence (or risk) of Heavy Metals in the Infant Formulas. 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 Products.

50. 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.

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

(a) Enfamil® A.R.;



(b) Enfamil® Gentlease;



(c) Enfamil® Enspire Gentlease;



(d) Enfamil® NeuroPro;



(e) Enfamil® NeuroPro Sensitive;



(f) Enfamil® Nutramigen; and



(g) Enfamil® ProSobee.



## **FACTUAL ALLEGATIONS**

### **I. A PATTERN AND PRACTICE OF MANUFACTURING INFANT FORMULA WITHOUT PROPER QUALITY CONTROL PROCEDURES**

52. Defendant has been regarded as one of the most-trusted manufacturers of Infant Formulas in the United States. However, multiple recalls and FDA investigations in recent years have revealed the truth about the company's repeated, systematic failures in its manufacturing conditions and quality controls.<sup>25</sup>

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<sup>25</sup> See Mead Johnson FDA Dashboard, *supra* (Defendant has been cited by the FDA four times from December 2017 to December 2023 for failing to implement and maintain proper sanitation or quality control measures in its manufacturing plants); Reckitt Recalls Two Batches of Prosobee, *supra* (Defendant recalled two batches of infant formula products in February 2023 due to bacterial contamination); FDA Issues Warning Letters to Three Infant Formula Manufacturers, *supra* (FDA found Defendant ignored their duties to ensure proper quality control measures in their manufacturing facilities and issued a formal "warning letter" to Defendants in August 2023); Mead Johnson Nutrition Voluntarily Recalls Select Batches of Nutramigen, *supra* (Defendant yet again recalled infant formula products at risk of bacterial contamination due to its failure to implement adequate quality control measures); CNN,

53. Further, supporting the lack of proper quality control measures in the manufacturing of Defendant's products, the need for the most recent recall was not discovered in-house. On December 14, 2023, "the Israeli Ministry of Health notified the FDA that product tested at the Israeli border as part of routine sampling tested positive for" *Cronobacter sakazakii*, bacteria that "can cause rare but potentially deadly infections in newborns." Only after the Israeli government's "routine testing" discovered the contamination did Defendant initiate the recall under FDA oversight.

54. Defendant's repeated failure to implement and maintain proper quality control measures – including routine testing sufficient to discover detectable adulteration of their products – exists despite the fact that Defendant sells products for infants who are hours, days and months old, and despite Defendant's regular practice of telling consumers that its products are of the highest quality, safe, and nutritious for infants, manufactured under strict and rigorous quality and safety assurance measures, and in compliance with all FDA regulations for infant formula.

55. Defendant was in a superior position to know that the Infant Formulas were manufactured with a lack of proper quality control.

56. Despite the known quality control failures and the risks those create, Defendant actively and knowingly concealed from and failed to disclose to consumers that the Infant Formulas were manufactured without proper quality control. Nowhere on the Infant Formulas'

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*Reckitt/Mead Johnson Voluntarily Recalls Specialty Infant Formula Due to Possible Bacterial Infection* (Dec. 31, 2023) available at <https://www.cnn.com/2023/12/31/business/reckitt-mead-johnson-recalls-specialty-infant-formula/index.html> (last accessed January 21, 2024) (Defendant's December 2023 recall affected 675,030 cans of Nutramigen formula, a specialty formula meant for infants with severe food allergies).



packaging does Defendant disclose the lack of proper manufacturing controls or material risk of contamination from failing to ensure proper manufacturing processes.

**II. DEFENDANT KNEW OR SHOULD HAVE KNOWN OF THE HEALTH RISKS PRESENTED TO INFANTS AND CHILDREN FROM HEAVY METALS AND THE LIKELIHOOD THEY WERE PRESENT IN ITS PRODUCTS**

57. 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>26</sup>

58. 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>27</sup>

59. Arsenic, cadmium, and lead—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>28</sup>

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<sup>26</sup> New York Times, *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 January 21, 2024) (“Some Baby Food May Contain Toxic Metals”).

<sup>27</sup>FDA, *Environmental Contaminants in Food*, available at <https://www.fda.gov/food/chemical-contaminants-pesticides/environmental-contaminants-food> (last accessed January 21, 2024) (“Environmental Contaminants in Food”).

<sup>28</sup> HBBF Report, *supra*, at 13.

60. 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>29</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>30</sup>

61. 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>31</sup>

62. 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>32</sup>

63. 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>33</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

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<sup>29</sup> *Id.* at 6.

<sup>30</sup> Congressional Committee Report, *supra*, at 1.

