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**UNITED STATES DISTRICT COURT
 FOR THE NORTHERN DISTRICT OF CALIFORNIA
 SAN FRANCISCO DIVISION**

IN RE: BABY FOOD PRODUCTS
 LIABILITY LITIGATION

This Document Relates To:

Miranda N. Hernandez, on Behalf of N.G.H, A
 MINOR,

Plaintiff,

v.

Beech-Nut Nutrition Company, Gerber Products
 Company, Hero A.G., Nestlé S.A., Walmart, Inc.,
 and DOES 1 through 10 inclusive

Defendants.

Case No. 24-MD-3101-JSC

MDL 3101

Hon. Jacqueline Scott Corley

**COMPLAINT AND JURY
 DEMAND**

Case no.:

INTRODUCTION

1
2 1. Defendants *knowingly* sold baby food products contaminated with lead, arsenic,
3 mercury, cadmium, and aluminum (collectively “Toxic Heavy Metals”). They did this knowing
4 that Toxic Heavy Metals, when consumed by babies, are known to cause brain damage and
5 neurodevelopmental harm. Thus, to the extent Defendants sold baby food that contained
6 detectable amounts of Toxic Heavy Metals (collectively “Contaminated Baby Food”) those
7 products were defective in their manufacture, design, and labeling. Babies are the most
8 vulnerable segment of the population, and they rely on that food for healthy neurodevelopment.
9 Defendants justify this callous disregard for the welfare of babies because, until recently, there
10 were no regulations governing the presence of Toxic Heavy Metals in baby foods—and,
11 because there were no regulations, they were free to do as they pleased.

12 2. This lawsuit aims to stop Defendants from poisoning infants with Contaminated
13 Baby Food. Baby food *should* be safe. It should *not* be contaminated with Toxic Heavy
14 Metals. Period. By sourcing ingredients from farms that have non-detectable levels of heavy
15 metal (using sufficiently sensitive testing), avoiding certain ingredients all together, and
16 systematically testing and screening finished products for Toxic Heavy Metals *before* the foods
17 are released for consumption, these Defendants would be able to provide baby food products
18 free of detectable levels of Toxic Heavy Metals. And, if some levels are truly unavoidable, or if
19 Defendants believe the identified levels are safe, then, at the very least, Defendants must warn
20 parents/guardians/caregivers about the presence of these Toxic Heavy Metals so they can make
21 informed decisions about what they are feeding their baby. Anything short of proper design,
22 manufacture, and warning, is unacceptable—especially for an industry that touts itself as
23 providing the most important sources of neurodevelopment for the most vulnerable population
24 of society.

25 3. Plaintiff, here, lives with brain injuries and neurodevelopmental harm caused by
26 exposure to the Defendants’ Contaminated Baby Food, which has manifested in a diagnosis of
27 autism spectrum disorder (“ASD”). Plaintiff’s parents were never warned that the Defendants’
28 food contained Toxic Heavy Metals and, thus, were never able to make an informed decision

about whether to feed their babies Defendants Contaminated Baby Foods. The consequences are stark—there is an unprecedented epidemic of ASD and ADHD spreading throughout the American population, driven, in part, by the systematic neurodevelopmental poisoning of infants from these Defendants’ Contaminated Baby Foods.

4. This case seeks to hold the Defendants accountable for their reprehensible conduct by compensating Plaintiff who was harmed by the Defendants’ Contaminated Baby Foods, and ensure each Defendant is punished to deter such conduct in the future.

PARTIES

I. Plaintiffs

5. Plaintiff is a child who lives with brain injuries and neurodevelopmental harm caused by exposure to the Defendants’ Contaminated Baby Food, which has manifested in a diagnosis of ASD.

6. Plaintiff consumed baby foods manufactured and/or sold by Beech-Nut Nutrition Company and Gerber Products Company.

7. Plaintiff consumed baby foods sold by Walmart, Inc.

8. The baby foods manufactured by Defendant Gerber and consumed by Plaintiff were manufactured at the direction of, and/or under the control of, and/or according to the specification of, and/or with input from the parent company, Nestlé S.A.

9. The baby foods manufactured by Defendant Beech-Nut Nutrition Company and consumed by Plaintiff were manufactured at the direction of, and/or under the control of, and/or according to the specification of, and/or with input from the parent company, Hero A.G.

10. Plaintiff consumed these baby foods from October 1, 2010 to March 1, 2014.

11. Plaintiff alleges that as a direct and proximate result of Plaintiff’s exposure to Toxic Heavy Metals from consumption of Defendants’ Contaminated Baby Foods, they suffered significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to, brain injury manifesting as the neurodevelopmental disorder ASD, other permanent physical deficits, permanent bodily impairment, and other *sequelae*. Plaintiff was diagnosed on September 22, 2015. Plaintiff’s injuries required medical intervention to

1 address the adverse neurological effects and damage caused by exposure to Toxic Heavy Metals
2 in Defendants' Contaminated Baby Foods. Additionally, Plaintiff has suffered severe mental
3 and physical pain, including but not limited to, pain, mental suffering, loss of enjoyment of life,
4 disfigurement, physical impairment, inconvenience, grief, anxiety, humiliation, and emotional
5 distress and has and will sustain such injuries, along with economic loss due to medical
6 expenses and living-related expenses as a result of lifestyle changes, into the future, as
7 determined by the Trier of Fact.

8 12. The product warnings for the Contaminated Baby Foods in effect during the time
9 period Plaintiff consumed the Contaminated Baby Foods were non-existent, vague, incomplete
10 and/or otherwise inadequate, both substantively and graphically, to alert consumers to the
11 presence of Toxic Heavy Metals in the Contaminated Baby Foods and/or the potentially severe
12 health risks associated with Toxic Heavy Metal exposure in babies. Thus, each Defendant did
13 not provide adequate warnings to consumers including Plaintiff, their parents, and the general
14 public about the presence of Toxic Heavy Metals in the Contaminated Baby Foods consumed
15 by Plaintiffs and the potential risk of the serious adverse events associated with Toxic Heavy
16 Metal exposure in infancy.

17 13. Had Plaintiff or their parents been adequately warned by the Defendants of the
18 potential for exposure to Toxic Heavy Metals from consumption of Defendants' Baby Foods,
19 and/or the potential for such exposure to result in harm, Plaintiff, or their parents would not
20 have purchased, used and/or consumed Contaminated Baby Foods or would have taken other
21 steps to potentially mitigate the harm caused by exposing a baby to Toxic Heavy Metals.

22 **II. Defendants**

23 14. The following are the Defendants listed in this Complaint. In alphabetical order:

- 24 1. Beech-Nut Nutrition Company ("Beech-Nut")
- 25 2. Gerber Products Company ("Gerber")
- 26 3. Hero A.G. ("Hero Group")
- 27 4. Nestlé S.A. ("Nestlé")
- 28 5. Walmart, Inc. ("Walmart")

15. Defendant Beech-Nut Nutrition Company (“Beech-Nut”) is a citizen of Delaware and New York with its principal place of business located at 1 Nutritious Pl., Amsterdam, New York 12010. Beech-Nut is wholly owned, controlled, and operated by the Hero Group, which considers Beech-Nut to be one of its brands. In the Hero Group’s 2023 annual report, it states “Hero markets baby food in the US and Canada under the brand names Beech[-]Nut and Baby Gourmet.” Beech-Nut branded baby foods aim at infants 4+ months up to 12+ months and include a variety of cereals, “jars,” and “pouches” for these age groups. At all relevant times, Beech-Nut has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial district and throughout the United States.

16. Defendant Hero A.G., aka Hero Group (“Hero Group”) is a citizen of Switzerland, with its principal place of business located at Karl Roth-Strasse 8, 5600, Lenzburg, Switzerland. Hero Group sells baby food through its subsidiary, Beech-Nut, which it controls. For example, Hero Group made executive-level decisions for Beech-Nut concerning the acquisition of testing machines need to test baby foods for heavy metal. Hero Group, thus, has been directly involved in the tortious conduct in the United States and its various states that give rise to these lawsuits. At all relevant times, Hero Group conducted business and derived substantial revenue through Beech-Nut by manufacturing, advertising, distributing, selling, and marketing baby foods within the judicial districts involved in this litigation.

17. The relationship between Beech-Nut and Hero Group was formed in 2005. Prior to that, starting in 1998, Beech-Nut was owned and operated by the Milnot Holding Corporation, and prior to that, starting in 1989, Beech-Nut was owned and operated by Ralston Purina, and prior that, starting in 1979, Beech-Nut was owned and operated by Defendant Nestlé.

18. For the purposes of this Complaint, allegations related to Beech-Nut apply equally to Hero Group, as each Defendant exercised authority and control over the sale, manufacture, and distribution of Beech-Nut’s Contaminated Baby Foods at issue in this MDL.

19. Defendant Gerber Products Company (“Gerber”) is a citizen of Michigan and

1 Virginia with its principal place of business located at 1812 N. Moore Street, Arlington,
2 Virginia 22209. Gerber sells Baby Foods under the brand name Gerber. Gerber organizes its
3 products into broad categories of “formula,” “baby cereal,” “baby food,” “snacks,” “meals &
4 sides,” “beverages,” and “organic.” At all relevant times, Gerber has conducted business and
5 derived substantial revenue from its manufacturing, labeling, advertising, distributing, selling,
6 and marketing of baby foods.

7 20. Defendant Nestlé is a citizen of Switzerland, with its principal place of business
8 located at Avenue Nestlé 55, 1800 Vevey, Switzerland. Nestlé is a global food and beverage
9 company with more than 2,000 brands. Nestlé sells baby foods under its subsidiary, Gerber.
10 Employees and scientists at Nestlé trained and set safety standards at Gerber. Indeed, in
11 discovery ongoing in other litigation, Gerber specifically identified scientists at Nestlé to testify
12 on behalf of Gerber regarding the safety of Gerber’s baby food products. Nestlé, thus, has been
13 directly involved in the tortious conduct in the United States and its various states that gives rise
14 to these lawsuits. At all relevant times, Nestlé conducted business and derived substantial
15 revenue through Gerber by manufacturing, advertising, distributing, selling, and marketing baby
16 foods within the judicial districts involved in this litigation.

17 21. The relationship between Gerber and Nestlé was formed in 2007. Prior to that,
18 starting in 1994, Gerber was owned and operated by Novartis, one of the largest pharmaceutical
19 companies in the world. However, in 2007, Gerber was sold to Nestlé for \$5.5 billion.

20 22. For the purposes of this Complaint, unless specifically stated otherwise, Nestlé
21 shall be referred to as “Nestlé.” Further, allegations related to Gerber apply equally to Nestlé, as
22 each Defendant exercised authority and control over the sale, manufacture, and distribution of
23 Gerber’s Contaminated Baby Foods at issue in this MDL.

24 23. Defendant Walmart, Inc. (“Walmart”) is a citizen of Delaware and Arkansas
25 with its principal place of business located at 702 S.W. 8th St. Bentonville, Arkansas 72716.
26 Walmart sells Baby Foods under the private label brand “Parent’s Choice.” The foods are
27 manufactured by co-manufacturers, but are sold under Walmart’s private label using Walmart’s
28 name. Walmart’s Parent’s Choice offers a wide selection of baby foods ranging from “sweet

potatoes & corn” to “toddler cookies” and “yogurt bites”. At all relevant times, Walmart has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial district and throughout the United States.

