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

13 IN RE: BABY FOOD PRODUCTS
 14 LIABILITY LITIGATION

15 This Document Relates To:

16 JENNIS RIVERA, on Behalf of B.M., A MINOR,

17 *Plaintiff,*

18 v.

19 Beech-Nut Nutrition Company, Campbell Soup
 20 Company, Gerber Products Company, Hain
 21 Celestial Group, Inc., Hero A.G., Neptune
 22 Wellness Solutions, Nestlé S.A., Plum, PBC,
 23 Sprout Foods, Inc., Sun-Maid Growers of
 24 California, 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.: 3:25-cv-1699

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 diagnoses of
27 autism spectrum disorder (“ASD”) and attention deficit hyperactivity disorder (“ADHD”).
28 Plaintiff’s parents were never warned that the Defendants’ food contained Toxic Heavy Metals

1 and, thus, were never able to make an informed decision about whether to feed their babies
2 Defendants Contaminated Baby Foods. The consequences are stark—there is an unprecedented
3 epidemic of ASD and ADHD spreading throughout the American population, driven, in part, by
4 the systematic neurodevelopmental poisoning of infants from these Defendants’ Contaminated
5 Baby Foods.

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

9 **PARTIES**

10 **I. Plaintiffs**

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

14 6. Plaintiff consumed baby foods manufactured and/or sold by Beech-Nut Nutrition
15 Company, Gerber Products Company, Hain Celestial Group, Inc., Plum, PBC, and Sprout
16 Foods, Inc.

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

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

23 9. The baby foods manufactured by Defendant Plum and consumed by Plaintiff
24 were manufactured at the direction of, and/or under the control of, and/or according to the
25 specification of, and/or with input from the parent company, Campbell Soup Company, and Sun
26 maid Sun-Maid Growers of California.

27 10. The baby foods manufactured by Defendant Sprout Foods, Inc. and consumed by
28 Plaintiff were manufactured at the direction of, and/or under the control of, and/or according to

1 the specification of, and/or with input from the parent company, Neptune Wellness Solutions.

2 11. Plaintiff alleges that as a direct and proximate result of Plaintiff's exposure to
3 Toxic Heavy Metals from consumption of Defendants' Contaminated Baby Foods, they
4 suffered significant harm, conscious pain and suffering, physical injury and bodily impairment
5 including, but not limited to, brain injury manifesting as the neurodevelopmental disorders ASD
6 and ADHD, other permanent physical deficits, permanent bodily impairment, and other
7 *sequelae*. Plaintiff's injuries required medical intervention to address the adverse neurological
8 effects and damage caused by exposure to Toxic Heavy Metals in Defendants' Contaminated
9 Baby Foods. Additionally, Plaintiff has suffered severe mental and physical pain, including but
10 not limited to, pain, mental suffering, loss of enjoyment of life, disfigurement, physical
11 impairment, inconvenience, grief, anxiety, humiliation, and emotional distress and has and will
12 sustain such injuries, along with economic loss due to medical expenses and living-related
13 expenses as a result of lifestyle changes, into the future, as determined by the Trier of Fact.

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

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

28 **II. Defendants**

- 1 14. The following are the Defendants listed in this Complaint. In alphabetical order:
- 2 1. Beech-Nut Nutrition Company (“Beech-Nut”)
- 3 2. Campbell Soup Company (“Campbell”)
- 4 3. Gerber Products Company (“Gerber”)
- 5 4. Hain Celestial Group, Inc. (“Hain”)
- 6 5. Hero A.G. (“Hero Group”)
- 7 6. Neptune Wellness Solutions (“Neptune”)
- 8 7. Nestlé S.A. (“Nestlé”)
- 9 8. Plum, PBC (“Plum”)
- 10 9. Sprout Foods, Inc. (“Sprout”)
- 11 10. Sun-Maid Growers of California (“Sun-Maid”)

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

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

1 substantial revenue through Beech-Nut by manufacturing, advertising, distributing, selling, and
2 marketing baby foods within the judicial districts involved in this litigation.

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

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

11 19. Defendant Gerber Products Company ("Gerber") is a citizen of Michigan and
12 Virginia with its principal place of business located at 1812 N. Moore Street, Arlington,
13 Virginia 22209. Gerber sells Baby Foods under the brand name Gerber. Gerber organizes its
14 products into broad categories of "formula," "baby cereal," "baby food," "snacks," "meals &
15 sides," "beverages," and "organic." At all relevant times, Gerber has conducted business and
16 derived substantial revenue from its manufacturing, labeling, advertising, distributing, selling,
17 and marketing of baby foods.

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

28 21. The relationship between Gerber and Nestlé was formed in 2007. Prior to that,

1 starting in 1994, Gerber was owned and operated by Novartis, one of the largest pharmaceutical
2 companies in the world. However, in 2007, Gerber was sold to Nestlé for \$5.5 billion.

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

7 23. The Hain Celestial Group, Inc. (“Hain”) is a citizen of Delaware and New York
8 with its principal place of business located at 1111 Marcus Ave., Lake Success, New York
9 11042. Hain sells baby foods under the brand name Earth’s Best Organics. Hain offers infant
10 and baby formula and foods as well as toddler foods covering products from “organic infant
11 cereal” to “organic snacks for toddlers and kids on the go.” At all relevant times, Hain has
12 conducted business and derived substantial revenue from its manufacturing, advertising,
13 distributing, selling, and marketing of Baby Foods within this judicial district and throughout
14 the United States.

15 24. Defendant Plum, PBC (“Plum”) is a citizen of Delaware and California with its
16 principal place of business located at 6795 N. Palm Ave., 2nd Floor, Fresno, California 93704.
17 Plum sells Baby Foods under the brand name “Plum Organics” and has done so since 2007.
18 Starting in 2013, and until May 3, 2021, Plum was directly controlled and owned by Defendant
19 Campbell. Plum’s products are divided into groups according to the targeted infant or toddler
20 age and/or type of food product. For example, there are five groups designated for the youngest
21 infants: Stage 1 (4+ months old), Stage 2 (6+ months old), Stage 3 (6+ months old), “Super
22 Puffs,” and “Little Teethers.” At all relevant times, Plum has conducted business and derived
23 substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of
24 baby foods within this judicial district and throughout the United States.