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

<sup>32</sup> *Id.*

<sup>33</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 January 21, 2024).

folding, maturation, apoptosis, ionic transportation, enzyme regulation, and release of neurotransmitters.”<sup>34</sup>

64. 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>35</sup>

65. 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>36</sup>

66. As Dr. James E. Rogers, the director of food safety research and testing at Consumer Reports has said “[t]*here is no safe level of heavy metals*, so the goal should be to have no measurable levels of any heavy metal in baby and toddler foods.”<sup>37</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,

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<sup>34</sup> Jaishankar, M., Tseten, T., Anbalagan, N., Mathew, B. B., & Beeregowda, K. N. (2014). *Toxicity, Mechanism and Health Effects of Some Heavy Metals*. *Interdisciplinary toxicology*, 7(2), 60–72. Available at <https://doi.org/10.2478/intox-2014-0009> (last accessed January 21, 2024).

<sup>35</sup> Consumer Reports: Heavy Metals in Baby Food, *supra*.

<sup>36</sup> *Id.*

<sup>37</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 January 21, 2024) (emphasis added).

formula is the only food babies younger than five months can eat for their development and growth.

67. Research continues to confirm that exposures to food containing arsenic, cadmium, and lead cause “troubling risks for babies, including cancer and lifelong deficits in intelligence[.]”<sup>38</sup>

68. 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***

69. 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 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>

70. Arsenic exposure can also cause respiratory, gastrointestinal, hematological, hepatic, renal, skin, neurological and immunological effects, and damage children’s central

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<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.

<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 January 21, 2024)).

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

nervous systems and cognitive development.<sup>43</sup> Exposure to arsenic can also cause diabetes, atherosclerosis, and cardiovascular disease.<sup>44</sup>

71. 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>

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

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

74. 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

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<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 January 21, 2024).

<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 January 21, 2024) (“Toxic Element Contamination of Natural Health Products”).

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

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

consumed by very young children.”<sup>49</sup> The FDA’s limit for inorganic arsenic in bottled water is 10 ppb.<sup>50</sup>

75. Despite this, laboratory tests indicate that Defendant sold Products containing undisclosed arsenic levels at 7.9 ppb, an amount that is especially concerning considering the amount of infant formula consumed by developing children.

### ***Cadmium***

76. 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.

77. 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>51</sup>

78. Cadmium, like lead, “displays a troubling ability to cause harm at low levels of exposure.”<sup>52</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

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<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 January 21, 2024).

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

<sup>51</sup> HBBF Report, *supra*, at 14.

<sup>52</sup> *Id.*

that cadmium is a probable human carcinogen.<sup>53</sup> Compounding such concerns is the fact that cadmium has a prolonged half-life as it “sequesters in [human] tissue.”<sup>54</sup>

79. 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>55</sup>

80. Despite this, laboratory tests indicate that Defendant sold Products containing undisclosed cadmium levels as high as 6.8 ppb.

### ***Lead***

81. The Infant Formulas contain (or have a material risk of containing) lead, which is a probable carcinogen.<sup>56</sup>

82. 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.

83. 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.

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<sup>53</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 January 21, 2024).

<sup>54</sup> Toxic Element Contamination of Natural Health Products, *supra*.

<sup>55</sup> Congressional Committee Report, *supra*, at 29.

<sup>56</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 January 21, 2024).



84. 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>57</sup> The FDA, CDC, American Academy of Pediatrics (AAP), and WHO have all plainly stated that there is no safe level of lead.<sup>58</sup>

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

86. 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>

87. 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>

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<sup>57</sup> HBBF Report, *supra*, at 13.

<sup>58</sup> FDA, *Lead in Food and Foodwares*, available at [\(https://www.fda.gov/food/environmental-contaminants-food/lead-food-and-foodwares#:~:text=Although%20no%20safe%20level%20for,blood%20\(%C2%B5g%20%2Fdl\)](https://www.fda.gov/food/environmental-contaminants-food/lead-food-and-foodwares#:~:text=Although%20no%20safe%20level%20for,blood%20(%C2%B5g%20%2Fdl)) (last accessed January 21, 2024); CDC, *Health Effects of Lead Exposure*, available at <https://www.cdc.gov/nceh/lead/prevention/health-effects.htm> (last accessed January 21, 2024); AAP, *Lead Exposure in Children*, available at <https://www.aap.org/en/patient-care/lead-exposure/lead-exposure-in-children/#:~:text=How%20Much%20Lead%20is%20Safe,Prevention%20recommends%20evaluation%20and%20intervention> (last accessed January 21, 2024); WHO, *Lead Poisoning*, available at [\(https://www.who.int/news-room/fact-sheets/detail/lead-poisoning-and-health#:~:text=The%20neurological%20and%20behavioural%20effects,and%20learning%20problems%20\(1\)](https://www.who.int/news-room/fact-sheets/detail/lead-poisoning-and-health#:~:text=The%20neurological%20and%20behavioural%20effects,and%20learning%20problems%20(1)) (last accessed January 21, 2024); see also USA Today, *FDA: Recalled Applesauce Pouches Had Elevated Lead Levels and Another Possible Contaminant* (Jan. 5, 2024), available at <https://www.usatoday.com/story/money/food/2024/01/05/applesauce-pouch-recall-contamination-spreads/72121869007/> (last accessed January 21, 2024).