JURISDICTION AND VENUE

24. Plaintiff(s) file this Complaint pursuant to CMO No. 5, and are to be bound by the rights, protections, and privileges, and obligations of that CMO and other Order of the Court. Further, in accordance with CMO No. 5, Plaintiff(s) hereby designate the United States District Court for the Southern District of Indiana and/or Eastern District of Kentucky as Plaintiff’s designated venue (“Original Venue”). Plaintiff makes this selection based upon one (or more) of the following factors (check the appropriate box(es))

☒ Plaintiff currently resides in Rising Sun, IN.

☒ Plaintiff purchased and consumed Defendant(s) products in Indiana and Kentucky.

☐ The Original Venue is a judicial district in which Defendant _____ resides, and all Defendants are residents of the State in which the district is located (28 U.S.C. 1391(b)(1)).

☒ The Original Venue is a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, specially (28 U.S.C. 1391 (b)(2)):

☐ There is no district in which an action may otherwise be brought under 28 U.S.C. 1391, and the Original Venue is a judicial district in which Defendant _____ is subject to the Court’s personal jurisdiction with respect to this action (28 U.S.C. 1391 (b)(3)).

☐ Other reason (please explain): _____

25. As an MDL transferee court, this Court has subject matter and personal jurisdiction to the same extent as the respective transferee courts do. In general, federal courts have subject matter jurisdiction over this action under 28 U.S.C. § 1332(d) because Plaintiffs are citizens of states other than states where Defendants are citizens. In addition, Plaintiff seeks damages in excess of \$75,000, exclusive of interest and costs.

26. This Court has personal jurisdiction over Defendants because their significant

1 contacts related to this litigation in each State make personal jurisdiction proper over any of
2 them.

3 27. In particular, this Court has personal jurisdiction over Defendants for cases filed
4 in this District insofar as Defendants are authorized and licensed to conduct business in the
5 State of California, maintain and carry on systematic and continuous contacts in this judicial
6 district, regularly transact business within this judicial district, and regularly avail themselves of
7 the benefits of this judicial district.

8 28. Additionally, Defendants caused tortious injury by acts and omissions in this
9 judicial district and caused tortious injury in this district by acts and omissions outside this
10 district while regularly doing and soliciting business, engaging in a persistent course of conduct,
11 and deriving substantial revenue from goods used or consumed and services rendered in this
12 judicial district.

13 29. Nestlé and Hero Group are subject to personal jurisdiction in the relevant judicial
14 districts insofar as they are authorized and licensed to conduct business in their respective
15 states. Additionally, these Defendants maintain and carry on systematic and continuous
16 contacts in these judicial districts, regularly transact business within these districts, and
17 regularly avail themselves of the benefits of these districts. These Defendants caused tortious
18 injury by acts and omissions in these judicial districts and by acts and omissions outside these
19 districts while regularly doing and soliciting business, engaging in a persistent course of
20 conduct, and deriving substantial revenue from goods used or consumed and services rendered
21 in these districts.

22 **FACTUAL ALLEGATIONS**

23 **I. Rising Concerns Regarding the Presence of Toxic Heavy Metals in Baby Foods**

24 30. In October 2019, an alliance of nonprofit organizations, scientists and donors
25 named “Happy Babies Bright Futures” (“HBBF”), dedicated to designing and implementing
26 “outcomes-based programs to measurably reduce babies’ exposures to toxic chemicals,”
27 published a report investigating the presence of Toxic Heavy Metals in baby foods. The HBBF
28 Report tested 168 different baby foods sold on the U.S. market and concluded that “[n]inety-

1 five percent of baby foods tested were contaminated with one or more of four toxic heavy
2 metals—arsenic, lead, cadmium and mercury. All but nine of 168 baby foods contained at least
3 one metal; most contained more than one.” Specifically, the HBBF report identified “puffs and
4 other snacks made with rice flour,” “[t]eething biscuits and rice rusks,” “infant rice cereal,”
5 “apple, pear, grape and other fruit juices,” and “carrots and sweet potatoes” manufactured by
6 the Defendants as particularly high in Toxic Heavy Metals.

7 31. The results of the HBBF report were consistent with that of the U.S. Food and
8 Drug Administration (“FDA”) which had, in 2017, detected one or more of the four Toxic
9 Heavy Metals in 33 of 39 types of baby food tested. However, the HBBF reported that “[f]or
10 88 percent of baby foods tested by HBBF—148 of 168 baby foods—FDA has failed to set
11 enforceable limits or issue guidance on maximum safe amounts.” The HBBF’s findings were
12 by no means an outlier. Eight months prior to publication of the HBBF report, a study
13 conducted by scientists at the University of Miami and the Clean Label Project “examined
14 lead...concentrations in a large convenience sample of US baby foods.” The study detected
15 lead in 37% of samples.

16 32. Moreover, earlier in 2017, HBBF commissioned a study to evaluate the presence
17 of arsenic in infant rice cereal products sold in the U.S., and the potential risks to children’s
18 neurodevelopment posed by contamination levels. The findings were concerning. The authors
19 concluded that “exposures to arsenic from infant rice cereal approach or exceed existing health-
20 based limits for arsenic levels...leaving little room for additional exposures from other dietary
21 sources, such as snacks, apple juice, and drinking water...Our analyses of arsenic exposures
22 from infant rice cereal during the first year of life suggest that these exposures are not
23 insignificant, and may place infants at risk for adverse health effects.”

24 **II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby** 25 **Foods Manufactured and/or Sold by Defendants, Sparking National Outrage**

26 33. On February 4, 2021, and September 29, 2021, respectively, the U.S. House of
27 Representatives’ Subcommittee on Economic and Consumer Policy, Committee on Oversight
28 and Reform, published two reports detailing its findings that Toxic Heavy Metals—including

1 lead, arsenic, mercury, and cadmium—were present in “significant levels” in numerous
2 commercial Baby Food Products. Four companies—Hain, Gerber (Nestlé), Nurture (Danone),
3 and Beech-Nut—produced internal testing policies, test results for ingredients and finished
4 products, and documentation about what the companies did with ingredients and/or finished
5 products that exceeded their internal testing limits. Three companies—Plum (Campbell),
6 Walmart, and Sprout—initially refused to cooperate.

7 34. Congress reported that the data submitted by the companies unequivocally
8 revealed that a substantial number of Defendants’ finished products and/or ingredients used to
9 manufacture the Baby Foods are tainted with Toxic Heavy Metals, namely lead, arsenic,
10 mercury, and cadmium. And, where the Defendants did set internal limits for the amount of
11 metals they allowed in their foods, Defendants routinely flouted their own limits and sold foods
12 that consistently tested above their limits. Congress found the following:

13 35. **Beech-Nut.** Beech-Nut, along with Hero Group, used ingredients after they
14 tested as high as 913.4 ppb arsenic. Beech-Nut routinely used high-arsenic additives that tested
15 over 300 ppb arsenic to address product characteristics such as “crumb softness.” On June 8,
16 2021, four months following the Congressional findings, Beech-Nut issued a voluntary recall of
17 its infant single grain rice cereal and exited the rice cereal market completely. In its recall,
18 Beech-Nut confirmed that its products exceed regulatory arsenic limits. And, Beech-Nut used
19 ingredients containing as much as 886.9 ppb lead, as well as 483 products that contained over 5
20 ppb lead, 89 that contained over 15 ppb lead, and 57 that contained over 20 ppb lead. In its
21 follow up Report in September 2021 Congress specifically focused on Defendants Beech-Nut
22 and Gerber’s infant rice cereals. Congress noted that Beech-Nut rice cereal tested up to 125 ppb
23 inorganic arsenic and averaged 85.47 ppb inorganic arsenic. Beech-Nut’s practice of testing
24 ingredients, rather than finished products, for toxic heavy metals appears to have contributed to
25 its failure to detect the dangerous inorganic arsenic levels in its recalled products. Lastly,
26 Beech-Nut does not even test for mercury in baby food.

27 36. **Gerber.** Gerber along with Nestlé used high-arsenic ingredients, using 67
28 batches of rice flour that had tested over 90 ppb inorganic arsenic. Nestlé and Gerber used

1 ingredients that tested as high as 48 ppb lead; and used many ingredients containing over 20
2 ppb lead. Nestlé and Gerber rarely test for mercury in their baby foods. In the September 2021
3 follow-up Congressional report, it was revealed that Nestlé and Gerber’s rice cereal tested up to
4 116 ppb inorganic arsenic, and their average rice cereal product contained 87.43 ppb inorganic
5 arsenic, which is even higher than the amount contained in Beech-Nut’s average rice cereal
6 product. While Beech-Nut recalled some of its products and completely discontinued sales of
7 its rice cereal, Nestlé and Gerber have taken no such actions to protect children.

8 37. **Walmart.** Walmart refused to cooperate with the House Subcommittee’s
9 investigation into its baby foods products, and as such, the Subcommittee was “greatly
10 concerned” that Walmart “might be obscuring the presence of higher levels of toxic metals in
11 their baby food products.” The Subcommittee noted that independent data from the HBBF
12 Report confirmed that Walmart’s baby foods are indeed tainted. For example, the HBBF Report
13 observed that one of Walmart’s products contained 56.1 ppb total arsenic, and 26.1 ppb cadmium.
14 Another product contained 108 ppb total arsenic, 66 ppb inorganic arsenic, 26.9 ppb lead, and
15 2.05 ppb mercury.

16 38. Following the publication of the Subcommittee Report, Walmart provided
17 documents to the Subcommittee. On September 29, 2021, the House Subcommittee released a
18 subsequent report entitled “New Disclosures Show Dangerous Levels of Toxic Heavy Metals in
19 Even More Baby Foods.” The Subcommittee report addendum described the documents from
20 Walmart as “revealing a concerning lack of attention to toxic heavy metal levels in baby food
21 and an abandonment of its previously more protective standards.” Walmart does not appear to
22 conduct any testing of its baby food products. Walmart sets maximum arsenic and lead levels
23 and asks the manufacturer of its private label to self-certify, but Walmart does not appear to
24 collect any test data or check the accuracy of those certifications. Walmart does not require any
25 mercury or cadmium testing and does not set any standards for mercury or cadmium levels.

26 39. The metal concentrations discussed above and further below surpass the limits
27 allowed by U.S. regulatory agencies. There are no FDA final regulations governing the
28 presence of Toxic Heavy Metals in the majority of Baby Foods with the exception of 100 ppb

1 inorganic arsenic in infant rice cereal and proposed (not yet final) limits for lead in certain baby
2 food categories. To the extent such regulations exist, the quantities of Toxic Heavy Metals in
3 Defendants' Baby Foods exceed any permissible FDA levels. To be sure, the FDA has set the
4 maximum contaminant levels ("MCL") in bottled water at 10 ppb inorganic arsenic, 5 ppb lead,
5 and the EPA has capped the allowable level of mercury in drinking water at 2 ppb. However,
6 these limits were created in reference to *adult* exposure, not infants. Compared to these
7 thresholds, the test results of the Defendants' baby foods and their ingredients are multiple folds
8 greater than the permitted metal levels. Moreover, compounding these troubling findings, the
9 Defendants set internal limits for the presence of Toxic Heavy Metals in their foods that were,
10 themselves, dangerously high and then routinely failed to abide by those inadequate standards,
11 as discussed below.