25 25. Defendant Campbell Soup Company (“Campbell”) is a Citizen of New Jersey
26 with its principal place of business located at One Campbell Pl., Camden, New Jersey 08103.
27 Campbell sells food and beverages and was the parent company of Plum until May 3, 2021,
28 wherein Campbell sold Plum to Defendant Sun-Maid, a few months after the first heavy metal

1 lawsuits were filed. Campbell sold baby food under the brand name Plum Organics through
2 Plum. Indeed, many of the scientists and researchers that monitored the safety of Toxic Heavy
3 Metals in Plum's baby foods were directly employed by Campbell or were directly controlled
4 and trained by Campbell agents and employees. For example, it was Campbell's attorneys that
5 responded to Congressional inquiries about heavy metals in Plum baby foods in 2019.
6 Campbell exercised control over Plum's baby food selling in the United States until May 3,
7 2021. At all relevant times, Campbell conducted business and derived substantial revenues
8 from its manufacturing, advertising, distributing, selling, and marketing of baby foods within
9 this judicial district and throughout the United States.

10 26. Defendant Sun-Maid Growers of California ("Sun-Maid") is a citizen of
11 California with its principal place of business located at 6795 N. Palm Ave., Fresno, California
12 93711. Sun-Maid sold baby food through Plum, starting on May 3, 2021. Sun-Maid acquired
13 Plum from Campbell on May 3, 2021. Sun-Maid has since been directly involved with all
14 aspects of the safety and testing of Plum's baby food products. For example, metal testing is
15 paid for directly and sent directly to Sun-Maid's scientists and executives, not directly to Plum.
16 All major executive functions related to Plum's operation were specifically transitioned from
17 Campbell to Sun-Maid. Like Campbell, Sun-Maid has exercised and continues to exercise
18 direct control over the manufacture, sale, and distribution of all Plum baby foods since May 3,
19 2021. At all relevant times, Sun-Maid conducted business and derived substantial revenue from
20 its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this
21 judicial district.

22 27. For the purposes of this Complaint, allegations related to Plum between 2013
23 and May 3, 2021 apply equally to Campbell, unless otherwise specified, and allegations related
24 to Plum after May 3, 2021 apply equally to Sun-Maid, as each Defendant exercised authority
25 and control over the sale, manufacture, and distribution of Plum's Contaminated Baby Foods at
26 issue in this MDL.

27 28. Defendant Sprout Foods, Inc. ("Sprout") is a citizen of Delaware and New Jersey
28 with its principal place of business located at 50 Chestnut Ridge Rd, Montvale, New Jersey

1 07645. Sprout sells Baby Foods under the brand name Sprout Organic Foods. Sprout organizes
2 its Baby Foods selection according to three categories: Stage 2 (6 months+); Stage 3 (8
3 months+); and Toddler. Sprout was founded in 2008 and was sold to Defendant Neptune
4 Wellness Solutions in February 2021. Since Neptune acquired Sprout, it has exercised
5 managerial control over the company, and thus has exercised direct control over the sale of
6 Sprout baby food since that time. At all relevant times, Sprout has conducted business and
7 derived substantial revenue from its manufacturing, advertising, distributing, selling, and
8 marketing of Baby Foods within the United States.

9 29. Defendant Neptune Wellness Solutions, Inc. (“Neptune”) is a citizen of Florida
10 and Canada, with its primary place of business in the United States located at 1044 N. US
11 Highway 1 - Suite 101, Jupiter, Florida 33477. Neptune has sold baby food through its
12 controlled subsidiary, Sprout, since February 2021. Neptune has exercised control over
13 Sprout’s baby food selling, and has been directly involved with all aspects of food safety testing
14 and specification setting for Sprout’s baby foods. Neptune also appears to have dictated all
15 public relations and public facing actions by Sprout since the lawsuits related to Contaminated
16 Baby Foods were filed. Neptune, thus, has been directly involved in the tortious conduct in the
17 United States and its various states that gives rise to these lawsuits. At all relevant times,
18 Neptune conducted business and derived substantial revenues from its manufacturing,
19 advertising, distributing, selling, and marketing of baby foods within this judicial district and
20 throughout the United States.

21 30. For the purposes of this Complaint, allegations related to Sprout after February
22 2021 apply equally to Neptune, unless otherwise specified, as each Defendant exercised
23 authority and control over the sale, manufacture, and distribution of Sprout’s Contaminated
24 Baby Foods at issue in this MDL.

25 **JURISDICTION AND VENUE**

26 31. Plaintiff(s) file this Complaint pursuant to CMO No. 5, and are to be bound by
27 the rights, protections, and privileges, and obligations of that CMO and other Order of the
28 Court. Further, in accordance with CMO No. 5, Plaintiff(s) hereby designate the United States

1 District Court for the Southern District of Florida as Plaintiff’s designated venue (“Original
2 Venue”). Plaintiff makes this selection based upon one (or more) of the following factors
3 (check the appropriate box(es))

4 Plaintiff currently resides in Miami, Florida.

5 Plaintiff purchased and consumed Defendant(s) products in Florida.

6 The Original Venue is a judicial district in which Defendant _____ resides, and
7 all Defendants are residents of the State in which the district is located (28 U.S.C.
8 1391(b)(1)).

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

11 There is no district in which an action may otherwise be brought under 28 U.S.C.
12 1391, and the Original Venue is a judicial district in which Defendant _____ is subject
13 to the Court’s personal jurisdiction with respect to this action (28 U.S.C. 1391 (b)(3)).

14 Other reason (please explain): _____

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

20 33. This Court has personal jurisdiction over Defendants because their significant
21 contacts related to this litigation in each State make personal jurisdiction proper over any of
22 them.

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

28 35. Additionally, Defendants caused tortious injury by acts and omissions in this

1 judicial district and caused tortious injury in this district by acts and omissions outside this
2 district while regularly doing and soliciting business, engaging in a persistent course of conduct,
3 and deriving substantial revenue from goods used or consumed and services rendered in this
4 judicial district.

5 36. Nestlé, Hero Group, and Neptune are subject to personal jurisdiction in the
6 relevant judicial districts insofar as they are authorized and licensed to conduct business in their
7 respective states. Additionally, these Defendants maintain and carry on systematic and
8 continuous contacts in these judicial districts, regularly transact business within these districts,
9 and regularly avail themselves of the benefits of these districts. These Defendants caused
10 tortious injury by acts and omissions in these judicial districts and by acts and omissions outside
11 these districts while regularly doing and soliciting business, engaging in a persistent course of
12 conduct, and deriving substantial revenue from goods used or consumed and services rendered
13 in these districts.