<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.

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

88. Despite this, laboratory tests indicate Defendant sold products containing undisclosed lead levels as high as 6.5 ppb.<sup>63</sup>

89. The Heavy Metals – arsenic, cadmium, and lead– are significant detriments to children.

90. 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>64</sup>

91. 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.

92. 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>65</sup> Consumer Reports,<sup>66</sup> and Politico,<sup>67</sup> and studies by the FDA,<sup>68</sup> University of Miami, the Clean Label Project, and Ellipse Analytics.<sup>69</sup>

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

<sup>64</sup> Environmental Contaminants in Food, *supra*.

<sup>65</sup> HBBF Report at 12, 20, *supra*.

<sup>66</sup> Consumer Reports, *Heavy Metals in Baby Food: What You Need to Know* (Aug. 16, 2018, updated Sept. 29, 2021), available at <https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/> (last accessed January 21, 2024) (“Consumer Reports: Heavy Metals in Baby Food”).

<sup>67</sup> Politico, *The FDA’s Food Failure* (Apr. 8, 2022), available at <https://www.politico.com/interactives/2022/fda-fails-regulate-food-health-safety-hazards/> (last accessed January 21, 2024).

93. Both the Congressional Committee Report, published on February 4, 2021, which acknowledged that Heavy Metals “can endanger infant neurological development,”<sup>70</sup> followed by a second report published on September 29, 2021, revealed alarming levels of Heavy Metals in baby foods.<sup>71</sup> The Congressional Committee Report acknowledged that Heavy Metals—including arsenic, cadmium, and lead—were present in “significant levels” in numerous commercial baby food products.<sup>72</sup>

94. 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>73</sup> and that, over time, these toxins can accumulate and remain in infants’ bodies, to their detriment.

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<sup>68</sup> FDA, *FDA Total Diet Study Report, Fiscal Years 2018-2020 Elements Data (July 2022)*, available at <https://www.fda.gov/media/159751/download?attachment> (last accessed January 23, 2024) (“FDA Total Diet Study”).

<sup>69</sup> Gardener, et al., *Lead and Cadmium Contamination In A Large Sample of United States Infant Formulas and Baby Foods*, 651 SCI. TOTAL ENVIRON. 1, 822-827 (2019), available at: <https://www.sciencedirect.com/science/article/abs/pii/S0048969718334442?via%3Dihub> (last accessed January 21, 2024) (“Lead and Cadmium Contamination in Infant Formulas and Baby Foods”).

<sup>70</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 January 21, 2024) (“Toxic Heavy Metals in Popular Baby Foods”).

<sup>71</sup> Congressional Committee Report, *supra*; Second Congressional Committee Report, *supra*.

<sup>72</sup> Congressional Committee Report, *supra*.

<sup>73</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).

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

### III. DEFENDANT FALSELY MARKETED ITS INFANT FORMULAS AS HEALTHY AND MADE WITH NUTRITIOUS INGREDIENTS BY OMITTING ANY MENTION OF HEAVY METALS

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

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

98. On its website, Defendant markets its Infant Formulas as the “#1 Trusted Brand of Pediatricians & Parents,” “#1 trusted brand for brain-building nutrition and immune support,” and “#1 infant formula brand recommended by pediatricians.”<sup>74</sup>



99. On its website, Defendant promises to “[s]upport your baby’s development right from the start with brain-building nutrition and MFGM components from the #1 trusted infant formula brand.”<sup>75</sup> Defendant represents that “using Enfamil gives you the confidence you’ve

<sup>74</sup> <https://www.enfamil.com/> (last accessed January 25, 2024).

<sup>75</sup> <https://www.enfamil.com/enfamil-neuropro/> (last accessed January 25, 2024).

made the right choice for your baby.”<sup>76</sup> Defendant boasts and reassures parents of the quality of its products, claiming “we know you’ve got lots of questions. Relax. We’ve got you covered. With a complete family of brain-building formulas to fuel the wonder of your little one. From everyday nutrition to specialty formulas.”<sup>77</sup>

100. Defendant touts its innovations to its Infant Formula and provides thorough information about the ingredients in its formulas to consumers throughout its website, including on its Frequently Asked Questions (“FAQ”) page.<sup>78</sup>

101. Based on Defendant’s decision to wholly omit any 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.

102. Defendant intentionally omitted from its packaging any mention of 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.

103. 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.

104. As a result of the material undisclosed information on the Infant Formulas’ packaging, 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

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<sup>76</sup> <https://www.enfamil.com/why-enfamil/> (last accessed January 25, 2024).

<sup>77</sup> <https://www.enfamil.com/why-enfamil/enfamil-formula-family/> (last accessed January 25, 2024).