12 40. As Congress observed, the Defendants have willfully sold—and continue to
13 sell—contaminated Baby Foods notwithstanding their full awareness of these unacceptably high
14 levels of Toxic Heavy Metals in their products.

15 **III. Defendants Engaged in a Pattern and Practice of Selling Contaminated Baby**
16 **Foods and Failed to Reduce Metal Levels**

17 41. Several factors drive the Toxic Heavy Metal contamination of Defendants' baby
18 foods, all of which are within Defendants' control.

19 42. *First*, at various times, all Defendants sourced ingredients that contained
20 elevated levels of Toxic Heavy Metals. These ingredients were then used to manufacture the
21 baby foods consumed by Plaintiffs, thereby exposing Plaintiffs to Toxic Heavy Metals that
22 cause brain damage and other neurodevelopmental harm. One way for Defendants to "deal"
23 with this issue involved relegating any testing of Toxic Heavy Metals to suppliers and co-
24 manufacturers, who were required to certify that Toxic Heavy Metals were below a certain
25 threshold. Defendants would audit those results, discover that the reported certifications were
26 false or inaccurate, and then take no action to stop the use of those ingredients or finished
27 products.

28 43. *Second*, some Defendants implemented dangerously high internal limits

1 (“specifications” or “specs”) for the maximum level of Toxic Heavy Metals that Defendants
2 allowed in the baby foods. Such high limits—untethered to any consideration of the low levels
3 at which metals are capable of damaging babies’ brains—allowed Defendants to source and use
4 ingredients that contained elevated Toxic Heavy Metals to manufacture the baby foods
5 consumed by Plaintiffs. In the highly competitive and lucrative baby food market, using
6 contaminated ingredients allows each Defendant to retain greater market share.

7 44. *Third*, some Defendants failed to implement *any* internal specifications for the
8 amount of Toxic Heavy Metals allowed in ingredients or finished baby foods. By simply not
9 looking at the issue, certain highly contaminated ingredients and finished products were allowed
10 to be used and sold to consumers. This would happen notwithstanding the Defendants’ specific
11 knowledge of the risk of Toxic Heavy Metals and their presence in ingredients and finished
12 products.

13 45. *Fourth*, Defendants did not routinely adhere to their own internal metal
14 specifications or standards, allowing contaminated ingredients and finished products to be
15 released as “exceptional releases” or other simpler terminology. This resulted in ingredients
16 being used and baby foods manufactured and sold that contained levels of Toxic Heavy Metals
17 far higher than what was internally set by Defendants. In other instances, Defendants would
18 test products that had been put on the market after-the-fact, learn about the products containing
19 extremely high levels of Toxic Heavy Metals, and then take no action to recall the product or
20 warn consumers about the issue.

21 46. *Fifth*, upon information and belief, Defendants’ manufacturing practices also
22 contributed to contamination. For example, the water used at some of the facilities where the
23 baby foods were manufactured contained Toxic Heavy Metals which, in turn, ended up in the
24 finished baby food product sold for consumption by babies.

25 47. **Beech-Nut.** Beech-Nut and Hero Group did not test their finished baby foods
26 for heavy metals, only ingredients. And, Beech-Nut and Hero Group regularly accepted
27 ingredients testing far higher than its internal limits for Toxic Heavy Metals. They justified
28 such deviations as “exceptional releases.” For example, Beech-Nut and Hero Group

1 “exceptionally released” 160,000 pounds of sweet potatoes for their baby food products
2 notwithstanding the ingredient testing twice as high as Beech-Nut’s internal heavy metal limit
3 for lead.

4 48. Moreover, Beech-Nut and Hero Group did not adequately test their ingredients
5 for heavy metals by limiting ingredient lots and ingredient quantities that were subject to metal
6 testing. For example, if a supplier supplied ingredients below a certain amount, they would not
7 test anything and simply use the ingredient in the finished product. Furthermore, in deciding to
8 violate their own internal limits, Beech-Nut and Hero Group took advantage of the fact that the
9 FDA does not routinely test baby foods for Toxic Heavy Metals.

10 49. Upon information and belief, Beech-Nut and Hero Group went so far as to
11 manipulate their testing practices by continually re-testing ingredients that tested above their
12 internal specs until they obtained a result that was at or below their internal specs, knowing full
13 well that the ingredient was nonetheless contaminated.

14 50. Beech-Nut and Hero Group’s internal specifications varied wildly by ingredient,
15 with Beech-Nut allowing very high levels of Toxic Heavy Metals for certain ingredients, and
16 insisting on lower levels for others. Thus, certain products like rice flour, were allowed to have
17 very high levels of metals like arsenic and lead, even in products that were 90% or more rice.
18 Beech-Nut and Hero Group did this because there were no regulations governing Toxic Heavy
19 Metal in baby food and, therefore, to remain competitive in the baby food marketplace, Beech-
20 Nut used contaminated ingredients because they were readily available.

21 51. **Gerber.** Gerber and Nestlé tested ingredients and, occasionally, finished
22 products. However, while Gerber and Nestlé were the only Defendants to test both ingredients
23 and finished products with any regularity, they set high heavy metal limits that rendered their
24 food unsafe. For baby foods generally, between 2012 and 2019, Gerber and Nestlé set a limit of
25 40 ppb for lead, 20 ppb for arsenic, and 10 ppb for mercury. For infant rice cereal, between
26 2012 and 2017, Gerber and Nestlé set a lead limit of 100 ppb, with a “target” of 50 ppb in 2016
27 and 2017. Between 2018 and 2019, Gerber and Nestlé set a lead limit for 50 ppb. For arsenic
28 in rice cereal, between 2012 and 2015, Gerber and Nestlé did not have a limit, merely a target of

1 100 ppb. Then, between 2016 and 2018, it set the arsenic limit at 100 ppb. By 2019, Gerber
2 and Nestlé increased the arsenic limit to 130 ppb for cereals with 90% rice (and kept the limit at
3 100 ppb for other cereals). For snack foods, Gerber and Nestlé had a lead limit of 150 ppb
4 between 2012 and 2014. It was reduced to 100 ppb in 2016 and 2017, and then went down to 50
5 ppb in 2018 and 2019. There was no limit for arsenic in snack food prior 2016, just a “target”
6 of 100 ppb. Then a 100-ppb arsenic limit was set starting in 2016. For both infant cereal and
7 snacks, Gerber and Nestlé imposed a 30-ppb limit for mercury in infant cereal between 2012
8 and 2016, and reduced it to 10 ppb from 2017 onward. With these exceptionally high limits,
9 Gerber and Nestlé sold baby foods that were dangerous for infant consumption. They did this
10 knowingly.

11 52. Gerber and Nestlé would also audit and re-test Toxic Heavy Metal results
12 submitted by suppliers, and find that the certification from suppliers were incorrect or false.
13 Gerber and Nestlé would nonetheless use the certified results and release products despite the
14 ingredients not meeting specifications or being safe for infant consumption.

15 53. Gerber and Nestlé often used high-arsenic ingredients, for example, using 67
16 batches of rice flour that had tested over 90 ppb inorganic arsenic. Furthermore, Gerber and
17 Nestlé regularly sold baby food products testing over 100 ppb arsenic, at times reaching 116
18 ppb, and their average rice cereal product contained 87.43 ppb inorganic arsenic. Indeed, this is
19 why Congress noted that “Gerber’s organic rice cereal is dangerous...” In other instances,
20 Gerber permitted as much as 300 ppb of arsenic in the rice flour ingredient used to manufacture
21 its U.S. baby foods, notwithstanding the fact that Gerber often implemented stricter standards
22 for baby foods sold in other countries.

23 54. Gerber’s baby foods are also contaminated with elevated levels of lead. Gerber
24 and Nestlé used ingredients that tested as high as 48 ppb lead and used many ingredients
25 containing over 20 ppb lead. Furthermore, Gerber and Nestlé sold baby food products testing at
26 and/or above 50 ppb of lead. Indeed, Gerber and Nestlé have historically permitted as much as
27 150 ppb lead in their baby food products. Although Gerber and Nestlé were fully aware that it
28 was very feasible to source lower-lead ingredients, they proceeded to use high-lead ingredients

1 in their baby foods. Gerber and Nestlé rarely test for mercury in their baby foods. This is
2 notwithstanding the fact that mercury is known to contaminate ingredients such as rice and
3 poses a severe risk to babies' brain development.

4 55. The February 4, 2021 Congressional Report found Gerber carrots tested for
5 cadmium at levels above 5 ppb, with some containing more than 87 ppb of cadmium. These are
6 exceptionally high levels.

7 56. Moreover, compounding these troubling findings, Gerber and Nestlé historically
8 only tested certain ingredients of its baby food products and only occasionally tested the
9 finished products consumed by babies. It was not until recently that Gerber and Nestlé started
10 to implement finished product testing on a more regular basis.

11 57. Gerber and Nestlé have known since at least the 1990s that inorganic arsenic was
12 neurotoxic and caused developmental issues. Despite this knowledge, in 2012, when Gerber's
13 infant rice cereal was on the front page of a Consumer Report article on arsenic, a Gerber
14 spokesperson told the public that arsenic in baby food posed no health risk.

15 58. **Walmart.** Walmart sold baby food under a "private" brand called "Parent's
16 Choice", which was manufactured by a different supplier but branded, promoted, and sold as a
17 Walmart product. Walmart did not test it for Toxic Heavy Metals whatsoever. Instead, Walmart
18 required certain specifications be met for the products provided by its suppliers, which included
19 some limits of heavy metals. These specifications were not enforced in any way. Walmart did
20 not require the submission of testing from suppliers, nor did it do any of its own testing.

21 59. The only efforts to police Toxic Heavy Metals in their Parent's Choice baby food
22 involved generic specifications for lead and arsenic—there were no other specifications or
23 limits for other Toxic Heavy Metals—which for most baby food products resulted in there
24 being no limits. The following chart reflects Walmart's Toxic Heavy Metal specifications prior
25 to December 2018.

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28 //

Type of Food	Lead	Arsenic	Mercury	Cadmium	Aluminum
Dry baby food with no juice or nectar	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
Dry baby food with juice or nectar	50 ppb	23 ppb	<i>None</i>	<i>None</i>	<i>None</i>
Wet baby food with no juice or nectar	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>
Wet baby food with juice or nectar	50 ppb	23 ppb	<i>None</i>	<i>None</i>	<i>None</i>
Yogurt baby food products	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>

60. In December 2018, Walmart changed its specification to 100 ppb of inorganic arsenic for all dry baby foods, making the products even less safe. Thus, for the vast majority of Walmart's baby food products, there was never a limit for any Toxic Heavy Metals.