14 **FACTUAL ALLEGATIONS**

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

16 37. In October 2019, an alliance of nonprofit organizations, scientists and donors
17 named “Happy Babies Bright Futures” (“HBBF”), dedicated to designing and implementing
18 “outcomes-based programs to measurably reduce babies’ exposures to toxic chemicals,”
19 published a report investigating the presence of Toxic Heavy Metals in baby foods. The HBBF
20 Report tested 168 different baby foods sold on the U.S. market and concluded that “[n]inety-
21 five percent of baby foods tested were contaminated with one or more of four toxic heavy
22 metals—arsenic, lead, cadmium and mercury. All but nine of 168 baby foods contained at least
23 one metal; most contained more than one.” Specifically, the HBBF report identified “puffs and
24 other snacks made with rice flour,” “[t]eething biscuits and rice rusks,” “infant rice cereal,”
25 “apple, pear, grape and other fruit juices,” and “carrots and sweet potatoes” manufactured by
26 the Defendants as particularly high in Toxic Heavy Metals.

27 38. The results of the HBBF report were consistent with that of the U.S. Food and
28 Drug Administration (“FDA”) which had, in 2017, detected one or more of the four Toxic

1 Heavy Metals in 33 of 39 types of baby food tested. However, the HBBF reported that “[f]or
2 88 percent of baby foods tested by HBBF—148 of 168 baby foods—FDA has failed to set
3 enforceable limits or issue guidance on maximum safe amounts.” The HBBF’s findings were
4 by no means an outlier. Eight months prior to publication of the HBBF report, a study
5 conducted by scientists at the University of Miami and the Clean Label Project “examined
6 lead...concentrations in a large convenience sample of US baby foods.” The study detected
7 lead in 37% of samples.

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

16 **II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby** 17 **Foods Manufactured and/or Sold by Defendants, Sparking National Outrage**

18 40. On February 4, 2021, and September 29, 2021, respectively, the U.S. House of
19 Representatives’ Subcommittee on Economic and Consumer Policy, Committee on Oversight
20 and Reform, published two reports detailing its findings that Toxic Heavy Metals—including
21 lead, arsenic, mercury, and cadmium—were present in “significant levels” in numerous
22 commercial Baby Food Products. Four companies—Hain, Gerber (Nestlé), Nurture (Danone),
23 and Beech-Nut—produced internal testing policies, test results for ingredients and finished
24 products, and documentation about what the companies did with ingredients and/or finished
25 products that exceeded their internal testing limits. Three companies—Plum (Campbell),
26 Walmart, and Sprout—initially refused to cooperate.

27 41. Congress reported that the data submitted by the companies unequivocally
28 revealed that a substantial number of Defendants’ finished products and/or ingredients used to

1 manufacture the Baby Foods are tainted with Toxic Heavy Metals, namely lead, arsenic,
2 mercury, and cadmium. And, where the Defendants did set internal limits for the amount of
3 metals they allowed in their foods, Defendants routinely flouted their own limits and sold foods
4 that consistently tested above their limits. Congress found the following:

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

19 43. **Gerber.** Gerber along with Nestlé used high-arsenic ingredients, using 67
20 batches of rice flour that had tested over 90 ppb inorganic arsenic. Nestlé and Gerber used
21 ingredients that tested as high as 48 ppb lead; and used many ingredients containing over 20
22 ppb lead. Nestlé and Gerber rarely test for mercury in their baby foods. In the September 2021
23 follow-up Congressional report, it was revealed that Nestlé and Gerber’s rice cereal tested up to
24 116 ppb inorganic arsenic, and their average rice cereal product contained 87.43 ppb inorganic
25 arsenic, which is even higher than the amount contained in Beech-Nut’s average rice cereal
26 product. While Beech-Nut recalled some of its products and completely discontinued sales of
27 its rice cereal, Nestlé and Gerber have taken no such actions to protect children.

28 44. **Hain (Earth’s Best Organic).** Hain sold finished baby food products

1 containing as much as 129 ppb inorganic arsenic. Hain typically only tested its ingredients, not
2 finished products. Documents show that Hain used ingredients testing as high as 309 ppb
3 arsenic. Hain used ingredients containing as much as 352 ppb lead. Hain used many
4 ingredients with high lead content, including 88 that tested over 20 ppb lead and six that tested
5 over 200 ppb lead. And, Hain does not even test for mercury in its baby food. However,
6 independent testing by HBBF of Hain’s Baby Foods confirm that Hain’s products contain as
7 much as 2.4 ppb of mercury.

8 45. **Plum.** Plum, along with Campbell, refused to cooperate with the Congressional
9 investigation. Instead of producing any substantive information, Campbell provided Congress
10 with a self-serving spreadsheet declaring that every one of its products sold through Plum
11 “meets criteria”, while declining to state what those criteria were. Disturbingly, Campbell
12 admitted that, for mercury (a powerful neurotoxin), Campbell and Plum have *no criterion*
13 whatsoever, stating: “No specific threshold established because no high-risk ingredients are
14 used.” However, despite Campbell and Plum having no mercury threshold, Campbell and Plum
15 still marked every food as “meets criteria” for mercury. Congress noted that “[t]his misleading
16 framing—of meeting criteria that do not exist—raises questions about what [Plum’s] other
17 thresholds actually are, and whether they exist.” This suspicion is confirmed by HBBF’s
18 independent testing which confirms the presence of Toxic Heavy Metals in Campbell and Plum
19 Baby Food, which found excess levels of lead, arsenic, and mercury in Campbell and Plum’s
20 Just Sweet Potato Organic Baby Foods; Just Peaches Organic Baby Food; Just Prune Organic
21 Baby Food; Pumpkin Banana Papaya Cardamom; Apple, Raisin & Quiona Organic Baby Food;
22 Little Teethers Organic Multigrain Teething Wafers-Banana with Pumpkin; and Mighty
23 Morning Bar-Blueberry Lemon-Tots. Furthermore, as discussed further below, based upon
24 information and belief, Plaintiffs submit that Campbell and Plum’s pattern and practice of
25 failing to test ingredients, willingly flouting their own internal standards, and selling products
26 notwithstanding internal acknowledgement of their high metal content, follows that of the other
27 Defendants discussed in this Complaint, and discovery here will further flesh out the extent of
28 Campbell and Plum’s culpable conduct.