<sup>78</sup> <https://www.enfamil.com/help-center/nutrients-ingredients/> (last accessed January 25, 2024).

(which are time consuming and expensive) or reviewing third-party scientific testing of these Products.

**IV. DUE TO THE PRESENCE AND MATERIAL RISK OF HEAVY METALS IN THE INFANT FORMULAS, THE PACKAGING WAS MATERIALLY MISLEADING**

105. 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.

106. 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.

107. 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, cadmium, and lead.

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

109. 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.

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

111. Defendant knew consumers purchased the Infant Formulas based on the reasonable expectation that Defendant manufactured the Infant Formulas to the highest standards. In fact, Defendant promised as much – at length – on its website:

Our products meet or exceed all **infant formula requirements set out by the FDA**, which are among the **most rigorous** in the food industry. Each of our manufacturing facilities adheres to safety guidelines among the **most rigorous in the food industry** and our own **stringent quality standards** so that we can assure the highest quality products. Parents can be assured that our infant formulas are safe and nutritious feeding options for their infants when prepared, stored, and handled according to package directions.

Our infant products undergo **extensive quality and safety checks** throughout the manufacturing process—from raw materials to finished product. A representative number of samples from every batch we produce are tested to ensure the product meets our **stringent quality standards**. Each batch of our products is assured to meet our **high quality and safety standards** as verified by our **proprietary Quality Systems** that exist in every manufacturing facility. We distribute our products only if they pass our **strict testing**. We track the path of every ingredient in our infant and toddler products from its initial supplier through all processing stages until it reaches our consumer.

The [FDA] has very **specific and rigorous manufacturing standards** for infant formulas and toddler drinks that we adhere to. All Mead Johnson formulas are in compliance with all FDA regulations, including Enfamil® NeuroPro™, Enfamil® Enspire™, Enfamil® Gentlease®, and Nutramigen®. Our products meet or exceed all **infant formula requirements set out by the FDA**, which are among the **most rigorous** in the food industry. The amounts of ingredients in Enfamil Infant Formulas are all within required guidelines established to ensure the safety and nutritional quality of infant formulas. **We are committed to the most stringent manufacturing, packaging, and quality assurance procedures.**<sup>79</sup>

Based on consumers' expectation that Defendant manufactured the Infant Formulas to the highest standards, Defendant knew or should have known consumers reasonably inferred that

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<sup>79</sup> <https://www.enfamil.com/why-enfamil/quality-assurance/> (last accessed January 25, 2024).



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.

112. A recent consumer survey done by Plaintiffs' counsel ("Consumer Survey") demonstrates such an expectation.<sup>80</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

113. Further, Defendant has recognized consumer concern for the possible presence of Heavy Metals in baby food products and infant formulas. As a member of the Infant Nutrition Council of America ("INCA") through its parent company Reckitt Benckiser Group PLC, Defendant joined two other major manufacturers of infant formula products to lobby against the promulgation of California Assembly Bill 899 ("AB 899") in 2023.<sup>81</sup> As introduced, the original version of AB 899 would have required infant formula manufacturers – like Defendant – to test for Heavy Metals in their products and disclose the testing results on the labels.<sup>82</sup> INCA vehemently opposed any disclosure of Heavy Metals to consumers, arguing the proposed measure would "confuse" consumers and "create fear and panic," and cause them to "mistrust"

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<sup>80</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.

<sup>81</sup> Analysis of AB 899 as amended March 13, 2023, available at <https://billtexts.s3.amazonaws.com/ca/ca-analysishttps-leginfo-legislature-ca-gov-faces-billAnalysisClient-xhtml-bill-id-202320240AB899-ca-analysis-357755.pdf> (last accessed January 25, 2024) ("Analysis of AB 899").

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

the manufacturers. Furthermore, INCA has argued that such requirements would cause consumers to change their purchasing behaviors.<sup>83</sup>

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

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

116. Defendant also knew that monitoring Heavy Metals was likewise important to its consumers to protect their babies.

**V. INFANT FORMULAS CAN BE MANUFACTURED WITHOUT MEASURABLE LEVELS OF HEAVY METALS**

117. 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 levels of Heavy Metals.

118. 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>

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<sup>83</sup> *Id.*; Analysis of AB 899 as amended April 12, 2023, available at <https://trackbill.com/s3/bills/CA/2023/AB/899/analyses/senate-health.pdf> (last accessed January 25, 2024).

<sup>84</sup> Clean Label Project Purity Award, available at <https://cleanlabelproject.org/purity-award/> (last accessed January 25, 2024).

119. 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>

120. 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)
Bobbie Organic Infant Formula	< 2.2	< 1.3	< 1.0

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

122. 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>

123. 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

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<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* (Jan. 25, 2022), available at <https://www.businesswire.com/news/home/20220125005905/en/Bobbie-Is-First-Ever-Infant-Formula-To-Receive-The-Clean-Label-Project-Purity-Award-and-Certification-as-a-Pesticide-Free-Product> (last accessed January 21, 2024).