IV. Defendants Abandon Efforts to Reduce Metal Levels in Baby Foods

61. In 2019, as concerns grew over contamination of certain baby foods on the U.S. market, a consortium of the Baby Food Manufacturers comprised of Defendants Beech-Nut and Gerber as well as certain interested third party groups such as the Environmental Defense Fund ("EDF") and HBBF, were formed with the intention "of reducing heavy metals in young children's food."

62. The consortium was named the Baby Food Council ("BFC"). The BFC involved the sharing of common testing data on the levels of metal contamination of Defendants' baby foods, a grant to Cornell University to further study the issue, and a proposed "voluntary Baby Food Standard to limit the amounts of heavy metals in baby food." The BFC specifically recognized the risk of neurodevelopmental harm caused by Toxic Heavy Metals to the developing brain of infants and that there were no safe levels of exposure.

63. The Baby Food Standard "would have provided companies with a common framework for progressively reducing contaminants by regularly testing products and improving management practices, and for being transparent with consumers about the safety of their products."

64. After several years of negotiations and discussions, including a proposed system for testing, the EDF and HBBF proposed voluntary limits of 1 ppb for lead. The baby food companies, however, rejected the proposal outright. Participation in the BFC was little more

1 than a façade—they had no intention of self-regulating their products as it related to Toxic
2 Heavy Metals.

3 65. This led EDF and HBBF to leave the BFC in protest in 2021. They explained
4 their departure publicly, noting that Defendants “all decided to backpedal on this project—even
5 though the standard was designed to protect babies’ brain development” and provide adequate
6 notice to consumers regarding the presence of Toxic Heavy Metals on Baby Food labeling.
7 EDF explained:

8 EDF cofounded the Council because we believed there was a shared commitment
9 to reduce levels of lead, arsenic and cadmium in baby food products to better
10 protect children’s developing brains from these toxins ... Unfortunately, the
11 companies chose to cease the Council’s development of a voluntary Baby Food
12 Standard that it had begun in late 2020. The Standard would have provided
13 companies with a common framework for progressively reducing contaminants
14 by regularly testing products and improving management practices, and for being
15 transparent with consumers about the safety of their products. Negotiations failed
16 to provide an alternative approach that EDF felt was sufficient to drive down
17 levels of lead, arsenic and cadmium in baby food.”

14 66. HBBF explained:

15 Healthy Babies Bright Futures is focused on tangibly reducing neurotoxic
16 exposures to babies. The baby food companies’ refusal to jointly set limits for
17 heavy metals in baby food has shown that the Council will no longer be the
18 powerful mechanism for this important work that the initial plans had promised.
19 The baby food companies’ decision to stop progress on a voluntary standard for
20 heavy metals in baby food is a disappointment ... What started as dedication has
21 turned into delay and intention has become inaction. So HBBF has decided to put
22 our effort into other initiatives that will move the needle on this important issue.

20 67. In short, the Defendants opted to continue “self-regulating,” the same self-
21 regulation which exposed—and continued to expose—Plaintiffs to Toxic Heavy Metals in
22 Defendants’ baby foods.

23 **V. The Dangers of Toxic Heavy Metals and Metal Exposure Through Consumption of**
24 **Baby Foods**

25 68. According to the World Health Organization (“WHO”), Toxic Heavy Metals,
26 specifically lead, arsenic, mercury, and cadmium pose a “major public health concern” for
27 children. The Occupational Safety and Health Administration (“OSHA”) has warned that these
28 metals “may build up in biological systems and become a significant health hazard.” Indeed,

1 the Department of Health and Human Services' Agency for Toxic Substances and Disease
2 Registry ("ATSDR") ranks arsenic as number *one* among substances present in the environment
3 that pose the most significant potential threat to human health, followed by lead (second),
4 mercury (third), and cadmium (seventh).

5 69. The threat presented by Toxic Heavy Metals to children's health is widely shared
6 by the global regulatory and scientific community. For example, the FDA has set an Interim
7 Reference Level ("IRL") of 2.2 micrograms/day for lead exposure through baby food products.
8 That is the amount of lead exposure at or above which the agency considers associated with
9 adverse neurodevelopmental effects in babies. The FDA, in its guidance documents for
10 inorganic arsenic and lead in baby food products has repeatedly acknowledged the dangers of
11 heavy metals to the neurodevelopment of infants.

12 Even low lead exposure can harm children's health and development, specifically
13 the brain and nervous system. Neurological effects of lead exposure during early
14 childhood include learning disabilities, behavior difficulties, and lowered IQ.
15 Lead exposures also may be associated with immunological, cardiovascular,
16 renal, and reproductive and/or developmental effects...Because lead can
17 accumulate in the body, even low-level chronic exposure can be hazardous over
18 time...Even though no safe level of lead exposure has yet been identified for
19 children's health, the IRL serves as a useful benchmark in evaluating the potential
20 for adverse effects of dietary lead. In particular, FDA is focused on the potential
21 for neurodevelopmental effects from lead exposure, as review of the scientific
22 literature indicates that *such adverse effects of lead consistently occur at a blood
23 lead level associated with FDA's IRL for children.* (emphasis added).

24 70. As one recent study observed, "[t]he implications of heavy metals with regards
25 to children's health have been noted to be more severe compared to adults. The elements'
26 harmful consequences on children health include mental retardation, neurocognitive disorders,
27 behavioral disorders, respiratory problems, cancer and cardiovascular diseases. Much attention
28 should be given to heavy metals because of their high toxicity potential, widespread use, and
prevalence." Children and, even more so, babies have higher exposure to metals compared to
adults because they consume more food in relation to their body weight and absorb metals more
readily than adults by 40 to 90%.

71. The mechanisms needed to metabolize and eliminate heavy metals are

1 comparatively undeveloped in childhood, with babies having weaker detoxifying mechanisms
2 and poorer immune systems than adults. For example, liver pathways that in adulthood
3 metabolize absorbed arsenic do not mature until mid-childhood; un-excreted arsenic thus
4 continues to circulate and is deposited in other organs. According to Linda McCauley, Dean of
5 the Nell Hodgson Woodruff School of Nursing at Emory University, who studies environmental
6 health effects, “[n]o level of exposure to these [heavy] metals has been shown to be safe in
7 vulnerable infants.”

8 72. Thus, “the major windows of developmental vulnerability occur during infancy
9 and early childhood due to continuing brain development after birth.” In short, even small
10 amounts of exposure to Toxic Heavy Metals can have devastating health outcomes for babies
11 and children.

12 **VI. Exposure to Toxic Heavy Metals Has Been Consistently Associated with**
13 **Neurodevelopmental Harm, i.e., Autism and ADHD in Pediatric Populations**

14 73. It is well-known that exposure to Toxic Heavy Metals in early life can interfere
15 with neurodevelopment at exceedingly low levels of exposure. And, one of the ways in which
16 such interference with neurodevelopment can present in a child is in the form of the
17 neurodevelopmental disorders ASD and ADHD. As the U.S. Centers for Disease Control
18 observed in its 2020 Toxicological Profile for Lead, at just ≤ 10 $\mu\text{g/dL}$: “The following
19 neurobehavioral effects in children have been associated with [lead]: “Altered mood and
20 behaviors that may contribute to learning deficits, including *attention deficits*, *hyperactivity*,
21 *autistic behaviors*, conduct disorders, and delinquency.” (emphasis added). Likewise, the NIH
22 states: “prenatal and early childhood exposure to heavy metals...may be linked to autism
23 spectrum disorder.”

24 74. Such conclusions have likewise been reached by a consortium of the country’s
25 leading epidemiologists, pediatricians, and medical groups, noting that Toxic Heavy Metals
26 such as lead and mercury are “prime examples of toxic chemicals that can contribute to
27 learning, behavioral, or intellectual impairment, as well as specific neurodevelopmental
28 disorders such as ADHD or autism spectrum disorder.”

1 75. Multiple studies, reviews, and meta-analyses conducted throughout various parts
2 of the world over the last decade have consistently observed that early life exposure to heavy
3 metals can cause brain injury and, specifically, brain injury which manifests as ASD.

4 76. For example, four meta-analyses published in 2014, 2017, 2019 and 2020,
5 respectively, observed consistent associations between exposure to arsenic, cadmium, and
6 mercury and ASD in children; with the authors in all three studies recommending – based on
7 the data – that exposure to such metals in children be reduced as much as possible, and one of
8 the study authors specifically concluding that “Results of the current meta-analysis revealed that
9 mercury is an important causal factor in the etiology of ASD.”

10 77. In a recent 2017 NIH-funded prospective observational study, the authors
11 examined the risk of ASD outcome in twins based on their respective body burden of lead. The
12 study concluded in no uncertain terms that “prenatal and early childhood disruption (excess or
13 deficiency) of multiple metals during critical developmental windows is associated with ASD,
14 and suggests a role for elemental dysregulation in the etiology of ASD.”

15 78. Similarly, a large, prospective study from 2016 in Korean school children
16 observed that low levels of lead exposure in early life are associated with autism, the authors
17 specifically concluding: “even low blood lead concentrations...are associated with more autistic
18 behaviors... underscoring the need for continued efforts to reduce lead exposure.”

19 79. Studies have repeatedly observed strong associations between exposure to
20 cadmium and aluminum and neurodevelopmental disorders such as ASD, as observed by a
21 recent study: “Environmental exposure to...cadmium (Cd)... and aluminum (Al) has been
22 associated with neurodevelopmental disorders including autism spectrum disorder (ASD).” For
23 example, a study from 2014 evaluated the body burden of lead, cadmium, and arsenic in
24 children with autism compared to controls and noted that, in addition to lead and arsenic, “our
25 study demonstrated elevation in the levels of...cadmium...in a child with autism,” while an
26 earlier study noted that “autism may be associated with significant alterations of some rare
27 element concentrations, including Cd...” Such results have been confirmed by meta-analyses
28 which “show *significant associations* between ASD and the metals Al [and] Cd.” And, such

1 earlier data is further supported by recent research, with a 2023 systematic review and meta-
2 analysis concluding that “compared with the healthy control group, the ASD group had higher
3 concentrations of Cd, Pb, arsenic, and Hg. These 4 heavy metals play different roles in the
4 occurrence and progression of ASD.”

5 80. Repeated associations between early life Toxic Heavy Metal exposure and ASD
6 have also been observed during the pre-natal timeframe, lending further strength to the findings
7 of post-natal studies. For example, in a 2021 study by Skogheim and colleagues, the authors
8 prospectively assessed the relationship between pre-natal metal exposure in various biomarkers
9 and autism risk. The study concluded that “[r]esults from the present study show several
10 associations between levels of metals and elements during gestation and ASD and ADHD in
11 children. The most notable ones involved arsenic...mercury...and lead. Our results suggest that
12 even population levels of these compounds may have negative impacts on neurodevelopment.”

13 81. Similarly, in a study by the research group assessing the New Hampshire Birth
14 Cohort, the authors evaluated the neurotoxic effects of heavy metals during various stages of
15 pregnancy and concluded: “Our results support the hypothesis that exposure to...As in mid to
16 late pregnancy may be neurodevelopmentally harmful.”