1 46. **Sprout.** Sprout initially refused to cooperate with the House Subcommittee’s
2 investigation, and as such the Subcommittee stated that Sprout’s failure to respond “raises
3 serious concerns about the presence of toxic heavy metals in its baby foods.” The
4 Subcommittee noted that independent data from the HBBF Report confirmed that Sprout’s baby
5 foods are indeed tainted. For example, the HBBF Report observed that Sprout’s Organic
6 Quiona Puffs Baby Cereal Snack-Apple Kale contained 107 ppb total arsenic, 47 ppb inorganic
7 arsenic, 39.3 ppb lead, and 41.5 ppb cadmium.

8 47. As outlined in the Subcommittee’s Addendum Report, Sprout eventually
9 provided a “handful of documents” to the Subcommittee, and the documents provided
10 “displayed a lax approach to testing for toxic heavy metals in its baby food.” Sprout relies on
11 its ingredients suppliers to test their ingredients for toxic heavy metals and only asks the
12 suppliers to test once a year. Upon information and belief, despite its representations to the
13 Subcommittee, Sprout did not require its raw ingredient suppliers to provide yearly heavy metal
14 test results prior to the Subcommittee’s inquiry into the company. Sprout provided only 11
15 toxic heavy metal test results to the Subcommittee stating that “[b]ecause Sprout requires
16 annual testing for heavy metals for its ingredients, rather than by lot, Sprout is unable to provide
17 testing information for each lot as requested.” The Subcommittee called this testing the “the
18 most reckless among baby food sellers on the market.”

19 48. The metal concentrations discussed above and further below surpass the limits
20 allowed by U.S. regulatory agencies. There are no FDA final regulations governing the
21 presence of Toxic Heavy Metals in the majority of Baby Foods with the exception of 100 ppb
22 inorganic arsenic in infant rice cereal and proposed (not yet final) limits for lead in certain baby
23 food categories. To the extent such regulations exist, the quantities of Toxic Heavy Metals in
24 Defendants’ Baby Foods exceed any permissible FDA levels. To be sure, the FDA has set the
25 maximum contaminant levels (“MCL”) in bottled water at 10 ppb inorganic arsenic, 5 ppb lead,
26 and the EPA has capped the allowable level of mercury in drinking water at 2 ppb. However,
27 these limits were created in reference to *adult* exposure, not infants. Compared to these
28 thresholds, the test results of the Defendants’ baby foods and their ingredients are multiple folds

1 greater than the permitted metal levels. Moreover, compounding these troubling findings, the
2 Defendants set internal limits for the presence of Toxic Heavy Metals in their foods that were,
3 themselves, dangerously high and then routinely failed to abide by those inadequate standards,
4 as discussed below.

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

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

10 50. Several factors drive the Toxic Heavy Metal contamination of Defendants' baby
11 foods, all of which are within Defendants' control.

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

21 52. *Second*, some Defendants implemented dangerously high internal limits
22 (“specifications” or “specs”) for the maximum level of Toxic Heavy Metals that Defendants
23 allowed in the baby foods. Such high limits—untethered to any consideration of the low levels
24 at which metals are capable of damaging babies' brains—allowed Defendants to source and use
25 ingredients that contained elevated Toxic Heavy Metals to manufacture the baby foods
26 consumed by Plaintiffs. In the highly competitive and lucrative baby food market, using
27 contaminated ingredients allows each Defendant to retain greater market share.

28 53. *Third*, some Defendants failed to implement *any* internal specifications for the

1 amount of Toxic Heavy Metals allowed in ingredients or finished baby foods. By simply not
2 looking at the issue, certain highly contaminated ingredients and finished products were allowed
3 to be used and sold to consumers. This would happen notwithstanding the Defendants' specific
4 knowledge of the risk of Toxic Heavy Metals and their presence in ingredients and finished
5 products.

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

14 55. *Fifth*, upon information and belief, Defendants' manufacturing practices also
15 contributed to contamination. For example, the water used at some of the facilities where the
16 baby foods were manufactured contained Toxic Heavy Metals which, in turn, ended up in the
17 finished baby food product sold for consumption by babies.

18 56. **Beech-Nut.** Beech-Nut and Hero Group did not test their finished baby foods
19 for heavy metals, only ingredients. And, Beech-Nut and Hero Group regularly accepted
20 ingredients testing far higher than its internal limits for Toxic Heavy Metals. They justified
21 such deviations as "exceptional releases." For example, Beech-Nut and Hero Group
22 "exceptionally released" 160,000 pounds of sweet potatoes for their baby food products
23 notwithstanding the ingredient testing twice as high as Beech-Nut's internal heavy metal limit
24 for lead.

25 57. Moreover, Beech-Nut and Hero Group did not adequately test their ingredients
26 for heavy metals by limiting ingredient lots and ingredient quantities that were subject to metal
27 testing. For example, if a supplier supplied ingredients below a certain amount, they would not
28 test anything and simply use the ingredient in the finished product. Furthermore, in deciding to

1 violate their own internal limits, Beech-Nut and Hero Group took advantage of the fact that the
2 FDA does not routinely test baby foods for Toxic Heavy Metals.

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

7 59. Beech-Nut and Hero Group's internal specifications varied wildly by ingredient,
8 with Beech-Nut allowing very high levels of Toxic Heavy Metals for certain ingredients, and
9 insisting on lower levels for others. Thus, certain products like rice flour, were allowed to have
10 very high levels of metals like arsenic and lead, even in products that were 90% or more rice.
11 Beech-Nut and Hero Group did this because there were no regulations governing Toxic Heavy
12 Metal in baby food and, therefore, to remain competitive in the baby food marketplace, Beech-
13 Nut used contaminated ingredients because they were readily available.