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

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

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

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>

124. 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>

125. 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 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>

126. 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.

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

<sup>90</sup> FDA Total Diet Study, *supra*, at 73, 81-82.

<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 January 21, 2024).

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

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

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

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

129. 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.

130. 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.

131. 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.

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

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

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

135. 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.

136. 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**

137. Defendant's packaging communications misled and deceived reasonable consumers because Defendant actively and knowingly concealed from and failed to disclose that the Infant Formulas were manufactured without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals, while representing nutritious quality and characteristics.

138. Based on the impression given by the packaging communications and Omissions, no reasonable consumer could expect or understand that the Infant Formulas were manufactured without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

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

(a) Enfamil® A.R.: “BRAIN BUILDING,” “expert-recommended,” “#1 ADDED RICE starch formula,” “#1 RECOMMENDED BRAND BY PEDIATRICIANS,” “Calcium for strong bones,” and “Vitamin C for immune support.”



(b) Enfamil® Enspire Gentlelease: “with LACTOFERRIN a key protein also found in BREAST MILK & COLOSTRUM,” “BRAIN BUILDING,” “IMMUNE HEALTH supported by LACTOFERRIN,” and “Naturally occurring MFGM components.”



(c) Enfamil® Gentlease: “BRAIN BUILDING,” “expert-recommended,” and “#1 RECOMMENDED BRAND BY PEDIATRICIANS.”



(d) Enfamil® NeuroPro: “EXCLUSIVE HuMO6 IMMUNE BLEND,” “BRAIN BUILDING,” “expert-recommended,” “inspired by BREAST MILK,” “supports IMMUNE HEALTH,” “naturally-occurring MFGM components,” “#1 RECOMMENDED BRAND BY PEDIATRICIANS,” and “Beta Carotene & DHA for baby’s eye health” .



**Beta Carotene & DHA  
for baby’s eye health**



(e) Enfamil® NeuroPro Sensitive: “BRAIN BUILDING,” “expert-recommended,” “HMO for IMMUNE SUPPORT,” “NON-GMO No Artificial Growth Hormones,” and “#1 RECOMMENDED BRAND BY PEDIATRICIANS.”



(f) Enfamil® Nutramigen: “BRAIN BUILDING,” “#1 RECOMMENDED BRAND BY PEDIATRICIANS” (front and back), “THE ONLY HYPOALLERGIC FORMULA WITH LGG® PROBIOTIC” (front and back), “NO ARTIFICIAL GROWTH HORMONES,” and “LGG® probiotic to help support digestive health.”



(g) Enfamil® ProSobee: “No artificial colors, flavors or sweeteners” (front), “BRAIN BUILDING,” “expert-recommended,” “IMMUNE HEALTH Vitamins A, C, E & Selenium” (front), “#1 RECOMMENDED BRAND BY PEDIATRICIANS,” “NO ARTIFICIAL colors, flavors or sweeteners” (back), and “vitamins A, C & E for IMMUNE SUPPORT” (back).



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

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

142. 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.

143. Plaintiffs' counsel had seven 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)
Enfamil® A.R.	3.4	3.2	1.2
Enfamil® Gentlease	3.7	2.6	1.7
Enfamil® Enspire Gentlease	5.0	2.3	< 1.0
Enfamil® NeuroPro	< 2.2	2.0	< 1.0
Enfamil® NeuroPro Sensitive	5.1	< 1.3	2.3
Enfamil® Nutramigen	7.9	4.6	6.5
Enfamil® ProSobee	6.7	6.8	3.5

144. Independent testing also confirmed Heavy Metals in two of Defendant's Products:<sup>94</sup>

Infant Formula	Arsenic (ppb)	Cadmium (ppb)	Lead (ppb)
Enfamil ProSobee Soy Infant Formula	6.2*	6.9	7.8
Enfamil Infant – Infant Formula Milk-Based with Iron, 0-12 months	< 2.2	0.7*	2.0

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

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

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

146. 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.

147. 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>

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

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

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

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

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<sup>96</sup> Department of Health and Human Services Fiscal Year 2023: *Food and Drug Administration, Justification of Estimates for Appropriations Committees*, available at <https://www.fda.gov/media/157192/download?attachment> (last accessed January 25, 2024).

<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

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

152. 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.

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

154. 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.

155. 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.

156. 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.

157. 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.

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

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

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

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

162. 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.

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

164. 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.

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

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

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

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

168. Plaintiffs read and relied upon the packaging of the Infant Formulas when making their purchasing decisions. Had they known Defendant omitted and failed to disclose the Infant Formula was manufactured without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals, they would not have purchased the Infant Formulas.