17 82. Such results have been replicated in studies throughout the world, including
18 China, Korea, the U.S., Europe, and Egypt, implicating arsenic, mercury, and lead in pediatric
19 diagnoses of autism and autistic behaviors, with a 2018 Chinese study concluding: “[t]he results
20 of this study are consistent with numerous previous studies, supporting an important role for
21 heavy metal exposure, particularly mercury, in the etiology of ASD.” Indeed, a 2015 Egyptian
22 study noted “[e]nvironmental exposure to these toxic heavy metals, *at key times in development*,
23 may play a *causal* role in autism.” (emphasis added).

24 83. Exposure to Toxic Heavy Metals, specifically lead, has also been repeatedly
25 associated with the development of ADHD in children, as demonstrated by numerous studies.

26 84. No fewer than four large meta-analyses, conducted in four different continents
27 (North America, South America, Europe and Asia), and some employing a cross-sectional
28 design, have observed a consistent association between various metals and ADHD in children.

1 Indeed, the authors of the meta-analysis from Spain noted that “the evidence from the studies
2 allowed us to establish that there is an association between lead and ADHD and that even *low*
3 *levels of lead raise the risk.*” (emphasis added).

4 85. The findings from the meta-analyses have been replicated in several Chinese
5 studies from 2006, 2014, and 2018, respectively. Notably, the authors of the 2014 Chinese
6 study observed that “[e]xposure to lead even at low levels correlates with attention-
7 deficit/hyperactivity disorder (ADHD). However, lead-contaminated environments are often
8 *contaminated with other heavy metals that could exacerbate lead-induced ADHD.*” (emphasis
9 added). This is particularly relevant—and disturbing—as children who consumed Defendants’
10 baby foods were repeatedly exposed to a cocktail of Toxic Heavy Metals that, synergistically,
11 further increased their risk of developing ADHD.

12 86. Moreover, studies have observed a dose-response relationship between exposure
13 to Toxic Heavy Metals and ADHD, as demonstrated by the 2016 Spanish study Donzelli, *et al.*
14 Another 2016 cross-sectional study from Spain was conducted on 261 children aged 6-9 to
15 examine the association between exposure to arsenic and ADHD. After adjusting for potential
16 confounders, the authors observed a dose-response relationship between urine arsenic levels and
17 inattention and impulsivity scores, concluding that “[urine arsenic] levels were associated with
18 impaired attention/cognitive function, *even at levels considered safe.* These results provide
19 additional evidence that postnatal arsenic exposure impairs neurological function in children.”
20 (emphasis added).

21 87. The fact that such results, and many more, have been observed in multiple
22 studies, conducted by different researchers, at different times, in different parts of the world, in
23 children of multiple ages, utilizing different study methods (prospective, case-control and cross-
24 sectional epidemiological analyses) and measuring a variety of end-points (including hair,
25 blood, and urine), strongly supports a causal relationship between exposure to Toxic Heavy
26 Metals and the development of ASD and ADHD in children.

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28 //

VII. Defendants' Baby Foods Contain Toxic Heavy Metals Capable of Interfering with Early Neurodevelopment

88. As illustrated above, Toxic Heavy Metal exposure is capable of inflicting damage to the developing brain at extremely low doses. And, upon information and belief, Defendants manufactured and sold baby foods containing Toxic Heavy Metals that can, under certain circumstances (based upon the genetic susceptibilities, medical history, and other factors of the exposed child) interfere with a baby's neurodevelopment sufficient to cause conditions such as ASD and ADHD.

89. As an initial matter, the study commissioned by HBBF and discussed above specifically evaluated the propensity for arsenic exposure through consumption of infant rice cereal to impact early life neurodevelopment. Following analyses of the levels of arsenic exposure from consumption of infant rice cereal, the authors concluded "that high consumers of infant rice cereal (i.e., infants eating three servings per day) eating products currently on the U.S. market would have a daily arsenic intake of 0.35-0.67 $\mu\text{g/kg bw/day}$...per the Tsuji et al. (2015) lower-bound estimate for an RfD for the neurodevelopmental effects of arsenic (0.4 $\mu\text{g/kg bw/day}$), high consumers of infant rice cereal may also be at risk for this endpoint. Even in average consumers of infant rice cereal (i.e., one serving per day), our estimates of arsenic intakes (0.15 to 0.29 $\mu\text{g/kg bw/day}$) leave little room for exposures to arsenic from other sources." Thus, consumption of Defendants' baby foods, including but not limited to infant rice cereal and rice-based snack baby food products manufactured and sold by Defendants can expose babies to levels of arsenic above that associated with neurodevelopmental harm in the scientific literature.

90. Defendants manufactured and sold baby food products that, with just a couple of servings, are capable of exposing a baby to lead levels at or above the 2.2 $\mu\text{g/day}$ considered by the FDA to be associated with neurodevelopmental harm. Each source of lead exposure is cumulative—making any detectable amount of Toxic Heavy Metal in baby food a contributing factor to potential neurodevelopmental harm.

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VIII. Defendants Knowingly Sold Baby Foods Containing Toxic Heavy Metals and Knew or Should Have Known of the Risks of Such Exposures in Children and Thus Breached their Duty of Care in Selling Contaminated Baby Foods

91. During the time that Defendants manufactured and sold baby foods in the United States, the weight of evidence showed that Defendants' baby foods exposed babies and children to Toxic Heavy Metals. Defendants failed to disclose this risk to consumers through any means.

92. As discussed above, both independent testing, the Defendants' internal evaluations of their baby foods, and the Defendants' representations and disclosures to Congress and the FDA reveal the presence of Toxic Heavy Metals in Defendants' products. As such, Defendants knew or should have known that their baby foods contain Toxic Heavy Metals with an attendant risk of causing neurodevelopmental harm.

93. Indeed, independent testing performed in early 2019 demonstrated elevated amounts of such Toxic Heavy Metals in Baby Food products on the U.S. market, and the HBBF Report further confirmed such contamination of Defendants' baby foods. And, as the Congressional investigation found, the Defendants continued to sell their baby foods even after testing of both ingredients and finished products revealed the presence of Toxic Heavy Metals.

94. Moreover, the scientific literature on the dangers of Toxic Heavy Metals—particularly as it relates to adverse effects on the neurodevelopment of children—have been well known for decades. Defendants, as manufacturers and sellers of baby foods, are held to the standard of experts and responsible for keeping abreast of the latest scientific developments related are held to the dangers of contaminants in their products. Defendants failed to take action to protect vulnerable children from exposure to the Toxic Heavy Metals in their foods and, thus, subjected them to the risk of brain injury which can manifest as neurodevelopmental disorders such as ASD, ADHD, and related *sequelae*.

95. To be clear, the Defendants are able to manufacture baby foods that do not pose such a dangerous risk to the health of infants and children by using alternative ingredients, not adding certain pre-mix minerals and vitamins high in Toxic Heavy Metals or sampling their

1 ingredients from other sources. At the very least, Defendants were under a duty to warn
2 unsuspecting parents of the presence of Toxic Heavy Metals in their Baby Foods.

3 **IX. Defendants' Baby Food Products Were Defective Due to Insufficient Warnings,**
4 **Manufacturing Defects, and/or Design Defects to the Extent the Baby Food**
5 **Products Contained Detectable Levels of Toxic Heavy Metal**

6 96. All of Defendants' baby food products that contained detectable levels of Toxic
7 Heavy Metals (or constituted finished products wherein the ingredients contained detectable
8 levels of Toxic Heavy Metals), assuming state of the art analytical testing, were defective as it
9 relates to warnings because no Defendant has ever warned about the presence of Toxic Heavy
10 Metals in their baby foods. Because discovery is ongoing, a complete list of Defendants'
11 specific baby foods that contained detectable levels of Toxic Heavy Metals is not known at this
12 time. Based on publicly available testing data, including data reported by HBBF and Congress,
13 the vast majority of Defendants' products contain detectable levels of Toxic Heavy Metals in
14 them, rendering them each defective as it relates to warnings.

15 97. Defendants' baby food products are also defective as manufactured, as they
16 contain detectable Toxic Heavy Metals which are not supposed to be there, by design. Toxic
17 Heavy Metals do not provide any nutritional or therapeutic value to infants or fully-grown
18 humans. They are only poisonous to neurodevelopment. None of these baby food products, by
19 design, should contain Toxic Heavy Metals in them and, thus, to the extent the products contain
20 detectable levels of Toxic Heavy Metals in them, those are manufacturing defects. Based on
21 publicly available data, most of Defendants' baby food products contain some detectable levels
22 of Toxic Heavy Metals in them.

23 98. If Defendants specifically designed their baby food products to contain Toxic
24 Heavy Metals, meaning their presence was not the product of a manufacturing defect, then the
25 products were defective by design. Toxic Heavy Metals should not be present in foods that are
26 being consumed by infants and products should be designed to not have detectable levels of
27 toxic heavy metal in them. Such designs are easily accomplished, by only using ingredients that
28 contain non-detectable levels of Toxic Heavy Metals and by testing finished products, before

1 release, to ensure they do not contain Toxic Heavy Metals within them. This is possible
2 because there are examples of Defendants' finished products not containing detectable levels of
3 Toxic Heavy Metals—even if, for that same products, there are instances where they did. Thus,
4 Defendants were able to design baby food products to not contain detectable levels of toxic
5 heavy metals, and to the extent that each Defendants' design contemplated there being
6 detectable levels of Toxic Heavy Metals in baby food, the design, itself, was defective.

7 99. Whether the Defendants' products were defective due to inadequate warnings,
8 manufacturing errors, or by design, the existing publicly available evidence indicates that
9 consumption of Defendants' baby food products exposed Plaintiff to Toxic Heavy Metals, and
10 that Defendants' baby food products contributed to Plaintiff's Toxic Heavy Metal burden
11 during a critical period of infant neurodevelopment. Plaintiff, thus, alleges that this cumulative
12 exposure from Defendants' products to Toxic Heavy Metals, substantially contributed to
13 causing neurodevelopmental harm that manifested as ASD. Moreover, Plaintiff alleges that had
14 these baby food products not been defective—by having sufficient warnings, being correctly
15 manufactured, and/or designed properly—Plaintiff would not have been exposed to levels of
16 Toxic Heavy Metals in Defendants' baby food products that would have contributed to the
17 neurodevelopmental harm that manifested as ASD.

18 **X. Exemplary / Punitive Damages Allegations**

19 100. Defendants' conduct as alleged herein was done with reckless disregard for
20 human life, oppression, and malice. Defendants' conduct is particularly reprehensible given
21 that their toxic foods were directed at vulnerable babies—a population group far more
22 susceptible than adults to the neurotoxic dangers of heavy metals.

23 101. Defendants were fully aware of the safety risks of Contaminated Baby Foods,
24 particularly the dangerous potential of Toxic Heavy Metals on neurodevelopment in infants and
25 children. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to
26 mislead consumers. Indeed, Defendants repeatedly market their baby foods as safe for
27 consumption and go so far as claiming that they adhere to “the strictest standards in the world;”
28 and provide “baby's food full of nutrition while meeting standards strict enough for tiny

1 tummies,” as well as other statements and representations that hold out their baby foods as safe
2 for consumption by infants. Indeed, each Defendant falsely reassured
3 parents/guardians/caregivers that their baby foods would foster healthy neurodevelopment when
4 consumed even though they knew their baby foods exposed infants’ developing brains to potent
5 neurotoxic heavy metals. In actual fact, as discussed above, Defendants routinely sold
6 Contaminated Baby Foods, regularly flouted their own internal limits of Toxic Heavy Metals
7 and failed to disclose to consumers that their products contained such dangerous contaminants.