14 60. **Gerber.** Gerber and Nestlé tested ingredients and, occasionally, finished
15 products. However, while Gerber and Nestlé were the only Defendants to test both ingredients
16 and finished products with any regularity, they set high heavy metal limits that rendered their
17 food unsafe. For baby foods generally, between 2012 and 2019, Gerber and Nestlé set a limit of
18 40 ppb for lead, 20 ppb for arsenic, and 10 ppb for mercury. For infant rice cereal, between
19 2012 and 2017, Gerber and Nestlé set a lead limit of 100 ppb, with a "target" of 50 ppb in 2016
20 and 2017. Between 2018 and 2019, Gerber and Nestlé set a lead limit for 50 ppb. For arsenic
21 in rice cereal, between 2012 and 2015, Gerber and Nestlé did not have a limit, merely a target of
22 100 ppb. Then, between 2016 and 2018, it set the arsenic limit at 100 ppb. By 2019, Gerber
23 and Nestlé increased the arsenic limit to 130 ppb for cereals with 90% rice (and kept the limit at
24 100 ppb for other cereals). For snack foods, Gerber and Nestlé had a lead limit of 150 ppb
25 between 2012 and 2014. It was reduced to 100 ppb in 2016 and 2017, and then went down to 50
26 ppb in 2018 and 2019. There was no limit for arsenic in snack food prior 2016, just a "target"
27 of 100 ppb. Then a 100-ppb arsenic limit was set starting in 2016. For both infant cereal and
28 snacks, Gerber and Nestlé imposed a 30-ppb limit for mercury in infant cereal between 2012

1 and 2016, and reduced it to 10 ppb from 2017 onward. With these exceptionally high limits,
2 Gerber and Nestlé sold baby foods that were dangerous for infant consumption. They did this
3 knowingly.

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

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

16 63. Gerber’s baby foods are also contaminated with elevated levels of lead. Gerber
17 and Nestlé used ingredients that tested as high as 48 ppb lead and used many ingredients
18 containing over 20 ppb lead. Furthermore, Gerber and Nestlé sold baby food products testing at
19 and/or above 50 ppb of lead. Indeed, Gerber and Nestlé have historically permitted as much as
20 150 ppb lead in their baby food products. Although Gerber and Nestlé were fully aware that it
21 was very feasible to source lower-lead ingredients, they proceeded to use high-lead ingredients
22 in their baby foods. Gerber and Nestlé rarely test for mercury in their baby foods. This is
23 notwithstanding the fact that mercury is known to contaminate ingredients such as rice and
24 poses a severe risk to babies’ brain development.

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

28 65. Moreover, compounding these troubling findings, Gerber and Nestlé historically

1 only tested certain ingredients of its baby food products and only occasionally tested the
2 finished products consumed by babies. It was not until recently that Gerber and Nestlé started
3 to implement finished product testing on a more regular basis.

4 66. Gerber and Nestlé have known since at least the 1990s that inorganic arsenic was
5 neurotoxic and caused developmental issues. Despite this knowledge, in 2012, when Gerber’s
6 infant rice cereal was on the front page of a Consumer Report article on arsenic, a Gerber
7 spokesperson told the public that arsenic in baby food posed no health risk.

8 67. **Hain.** Hain did not test its baby food products for heavy metals until 2020 (rice
9 cereal) and 2021 (other baby food). Instead, Hain tested some ingredients used in their foods
10 (but not all ingredients). Ingredients were required to meet specific specifications for each
11 specific ingredient. Those specifications, however, would change wildly without explanation.
12 For example, prior to August 2014, Hain’s lead specification for Oat Flour was 200 ppb. Then
13 it was reduced to 50 ppb for four months, went back up to 100 ppb for three months, went back
14 up to 200 ppb for a month, came down to 20 ppb for seven months, went to 25 ppb for six
15 months, and then went back to 200 ppb for the next fourteen months. When asked about this
16 seemingly chaotic shifting of specifications, Hain could not explain it.

17 68. Hain would routinely accept ingredients that tested above specifications and use
18 them in baby foods anyway. These “exceptional” releases were made because there were no
19 FDA regulations specifically preventing them.

20 69. Because Hain only tested ingredients, and not finished products, they would
21 underestimate metal exposure. For example, in August 2019, the FDA did what Hain had
22 refused: it actually tested Hain’s baby food products for heavy metals. FDA sampled Hain’s rice
23 cereal and found levels in excess of 100 ppb. FDA tested 20 of Hain’s rice cereal products (all
24 manufactured by Beech-Nut for Hain) sold between September 2017 and June 2018, and found
25 9 samples in excess of 100 ppb of inorganic arsenic, and 16 (80%) above 90 ppb. The FDA
26 raised concern about Hain’s failure to test finished product, and asked Hain to conduct an
27 investigation. These concerns about Hain’s rice cereal were independently confirmed by HBBF,
28 where they found 113 and 107 ppb of inorganic arsenic (138 and 126 ppb of arsenic) in those

1 same products. As a result of the FDA-ordered investigation, Hain learned that its rice cereal
2 exceeded FDA arsenic levels because Hain never accounted for the arsenic added to the product
3 from the vitamin premix. Hain discovered that the vitamin premix specification was 3,000 ppb
4 for arsenic and 4,000 ppb for lead. They realized that their products needed to be tested in
5 finished form to actually estimate the levels of heavy metals in their foods. Hain also realized
6 that the use of brown rice was contributing to the high levels of arsenic, so, thereafter, they
7 started using white rice (as opposed to brown rice) to reduce arsenic levels and began testing
8 rice cereal regularly.

9 70. Hain's inept process of monitoring the safety of their baby foods resulted in
10 products being sold that contained Toxic Heavy Metals, and this was done with full knowledge
11 of the risks. When asked why Hain did not warn consumers of the Toxic Heavy Metals in their
12 foods, Hain responded that if they warned, people would not buy their products.

13 71. **Plum.** Plum was founded in 2007 and has sold a wide variety of baby food
14 products under the name Plum Organics since that time. Plum was owned and controlled by
15 Campbell from roughly 2013 until roughly May 2021 when Plum was sold to Sun-Maid.

16 72. Despite Plum's public facing statements that "little ones deserve the very best
17 food from the very first bite" and despite understanding that environmental toxins like heavy
18 metals can cause neurodevelopmental disorders in children, Plum and Campbell/Sun-Maid did
19 very little to ensure that the Plum baby food products marketed for consumption by children are
20 not contaminated with dangerous levels of heavy metals. For example, though Plum and
21 Campbell/Sun-Maid knew that the heavy metal contents of the ingredients used in its products
22 varied by growing region and supplier, they did not undertake an effort to source ingredients
23 with the lowest amount of heavy metals available. And, despite knowing that certain
24 ingredients carry a higher risk for heavy metal contamination, Plum and Campbell/Sun-Maid
25 did not reformulate their products to ensure that they were being made with the lowest
26 achievable amount of heavy metals.