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

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

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

171. In 2017 and 2019, the Clean Label Project published results and findings from an investigation of heavy metals in baby and toddler food products, including infant formula. The findings showed the presence of Heavy Metals in Defendant’s Infant Formulas. In response to the Clean Label Project’s study, Defendant stated that it “specifically monitors the presence of many materials, including arsenic, cadmium, [and] lead . . . to ensure ‘safety and high quality.’”<sup>98</sup>

172. 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>99</sup> The FDA has also released a study showing the presence of Heavy Metals in baby foods, including infant formulas.<sup>100</sup>

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<sup>98</sup> USA Today, *These Baby Foods and Formulas Tested Positive for Arsenic, Lead, and BPA in New Study* (Oct. 25, 2017), available at <https://www.usatoday.com/story/news/nation-now/2017/10/25/these-baby-foods-and-formulas-tested-positive-arsenic-lead-and-bpa-new-study/794291001/> (last accessed January 21, 2024).

<sup>99</sup> Congressional Committee Report, *supra*; Second Congressional Committee Report, *supra*.

<sup>100</sup> FDA Total Diet Study, *supra*, at 73, 81-82.



173. Defendant was likewise given notice through its membership in INCA, for example, through INCA's lobbying efforts in opposition to AB 899 that would have required infant formula manufacturers to test for and disclose levels of Heavy Metals.<sup>101</sup>

174. Similarly, Defendant was made aware that it failed to implement or maintain proper manufacturing and quality control measures for detecting and controlling the presence of adulterating substances through the FDA's investigations from 2017 to 2023 and the multiple recalls by Defendant in 2023 alone due to bacterial contamination of its formula products.

175. Defendant has not changed its packaging to include any disclaimer on the Omissions.

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

176. 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.

177. 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.

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

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

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<sup>101</sup> Analysis of AB 899, *supra*.

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

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

181. 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 improper quality control procedures where it manufactured the Infant Formulas and that contained (or had a material risk of containing) Heavy Metals. Defendant intentionally concealed these material facts from Plaintiffs.

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

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

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

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

186. Plaintiffs did not know that the Infant Formula was manufactured 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 ingredients to support growing infants.

**CLASS ACTION ALLEGATIONS**

187. 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 January 25, 2018, to the present, purchased the Infant Formulas for household use, and not for resale (the “Class”).

188. Plaintiff Lopez brings this action individually and on behalf of the following California Subclass:

All persons who are residents of California who, from January 1, 2018, to the present, purchased the Infant Formulas in California for household use, and not for resale (the “California Subclass”).

189. Plaintiffs Raya and Thomas bring this action individually and on behalf of the following Illinois Subclass:

All persons who are residents of Illinois who, from January 1, 2018, to the present, purchased the Infant Formulas in Illinois for household use, and not for resale (the “Illinois Subclass”).

190. Plaintiff Seutter brings this action individually and on behalf of the following Minnesota Subclass:

All persons who are residents of Minnesota who, from January 1, 2018, to the present, purchased the Infant Formulas in Minnesota for household use, and not for resale (the “Minnesota Subclass”).

191. Excluded from the Class and California, Illinois, and Minnesota 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.

192. 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.

193. 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.

194. 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 without proper quality control procedures;
- (d) whether Defendant knew or should have known that the Infant Formulas contained or may contain Heavy Metals;
- (e) whether Defendant failed to disclose the Omissions;
- (f) whether the claims of the Plaintiffs and the Classes serve a public benefit;
- (g) whether Defendant's packaging is false, deceptive, and misleading based on the Omissions;
- (h) whether the Omissions are material to a reasonable consumer;
- (i) whether the Omissions are likely to deceive a reasonable consumer;
- (j) whether Defendant had knowledge that the Omissions were material and false, deceptive, and/or misleading;
- (k) whether Defendant breached its duty of care;
- (l) whether Defendant breached its duty to disclose;
- (m) whether Defendant violated the laws of the State of Illinois;
- (n) whether Defendant violated the laws of the State of California;

- (o) whether Defendant violated the laws of the State of Minnesota;
- (p) whether Defendant breached its implied warranties;
- (q) whether Defendant engaged in unfair trade practices;
- (r) whether Defendant engaged in false advertising;
- (s) whether Defendant made fraudulent omissions;
- (t) whether Plaintiffs and Class members' claims are tolled based on Defendant's fraudulent concealment;
- (u) whether Plaintiffs and members of the Classes are entitled to actual, statutory, and punitive damages; and
- (v) whether Plaintiffs and members of the Classes are entitled to declaratory and injunctive relief.

195. 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 harm are involved. Individual questions, if any, are not prevalent in comparison to the numerous common questions that dominate this action.

196. 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.

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

198. 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.