8 102. This was not done by accident or through some justifiable negligence. Rather,
9 Defendants knew they could profit by convincing consumers that their baby foods were healthy
10 and safe for infants, and that full disclosure of presence and/or risks of the Toxic Heavy Metals
11 present in the baby foods would limit the amount of money Defendants would make selling the
12 products. Defendants’ object was accomplished not only through a misleading label, but
13 through a comprehensive scheme of selective misleading research and testing, failure to test,
14 false advertising, and deceptive omissions as more fully alleged throughout this Complaint.
15 Parents/guardians/caregivers were denied the right to make an informed decision about whether
16 to purchase Defendants’ baby food for their babies without knowing the full risks attendant to
17 that use. Such conduct was done with conscious disregard of Plaintiffs’ welfare and rights.

18 **PLAINTIFF’S USE AND INJURY**

19 103. Plaintiff was diagnosed with ASD at approximately 5 years of age.

20 104. Plaintiff started consuming Baby Food products manufactured and/or sold by the
21 Defendants in approximately 2010 and consumed Defendants’ Baby Food products at various
22 times through 2014.

23 105. Upon information and belief, the Baby Food products manufactured/marketed by
24 Defendants and consumed by Plaintiff were all contaminated with substantial quantities of
25 Toxic Heavy Metals.

26 106. Upon information and belief, as a direct and proximate result of consuming
27 Defendants’ Baby Foods, Plaintiff was exposed to substantial quantities of Toxic Heavy Metals.

28 107. As a direct and proximate result of consuming Defendants’ Baby Foods and the

1 exposure to the Toxic Heavy Metals therein – Plaintiff suffered brain injury which manifested
2 as ASD and related *sequae*.

3 108. Based on prevailing scientific evidence, exposure to the Toxic Heavy Metals at
4 the levels contained in Defendants’ Baby Foods can cause brain injury which can manifest as
5 the neurodevelopmental disorders ASD and related *sequae* in humans.

6 109. Had any Defendant warned Plaintiff’s parents that Defendants’ Baby Foods
7 could lead to exposure to Toxic Heavy Metals or, in turn, brain injury, Plaintiff would not have
8 consumed the Baby Foods.

9 110. Plaintiff alleges that as a direct and proximate result of Plaintiff’s consumption
10 of Baby Foods supplied and distributed by Defendants, Plaintiff suffered significant harm,
11 conscious pain and suffering, physical injury and bodily impairment including, but not limited
12 to brain injury which manifested as ASD and related *sequae*.

13 CAUSES OF ACTION

14 COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

15 111. Plaintiff incorporates by reference each allegation set forth in preceding
16 paragraphs as if fully stated herein.

17 112. At all relevant times, Defendants engaged in the business of researching, testing,
18 developing, designing, manufacturing, labeling, marketing, selling, inspecting, distributing, and
19 promoting baby foods, which are defective and unreasonably dangerous to consumers,
20 including Plaintiff, because they do not contain adequate warnings or instructions concerning
21 the dangerous characteristics of baby foods in the form of the presence of Toxic Heavy Metals.
22 These actions were under the ultimate control and supervision of Defendants. At all relevant
23 times, Defendants registered, researched, manufactured, distributed, marketed, and sold baby
24 foods and aimed at a consumer market.

25 113. Defendants researched, tested, developed, designed, manufactured, labeled,
26 marketed, sold, inspected, distributed, and promoted, and otherwise released into the stream of
27 commerce their Contaminated Baby Foods, and in the course of same, directly advertised or
28 marketed the products to consumers and end users, including Plaintiff, and therefore had a duty

1 to warn about the presence of and risks associated with exposure to Toxic Heavy Metals from
2 the consumption of Contaminated Baby Foods.

3 114. At all relevant times, Defendants had a duty to properly test, develop, design,
4 manufacture, inspect, package, label, market, promote, sell, and distribute, maintain, supply,
5 provide proper warnings, and take such steps as necessary to ensure their Contaminated Baby
6 Foods did not cause users and consumers to suffer from unreasonable and dangerous risks.
7 Defendants had a continuing duty to warn Plaintiff of dangers associated with exposure to
8 Toxic Heavy Metals from consumption of the Contaminated Baby Foods. Defendants, as a
9 manufacturer, seller, or distributor of food, are held to the knowledge of an expert in the field.

10 115. At the time of manufacture, Defendants could have provided the warnings or
11 instructions regarding the full and complete risks of exposure to Toxic Heavy Metals in the
12 Contaminated Baby Foods because they knew or should have known of the unreasonable risks
13 of harm associated with the use of and/or exposure to such toxins.

14 116. At all relevant times, Defendants failed and deliberately refused to investigate,
15 study, test, or promote the safety or to minimize the dangers to users and consumers of their
16 product and to those who would foreseeably use or be harmed by exposure to the Toxic Heavy
17 Metals in Defendants' Baby Foods.

18 117. Even though Defendants knew or should have known that the presence of Toxic
19 Heavy Metals in Contaminated Baby Foods posed a risk of harm, they failed to exercise
20 reasonable care to warn of the dangerous risks associated with use and exposure to the toxins in
21 the products. The neurotoxic characteristic of Toxic Heavy Metals contained in Defendants'
22 Contaminated Baby Foods, as described above, were known to Defendants, or scientifically
23 knowable to Defendants through appropriate research and testing by known methods, at the
24 time they distributed, supplied, or sold the products, and were not known to end users and
25 consumers, such as Plaintiff. The product warnings for Contaminated Baby Foods in effect
26 during the time period Plaintiff consumed those foods were inadequate, both substantively and
27 graphically, to alert consumers to the presence of and health risks associated with exposure to
28 the Toxic Heavy Metals from Contaminated Baby Food consumption.

1 118. At all relevant times, Defendants' Contaminated Baby Foods reached the
2 intended consumers, handlers, and users or other persons coming into contact with these
3 products, including Plaintiff, without substantial change in their condition as manufactured,
4 sold, distributed, labeled, and marketed by Defendants.

5 119. Plaintiff was exposed to the Toxic Heavy Metals in Defendants' Contaminated
6 Baby Foods without knowledge of the potential for such exposure to Toxic Heavy Metals from
7 consumption of the products and the dangerous characteristics of the toxins.

8 120. At all relevant times, Plaintiff was exposed to the Toxic Heavy Metals in the
9 Defendants' Contaminated Baby Foods while consuming the foods for their intended or
10 reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

11 121. Plaintiff could not have reasonably discovered the defects and risks associated
12 with exposure to the Toxic Heavy Metals in the Contaminated Baby Foods prior to or at the
13 time of Plaintiff consuming those foods. Plaintiff relied upon the skill, superior knowledge, and
14 judgment of Defendants to know about and disclose serious health risks associated with
15 exposure to the toxins in Defendants' products.

16 122. The information that Defendants did provide or communicate failed to contain
17 relevant warnings, hazards, and precautions that would have enabled consumers such as
18 Plaintiffs to avoid consuming the products and, in turn, exposure to the Toxic Heavy Metals.
19 Instead, Defendants disseminated information that was inaccurate, false, and misleading, and
20 which failed to communicate accurately or adequately the comparative severity, duration, and
21 extent of the risk of injuries with use of and/or exposure to the Toxic Heavy Metals in the
22 Contaminated Baby Foods; continued to aggressively promote the safety of their products, even
23 after they knew or should have known of the unreasonable risks from use or exposure; and
24 concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion,
25 any information or research about the risks and dangers of exposure to Toxic Heavy Metals
26 from consumption of Contaminated Baby Foods.

27 123. This alleged failure to warn is not limited to the information contained on
28 Contaminated Baby Foods labeling. The Defendants were able, in accord with federal law, to

1 comply with relevant state law by disclosing the known risks associated with exposure to Heavy
2 Metals in Contaminated Baby Foods through other non-labeling mediums, i.e., promotion,
3 advertisements, public service announcements, and/or public information sources. But the
4 Defendants did not disclose these known risks through any medium. The ability to provide such
5 warnings is not prohibited by any federal law.

6 124. Furthermore, Defendants possess a First Amendment Right to make truthful
7 statements about the products they sell, and no law could lawfully restrict that constitutional
8 right. This included making statements about the presence of and risks associated with Toxic
9 Heavy Metals in Contaminated Baby Foods.

10 125. Had Defendants provided adequate warnings and instructions and properly
11 disclosed and disseminated the risks associated with exposure to the toxins in their
12 Contaminated Baby Foods, Plaintiffs could have avoided the risk of developing injuries and
13 could have obtained or used alternative products. However, as a result of Defendants'
14 concealment of the dangers posed by the Toxic Heavy Metals in their Contaminated Baby
15 Foods, Plaintiff could not have averted their exposures.

16 126. Defendants' conduct, as described above, was reckless. Defendants risked the
17 lives of babies and children, including Plaintiff, with knowledge of the safety problems
18 associated with Contaminated Baby Foods, and suppressed this knowledge from the general
19 public. Defendants made conscious decisions not to warn or inform the unsuspecting public.

20 127. The Defendants' lack of adequate warnings and instructions accompanying their
21 Contaminated Baby Foods caused Plaintiff's injuries.

22 128. As a direct and proximate result of the Defendants' failure to provide an
23 adequate warning of the risks of exposure to the Toxic Heavy Metals in their Contaminated
24 Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering,
25 disability, impairment, loss of enjoyment of life, economic loss and damages including, but not
26 limited to past and future medical expenses, lost income, and other damages.

27 129. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
28 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and

1 all such other and further relief as this Court deems just and proper.

2 **COUNT II: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

3 130. Plaintiff incorporates by reference each allegation set forth in preceding
4 paragraphs as if fully stated herein.

5 131. At all times herein mentioned, Defendants designed, manufactured, tested,
6 marketed, sold, handled, and distributed the Contaminated Baby Foods consumed by Plaintiff.

7 132. At all relevant times, the Contaminated Baby Foods consumed by Plaintiff were
8 expected to and did reach Plaintiff without a substantial change in their condition as
9 manufactured, handled, distributed, and sold by Defendants.

10 133. At all relevant times, the Contaminated Baby Foods consumed by Plaintiff were
11 used in a manner that was foreseeable and intended by Defendants.

12 134. The Contaminated Baby Foods consumed by Plaintiff were not reasonably safe
13 for their intended use and were defective with respect to their manufacture, as described herein,
14 in that Defendants deviated materially from their design and manufacturing specifications
15 and/or such design and manufacture posed an unreasonable risk of harm to Plaintiffs.¹ Baby
16 food should not, by design, contain any detectable levels of Toxic Heavy Metals in them. Thus,
17 Defendants' Contaminated Baby Foods contain manufacturing defects.