27 73. Plum and Campbell failed to set limits on the amount of heavy metals that could
28 be present in Plum's finished baby food products. From 2007 to at least April 2021, they did

1 not set *any* limits for the amount of lead, arsenic, mercury, cadmium, or aluminum that their
2 finished products could contain.

3 74. Plum and Campbell also failed to set limits on the amount of heavy metals that
4 could be present in the ingredients used in Plum's baby food products. Prior to 2016, they did
5 not set limits for the amount of heavy metals that could be present in the ingredients used in
6 Plum products. When Plum and Campbell did begin to implement heavy metal limits for Plum
7 ingredients (in or around 2017), it did so only for lead, arsenic, and cadmium. As of April
8 2021, Plum and Campbell still had no limits for the amount of mercury and aluminum that
9 could be in the ingredients used in their baby food products.

10 75. When Plum did set some heavy metal limits (for lead and arsenic for ingredients
11 only) it set those limits several times in excess of what was achievable for most ingredients.
12 For example, despite certain fruits and vegetables normally containing less than 5 ppb lead or
13 arsenic, Plum set the heavy metal limits for all Plum ingredients for lead and arsenic at 100 ppb.
14 And, even still, despite setting these limits dangerously high, Plum and Campbell/Sun-Maid still
15 utilized ingredients that tested in excess of those limits.

16 76. Plum and Campbell/Sun-Maid also conducted very little oversight of their co-
17 manufacturers to ensure that the heavy metal limits for ingredients used in Plum products were
18 adhered to. For example, prior to 2017, Plum and Campbell did not require the ingredient
19 suppliers they contracted with to submit heavy metal testing data but instead relied on supplier
20 assurances that the ingredients did not contain heavy metals and/or complied with all
21 government regulations regarding heavy metals. When Plum and Campbell/Sun-Maid did
22 begin to require testing on some of the ingredients used in its products for lead and arsenic,
23 those efforts were scattershot and did not extend to all lots of all ingredients used in Plum baby
24 food products. Where verification testing was conducted on ingredients, it was often done in an
25 unaccredited lab.

26 77. Despite not having a comprehensive ingredient testing program to ensure that
27 Plum food marketed for babies was not contaminated with Toxic Heavy Metals, Plum and
28 Campbell/Sun-Maid also did not conduct heavy metal testing on Plum products prior to sale.

1 Plum only first conducted finished product testing in the wake of public reports that exposed
2 Plum baby food products as being contaminated with dangerous levels of heavy metals. Upon
3 information and belief, no rigorous heavy metal testing program on ingredients and finished
4 product was ever implemented and Plum and Campbell/Sun-Maid continued and continue to
5 sell baby food contaminated with elevated levels of heavy metals without first testing to ensure
6 their safety.

7 78. **Sprout.** Sprout's baby foods are contaminated with Toxic Heavy Metals. For
8 example, the HBBF Report observed that Sprout's Organic Quiona Puffs Baby Cereal Snack-
9 Apple Kale contained 107 ppb total arsenic, 47 ppb inorganic arsenic, 39.3 ppb lead, and 41.5
10 ppb cadmium. These levels are all highly dangerous for consumption by an infant.

11 79. Sprout's testing and oversight are extremely lacking. Sprout claims that it relies
12 on its ingredients suppliers to test their ingredients for some Toxic Heavy Metals and only asks
13 the suppliers to test once a year—a frequency that cannot ensure any safety. However, upon
14 information and belief, despite its representations, Sprout did not require its raw ingredient
15 suppliers to provide yearly heavy metal test results prior to the Subcommittee's inquiry into the
16 company.

17 80. Sprout provided only 11 toxic heavy metal test results to the Subcommittee
18 stating that “[b]ecause Sprout requires annual testing for heavy metals for its ingredients, rather
19 than by lot, Sprout is unable to provide testing information for each lot as requested.” The
20 Subcommittee called this testing the “the most reckless among baby food sellers on the market.”

21 81. Since it began testing in 2021, the results observed in Sprout's food are
22 disturbing. For example, testing showed, on average, over 300 ppb of arsenic in Sprout's puff
23 products, with levels as high as 470 ppb. Testing on other Toxic Heavy Metals also shows
24 exceptionally high levels in various Sprout products. Sprout's consistent failure to test,
25 regulate, or monitor their baby food products, has led to the sale of an alarming number of baby
26 food products that were contaminated with Toxic Heavy Metals.

27 82. Internal documents within Sprout confirm that the companies were aware of
28 these issues, even made jokes about it, but took no action to take reasonable care to avoid harm

1 to infants until Congress blew the whistle on Sprout—and then, only after Sprout initially
2 refused to cooperate with a Congressional investigation.

3 83. Despite these findings, Sprout continues to market its products as safe, stating on
4 its website, “[i]f it isn’t safe, healthy, and delicious, we don’t make it.” Considering they never
5 tested their products prior to 2021, this statement is, at best, an overstatement.

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

7 84. In 2019, as concerns grew over contamination of certain baby foods on the U.S.
8 market, a consortium of the Baby Food Manufacturers comprised of Defendants Beech-Nut,
9 Plum/Campbell, Gerber, Hain, and Sprout, as well as certain interested third party groups such
10 as the Environmental Defense Fund (“EDF”) and HBBF, were formed with the intention “of
11 reducing heavy metals in young children’s food.”

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

18 86. The Baby Food Standard “would have provided companies with a common
19 framework for progressively reducing contaminants by regularly testing products and
20 improving management practices, and for being transparent with consumers about the safety of
21 their products.”

22 87. After several years of negotiations and discussions, including a proposed system
23 for testing, the EDF and HBBF proposed voluntary limits of 1 ppb for lead. The baby food
24 companies, however, rejected the proposal outright. Participation in the BFC was little more
25 than a façade—they had no intention of self-regulating their products as it related to Toxic
26 Heavy Metals.