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

200. 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, Plaintiffs Raya and Thomas and the Illinois Subclass**

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

202. Plaintiffs and the Class are “persons” within the meaning of 815 Illinois Compiled Statute §505/1(c).

203. Defendant is a “person” within the meaning of 815 Illinois Compiled Statute §505/1(c).

204. The Infant Formulas are “merchandise” within the meaning of 815 Illinois Compiled Statute §505/1(b).

205. There was a sale of merchandise within the meaning of 815 Illinois Compiled Statute §505/1(d).

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

207. 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.

208. Defendant's deceptive acts and practices are continuing.

209. 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.

210. 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.

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

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

213. 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.

214. 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.

215. 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.

216. The facts concealed, omitted, or not disclosed by Defendant, including that the Infant Formula was manufactured 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.

217. If Plaintiffs and the Class members had known that the Infant Formula was manufactured 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.

218. 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.

219. 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 manufactured with 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 the Omissions been disclosed; and/or (3) receiving Products that were worthless because they were manufactured without proper quality control procedures and contain or risk containing Heavy Metals.

220. 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.



221. 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.

222. 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**

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

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

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

226. 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).

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

228. The Infant Formulas were not fit for their ordinary use (consumption by infants with no development or health risks) as they were manufactured without proper quality control

procedures and contained (or had a material risk of containing) Heavy Metals that do not conform to the packaging.

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

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

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

232. 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 Formulas were manufactured with proper quality control measures; however, Defendant failed to mention or disclose the Infant Formulas were manufactured without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

233. 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 manufactured with 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 without proper quality control procedures and contain or risk containing Heavy Metals.

234. Plaintiffs, on behalf of herself and the Class, seek actual damages for Defendant's 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**

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

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

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

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

239. Defendant knowingly and actively concealed the Omissions from Plaintiffs and the Class.

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

241. Defendant knew or should have known the Infant Formulas were manufactured without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

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

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

244. 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.

245. Defendant knows reasonable consumers expected the Infant Formulas to be manufactured with proper quality control procedures and not contain (or have a material risk of containing) Heavy Metals.

246. 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 with proper quality control procedures, and that these consumers will pay for infant formulas they believe possess these qualities.

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

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

249. 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.

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

251. 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 manufactured with proper quality control procedures and do not contain (or have a material risk of containing) Heavy Metals.

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

253. 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 manufactured with 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 without proper quality control procedures and contain or risk containing Heavy Metals.

254. 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**

255. Plaintiffs incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

256. Defendant knew or should have known the Infant Formulas were manufactured without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

257. 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.

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

259. Defendant actively and knowingly concealed from and failed to disclose to Plaintiffs and the Class that the Infant Formulas included were manufactured without proper quality control procedures and contained undisclosed levels (or had a material risk of containing) Heavy Metals that do not conform to the Products' packaging.

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

261. 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.

262. Defendant knows its customers trust the quality of its products and expect Defendant's Infant Formulas to be manufactured with proper quality control procedures 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.

263. Due to the Omissions on the Infant Formulas' packaging, Defendant had a duty to disclose the whole truth about the improper quality control procedures and that the Infant Formula contained (or had a material risk of containing) Heavy Metals.

264. 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.

265. 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.

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

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

268. 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.

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

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

271. 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.

272. 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 manufactured with 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 without proper quality control procedures and contain or risk containing Heavy Metals.

273. 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**

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

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

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

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

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

278. Plaintiff Lopez and each California Subclass member’s purchase of the Products constituted a “transaction” as that term is defined in California Civil Code section 1761(e).

279. 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 Formulas were of a particular standard, quality, or grade, when they were of another;

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

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

280. The omissions were material as reasonable consumers such as Plaintiff Lopez and the California Subclass would deem that the Infant Formulas were manufactured 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.

281. As a direct and proximate result of these violations, Plaintiff Lopez 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.

282. Plaintiff Lopez seeks an award of attorneys' fees pursuant to, *inter alia*, California Civil section 1780(e) and California Code of Civil Procedure section 1021.5.

### **COUNT VI**

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

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

284. 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.

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

286. Defendant failed to disclose that the Products were manufactured without proper quality control procedures and the presence (or material risk) of Heavy Metals.

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

288. Defendant's conduct is ongoing and continuing, such that prospective injunctive relief is necessary, especially given Plaintiff Lopez's desire to purchase these Products in the future if she can be assured that the Infant Formulas are as advertised, are manufactured with proper quality control measures, and do not contain Heavy Metals.

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

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

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

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

**Fraudulent**

292. Defendant failed to disclose the Omissions.

**Unlawful**

293. As alleged herein, Defendant has advertised the Infant Formulas 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**

294. 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.

295. 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.

296. 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 that consumers themselves can reasonably avoid.

297. In accordance with California Business & Professions Code section 17203, Plaintiff Lopez, 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 Lopez's desire to purchase these Products in the future if she can be assured that the Infant Formulas were manufactured with proper quality control procedures and did not contain (or have a material risk of containing) Heavy Metals.