18 135. The Defendants' Contaminated Baby Foods contained Toxic Heavy Metals
19 because, while in the control and possession of Defendants, they manufactured ingredients and
20 used manufacturing processes that result in the finished product being contaminated with Toxic
21 Heavy Metals. Had Defendants properly manufactured (directly or through co-manufacturers)
22 the baby foods, they would not have contained detectable levels of Toxic Heavy Metals in them
23 and, thus, would not have contained a manufacturing defect.

24 136. Nothing under federal law limited or restricted Defendants from taking action to
25 reduce or eliminate the Toxic Heavy Metals from being present in their baby foods.

26 137. This manufacturing defect caused Plaintiff to be exposed to Toxic Heavy Metals

27 ¹ If, through discovery and further litigation, it is discovered that Defendants' baby food
28 products contained detectable levels of Toxic Heavy Metals by design, then Plaintiff will
pursue a design defect claim (Count III) in the alternative.

1 through ingestion of the Contaminated Baby Foods which, in turn, caused neurodevelopmental
2 harm that manifested as ASD.

3 138. The exposure to the Toxic Heavy Metals in the Contaminated Baby Foods
4 creates risks to the health and safety of babies that are far more significant than the risks posed
5 by non- Contaminated Baby Food products, and which far outweigh the utility of the
6 Contaminated Baby Foods products because of Defendants' manufacturing defects.

7 139. Defendants have intentionally and recklessly manufactured the Contaminated
8 Baby Foods with wanton and willful disregard for the rights and health of Plaintiff, and with
9 malice, placing their economic interests above the health and safety of Plaintiff.

10 140. As a direct and proximate result of the Defendants' defective manufacture of the
11 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
12 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages
13 including, but not limited to medical expenses, lost income, and other damages.

14 141. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
15 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and
16 all such other and further relief as this Court deems just and proper.

17 **COUNT III: STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

18 142. Plaintiff incorporates by reference each allegation set forth in preceding
19 paragraphs as if fully stated herein.

20 143. At all times herein mentioned, Defendants designed, manufactured, tested,
21 marketed, sold, handled, and distributed the Contaminated Baby Foods consumed by Plaintiff.
22 These actions were under the ultimate control and supervision of Defendants.

23 144. At all relevant times, Defendants' Baby Food products were designed and
24 labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use or
25 consumption by infants and babies, including Plaintiff.

26 145. Defendants' Contaminated Baby Food products as researched, tested, developed,
27 designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by
28 Defendants were defective in design and formulation in that, when they were placed into the

1 stream of commerce, they were unreasonably dangerous and dangerous to an extent beyond that
2 which an ordinary consumer would contemplate.

3 146. Defendants' Contaminated Baby Food products, as researched, tested,
4 developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed
5 by Defendants were defective in design and formulation in that, when they left the hands of
6 Defendants, the foreseeable risks exceeded the alleged benefits associated with their design and
7 formulation.

8 147. At all relevant times, the Contaminated Baby Food products consumed by
9 Plaintiff were expected to and did reach Plaintiff without a substantial change in its condition as
10 designed, manufactured, handled, distributed, and sold by Defendants.

11 148. At all relevant times, Defendants knew or had reason to know that their
12 Contaminated Baby Food products were defective and were inherently dangerous and unsafe
13 when used in the manner instructed and provided by Defendants.

14 149. Therefore, at all relevant times, Defendants' Baby Food products, as researched,
15 tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed,
16 sold and marketed by Defendants were defective in design and formulation, in one or more of
17 the following ways:

18 A. When placed in the stream of commerce, Defendants' Contaminated
19 Baby Food products were unreasonably dangerous in that they contained Toxic Heavy Metals
20 that posed a risk of causing interference with neurodevelopment in babies that manifests as the
21 neurodevelopmental disorders ASD, ADHD and related *sequelae* when used in a reasonably
22 anticipated manner;

23 B. When placed in the stream of commerce, Defendants' designed
24 Contaminated Baby Food products to contain unreasonably dangerous design defects and were
25 not reasonably safe when used in a reasonably anticipated or intended manner;

26 C. Defendants, by design, did not sufficiently test, investigate, or study their
27 Contaminated Baby Food products;

28 D. Exposure to the Toxic Heavy Metals in Defendants' Contaminated Baby

1 Food products present a risk of harmful effects that outweigh any potential utility stemming
2 from their use;

3 E. Defendants, by design, did not conduct adequate post-marketing
4 surveillance of their Contaminated Baby Food products which would have alerted the public to
5 risks; and

6 F. Defendants could have employed safer alternative designs and
7 formulations for Contaminated Baby Foods, such as ensuring the baby food did not have any
8 detectable level of Toxic Heavy Metals.

9 150. Plaintiff consumed Defendants' Contaminated Baby Food products in an
10 intended or reasonably foreseeable manner without knowledge of their dangerous
11 characteristics.

12 151. Defendants' Contaminated Baby Food products were and are more dangerous
13 than alternative products, and Defendants could have designed their Contaminated Baby Food
14 products to avoid harm to children. Indeed, at the time Defendants designed the Contaminated
15 Baby Food products, the state of the industry's scientific knowledge was such that a less risky
16 design or formulation was attainable.

17 152. At the time the Contaminated Baby Food products left Defendants' control, there
18 was a practical, technically feasible, and safer alternative design that would have prevented the
19 harm without substantially impairing the reasonably anticipated or intended function of
20 Defendants' Contaminated Baby Foods.

21 153. Defendants intentionally and recklessly defectively designed the Contaminated
22 Baby Foods with wanton and willful disregard for the rights and health of Plaintiff, and with
23 malice, placing their economic interests above the health and safety of Plaintiff.

24 154. The design defects in Defendants' Contaminated Baby Foods were substantial
25 factors in causing Plaintiff's injuries.

26 155. As a direct and proximate result of the Defendants' defective design of the
27 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
28 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages

1 including, but not limited to medical expenses, lost income, and other damages.

2 156. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
3 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and
4 all such other and further relief as this Court deems just and proper.

5 **COUNT IV: NEGLIGENCE – FAILURE TO WARN**

6 157. Plaintiff incorporates by reference each allegation set forth in preceding
7 paragraphs as if fully stated herein.

8 158. At all relevant times, Defendants engaged in the business of testing, developing,
9 designing, manufacturing, marketing, selling, distributing, and promoting baby foods.
10 Defendants knew, or, by the exercise of reasonable care, should have known that their
11 Contaminated Baby Foods are not accompanied with adequate warnings concerning the
12 dangerous characteristics of exposure to Toxic Heavy Metals from consumption. These actions
13 were under the ultimate control and supervision of Defendants.

14 159. Defendants researched, developed, designed, tested, manufactured, inspected,
15 labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of
16 commerce their Contaminated Baby Foods, and in the course of same, directly advertised or
17 marketed the products to consumers and end users, including Plaintiff, and therefore had a duty
18 to warn of the risks associated with the presence of and exposure to Toxic Heavy Metals from
19 consumption of Contaminated Baby Foods.

20 160. At all relevant times, Defendants had a duty to properly test, develop, design,
21 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide
22 proper warnings, and take such steps as necessary to ensure their Contaminated Baby Foods did
23 not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants
24 had a continuing duty to warn Plaintiff of dangers associated with the presence of and exposure
25 to Toxic Heavy Metals from consumption of Contaminated Baby Foods. Defendants, as a
26 manufacturer, seller, or distributor of food products, are held to the knowledge of an expert in
27 the field.

28 161. At the time of manufacture, Defendants could have provided warnings regarding

1 the presence of and risks of exposure to Toxic Heavy Metals from consumption of
2 Contaminated Baby Foods because they knew or should have known exposure to Toxic Heavy
3 Metals from consumption of Contaminated Baby Foods was dangerous, harmful and injurious
4 when the Contaminated Baby Foods were consumed by Plaintiff in a reasonably foreseeable
5 manner.

6 162. At all relevant times, Defendants failed and deliberately refused to investigate,
7 study, test, or promote the safety or to minimize the dangers to users and consumers of their
8 products and to those who would foreseeably use or be harmed by Defendants' Contaminated
9 Baby Foods.

10 163. Defendants knew or should have known that exposure to Toxic Heavy Metals
11 from consumption of Contaminated Baby Foods posed a risk of harm, but failed to exercise
12 reasonable care to warn of the dangerous risks associated with use and exposure to the toxins in
13 the products. The dangerous propensities of exposure to Toxic Heavy Metals from consumption
14 of the Contaminated Baby Foods, as described above, were known to Defendants, or
15 scientifically knowable to Defendants through appropriate research and testing by known
16 methods, at the time they distributed, supplied, or sold the products, and were not known to end
17 users and consumers, such as Plaintiff.

18 164. At all relevant times, Plaintiff was exposed to Toxic Heavy Metals through
19 consumption of the Contaminated Baby Foods while using the products for their intended or
20 reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

21 165. Defendants knew or should have known that the non-extant warnings
22 disseminated with their Contaminated Baby Foods were inadequate, failed to communicate
23 adequate information on the presence of and dangers of exposure to toxins contained therein,
24 and failed to communicate warnings and instructions that were appropriate and adequate to
25 render the products safe for their ordinary, intended and reasonably foreseeable uses.

26 166. The information that Defendants did provide or communicate failed to contain
27 relevant warnings, hazards, and precautions that would have enabled consumers such as
28 Plaintiffs to avoid using the product and, in turn, prevented exposure to the Toxic Heavy Metals

1 contained therein. Instead, Defendants disseminated information that was inaccurate, false, and
2 misleading, and which failed to communicate accurately or adequately the comparative severity,
3 duration, and extent of the risk of injuries with use of and/or exposure to the Toxic Heavy
4 Metals in the Contaminated Baby Foods; continued to aggressively promote the efficacy of their
5 products, even after they knew or should have known of the unreasonable risks from use or
6 exposure to the toxins contained therein; and concealed, downplayed, or otherwise suppressed,
7 through aggressive marketing and promotion, any information or research about the risks and
8 dangers of exposure to Toxic Heavy Metals from consumption of the Contaminated Baby
9 Foods.

10 167. A reasonable company under the same or similar circumstance would have
11 warned and instructed of the dangers of exposure to Toxic Heavy Metals from consumption of
12 Contaminated Baby Foods.

13 168. This alleged failure to warn is not limited to the information contained on the
14 labeling of Defendants' Contaminated Baby Foods. Defendants were able, in accord with
15 federal law, to comply with relevant state law by disclosing the known risks associated with
16 exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods through other
17 non-labeling mediums, i.e., promotion, advertisements, public service announcements, and/or
18 public information sources. But the Defendants did not disclose these known risks through any
19 medium.

20 169. Furthermore, Defendants possess a First Amendment Right to make truthful
21 statements about the products they sell, and no law could lawfully restrict that constitutional
22 right.

23 170. Had Defendants provided adequate warnings and instructions and properly
24 disclosed and disseminated the risks associated with the presence of and exposure to Toxic
25 Heavy Metals in the Contaminated Baby Foods, Plaintiff could have avoided the risk of
26 developing injuries and could have obtained or used alternative products. However, as a result
27 of Defendants' concealment of the dangers posed by their Contaminated Baby Foods, Plaintiff
28 could not have averted their injuries.

171. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety problems associated with Contaminated Baby Foods, and suppressed this knowledge from the general public. Defendants made conscious decisions not to warn or inform the unsuspecting public.

172. The Defendants' lack of adequate warnings and instructions accompanying their Contaminated Baby Foods were a substantial factor in causing Plaintiff's injuries.

173. As a direct and proximate result of the Defendants' failure to provide an adequate warning of the risks of exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

174. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT V: NEGLIGENCE – MANUFACTURING

175. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

176. At all relevant times, the Defendants manufactured, tested, marketed, sold, and distributed the Contaminated Baby Foods that Plaintiff consumed.

177. The Defendants had a duty to exercise reasonable care, in the manufacturing, testing, marketing, sale, and distribution of baby foods.

178. The Defendants knew or, by the exercise of reasonable care, should have known, that exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods rendered the foods carelessly manufactured, dangerous, harmful and injurious when used by Plaintiff in a reasonably foreseeable manner.

179. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of

1 exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods.

2 180. Without limitation, examples of the manner in which Defendants breached their
3 duty to exercise reasonable care in manufacturing Contaminated Baby Foods, included:

4 A. Failure to adequately inspect/test the Contaminated Baby Foods, and
5 their ingredients, during and after the manufacturing process;

6 B. Failure to implement procedures that would reduce or eliminate Toxic
7 Heavy Metals in baby foods;

8 C. Failure to investigate suppliers and ingredient sources to reduce and
9 eliminate the risk of ingredients containing Toxic Heavy Metals; and

10 D. Failure to avoid using ingredients free from, or which contain far less,
11 Toxic Heavy Metals to manufacture baby food.

12 181. A reasonable manufacturer under the same or similar circumstances would have
13 implemented appropriate manufacturing procedures to better ensure the quality and safety of
14 their product.

15 182. Plaintiff was harmed directly and proximately by the Defendants' failure to use
16 reasonable care in the manufacture of their Contaminated Baby Foods. Such harm includes
17 exposure to Toxic Heavy Metals, which can cause or contribute to interference with early
18 neurodevelopment which manifests as ASD and related *sequelae*.

19 183. Defendants' improper manufacturing of Baby Foods was willful, wanton,
20 malicious, and conducted with reckless disregard for the health and safety of users of the
21 Contaminated Baby Foods, including Plaintiff.

22 184. The defects in Defendants' Contaminated Baby Foods were substantial factors in
23 causing Plaintiff's injuries.

24 185. As a direct and proximate result of the Defendants' improper manufacturing of
25 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
26 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages
27 including, but not limited to past and future medical expenses, lost income, and other damages.

28 186. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in

1 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and
2 all such other and further relief as this Court deems just and proper.

3 **COUNT VI: NEGLIGENCE – PRODUCT DESIGN**

4 187. Plaintiff incorporates by reference each allegation set forth in preceding
5 paragraphs as if fully stated herein.

6 188. Defendants knew or, by the exercise of reasonable care, should have known,
7 ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of
8 Contaminated Baby Foods.

9 189. The Defendants owed a duty to all reasonably foreseeable users to design a safe
10 product.

11 190. The Defendants breached their duty by failing to use reasonable care in the
12 design of Contaminated Baby Foods because the products exposed babies to Toxic Heavy
13 Metals.

14 191. The Defendants breached their duty by failing to use reasonable care in the
15 design of Contaminated Baby Foods by negligently designing the foods with ingredients and/or
16 components contaminated with Toxic Heavy Metals.

17 192. The Defendants breached their duty by failing to use reasonable care in the
18 design of Contaminated Baby Foods by negligently designing and formulation, in one or more
19 of the following ways:

20 A. When placed in the stream of commerce, Defendants' Contaminated
21 Baby Foods were defective in design and formulation, and, consequently, dangerous to an
22 extent beyond that which an ordinary consumer would contemplate;

23 B. When placed in the stream of commerce, Defendants' Contaminated
24 Baby Foods were unreasonably dangerous in that they were hazardous and posed a risk of
25 neurodevelopmental disorders and other serious illnesses when used in a reasonably anticipated
26 manner;

27 C. When placed in the stream of commerce, Defendants' Contaminated
28 Baby Foods contained unreasonably dangerous design defects and were not reasonably safe

1 when used in a reasonably anticipated or intended manner;

2 D. Defendants did not sufficiently test, investigate, or study their
3 Contaminated Baby Foods and, specifically, the content of Toxic Heavy Metals in the
4 ingredients used to manufacture the foods and/or the finished products;

5 E. Defendants did not sufficiently test, investigate, or study their
6 Contaminated Baby Foods and, specifically, the ability for those foods to expose babies to
7 Toxic Heavy Metals; and

8 F. Exposure to the Toxic Heavy Metals in Contaminated Baby Foods
9 presents a risk of harmful effects that outweigh any potential utility stemming from the use of
10 the products;

11 193. Defendants knew or should have known at the time of marketing Contaminated
12 Baby Foods that exposure to Toxic Heavy Metals contained in the Baby Foods could result in
13 interference with early neurodevelopment that that manifests as ASD, ADHD and other severe
14 illnesses and injuries.

15 194. Defendants, by design, did not conduct adequate post-marketing surveillance of
16 their Contaminated Baby Foods.

17 195. Defendants could have employed safer alternative designs and formulations. For
18 example, the Defendants could have avoided use of certain ingredients contaminated with Toxic
19 Heavy Metals, avoided using pre-mix vitamins contaminated with Toxic Heavy Metals, and/or
20 sampled their ingredients from other sources.

21 196. The Defendants breached their duty by failing to use reasonable care by failing
22 to use cost effective, reasonably feasible alternative designs. There was a practical, technically
23 feasible, and safer alternative design that would have prevented the harm without substantially
24 impairing the reasonably anticipated or intended function of Defendants' Contaminated Baby
25 Foods.

26 197. A reasonable company under the same or similar circumstances would have
27 designed a safer product.

28 198. Plaintiff was harmed directly and proximately by the Defendants' failure to use

1 reasonable care in the design of their Contaminated Baby Foods. Such harm includes exposure
2 to Toxic Heavy Metals, which can cause or contribute to interference with neurodevelopment
3 that manifests as ASD and related *sequelae*.

4 199. Defendants' defective design of Contaminated Baby Foods was willful, wanton,
5 malicious, and conducted with reckless disregard for the health and safety of consumers of the
6 Baby Foods, including Plaintiff.

7 200. The defects in Defendants' Contaminated Baby Foods were substantial factors in
8 causing Plaintiff's injuries.

9 201. As a direct and proximate result of the Defendants' negligent design of the
10 Contaminated Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
11 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages
12 including, but not limited to past and future medical expenses, lost income, and other damages.

13 202. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
14 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and
15 all such other and further relief as this Court deems just and proper.

16 **COUNT VII: GENERAL NEGLIGENCE**

17 203. Plaintiff incorporates by reference each allegation set forth in preceding
18 paragraphs as if fully stated herein.

19 204. Plaintiff pleads claims for negligence under all theories that may be actionable
20 under any applicable state laws.

21 205. Defendants owed Plaintiff a duty to act with reasonable care.

22 A. Defendants owed a duty because they distributed and promoted their
23 products as safe for children to consume.

24 B. Defendants owed a duty because their conduct created a risk of harm to
25 Plaintiffs and caused Plaintiff actual harm.

26 C. Defendants owed a duty because the risk of harm to Plaintiff was
27 embedded in, and an inherent component of, their negligent business practices.

28 D. Defendants owed a duty because they designed, manufactured,

1 controlled, distributed, and sold their products to Plaintiff.

2 206. Defendants breached their duty to Plaintiff.

3 207. Defendants' negligence includes, but is not limited to, their marketing,
4 designing, manufacturing, producing, supplying, inspecting, testing, selling and/or distributing
5 Contaminated Baby Foods in one or more of the following respects:

6 A. Failure to implement procedures that would reduce or eliminate Toxic
7 Heavy Metals in baby foods;

8 B. Failure to investigate suppliers and ingredient sources to reduce and
9 eliminate the risk of ingredients containing Toxic Heavy Metals; and

10 C. Failure to avoid using ingredients free from, or which contain far less,
11 Toxic Heavy Metals to manufacture baby food.

12 D. When placed in the stream of commerce, Defendants' Contaminated
13 Baby Foods were defective in design and formulation, and, consequently, dangerous to an
14 extent beyond that which an ordinary consumer would contemplate;

15 E. When placed in the stream of commerce, Defendants' Contaminated
16 Baby Foods were unreasonably dangerous in that they were hazardous and posed a risk of
17 neurodevelopmental disorders and other serious illnesses when used in a reasonably anticipated
18 manner;

19 F. When placed in the stream of commerce, Defendants' Contaminated
20 Baby Foods contained unreasonably dangerous design defects and were not reasonably safe
21 when used in a reasonably anticipated or intended manner;

22 G. Defendants, by design, did not conduct adequate post-marketing
23 surveillance of their Contaminated Baby Food products which would have alerted the public to
24 risks; and

25 H. Defendants did not sufficiently test, investigate, or study their
26 Contaminated Baby Foods and, specifically, the ability for those foods to expose babies to
27 Toxic Heavy Metals;

28 I. Defendants could have employed safer alternative designs and

1 formulations for Contaminated Baby Foods, such as ensuring the baby food did not have any
2 detectable level of Toxic Heavy Metal.

3 J. Defendants did not sufficiently test, investigate, or study their
4 Contaminated Baby Foods and, specifically, the content of Toxic Heavy Metals in the
5 ingredients used to manufacture the foods and/or the finished products; and

6 K. Exposure to the Toxic Heavy Metals in Contaminated Baby Foods
7 presents a risk of harmful effects that outweigh any potential utility stemming from the use of
8 the products;

9 208. Defendants knew or should have known that their products contained detectable
10 levels of heavy metals that created an unreasonable risk of harm to children who consumed their
11 products.

12 209. At all relevant times, the Defendants knew or should have known that the
13 Products were unreasonably dangerous and defective when put to their reasonably anticipated
14 use.

15 210. As a proximate result of Defendants' negligence, Plaintiff has been injured,
16 sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of
17 life, economic loss, and damages including, but not limited to past and future medical expenses,
18 lost income, and other damages.

19 211. **WHEREFORE**, Plaintiff respectfully requests this Court enter judgment in
20 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and
21 all such other and further relief as this Court deems just and proper.

22 **JURY TRIAL DEMAND**

23 212. Plaintiff demands a trial by jury on all the triable issues within this pleading.

24 **PRAYER FOR RELIEF**

25 213. **WHEREFORE**, Plaintiff requests that the Court enter judgment in Plaintiff's
26 favor and against the Defendants for:

- 27 a. actual or compensatory damages in such amount to be determined at trial and
28 as provided by applicable law;

- b. exemplary and punitive damages sufficient to punish and deter the Defendants and others from future wrongful practices;
- c. pre-judgment and post-judgment interest;
- d. costs including reasonable attorneys' fees, court costs, and other litigation expenses; and
- e. any other relief the Court may deem just and proper.

Respectfully submitted,

Dated: January 24, 2025

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