27 88. This led EDF and HBBF to leave the BFC in protest in 2021. They explained
28 their departure publicly, noting that Defendants “all decided to backpedal on this project—even

1 though the standard was designed to protect babies’ brain development” and provide adequate
2 notice to consumers regarding the presence of Toxic Heavy Metals on Baby Food labeling.

3 EDF explained:

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

14 89. 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.

23 90. In short, the Defendants opted to continue “self-regulating,” the same self-
24 regulation which exposed—and continued to expose—Plaintiffs to Toxic Heavy Metals in
25 Defendants’ baby foods.

26 **22. The Dangers of Toxic Heavy Metals and Metal Exposure Through** 27 **Consumption of Baby Foods**

28 91. According to the World Health Organization (“WHO”), Toxic Heavy Metals,
specifically lead, arsenic, mercury, and cadmium pose a “major public health concern” for
children. The Occupational Safety and Health Administration (“OSHA”) has warned that these
metals “may build up in biological systems and become a significant health hazard.” Indeed,
the Department of Health and Human Services’ Agency for Toxic Substances and Disease
Registry (“ATSDR”) ranks arsenic as number *one* among substances present in the environment
that pose the most significant potential threat to human health, followed by lead (second),
mercury (third), and cadmium (seventh).

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

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

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

28 94. The mechanisms needed to metabolize and eliminate heavy metals are
comparatively undeveloped in childhood, with babies having weaker detoxifying mechanisms
and poorer immune systems than adults. For example, liver pathways that in adulthood
metabolize absorbed arsenic do not mature until mid-childhood; un-excreted arsenic thus
continues to circulate and is deposited in other organs. According to Linda McCauley, Dean of

1 the Nell Hodgson Woodruff School of Nursing at Emory University, who studies environmental
2 health effects, “[n]o level of exposure to these [heavy] metals has been shown to be safe in
3 vulnerable infants.”

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

8 **VI. Exposure to Toxic Heavy Metals Has Been Consistently Associated with** 9 **Neurodevelopmental Harm, i.e., Autism and ADHD in Pediatric Populations**

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

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

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

28 99. For example, four meta-analyses published in 2014, 2017, 2019 and 2020,

1 respectively, observed consistent associations between exposure to arsenic, cadmium, and
2 mercury and ASD in children; with the authors in all three studies recommending – based on
3 the data – that exposure to such metals in children be reduced as much as possible, and one of
4 the study authors specifically concluding that “Results of the current meta-analysis revealed that
5 mercury is an important causal factor in the etiology of ASD.”

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

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

15 102. Studies have repeatedly observed strong associations between exposure to
16 cadmium and aluminum and neurodevelopmental disorders such as ASD, as observed by a
17 recent study: “Environmental exposure to...cadmium (Cd)... and aluminum (Al) has been
18 associated with neurodevelopmental disorders including autism spectrum disorder (ASD).” For
19 example, a study from 2014 evaluated the body burden of lead, cadmium, and arsenic in
20 children with autism compared to controls and noted that, in addition to lead and arsenic, “our
21 study demonstrated elevation in the levels of...cadmium...in a child with autism,” while an
22 earlier study noted that “autism may be associated with significant alterations of some rare
23 element concentrations, including Cd...” Such results have been confirmed by meta-analyses
24 which “show *significant associations* between ASD and the metals Al [and] Cd.” And, such
25 earlier data is further supported by recent research, with a 2023 systematic review and meta-
26 analysis concluding that “compared with the healthy control group, the ASD group had higher
27 concentrations of Cd, Pb, arsenic, and Hg. These 4 heavy metals play different roles in the
28 occurrence and progression of ASD.”

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

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

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

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

22 107. No fewer than four large meta-analyses, conducted in four different continents
23 (North America, South America, Europe and Asia), and some employing a cross-sectional
24 design, have observed a consistent association between various metals and ADHD in children.
25 Indeed, the authors of the meta-analysis from Spain noted that “the evidence from the studies
26 allowed us to establish that there is an association between lead and ADHD and that even *low*
27 *levels of lead raise the risk.*” (emphasis added).

28 108. The findings from the meta-analyses have been replicated in several Chinese

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

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

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

23 **VII. Defendants’ Baby Foods Contain Toxic Heavy Metals Capable of Interfering with** 24 **Early Neurodevelopment**

25 111. As illustrated above, Toxic Heavy Metal exposure is capable of inflicting
26 damage to the developing brain at extremely low doses. And, upon information and belief,
27 Defendants manufactured and sold baby foods containing Toxic Heavy Metals that can, under
28 certain circumstances (based upon the genetic susceptibilities, medical history, and other factors

1 of the exposed child) interfere with a baby's neurodevelopment sufficient to cause conditions
2 such as ASD and ADHD.

3 112. As an initial matter, the study commissioned by HBBF and discussed above
4 specifically evaluated the propensity for arsenic exposure through consumption of infant rice
5 cereal to impact early life neurodevelopment. Following analyses of the levels of arsenic
6 exposure from consumption of infant rice cereal, the authors concluded "that high consumers of
7 infant rice cereal (i.e., infants eating three servings per day) eating products currently on the
8 U.S. market would have a daily arsenic intake of 0.35-0.67 $\mu\text{g}/\text{kg bw}/\text{day}$...per the Tsuji et al.
9 (2015) lower-bound estimate for an RfD for the neurodevelopmental effects of arsenic (0.4
10 $\mu\text{g}/\text{kg bw}/\text{day}$), high consumers of infant rice cereal may also be at risk for this endpoint. Even
11 in average consumers of infant rice cereal (i.e., one serving per day), our estimates of arsenic
12 intakes (0.15 to 0.29 $\mu\text{g}/\text{kg bw}/\text{day}$) leave little room for exposures to arsenic from other
13 sources." Thus, consumption of Defendants' baby foods, including but not limited to infant rice
14 cereal and rice-based snack baby food products manufactured and sold by Defendants can
15 expose babies to levels of arsenic above that associated with neurodevelopmental harm in the
16 scientific literature.

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

22 114. Similarly, upon information and belief, Defendant Hain was aware of the
23 neurotoxic propensities of lead, arsenic, and mercury at low levels, but proceeded to
24 manufacture and sell Baby Foods containing arsenic and lead levels that, upon information and
25 belief, Hain considered as capable of inflicting neurodevelopmental harm.