298. Plaintiff Lopez, 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 VIII**

**Breach of the Implied Warranty of Merchantability – California Uniform Commercial Code, California Commercial Code §2314, Against Defendant on Behalf of Plaintiff Lopez and the California Subclass**

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

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

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

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

303. Plaintiff Lopez 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.

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

305. Defendant impliedly warranted that the Products were in merchantable condition and fit for consumption or ingestion by infants. 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 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.

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

307. Defendant was provided notice as described above by the FDA inspections, its product recalls, and membership with INCA (and e.g., through INCA's lobbying efforts in opposition to AB 899). 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.

308. As a direct and proximate result of Defendant's breach of the implied warranty of merchantability, Plaintiff Lopez 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 manufactured with 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 without proper quality control procedures and contain or risk containing Heavy Metals.

309. Plaintiff Lopez 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 IX**

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

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

311. Defendant is a “person” within the meaning of the Minnesota Unlawful Trade Practices Act (“MUTPA”).

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

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

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

315. Defendant intended for Plaintiff Seutter 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.

316. 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.

317. 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.

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

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

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

321. As a direct and proximate result of Defendant's conduct, Plaintiff Seutter and the Minnesota Subclass suffered actual damages by: (1) paying a premium price for Products they reasonably believed were manufactured with 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 without proper quality control procedures and contain or risk containing Heavy Metals.

322. Plaintiff Seutter 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.

323. Pursuant to Minn. Stat. §8.31, subd. 3a, and §325D.15, Plaintiff Seutter 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 X**

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

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

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

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

327. Defendant knew or should have known the Infant Formulas were manufactured without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals.

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

329. Defendant intended that Plaintiff Seutter 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.

330. 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.

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

Minnesota Subclass known the Infant Formulas did not have the quality advertised by Defendant, they would not have purchased the Infant Formulas.

332. Defendant intended that Plaintiff Seutter 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.

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

334. 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.

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

336. As a direct and proximate result of Defendant's conduct, Plaintiff Seutter and the Minnesota Subclass suffered actual damages by: (1) paying a premium price for Products they reasonably believed were manufactured with 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 without proper quality control procedures and contain or risk containing Heavy Metals.

337. Plaintiff Seutter and the members of the Minnesota Subclass would not have purchased the Infant Formulas at all had they known of the Omissions.

338. Pursuant to Minn. Stat. § 8.31, subd. 3a, and § 325D.45, Plaintiff Seutter 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 XI**

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

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

340. Plaintiff Seutter 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”).

341. Plaintiff Seutter 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.

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

343. 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.

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

345. The Omissions were likely to deceive or cause misunderstanding and did in fact deceive Plaintiff Seutter 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.

346. 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.

347. The Omissions were made to customers in Minnesota, including Plaintiff Seutter and the Minnesota Subclass, thus the cause of action serves the public benefit of informing Minnesota consumers about the Infant Formulas' manufacturing conditions that lacked proper quality control procedures and that the Products contained (or had a material risk of containing) Heavy Metals.

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

349. Defendant intended that Plaintiff Seutter 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.

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

351. As a direct and proximate result of Defendant's conduct, Plaintiff Seutter and the Minnesota Subclass suffered actual damages by: (1) paying a premium price for Products they reasonably believed were manufactured with 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 without proper quality control procedures and contain or risk containing Heavy Metals.

352. Plaintiff Seutter 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.

353. Pursuant to Minn. Stat. §8.31, subd. 3a, and §325F.67, Plaintiff Seutter 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 XII**

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

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

355. Plaintiff Seutter at times relevant hereto was a citizen of the State of Minnesota.

356. Defendant is a "person" within the meaning of the Minnesota Prevention of Consumer Fraud Act ("MPCFA").

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

358. 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 without proper quality control procedures.

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

360. 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 Seutter 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.

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

362. Defendant's Omissions were made to customers in Minnesota, including Plaintiff Seutter and the Minnesota Subclass, thus the cause of action serves the public benefit of informing Minnesota consumers about the Infant Formulas' manufacturing conditions that lacked proper quality control procedures and that the Products contained (or had a material risk of containing) Heavy Metals.

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

364. As a direct and proximate result of Defendant's conduct, Plaintiff Seutter and the Minnesota Subclass suffered actual damages by: (1) paying a premium price for Products they reasonably believed were manufactured with 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 without proper quality control procedures and contain or risk containing Heavy Metals.

365. Plaintiff Seutter 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.

366. Pursuant to Minn. Stat. §8.31, subd. 3a, and §325F.69, Plaintiff Seutter 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 XIII**  
**Unjust Enrichment Against Defendant on Behalf of the Class**  
**or, Alternatively, the State Subclasses**

367. Plaintiffs incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

368. 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.

369. 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 be manufactured with 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.

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

371. 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.

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

373. 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, prays 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 proper quality control procedures are implemented;

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: January 26, 2024

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