26 //

27 //

28 //

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

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

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

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

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

26 119. To be clear, the Defendants are able to manufacture baby foods that do not pose
27 such a dangerous risk to the health of infants and children by using alternative ingredients, not
28 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**

6 120. 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.

15 121. 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.

23 122. 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.

7 123. 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 and ADHD. Moreover, Plaintiff
14 alleges that had these baby food products not been defective—by having sufficient warnings,
15 being correctly manufactured, and/or designed properly—Plaintiff would not have been
16 exposed to levels of Toxic Heavy Metals in Defendants’ baby food products that would have
17 contributed to the neurodevelopmental harm that manifested as ASD and ADHD.

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

19 124. 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.

23 125. 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.

8 126. 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**

19 127. Plaintiff was diagnosed with ASD and ADHD at approximately 2 years of age.

20 128. Plaintiff consumed Baby Food products manufactured and/or sold by the
21 Defendants.

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

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

27 131. As a direct and proximate result of consuming Defendants’ Baby Foods and the
28 exposure to the Toxic Heavy Metals therein – Plaintiff suffered brain injury which manifested

1 as ASD and ADHD and related *sequalae*.

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

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

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

12 CAUSES OF ACTION

13 COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

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

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

24 137. Defendants researched, tested, developed, designed, manufactured, labeled,
25 marketed, sold, inspected, distributed, and promoted, and otherwise released into the stream of
26 commerce their Contaminated Baby Foods, and in the course of same, directly advertised or
27 marketed the products to consumers and end users, including Plaintiff, and therefore had a duty
28 to warn about the presence of and risks associated with exposure to Toxic Heavy Metals from

1 the consumption of Contaminated Baby Foods.

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

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

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

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

28 142. At all relevant times, Defendants' Contaminated Baby Foods reached the

1 intended consumers, handlers, and users or other persons coming into contact with these
2 products, including Plaintiff, without substantial change in their condition as manufactured,
3 sold, distributed, labeled, and marketed by Defendants.

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

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

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

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

26 147. This alleged failure to warn is not limited to the information contained on
27 Contaminated Baby Foods labeling. The Defendants were able, in accord with federal law, to
28 comply with relevant state law by disclosing the known risks associated with exposure to Heavy

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

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

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

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

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

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

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

COUNT II: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

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

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

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

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

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

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

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

161. This manufacturing defect caused Plaintiff to be exposed to Toxic Heavy Metals through ingestion of the Contaminated Baby Foods which, in turn, caused neurodevelopmental

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

1 harm that manifested as ASD and ADHD.

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

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

9 164. As a direct and proximate result of the Defendants' defective manufacture 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 medical expenses, lost income, and other damages.

13 165. **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 III: STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

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

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

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

25 169. Defendants' Contaminated Baby Food products as researched, tested, developed,
26 designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by
27 Defendants were defective in design and formulation in that, when they were placed into the
28 stream of commerce, they were unreasonably dangerous and dangerous to an extent beyond that

1 which an ordinary consumer would contemplate.

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

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

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

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

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

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

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

27 4. Exposure to the Toxic Heavy Metals in Defendants' Contaminated Baby
28 Food products present a risk of harmful effects that outweigh any potential utility stemming

1 from their use;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27 185. At the time of manufacture, Defendants could have provided warnings regarding
28 the presence of and risks of exposure to Toxic Heavy Metals from consumption of

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

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

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

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

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

25 190. The information that Defendants did provide or communicate failed to contain
26 relevant warnings, hazards, and precautions that would have enabled consumers such as
27 Plaintiffs to avoid using the product and, in turn, prevented exposure to the Toxic Heavy Metals
28 contained therein. Instead, Defendants disseminated information that was inaccurate, false, and

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

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

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

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

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

28 195. Defendants' conduct, as described above, was reckless. Defendants risked the

1 lives of consumers and users of their products, including Plaintiff, with knowledge of the safety
2 problems associated with Contaminated Baby Foods, and suppressed this knowledge from the
3 general public. Defendants made conscious decisions not to warn or inform the unsuspecting
4 public.

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

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

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

15 **COUNT V: NEGLIGENCE – MANUFACTURING**

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

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

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

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

26 203. The Defendants knew or, by the exercise of reasonable care, should have known,
27 ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of
28 exposure to Toxic Heavy Metals from consumption of Contaminated Baby Foods.

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

- 3 1. Failure to adequately inspect/test the Contaminated Baby Foods, and
4 their ingredients, during and after the manufacturing process;
- 5 2. Failure to implement procedures that would reduce or eliminate Toxic
6 Heavy Metals in baby foods;
- 7 3. Failure to investigate suppliers and ingredient sources to reduce and
8 eliminate the risk of ingredients containing Toxic Heavy Metals; and
- 9 4. Failure to avoid using ingredients free from, or which contain far less,
10 Toxic Heavy Metals to manufacture baby food.

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

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

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

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

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

27 210. **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 VI: NEGLIGENCE – PRODUCT DESIGN**

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

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

8 213. The Defendants owed a duty to all reasonably foreseeable users to design a safe
9 product.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27 222. Plaintiff was harmed directly and proximately by the Defendants' failure to use
28 reasonable care in the design of their Contaminated Baby Foods. Such harm includes exposure

1 to Toxic Heavy Metals, which can cause or contribute to interference with neurodevelopment
2 that manifests as ASD, ADHD, and related *sequalae*.

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

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

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

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

15 **COUNT VII: GENERAL NEGLIGENCE**

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

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

20 229. Defendants owed Plaintiff a duty to act with reasonable care.

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

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

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

27 4. Defendants owed a duty because they designed, manufactured,
28 controlled, distributed, and sold their products to Plaintiff.

1 230. Defendants breached their duty to Plaintiff.

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

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

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

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

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

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

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

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

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

27 9. Defendants could have employed safer alternative designs and
28 formulations for Contaminated Baby Foods, such as ensuring the baby food did not have any

1 detectable level of Toxic Heavy Metal.

2 10. 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; and

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

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

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

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

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

21 **JURY TRIAL DEMAND**

22 236. Plaintiff demands a trial by jury on all the triable issues within this pleading.

23 **PRAYER FOR RELIEF**

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

- 26 a. actual or compensatory damages in such amount to be determined at trial and
27 as provided by applicable law;
28 b. exemplary and punitive damages sufficient to punish and deter the

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- 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: February 18, 2025

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